

NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* first as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council or the Attorney General. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Register* after the final rules have been submitted for filing and publication.

NOTICE OF FINAL RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 6. DEPARTMENT OF HEALTH SERVICES COMMUNICABLE DISEASES AND INFESTATIONS

[R07-326]

PREAMBLE

1. Sections Affected

R9-6-401
R9-6-403
R9-6-404
R9-6-405
R9-6-406
R9-6-406
R9-6-407
R9-6-407
R9-6-407
R9-6-408
R9-6-408
R9-6-409
R9-6-409
R9-6-410
R9-6-410

Rulemaking Action

Amend
Amend
Amend
Amend
Renumber
New Section
Renumber
Amend
Repeal
New Section
Renumber
Amend
Renumber
Amend

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 36-136(A)(7) and (F)

Implementing statutes: A.R.S. § 36-136(H)(1)

3. The effective date of the rule:

November 10, 2007

4. A list of all previous notices appearing in the *Register* addressing the final rules:

Notice of Rulemaking Docket Opening: 12 A.A.R. 765, March 10, 2006

Notice of Rulemaking Docket Opening: 13 A.A.R. 1051, March 23, 2007

Notice of Proposed Rulemaking: 13 A.A.R. 1674, May 18, 2007

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

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6. An explanation of the rules, including the agency's reasons for initiating the rules:

A.R.S. § 36-136(H)(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” and prescribing measures “reasonably required to prevent the occurrence of, or to seek early detection and alleviation of, disability, insofar as possible, from communicable or preventable diseases.” *Arizona Administrative Code* Title 9, Chapter 6, Article 4 implements A.R.S. § 36-136(H)(1) by establishing rules related to the AIDS Drug Assistance Program (ADAP), a primarily Federally-funded program, through which the Department provides prescription drugs to HIV-infected residents of Arizona to prevent the occurrence of or to seek alleviation of disability from HIV-related diseases, including AIDS.

Beginning in January 2006, elderly and disabled individuals who are eligible for enrollment in Medicare are able to obtain prescription drugs under Medicare Part D through prescription drug plans under contract to Medicare. Those who qualify for a full low-income subsidy through Medicare do not pay for Medicare Part D drug coverage. ADAP is funded by the Federal Ryan White CARE Act, which specifies that ADAP is the payor of last resort for HIV-related prescription drugs for those enrolled in ADAP. To conform to the requirements of the Ryan White CARE Act, the current rules are being amended to require those eligible for Medicare to apply for a Medicare prescription drug plan and for a low-income subsidy for prescription drugs. The new rules exclude those eligible to receive a full Medicare low-income subsidy for prescription drugs from enrolling in ADAP. The new rules also add definitions, clarify the application process and notification requirements, and define the requirements for distribution of prescription drugs, including those prescription drugs that are available through ADAP only on a case-by-case basis. Many of the revisions specified in this rulemaking reflect changes that have already been made in the operation of the program due to the implementation of Medicare Part D and the use of a vendor pharmacy for drug distribution or to address issues described in the Five-Year-Review Report approved by the Governor's Regulatory Review Council in October 2004.

All changes conform to current rulemaking format and style requirements of the Governor's Regulatory Review Council and the Office of the Secretary of State.

7. A reference to any study relevant to the rules that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rules, 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 related to this rulemaking package.

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

Not applicable

9. The preliminary summary of the economic, small business, and consumer impact:

As used in this summary, annual costs/revenues are designated as minimal when less than \$1,000, moderate when between \$1,000 and \$10,000, and substantial when greater than \$10,000. Costs are listed as significant when meaningful or important, but not readily subject to quantification.

The Department may bear a minimal cost associated with providing education on the new rules and is expected to receive a minimal benefit from both the increased clarity of the rules and the alignment of the rules with the current operation of the program.

Small businesses affected by the rule changes include the practices of physicians, registered nurse practitioners, and physician assistants; the pharmacy under contract with the Department to distribute prescription drugs to individuals enrolled in ADAP; and community service organizations. The Department has begun using a vendor pharmacy for the distribution of prescription drugs to individuals enrolled in ADAP, but the current rules specify the requirements for the Department's distribution of drugs and are in conflict with this new drug distribution scheme. The requirements for the vendor pharmacy are specified in a contract between the Department and the vendor pharmacy, but those contract provisions that affect physicians, registered nurse practitioners, physician assistants, or individuals applying for or enrolled in ADAP are also specified in rule. The requirements in the new rules for the vendor phar-

macy provide a minimal benefit to the vendor pharmacy because they clarify for the affected persons what the vendor pharmacy is required by contract to do.

Under the current rules, primary care providers are the physicians, registered nurse practitioners, and physician assistants who treat individuals for HIV infection. Primary care providers are required to complete a portion of the application for initial or continuing enrollment of an individual in ADAP, inform the Department within 30 days of changes that may affect an individual's enrollment in ADAP, notify the Department when an enrolled individual changes to another primary care provider, and write prescription orders for the quantity of a drug supplied by a manufacturer. The new rules continue to require a primary care provider to complete a portion of the application for initial or continuing enrollment of an individual in ADAP, and also require a primary care provider to acknowledge the requirement to notify the Department. However, under the new rules, a primary care provider is only required to notify the Department upon learning that an enrolled individual has changed to a different primary care provider or has died. The burden of notifying the Department of other changes that may affect an individual's eligibility for ADAP is placed on those in a better position to know of the change – the individual, the individual's representative, or the individual's case manager. The Department's use of a vendor pharmacy for the distribution of prescription drugs to individuals enrolled in ADAP also allows primary care providers to issue written or oral prescription orders to the vendor pharmacy for ADAP-supplied drugs, just as they would issue prescription orders to any pharmacy for drugs supplied through other sources, simplifying the process for primary care providers. Thus, these changes in the new rules may provide a minimal benefit to a primary care provider.

The Department currently has a process through which primary care providers may request certain very expensive drugs for an ADAP-enrolled individual through ADAP. These restricted drugs are now approved on a case-by-case basis for individuals enrolled in ADAP. Although the process is not specified in the current rules, the process has been in place for several years and is specified in the new rules. This requirement in the new rules may impose a minimal time cost on a primary care provider who requests approval of a restricted drug for an individual enrolled in ADAP.

While community service organizations and case managers employed by community service organizations are not mentioned in the current rules, they play an important role in assisting and supporting the individuals who apply for or are enrolled in ADAP. Their roles in the services provided to HIV-infected individuals are specified in the Federal Ryan White CARE Act. The new rules specify which ADAP-related activities that community service organizations are already performing, such as receiving written communications for an HIV-infected individual or issuing a statement to verify an individual's Arizona residency, may be used by the HIV-infected individual to support eligibility for ADAP. The new rules also specify that a case manager is required to notify the Department of changes that may affect an individual's eligibility for ADAP. An HIV-infected individual's case manager may also issue a statement to verify an individual's Arizona residency and, when assisting the individual to complete a form to establish that the individual has no steady supply of income, is required to attest that information on the form is correct to the best of the case manager's knowledge. The Department anticipates that the new rules will impose a minimal time cost on a community service organization or case manager.

The current rules specify the eligibility requirements for individuals to enroll in ADAP, the information an individual must submit to the Department to enroll or to continue enrollment in ADAP, the notification requirements for changes that may affect an individual's eligibility, and how the Department distributes drugs for enrolled individuals. The current rules also specify that an individual is required to give the Department permission to contact AHCCCS regarding the individual's eligibility for AHCCCS. The new rules clarify the eligibility requirements for ADAP by delineating what is termed "inadequate health insurance" in the current rules, specify under what circumstances and how an individual would notify the Department of changes that may affect eligibility, and change the ADAP eligibility requirements specified in rule to conform to the Federal ADAP requirements. The new rules also specify the Department's requirements for an individual to allow the Department to verify the individual's Medicare status, what information the individual may submit to verify Arizona residency, and under what circumstances the Department may terminate an individual's enrollment in ADAP. With the Department's use of a vendor pharmacy to distribute drugs and improvements in the Department's data system, the Department will review and approve or disapprove an application for enrollment or continuing enrollment within five business days. The new rules address this decrease in time from the 45 days allowed under the current rules. The new rules also allow an individual to name individuals with whom the Department may speak about the individual's enrollment in ADAP, add new documents that an individual may use to establish eligibility for ADAP, and address the fact that the individual submitting information to the Department to enroll an HIV-infected individual in ADAP may be the HIV-infected individual's representative, rather than the HIV-infected individual. All these changes are expected to expedite an individual's enrollment and allow the individual to begin receiving drugs through ADAP sooner. Although the new rules do not change the process that an individual applying for enrollment or continuing enrollment in ADAP is currently following, the process by which the Department reviews the documents submitted to the Department, or the mechanisms by which an enrolled individual is currently receiving drugs, the new rules do constitute a change from the requirements in the current rules and may impose a minimal cost and may provide a minimal benefit to individuals applying for or enrolled in ADAP.

The families of HIV-infected individuals and the public may benefit to a minimal extent from the new rules in that the improved clarity of the rules and specification of the types of documents that may be submitted to support an application for ADAP may encourage HIV-infected individuals not currently applying for or enrolled in ADAP to apply. The education provided by the Department about the new rules may also increase awareness of the ADAP program. If an HIV-infected individual is able to obtain drugs through the individual's insurance, ADAP, a Medicare drug plan, or

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AHCCCS, the progression of the HIV-infected individual's disease may slow, and the drugs may prevent the occurrence of or alleviate disability from HIV-related diseases, including AIDS. A slower disease progression may add years to an HIV-infected individual's working life and decrease the work time lost by families of HIV-infected individuals.

The Department has determined that the benefits related to public health outweigh any potential costs associated with this rulemaking.

10. A description of the changes between the proposed rule, including supplemental notices, and final rule:

Minor technical and grammatical changes were made by the Department and at the suggestion of Council staff to improve clarity, conciseness, and understandability.

11. A summary of the comments made regarding the rule and the agency response to them:

There were no oral comments at the Oral Proceeding, and the Department received written comments from two individuals, each addressing multiple issues, which are summarized below.

Comment	Rule Addressed	Department's Response
The definitions of "annual family income" and "family unit" should be changed to only include the individual, a spouse, and dependents.	R9-6-401(5) and (23)	No rule change will be made. If the applicant lives with a relative, including a parent, the relative is considered to be contributing to the support of the individual.
The current annual income requirement is less than or equal to 300% of the federal poverty level. Can this be worded to allow for an easy change if the level is increased?	R9-6-403(3)	No rule change will be made. The rules must be specific in delineating a requirement for enrollment in ADAP.
The requirement for a written prescription order or copy to be sent to the Department as part of an initial application should be removed.	R9-6-404(A)(3), R9-6-409(A)(2), and R9-6-409(B)	No rule change will be made. With the recent change to a vendor pharmacy, the Department may use a copy of the prescription to ensure that a prescribed drug is in the ADAP formulary, provide guidance if the drug is a restricted drug, and monitor the actions of the vendor pharmacy.
Proof of income for self-employed individuals is unrealistic. Self-employed individuals should only need to fill out the form described in R9-6-404(A)(8) and state how much they make.	R9-6-404(A)(7)(b)	No rule change will be made. In order to provide stewardship over the funds provided for ADAP, the Department currently requires documentation to substantiate an individual's claim of income from employment. The items listed in R9-6-404(A)(7)(b) are examples of the types of documentation that a self-employed individual could provide to the Department, but others will be accepted.
Requirements have been imposed in addition to those noted in the rules in R9-6-404(A)(8). A letter from an employer stating what the person makes is being asked for, which put stress on one of our undocumented clients.	R9-6-404(A)(8)	No rule change will be made. The form specified in R9-6-404(A)(8) is to be used only if an applicant is not employed or self-employed. Documentation specified in R9-6-404(A)(7) is used if an applicant is employed or self-employed. The definitions of "employed" and "self-employed" are given in R9-6-401. The Department will provide education about the use of the form specified in R9-6-404(A)(8).
A statement by a primary care provider that information submitted is accurate is inappropriate. Only the individual and the individual's case manager should verify a statement of income or residency.	R9-6-404(A)(8)(d) and (9)(viii)	No rule change will be made. The rules do not require a primary care provider to verify a statement of income or residency, but just allow the primary care provider to do so. This provides a benefit to an individual applying for ADAP in that it allows either a case manager or a primary care provider to verify a statement of income or residency.

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Additional proofs of residency beyond those listed in R9-6-404(A)(9) should be accepted.	R9-6-404(A)(9)	No rule change will be made. The Department considers the documents specified in R9-6-404(A)(9)(a) to be sufficient to document Arizona residency. The documents specified in R9-6-404(A)(9)(b) or (c) are not individually sufficient to demonstrate Arizona residency since they do not specifically demonstrate that the individual is currently living at the indicated address.
The information of the most recent laboratory test results should not be required.	R9-6-404(B)(4)	No rule change will be made. The Department needs this information as baseline data for outcome reporting requirements from the Federal agency funding the ADAP program. Since it is the responsibility of the primary care provider to complete the information about laboratory test results, the Department does not deny enrollment to an applicant on the basis of a primary care provider not submitting this information as part of the application, but will work with the primary care provider to get the information.
The list of each drug prescribed by a primary care provider should not be necessary.	R9-6-404(B)(5)	No rule change will be made. The Department may use this information to verify that a prescribed drug is in the ADAP formulary, provide guidance if the drug is a restricted drug, and monitor the actions of the vendor pharmacy. Providing this information is also a requirement for a primary care provider, so the Department does not deny enrollment to an applicant on this basis if a primary care provider does not submit the information as part of the application, but will work with the primary care provider to get the information.
The statement that a primary care provider understands the notification requirements specified in R9-6-406(B) should be removed from the form specified in R9-6-404(B).	R9-6-404(B)(6) and R9-6-406(B)	No rule change will be made. The statement provides notice to a primary care provider that the primary care provider is required to notify the Department when the primary care provider learns that an enrolled individual has changed primary care providers or has died.
How annual family income is calculated should be changed to state that annual family income may be “determined by [the] most recent income tax form and utilizing actual income combined with estimated where a person’s income situation has changed.”	R9-6-404(C)	No rule change will be made. The rule already provides flexibility in determining annual family income by allowing either actual or estimated income to be reported.
There needs to be an emergency provision for ADAP enrollment within 24 hours for individuals discharged from a hospital and needing HIV-related drugs, which should be able to be picked up at the pharmacy rather than being mailed.	R9-6-405 and R9-6-409	No rule change will be made. The Arizona ADAP Program was not instituted to provide emergency access to drugs. Other portions of the Ryan White CARE Act have within their scopes the provision of emergency services, including HIV-related drugs, and should be used in such situations.

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<p>The commenter was told that ADAP has 45 days to complete the enrollment, and may need to consider allocating more money in emergency assistance for drugs for individuals getting out of the hospital and needing drugs before ADAP enrollment is completed.</p>	<p>R9-6-405(A)(4)</p>	<p>No rule change will be made. Under the current rules, the Department has 45 days in which to complete the review of an application for enrollment in ADAP. Under the new rules, the Department will complete the review within five days. During the last year, the longest time the Department has taken to review a complete application has been three days. The Department will provide education about the enrollment process.</p>
<p>When an individual's address changes, the individual should not need to submit a new application, just a form indicating the change of address and proof of residency.</p>	<p>R9-6-407(B)</p>	<p>No rule change will be made. When an individual's address changes, it is often accompanied by a change in income, employment status, or the composition of the family unit. The individual does not know if the information in the Department's records reflects the individual's current situation. Therefore, even if the individual believes that information has not changed, this information is required on the form provided by the Department to ensure that the information in the Department's records is correct and the individual is still eligible for ADAP.</p>
<p>What is the purpose of R9-6-407(H)?</p>	<p>R9-6-407(H)</p>	<p>No rule change will be made. The purpose of this subsection is to specify the documentation required to be submitted by an individual every 24 months after an initial application for the individual to continue enrollment in ADAP.</p>
<p>The provision concerning the ability of ADAP to terminate enrollment if an individual does not pick up refills for 90 days should be removed.</p>	<p>R9-6-408(A)(2)</p>	<p>No rule change will be made. The rule states that the Department "may" terminate enrollment if an individual does not request a refill of a drug for 90 days, not that the Department "shall" terminate enrollment. The Department needs a mechanism to terminate enrollment of an individual who is not using ADAP services to enable another individual who could benefit from ADAP to enroll. Drugs are dispensed in quantities sufficient to last 30 days. After 90 days without a request for a refill, the Department assumes that the individual no longer lives in Arizona or does not need ADAP services. In the last five years, the Department has not received any information to contradict this assumption. If the Department were to receive information from an individual who has a circumstance causing the individual to temporarily suspend the use of drugs received through ADAP, the Department would not terminate enrollment.</p>

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<p>All drugs are mailed from the vendor pharmacy in Tucson, which may cause problems that would be avoided if an individual could pick up the drugs at a neighborhood pharmacy. The vendor pharmacy also has to contact the individual before drugs are dispensed to verify where they should be sent. This could cause a problem if the individual does not have a phone.</p>	<p>R9-6-409(C)</p>	<p>No rule change will be made. The Department contracts with one vendor pharmacy, which has many locations in Tucson and Phoenix at which an individual could pick up a prescription, but which mails most orders for the convenience of the individual. The vendor pharmacy must establish contact with the individual before dispensing a drug to ensure that the drug is sent where the individual wants it to go. The vendor pharmacy has an “800” number, which could be used by an individual without a phone to inform the vendor pharmacy where the ADAP-provided drugs should be sent.</p>
<p>There needs to be a provision for a newly enrolled individual to pick up ADAP drugs within 24 hours.</p>	<p>R9-6-409(C)</p>	<p>No rule change will be made. See the response to the comment made regarding R9-6-405. The goal of the vendor pharmacy is to dispense drugs within 24 hours after receiving a prescription order or request for refill and verifying the address to which the drugs are to be sent. However, the rules reflect the minimum requirement for the vendor pharmacy to dispense drugs no later than three business days after receiving a prescription order or request for refill and verifying the address to which the drugs are to be sent.</p>
<p>“There is a lack of flexibility in the ADAP process and preoccupation with rules to the detriment of keeping [an individual] on medications. Some flexibility needs to be written into these rules.”</p>		<p>No rule change will be made. The requirements specified in R9-6-403 conform to Federal requirements for receiving ADAP funds. The rules provide many options for an individual to use in documenting that the individual meets the requirements specified in R9-6-403. The rules reflect changes that have already been made in the operation of the program due to the implementation of Medicare Part D and the use of a vendor pharmacy for drug distribution. The basic process for applying for ADAP and for continuing enrollment is unchanged from the current rules and has only been clarified in the new rules. The Department will provide education about ADAP requirements and the new rules to assist individuals and case managers in meeting the requirements.</p>
<p>“If all the information is provided but isn’t on a specific ADAP form, that should be acceptable.”</p>	<p>R9-6-404(A)(1), R9-6-404(A)(8), R9-6-404(B), R9-6-407(B)(1), R9-6-407(D), and R9-6-409(E)(1)</p>	<p>No rule change will be made. To ensure that an application may be reviewed and enrollment is granted or denied in as short a time as possible, the Department requires the specified information be submitted on Department-provided forms.</p>

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

13. Incorporations by reference and their location in the rule:

None

14. Was this rule previously made as an emergency rule?

No

15. The full text of the rule follows:

TITLE 9. HEALTH SERVICES

CHAPTER 6. DEPARTMENT OF HEALTH SERVICES
COMMUNICABLE DISEASES AND INFESTATIONS

ARTICLE 4. AIDS DRUG ASSISTANCE PROGRAM (ADAP)

Section

- R9-6-401. Definitions
- R9-6-403. Eligibility Requirements
- R9-6-404. Initial Application Process
- R9-6-405. Enrollment Process; Provisional Enrollment
- R9-6-406. Notification Requirements
- ~~R9-6-406~~R9-6-407. Continuing Enrollment
- R9-6-408. ~~Time frames~~ Termination from ADAP Services
- ~~R9-6-407~~R9-6-409. Drug Prescription and Distribution Requirements
- ~~R9-6-410~~. Renumbered
- ~~R9-6-409~~R9-6-410. Confidentiality

ARTICLE 4. AIDS DRUG ASSISTANCE PROGRAM (ADAP)

R9-6-401. Definitions

In this Article, unless otherwise specified:

1. "ADAP" means the AIDS Drug Assistance Program.
2. "Adult" means an individual who is:
 - a. Eighteen or more years old;
 - b. Married; or
 - c. Emancipated, as specified in A.R.S. Title 12, Chapter 15.
3. "Advocacy" means the act of supporting, recommending, or arguing in favor of a cause or course of action for the benefit of an individual or group of individuals.
- ~~2-4~~ "AHCCCS" means the Arizona Health Care Cost Containment System.
5. "Annual family income" means the combined yearly gross earned income and unearned income of all adult individuals within a family unit.
- ~~3-6~~ "Applicant" means an individual who submits an application for ADAP to the Department for whom a request for initial enrollment in ADAP is submitted to the Department, as specified in R9-6-404.
7. "Applying for a low-income subsidy" means submitting forms and supporting documentation to the Social Security Administration for determining eligibility for receiving a low-income subsidy.
8. "Biological substance" means a compound made by or derived from a plant or animal source.
9. "Business day" means any day of the week other than a Saturday, Sunday, legal holiday, or day on which the Department is authorized or obligated by law or executive order to close.
10. "Calendar day" means any day of the week, including a Saturday, Sunday, or legal holiday.
11. "Case management services" means the activities performed by a case manager for an HIV-infected individual or the individuals in the HIV-infected individual's family unit.
12. "Case manager" means an individual who:
 - a. Assesses the needs of an HIV-infected individual for health services, housing, support services, and financial assistance;
 - b. Assists the HIV-infected individual with obtaining health services, housing, support services, or financial assistance, as applicable;
 - c. Coordinates the interaction of the HIV-infected individual with service providers; and
 - d. Monitors the interaction of the HIV-infected individual with service providers to:
 - i. Determine the effects of each service provider's activities on the needs of the HIV-infected individual, and
 - ii. Develop strategies to reduce unmet needs.
13. "CD4-T-lymphocyte count" means the number of a specific type of white blood cell in a cubic millimeter of blood.
14. "Community service organization" means a nonprofit entity that assists an individual who is infected with HIV or affected by another individual's infection with HIV by providing the services listed below or coordinating the interaction of the individual with service providers to obtain or retain:
 - a. Rehabilitation services.
 - b. Case management services.
 - c. Support services.

- d. Advocacy.
- e. Financial assistance, or
- f. Housing.
- 15. "Confirmatory test" means a laboratory analysis, such as a Western blot analysis, approved by the U.S. Food and Drug Administration to be used after a screening test to diagnose or monitor the progression of HIV infection.
- 16. "Current" means within the six months before the:
 - a. Date of application, or
 - b. Date on which an enrolled individual submits to the Department the documents required in R9-6-407 for continuing enrollment.
- 17. "Date of application" means the month, day, and year that an individual submits the documents specified in R9-6-404 to the Department as an application for initial enrollment in ADAP.
- 4-18. "Diagnosis" means an identification of a communicable disease by an individual authorized by law to make the identification.
- 5-19. "Drug" means a chemical or biological substance determined by the ~~United States~~ U.S. Food and Drug Administration to be useful in the treatment of individuals with HIV infection and available only through a prescription order.
- 6-20. "Earned income" means monetary payments received by an individual as a result of work performed or rental of property owned or leased by the individual, including:
 - a. Wages,
 - b. Commissions and fees,
 - c. Salaries and tips,
 - d. Profit from self-employment,
 - e. Profit from rent received from a tenant or boarder, and
 - f. Any other monetary payments received by an individual for work performed or rental of property.
- 21. "Employed" means working for a person for money in the form of wages or a salary.
- 22. "Enrolling in a Medicare drug plan" means submitting information to the Centers for Medicare and Medicaid Services during an initial enrollment period or general enrollment period and selecting a Medicare drug plan.
- 7. "Family income" means the combined gross earned income and unearned income of all individuals within the family unit.
- 8-23. "Family unit" means:
 - a. A group of individuals residing together who are related by birth, marriage, or adoption; or
 - b. ~~An individual who does not reside with any individual to whom the individual is related by birth, marriage, or adoption.~~
 - b. An individual who:
 - i. Does not reside with another individual; or
 - ii. Resides only with another individual or group of individuals to whom the individual is unrelated by birth, marriage, or adoption.
- 24. "Formulary" means a list of drugs that are available to an individual through the individual's health insurance or ADAP.
- 25. "General enrollment period" means the interval of time between November 15 and December 31 of each calendar year during which an individual:
 - a. May enroll in a Medicare drug plan if the individual, before May 15, 2006:
 - i. Was enrolled in Medicare,
 - ii. Was eligible to enroll in a Medicare drug plan, and
 - iii. Did not enroll in a Medicare drug plan; or
 - b. Currently enrolled in a Medicare drug plan may select a different Medicare drug plan.
- 26. "Gift" means something given voluntarily by an individual to another individual without payment in return.
- 27. "Guardian" means an individual appointed as a legal guardian by a court of competent jurisdiction.
- 28. "Health-related services" means the same as in A.R.S. § 36-401.
- 29. "Health services" means medical services, nursing services, or health-related services provided to an individual.
- 30. "HIV infection" means the same as in A.R.S. § 36-661.
- 31. "Homeless" means having a primary nighttime sleeping place that is not:
 - a. Designed to be a sleeping place for human beings, or
 - b. Ordinarily used as a primary nighttime sleeping place for human beings.
- 32. "Initial enrollment period" means the interval of time during which an individual may first enroll in a Medicare drug plan.
- 33. "Job" means a position in which an individual is employed.
- 34. "Low-income subsidy" means Medicare-provided assistance that may partially or fully cover the costs of drugs and is based on the income of an individual and, if applicable, the individual's spouse.
- 35. "Medical services" means the same as in A.R.S. § 36-401.

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36. “Medicare” means a federal health insurance program established under Title XVIII of the Social Security Act.
37. “Medicare drug plan” means insurance approved by Medicare to cover some of the costs of drugs for individuals enrolled in Medicare.
38. “Non-permanent housing” means a living situation in which an individual is:
- a. Homeless, or
 - b. Living in a shelter or other temporary living arrangement.
39. “Nonprofit” means owned and operated under the direction of an entity that is recognized as exempt under § 501 of the U.S. Internal Revenue Code.
40. “Nursing services” means the same as in A.R.S. § 36-401.
9. “Outpatient” means in an ambulatory setting.
41. “Physician” means an individual licensed as a doctor of allopathic medicine under A.R.S. Title 32, Chapter 13, or as a doctor of osteopathic medicine under A.R.S. Title 32, Chapter 17.
42. “Physician assistant” means an individual licensed under A.R.S. Title 32, Chapter 25.
- 40-43. “Poverty level” means the annual family income for a family unit of a particular size, as specified included in the poverty guidelines updated annually in the Federal Register by the United States U.S. Department of Health and Human Services.
44. “Prescription order” means the same as in A.R.S. § 32-1901.
- 44-45. “Primary care provider” means a the physician, registered nurse practitioner, or physician assistant who is treating an applicant or enrolled individual for HIV disease or HIV infection.
46. “Provisional enrollment” means an interval of time, determined by the Department, during which an individual who meets the eligibility criteria specified in R9-6-403 (1) through (4) may receive drugs on the ADAP formulary through the vendor pharmacy while the individual is waiting for:
- a. An eligibility determination for AHCCCS enrollment or a low-income subsidy; or
 - b. Enrollment in a Medicare drug plan.
- 42-47. “Public assistance” means a government program that provides benefits a monetary payment, or that supplies goods or services that have a monetary value, to individuals, based on need, such as Aid to Families with Dependent Children, SSI Supplemental Security Income, Temporary Aid to Needy Families, Food Stamps, or non-federally funded general assistance General Assistance.
48. “Registered nurse practitioner” means an individual who meets the definition of registered nurse practitioner in A.R.S. § 32-1601 and is licensed under A.R.S. Title 32, Chapter 15.
49. “Regular” means recurring at fixed intervals.
50. “Rehabilitation services” means the same as in A.A.C. R9-10-201.
51. “Representative” means the:
- a. Guardian of an individual;
 - b. Parent of an individual who is not an adult; or
 - c. Person designated as an agent for an individual through a power of attorney, as specified in A.R.S. Title 14, Chapter 5, Article 5.
52. “Reservist” means a member of the Reserves of the U.S. Army, Air Force, Navy, Marine Corps, or Coast Guard.
- 43-53. “Resident” means an individual who has a place of habitation in Arizona and lives in Arizona as other than a tourist.
54. “Restricted drug” means a drug on the ADAP formulary that is approved by the Department on a case-by-case basis for enrolled individuals who meet medical indications for the use of the drug.
55. “Routine training” means military education and related hands-on activities designed to make an individual ready for the tasks the individual would be expected to perform as a member of the U.S. Air Force, Army, Coast Guard, Marine Corps, or Navy.
56. “Screening test” means a laboratory analysis approved by the U.S. Food and Drug Administration as an initial test to indicate the possibility that an individual is HIV infected.
57. “Self-employed” means receiving money as a direct result of the work performed by an individual rather than from wages or a salary paid to the individual.
58. “Service provider” means an individual who provides medical services, nursing services, health-related services, or support services for an HIV-infected individual.
59. “Shelter” means a facility that provides individuals with a temporary place to sleep at night with the expectation that the individual will go elsewhere during the daylight hours.
14. “SSI” means Supplemental Security Income, a program of the Social Security Administration.
60. “Support services” means activities, not related to the treatment of HIV infection, intended to maintain or improve the physical, mental, or psychosocial capabilities of an HIV-infected individual or the individual’s family unit and that may include:
- a. Providing opportunities for social interactions for HIV-infected individuals;
 - b. Taking care of a child of an HIV-infected individual while the HIV-infected individual receives medical services;

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- c. Providing food or meals to an HIV-infected individual in the HIV-infected individual's residence; or
- d. Providing information about available support services or materials about how to reduce the risk of spreading HIV.
- 61. "Temporary" means transient, with no expectation of permanence.
- 62. "Third-party payor" means a person other than an HIV-infected individual, such as health insurance or an employer, that is responsible for paying a portion of the costs of drugs for the HIV-infected individual.
- 63. "Tourist" means an individual who is living in Arizona but maintains a place of habitation outside of Arizona and lives outside of Arizona for more than six months during a calendar year.
- 64. "Treatment" means the administration to an individual of health services intended to relieve illness or injury.
- 15-65. "Unearned income" means non-gift monetary payments received by an individual that are unrelated to not compensation for work performed or rental of property owned or leased by the individual, including:
 - a. Unemployment insurance;
 - b. Workers' compensation;
 - c. Disability payments;
 - d. ~~Social security payments~~ Payments from the Social Security Administration;
 - e. ~~Public assistance payments~~ Payments from public assistance;
 - f. Periodic insurance or annuity payments;
 - g. Retirement or pension payments;
 - h. Strike benefits from union funds;
 - i. Training stipends;
 - j. Child support payments;
 - k. Alimony payments;
 - l. Military family allotments;
 - m. ~~Regular or other regular~~ Regular support payments from a relative or other individual not residing in the household;
 - ~~n. Investment income;~~
 - ~~o. Royalty payments;~~
 - ~~p. Periodic payments from estates or trusts; and~~
 - p. ~~Any other non-gift monetary payments received by an individual that are unrelated to work performed by the individual and that are not capital gains, lump-sum inheritance or insurance payments, or payments made to compensate for personal injury.~~
 - q. Any other monetary payments received by an individual that are not:
 - i. As a result of work performed or rental of property owned by the individual,
 - ii. Gifts,
 - iii. Lump-sum capital gains payments,
 - iv. Lump-sum inheritance payments,
 - v. Lump-sum insurance payments, or
 - vi. Payments made to compensate for personal injury.
- 66. "Vendor pharmacy" means an entity that contracts with the Department to perform the activities specified in R9-6-409(C).
- 67. "Veteran" means an individual who has served in the United States Armed Forces.
- 68. "Viral load test" means a laboratory analysis to determine the amount of HIV circulating in the body of an individual.

R9-6-403. Eligibility Requirements

- ~~A. An individual is eligible to participate in ADAP if the individual:~~
 - 1. ~~Applies for enrollment in AHCCCS and possesses one of the following:~~
 - a. ~~A letter from AHCCCS stating that an application for eligibility is pending, or~~
 - b. ~~A letter from AHCCCS denying eligibility;~~
 - 2. ~~Has no or inadequate health insurance to cover the cost of the drugs that are or may become available from ADAP on an outpatient basis or is an American Indian or Alaska Native who is eligible for but chooses not to use Indian Health Services;~~
 - 3. ~~Has annual family income that is less than or equal to 300% of the poverty level;~~
 - 4. ~~Is ineligible for Veterans' Administration benefits;~~
 - 5. ~~Has a medical diagnosis of HIV disease or HIV infection; and~~
 - 6. ~~Is a resident of Arizona.~~
- ~~B. For purposes of ADAP application, an individual may report annual family income using actual family income for the most recent 12 months or estimated annual family income determined by multiplying the current monthly family income by 12.~~

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)(9);

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3. Has an annual family income that is less than or equal to 300% of the poverty level;
4. Satisfies one of the following:
 - a. Has no health insurance coverage;
 - b. Has health insurance coverage that:
 - i. Does not cover drugs, or
 - ii. Does not include on its formulary at least one of the drugs prescribed for the individual that is on the ADAP formulary;
 - c. Is an American Indian or Alaska Native who:
 - i. Is eligible for, but chooses not to use, the Indian Health Service to receive drugs; and
 - ii. Either has no other health insurance coverage or has health insurance coverage that:
 - (1) Does not cover drugs, or
 - (2) Does not include on its formulary at least one of the drugs prescribed for the individual that is on the ADAP formulary; or
 - d. Is a veteran 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 health insurance coverage that:
 - (1) Does not cover drugs, or
 - (2) Does not include on its formulary at least one of the drugs prescribed for the individual that is on the ADAP formulary;
5. Is ineligible for enrollment in AHCCCS, as established by documentation issued by AHCCCS; and
6. If eligible for Medicare:
 - a. Is ineligible for a full low-income subsidy, as established by documentation issued by the Social Security Administration; and
 - b. Has enrolled in a Medicare drug plan.

R9-6-404. Initial Application Process

An applicant shall submit to the Department the following documents:

1. An application completed by the applicant, on a form provided by the Department, including the following:
 - a. The applicant's name, date of birth, and sex;
 - b. The applicant's address;
 - c. The applicant's telephone number;
 - d. The number of individuals in the applicant's family unit;
 - e. The applicant's annual family income;
 - f. The applicant's social security number;
 - g. The applicant's residency;
 - h. The applicant's race and ethnicity;
 - i. The applicant's employment status;
 - j. Whether the applicant is receiving benefits from SSI or AHCCCS;
 - k. Whether the applicant is eligible to receive benefits from the Veterans' Administration;
 - l. Whether the applicant has health insurance that would pay for drugs and, if so, to what extent;
 - m. The applicant's scheduled AHCCCS eligibility appointment date, if any;
 - n. A statement by the applicant or the parent or guardian of a minor applicant that:
 - i. The information on the form is accurate and complete;
 - ii. The applicant does not have health insurance coverage for the requested drugs or is an American Indian or Alaska Native who is eligible for but chooses not to use Indian Health Services;
 - iii. The applicant, or the parent or guardian of a minor applicant, understands that eligibility does not create an entitlement; and
 - iv. The applicant, or the parent or guardian of a minor applicant, grants permission to the Department to discuss the applicant's application with AHCCCS for purposes of determining AHCCCS eligibility; and
 - o. The signature of the applicant or the parent or guardian of a minor applicant and the date of signature;
2. An application completed by the applicant's primary care provider, on a form provided by the Department, including the following:
 - a. The applicant's name;
 - b. The primary care provider's name and business address, telephone number, and facsimile number;
 - c. A statement that the applicant has been diagnosed with HIV disease or HIV infection;
 - d. The dates, results, and laboratory names and addresses for the most recent HIV-related tests conducted for the applicant;
 - e. Each drug prescribed by the primary care provider for the applicant;
 - f. A statement by the primary care provider that the information presented on the application is accurate and complete; and

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- g. ~~The signature of the primary care provider and the date of signature;~~
 - 3. ~~An original prescription signed by the primary care provider for each drug indicated as prescribed on the primary care provider's application;~~
 - 4. ~~A copy of one of the following:~~
 - a. ~~A letter from AHCCCS stating that an application for eligibility is pending, or~~
 - b. ~~A letter from AHCCCS denying eligibility; and~~
 - 5. ~~Proof of annual family income, including the following items, as applicable:~~
 - a. ~~The most recent paycheck stub, or a statement from the employer listing gross wages, from each job;~~
 - b. ~~Business records showing net income from self employment;~~
 - e. ~~A letter describing any monetary award received by a student to cover non-tuition expenses;~~
 - d. ~~A letter describing each public assistance award; and~~
 - e. ~~Documentation showing the amount and source of any other income.~~
- A. An applicant for initial enrollment in ADAP or the applicant's representative shall submit to the Department the following documents:**
- 1. A Department-provided form, 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 community service organization that has agreed to receive written communications for the applicant;
 - d. 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;
 - e. The telephone number of the applicant or a person that has agreed to receive telephone communications for the applicant;
 - f. The number of individuals in the applicant's family unit and the names and ages of the individuals;
 - g. The names of individuals, other than the persons specified in subsection (A)(1)(q)(iii), with whom the applicant authorizes the Department to speak about the applicant's enrollment in ADAP;
 - h. The applicant's annual family income;
 - i. The applicant's race and ethnicity;
 - j. Whether the applicant or an adult in the applicant's family unit:
 - i. Is employed;
 - ii. Is self-employed;
 - iii. Is receiving public assistance;
 - iv. Is receiving regular monetary payments from a source not specified in subsection (A)(1)(j)(i) through subsection (A)(1)(j)(iii) and, if so, an identification of the source of the monetary payments; or
 - v. Is using a source not specified in subsection (A)(1)(j)(i) through subsection (A)(1)(j)(iv) or savings to assist the applicant in obtaining food, water, housing, or clothing for the applicant and if so, an identification of the source;
 - k. Whether the applicant is receiving benefits from AHCCCS;
 - l. The date the applicant or the applicant's representative is scheduled to meet with AHCCCS to discuss eligibility for AHCCCS, if applicable;
 - m. Whether the applicant is eligible for Medicare benefits and, if not, the date on which the applicant will be eligible for Medicare benefits;
 - n. If the applicant is eligible for Medicare benefits, 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 has health insurance other than Medicare that would pay for drugs on the ADAP formulary;
 - p. Whether the applicant has served on active duty:
 - i. In the U.S. Air Force, Army, Coast Guard, Marine Corps, or Navy;
 - ii. In the Army National Guard or Air National Guard; or
 - iii. As a reservist serving on active duty other than for routine training purposes;
 - q. A statement by the applicant or the applicant's representative confirming that the applicant or the applicant's representative:
 - i. Understands that the applicant or the applicant's representative is required to submit to the Department proof of ineligibility for enrollment in AHCCCS and for a low-income subsidy within 30 calendar days after the

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- a. Information completed by the applicant or the applicant's representative stating whether:
 - i. An adult in the applicant's family unit receives money from intermittent work performed by the adult in the family unit for which no paycheck stub is received and, if so, the average monthly earnings, and the adult's occupation;
 - ii. The applicant is homeless or living in a shelter;
 - 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)(8)(a) is accurate and complete;
 - c. The dated signature of the applicant or the applicant's representative;
 - d. A statement by the applicant's case manager or primary care provider attesting that to the best of the knowledge and belief of the applicant's case manager or primary care provider the information submitted under subsection (A)(8)(a) is accurate and complete; and
 - e. The dated signature of the applicant's case manager or primary care provider;
9. Proof that the applicant is a resident of Arizona that includes:
- a. One of the following that shows the Arizona residential address included on the Department-provided form specified in subsection (A)(1) and the name of the applicant or an adult in the applicant's family unit:
 - i. Documentation issued by a governmental entity related to participation in public assistance, dated within 60 calendar days before the date of application;
 - ii. Current documentation from AHCCCS related to the applicant's eligibility for enrollment in AHCCCS;
 - iii. Current documentation from the Social Security Administration or the Department of Veterans Affairs related to the applicant's eligibility for benefits;
 - iv. Current documentation from the Arizona Department of Economic Security related to the applicant's eligibility for unemployment insurance benefits;
 - v. A property tax statement for the most recent tax year issued by a governmental entity;
 - vi. A homeowners' association assessment or fee statement, dated within 60 calendar days before the date of application;
 - vii. A current lease agreement; or
 - viii. A mortgage statement for the most recent tax year;
 - b. If the applicant is unable to produce documentation that satisfies subsection (A)(9)(a), two of the following that show the Arizona residential address included on the Department-provided form specified in subsection (A)(1) and the name of the applicant or an adult in the applicant's family unit:
 - i. A utility bill dated within 60 calendar days before the date of application;
 - ii. A tax statement, other than a property tax statement, issued by a governmental entity for the most recent tax year;
 - iii. An Internal Revenue Service Form W-2 for the most recent tax year;
 - iv. A check stub or statement of direct deposit issued by an employer for the most recent pay period;
 - v. A bank or credit union statement dated within 60 calendar days before the date of application;
 - vi. A non-expired Arizona driver license issued by the Arizona Department of Transportation's Motor Vehicle Division;
 - vii. A non-expired Arizona vehicle registration issued by the Arizona Department of Transportation's Motor Vehicle Division;
 - viii. A non-expired Arizona identification card issued by the Arizona Department of Transportation's Motor Vehicle Division;
 - ix. A tribal enrollment card or other type of tribal identification; or
 - x. A current immigration identification card issued by U.S. Citizenship and Immigration Services; or
 - c. If the applicant is unable to produce documentation that satisfies either subsection (A)(9)(a) or (b), two of the following that include the name of the applicant or an adult in the applicant's family unit:
 - i. A document listed in subsection (A)(9)(b)(i) through subsection (A)(9)(b)(x) that includes the Arizona residential address shown on the Department-provided form specified in subsection (A)(1);
 - ii. A letter issued by an entity providing non-permanent housing to the applicant, including the Arizona residential address of the non-permanent housing that is the same as the Arizona residential address for the applicant shown on the Department-provided form specified in subsection (A)(1);
 - iii. A written statement issued by a community service organization, verifying that the applicant is homeless and a resident of Arizona;
 - iv. A credit card, primary care provider's office, insurance company, or mobile telephone company billing statement dated within 60 calendar days before the date of application, including the Arizona residential

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- address shown on the Department-provided form specified in subsection (A)(1);
 - v. A current vehicle insurance card, including the Arizona residential address shown on the Department-provided form specified in subsection (A)(1);
 - vi. An official document, such as an Arizona voter registration card, issued by a governmental entity and including the Arizona residential address shown on the Department-provided form specified in subsection (A)(1);
 - vii. 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 shown on the Department-provided form specified in subsection (A)(1) within 30 calendar days before the date of application; or
 - viii. A written statement issued by the applicant's primary care provider, verifying that the applicant is a resident of Arizona; and
 - 10. If the applicant or the applicant's representative has stated on the Department-provided form specified in subsection (A)(8) 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 primary care provider of an applicant for initial enrollment in ADAP shall complete for the applicant a Department-provided form containing:
- 1. The applicant's name;
 - 2. The primary care provider's name, business address, telephone number, fax number, and professional license number;
 - 3. A statement that the applicant has been diagnosed with HIV infection;
 - 4. The dates of and results for the most recent confirmatory test, CD4-T-lymphocyte count, and, if available, viral load test conducted for the applicant;
 - 5. A list of each drug from the current ADAP formulary prescribed for the applicant by the primary care provider;
 - 6. A statement by the primary care provider that the primary care provider understands that the primary care provider is required to notify the Department of changes specified in R9-6-406(B);
 - 7. A statement by the primary care provider attesting that, to the best of the primary care provider's knowledge and belief, the information provided to the Department as specified in subsection (B) is accurate and complete; and
 - 8. The dated signature of the primary care provider.
- C.** For purposes of enrollment in ADAP, an applicant or the applicant's representative may report annual family income using actual family income for the most recent 12 months or estimated annual family income determined by multiplying the most recent monthly family income by 12.

R9-6-405. Enrollment Process; Provisional Enrollment

- A.** The Department shall review each completed application received and determine enrollment based on applicant eligibility, the date on which the application is completed, and the availability of funds.
- B.** An applicant shall execute any consent forms or releases of information necessary for the Department to verify eligibility.
- C.** The time frames for approving or denying an application are described in R9-6-408.
- A.** The Department shall:
- 1. Review the documents submitted by an applicant as required in R9-6-404(A);
 - 2. Determine whether the applicant is eligible under R9-6-403;
 - 3. Grant or deny enrollment based on applicant eligibility, the date of application, and the availability of funds; and
 - 4. Notify the applicant or the applicant's representative of the Department's decision within five business days after receiving the documents specified in R9-6-404(A).
- B.** An applicant or the applicant's representative shall execute any consent forms or releases of information necessary for the Department to verify eligibility.
- C.** The Department shall send an applicant or the applicant's representative a written notice of denial, setting forth the information required under A.R.S. § 41-1092.03, if:
- 1. The applicant or the applicant's representative fails to provide documentation establishing eligibility for enrollment in ADAP;
 - 2. The documentation submitted to the Department under R9-6-404 is found to contain false information, or
 - 3. The Department does not have funds available to enroll the applicant in ADAP.
- D.** The Department shall grant a 30-day provisional enrollment in ADAP to an applicant if:
- 1. The Department determines that the applicant meets the requirements of R9-6-403(1) through (4); and
 - 2. The applicant or the applicant's representative attests in writing that the applicant has applied for AHCCCS enrollment and, if eligible for Medicare, a low-income subsidy and a Medicare drug plan, but is unable to provide documentation that complies with R9-6-403(5) or (6) or both.
- E.** The Department shall provide an applicant to whom the Department has granted provisional enrollment in ADAP with the drugs on the list specified in R9-6-404(B)(5) during the provisional enrollment period.
- F.** Except as specified in subsection (H), to continue ADAP enrollment beyond a 30-day provisional enrollment period, an applicant or the applicant's representative shall provide to the Department, before the end of the 30-day provisional enrollment period, documentation that complies with R9-6-403(5) and, if applicable, R9-6-403(6).

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- G.** Except as specified in subsection (H), if an applicant with provisional enrollment or the applicant's representative fails to provide documentation as required in subsection (F) to the Department before end of a 30-day provisional enrollment period, the Department shall send the applicant or the applicant's representative a written notice of denial, setting forth the information required under A.R.S. § 41-1092.03.
- H.** The Department may grant an extension of provisional enrollment to an applicant beyond a 30-day provisional enrollment period if the applicant or the applicant's representative provides documentation to the Department that the applicant has applied for AHCCCS enrollment and, if eligible for Medicare, a low-income subsidy and Medicare drug plan and:
1. AHCCCS has not yet determined whether the applicant is eligible for AHCCCS enrollment; or
 2. If the applicant is eligible for Medicare:
 - a. The Social Security Administration has not yet determined whether the applicant is eligible for a low-income subsidy; or
 - b. The applicant cannot enroll in a Medicare drug plan until the next general enrollment period.

R9-6-406. Notification Requirements

- A.** An enrolled individual or the enrolled individual's representative shall notify the Department in writing or by telephone and comply with the applicable requirements specified in R9-6-407 within 30 calendar days after any of the following occurs:
1. The residential or mailing address or the telephone number of the enrolled individual changes from that provided to the Department under R9-6-404(A)(1) or R9-6-407;
 2. The enrolled individual adds or deletes an individual with whom the Department may speak about the enrolled individual's ADAP enrollment from the list specified in R9-6-404(A)(1)(g);
 3. The enrolled individual begins receiving treatment for HIV infection from a primary care provider different from the primary care provider who completed:
 - a. The form specified in R9-6-404(B), or
 - b. The most recent form specified in R9-6-407(D);
 4. The enrolled individual has:
 - a. Been determined eligible for and enrolled to receive drug coverage through AHCCCS;
 - b. Received notification of drug coverage from a third-party payor other than AHCCCS, the Indian Health Service, or the Veterans Health Administration; or
 - c. Been determined eligible for a low-income subsidy;
 5. The enrolled individual's annual family income has:
 - a. Increased to an amount above 300% of the poverty level, or
 - b. Decreased to an amount that may make the enrolled individual eligible for enrollment in AHCCCS; or
 6. The enrolled individual establishes residency outside Arizona.
- B.** An enrolled individual's primary care provider shall:
1. Notify the Department in writing or by telephone:
 - a. That the enrolled individual has died, within 14 calendar days after the primary care provider learns of the death; and
 - b. That the enrolled individual is receiving treatment for HIV infection from a different primary care provider, within 14 calendar days after the primary care provider learns of the change in primary care provider; and
 2. Include in the notification:
 - a. The name and date of birth of the enrolled individual;
 - b. If notifying under subsection (B)(1)(a), the date of death; and
 - c. If notifying under subsection (B)(1)(b), the name, business address, and telephone number of the new primary care provider.
- C.** An enrolled individual's primary care provider shall notify the vendor pharmacy, as specified in R9-6-409(A):
1. When prescribing a new drug for the enrolled individual, or
 2. Within seven calendar days after discontinuing a drug that was contained in the list completed by the enrolled individual's primary care provider under R9-6-404(B) or R9-6-407(D).
- D.** An enrolled individual's case manager shall notify the Department in writing or by telephone within 30 calendar days after the case manager learns that:
1. The residential or mailing address or the telephone number of the enrolled individual has changed from that provided to the Department under R9-6-404(A)(1) or R9-6-407;
 2. The enrolled individual has begun receiving treatment for HIV infection from a primary care provider who is different from the primary care provider who completed:
 - a. The form specified in R9-6-404(B), or
 - b. The most recent form specified in R9-6-407(D);
 3. The enrolled individual has:
 - a. Been determined eligible for and enrolled to receive drug coverage through AHCCCS;
 - b. Received notification of drug coverage from a third-party payor other than AHCCCS, the Indian Health Service,

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- or the Veterans Health Administration; or
- c. Been determined eligible for a low-income subsidy;
- 4. The enrolled individual's annual family income has:
 - a. Increased to an amount above 300% of the poverty level; or
 - b. Decreased to an amount that may make the enrolled individual eligible for enrollment in AHCCCS;
- 5. The enrolled individual has established residency outside Arizona; or
- 6. The enrolled individual has died.

~~R9-6-406~~**R9-6-407. Continuing Enrollment**

- ~~A.~~ The Department shall review eligibility every six months after enrollment unless one of the following events occurs within the six-month period to end eligibility:
 - 1. ~~The enrolled individual dies;~~
 - 2. ~~The enrolled individual stops using the drug or drugs on the advice of a primary care provider;~~
 - 3. ~~The enrolled individual is determined eligible and enrolled to receive medical services through AHCCCS or another third-party payor other than Indian Health Services;~~
 - 4. ~~The enrolled individual's annual family income increases to an amount above 300% of the poverty level; or~~
 - 5. ~~The enrolled individual establishes residency outside Arizona.~~
- ~~B.~~ The enrolled individual or the enrolled individual's primary care provider shall notify the Department within 30 days after any of the events listed in subsection (A) occurs.
- ~~C.~~ Before the expiration of each six-month period, the Department shall send each enrolled individual a letter requesting that the enrolled individual submit proof of annual family income and complete and submit a follow-up application form provided by the Department.
 - 1. ~~The enrolled individual shall submit to the Department proof of annual family income as described in R9-6-404(5) and a completed follow-up application form within 30 days after the date of the letter.~~
 - 2. ~~The completed follow-up application form shall contain the following:~~
 - ~~a. The enrolled individual's name, address, and telephone number;~~
 - ~~b. The enrolled individual's race and ethnicity, date of birth, sex, and social security number;~~
 - ~~c. The enrolled individual's residency;~~
 - ~~d. The number of individuals in the enrolled individual's family unit;~~
 - ~~e. The enrolled individual's employment status;~~
 - ~~f. The enrolled individual's annual family income;~~
 - ~~g. Whether the enrolled individual is receiving benefits from SSI or AHCCCS;~~
 - ~~h. Whether the enrolled individual is eligible to receive benefits from the Veterans' Administration;~~
 - ~~i. Whether the enrolled individual has health insurance that would pay for drugs and, if so, to what extent;~~
 - ~~j. The status of any application made to AHCCCS since the individual's enrollment in ADAP;~~
 - ~~k. A statement by the enrolled individual or the parent or guardian of an enrolled minor individual that:~~
 - ~~i. The information on the form is accurate and complete;~~
 - ~~ii. The enrolled individual does not have health insurance coverage for the requested drugs or is an American Indian or Alaska Native who is eligible for but chooses not to use Indian Health Services;~~
 - ~~iii. The enrolled individual, or the parent or guardian of an enrolled minor individual, understands that eligibility does not create an entitlement; and~~
 - ~~iv. The enrolled individual, or the parent or guardian of an enrolled minor individual, grants permission to the Department to discuss the enrolled individual's follow-up application with AHCCCS for purposes of determining AHCCCS eligibility;~~
 - ~~l. The signature of the enrolled individual or the parent or guardian of an enrolled minor individual and the date of signature; and~~
 - ~~m. After every 24 months of continuous enrollment, a portion of the follow-up application completed by the enrolled individual's primary care provider including the following:~~
 - ~~i. The primary care provider's name and business address, telephone number, and facsimile number;~~
 - ~~ii. A statement by the primary care provider that treatment with the drug or drugs is still appropriate;~~
 - ~~iii. The results and dates of the most recent HIV-related tests for the enrolled individual, if available;~~
 - ~~iv. A statement by the primary care provider that the information presented on the application is accurate and complete; and~~
 - ~~v. The signature of the primary care provider and the date of signature.~~
- ~~D.~~ The Department shall determine continuing enrollment based on the enrolled individual's eligibility and the availability of funds.
- ~~E.~~ The time frames for approving or denying continuing enrollment are described in R9-6-408.
- ~~A.~~ To continue enrollment in ADAP, an enrolled individual or the enrolled individual's representative shall:
 - 1. When the enrolled individual's residential or mailing address changes, comply with subsection (B);
 - 2. When the enrolled individual's primary care provider changes, comply with subsection (C);

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3. When the enrolled individual's annual family income decreases to an amount that may make the individual eligible for enrollment in AHCCCS, comply with subsection (E);
4. When the enrolled individual becomes eligible for Medicare, comply with subsection (F);
5. Before the expiration of each six-month period after an individual's initial enrollment, comply with subsection (G); and
6. Before the expiration of each 24-month period after an individual's initial enrollment, comply with subsection (H).
- B.** When an enrolled individual's residential or mailing address changes, the enrolled individual or the enrolled individual's representative shall:
 1. Complete a Department-provided form containing for the enrolled individual the information specified in R9-6-404(A)(1)(a) through R9-6-404(A)(1)(h) and R9-6-404(A)(1)(j), (k), (m), (n), and (o);
 2. Attest on the form specified in subsection (B)(1) that:
 - a. To the best of the knowledge and belief of the enrolled individual or the enrolled individual's representative, the information submitted in the form and the documents submitted with the form are accurate and complete;
 - b. The enrolled individual meets the eligibility criteria specified in R9-6-403; and
 - c. The enrolled individual or the enrolled individual's representative understands that eligibility does not guarantee that the Department will be able to provide drugs and that an individual's enrollment in ADAP may be terminated as specified in R9-6-408;
 3. Grant permission on the form specified in subsection (B)(1) for the Department to discuss the enrolled individual's enrollment with:
 - a. AHCCCS, for the purpose of determining AHCCCS eligibility;
 - b. Medicare and the Social Security Administration, for the purpose of determining eligibility for a low-income subsidy and enrollment in a Medicare drug plan;
 - c. The applicant's primary care provider or designee;
 - d. The vendor pharmacy, to assist with drug distribution; and
 - e. Any other entity as necessary to establish eligibility for enrollment in ADAP or assist with drug distribution;
 4. Sign and date the form specified in subsection (B)(1); and
 5. Submit to the Department within 30 calendar days of the change:
 - a. The form specified in subsection (B)(1); and
 - b. Proof of Arizona residency, as specified in R9-6-404(A)(9), showing the new Arizona residential address included on the form specified in subsection (B)(1).
- C.** When an enrolled individual's primary care provider changes, the enrolled individual or the enrolled individual's representative shall:
 1. Comply with subsections (B)(1) through (4);
 2. Obtain from the new primary care provider the Department-provided form specified in subsection (D), completed by the new primary care provider; and
 3. Submit the form specified in subsection (B)(1) and the form specified in subsection (C)(2) to the Department within 30 calendar days after the change.
- D.** The primary care provider of an enrolled individual shall complete for the enrolled individual a Department-provided form containing:
 1. The information required under R9-6-404(B)(1), (2), and (5) through (8); and
 2. The dates of and results for the most recent CD4-T-lymphocyte count and, if available, viral load test conducted for the enrolled individual.
- E.** When an enrolled individual's annual family income decreases to an amount that may make the individual eligible for enrollment in AHCCCS, the enrolled individual or the enrolled individual's representative shall:
 1. Apply for enrollment in AHCCCS within 30 calendar days after the change in annual family income; and
 2. If the enrolled individual is determined to be ineligible for AHCCCS enrollment, submit to the Department within 30 calendar days after the change, documentation that complies with R9-6-403(5).
- F.** When an enrolled individual becomes eligible for Medicare, the enrolled individual or the enrolled individual's representative shall, within 30 calendar days after the enrolled individual becomes eligible for Medicare:
 1. Apply for a low-income subsidy and for a Medicare drug plan, and
 2. If the enrolled individual is determined to be ineligible for a low-income subsidy, submit to the Department documentation that complies with R9-6-403(6).
- G.** Before the expiration of each six-month period after an individual's initial enrollment, the enrolled individual or the enrolled individual's representative shall submit to the Department:
 1. Proof of annual family income, as specified in R9-6-404(A)(7) or (8); and
 2. Proof that the enrolled individual is a resident of Arizona, as specified in R9-6-404(A)(9).
- H.** Before the expiration of each 24-month period after an individual's initial enrollment, the enrolled individual or the enrolled individual's representative shall:
 1. Comply with subsections (B)(1) through (4);

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2. Obtain from the enrolled individual's primary care provider the Department-provided form completed as specified in subsection (D); and
3. Submit to the Department:
 - a. The form specified in subsection (H)(1).
 - b. The form specified in subsection (H)(2).
 - c. Proof of annual family income, as specified in R9-6-404(A)(7) or (8), and
 - d. Proof that the enrolled individual is a resident of Arizona, as specified in R9-6-404(A)(9).
- I.** The Department shall:
 1. Review information about an enrolled individual and determine eligibility for continuing enrollment for the enrolled individual:
 - a. Every six months after the individual's initial enrollment;
 - b. When the Department receives information from the enrolled individual or the enrolled individual's representative under subsection (A); or
 - c. When the Department no longer has sufficient funds to provide continuing enrollment to all enrolled individuals;
 2. Grant continuing enrollment to an enrolled individual, subject to the availability of funds, when:
 - a. The enrolled individual or the enrolled individual's representative complies with subsection (A); and
 - b. The Department determines that:
 - i. The information in the documents submitted to the Department is accurate and complete, and
 - ii. The enrolled individual is eligible under R9-6-403; and
 3. Notify the enrolled individual or the enrolled individual's representative of the Department's decision within five business days after receipt of the documents required in subsection (A).
- J.** If the Department denies continuing enrollment to an enrolled individual, the Department shall send to the enrolled individual or the enrolled individual's representative a written notice of denial setting forth the information required under A.R.S. § 41-1092.03.

R9-6-408. Time-frames Termination from ADAP Services

- A.** The overall time frame described in A.R.S. § 41-1072 for each type of approval granted by the Department under this Article is provided in Table 1. The applicant or enrolled individual and the Department may agree in writing to extend the substantive review time frame and the overall time frame. An extension of the substantive review time frame and the overall time frame may not exceed 25% of the overall time frame.
- B.** The administrative completeness review time frame described in A.R.S. § 41-1072 for each type of approval granted by the Department under this Article is provided in Table 1 and begins on the date that the Department receives an application.
 1. The Department shall send a notice of administrative completeness or deficiencies to the applicant or enrolled individual within the administrative completeness review time frame.
 - a. A notice of deficiencies shall list each deficiency and the information and documentation needed to complete the application.
 - b. If the Department issues a notice of deficiencies within the administrative completeness review time frame, the administrative completeness review time frame and the overall time frame are suspended from the date that the notice is issued until the date that the Department receives the missing information from the applicant or enrolled individual.
 - c. If the applicant or enrolled individual fails to submit to the Department all of the information and documents listed in the notice of deficiencies within 30 days from the date that the Department sent the notice of deficiencies, the Department shall consider the application or follow-up application withdrawn.
 2. If the Department issues an approval to the applicant or enrolled individual during the administrative completeness review time frame, the Department shall not issue a separate written notice of administrative completeness.
- C.** The substantive review time frame described in A.R.S. § 41-1072 for each type of approval granted by the Department under this Article is provided in Table 1 and begins as of the date on the notice of administrative completeness.
 1. The Department shall send written notification of approval or denial of enrollment or continuing enrollment to the applicant or enrolled individual within the substantive review time frame.
 2. During the substantive review time frame, the Department may make one comprehensive written request for additional information, unless the Department and the applicant or enrolled individual have agreed in writing to allow the Department to submit supplemental requests for information.
 3. If the Department issues a comprehensive written request or a supplemental request for information, the substantive review time frame and the overall time frame are suspended from the date that the Department issues the request until the date that the Department receives all of the information requested.
 4. The Department shall issue an approval of enrollment or continuing enrollment unless:
 - a. The Department determines that the applicant or enrolled individual is ineligible,
 - b. The Department does not have funds available to enroll the applicant in or to continue the enrolled individual's enrollment in ADAP,

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- e. The Department determines that the applicant or enrolled individual submitted false or inaccurate information to the Department;
 - d. The Department determines that the applicant or enrolled individual failed to submit to the Department all of the information requested in a comprehensive or supplemental written request for information within 30 days after the request; or
 - e. The Department determines that the enrolled individual failed to submit to the Department proof of annual family income or a completed follow-up application as requested in the letter described in R9-6-406.
- D.** The Department shall send a written notice of appealable agency action that complies with A.R.S. Title 41, Chapter 6, Article 10 to each applicant or enrolled individual who is denied enrollment or continuing enrollment. The applicant or enrolled individual may file a notice of appeal with the Department within 30 days after receiving the notice of appealable agency action. The appeal shall be conducted in accordance with A.R.S. Title 41, Chapter 6, Article 10.
- E.** For the purpose of computing time frames in this Section, the day of the act, event, or default from which the designated period of time begins to run is not included. Intermediate Saturdays, Sundays, and legal holidays are included in the computation. The last day of the period so computed is included unless it is a Saturday, a Sunday, or a legal holiday, in which event the period runs until the end of the next day that is not a Saturday, a Sunday, or a legal holiday.

Table 1. Time-frames (in days)

Type of Approval	Statutory Authority	Overall Time-frame	Administrative Completeness Review Time-frame	Substantive Review Time-frame
Application for ADAP-Enrollment	A.R.S. § 36-136	52	10	42
Follow-up Application for ADAP Continuing-Enrollment	A.R.S. § 36-136	30	10	20

- A.** The Department may terminate an individual’s enrollment in ADAP if:
1. The Department learns that information submitted to the Department by the individual or the individual’s representative under R9-6-404(A) or (C), R9-6-407(A), or R9-6-409(E) is inaccurate or incomplete;
 2. The vendor pharmacy does not receive a request from the individual or the individual’s representative for any refill of a drug for a period of 90 calendar days; or
 3. The individual or the individual’s representative exhibits violent or threatening behavior to an employee of the Department or the vendor pharmacy, as established by documentation such as a police report or a written document from the individual.
- B.** The Department may terminate approval of a restricted drug for an individual enrolled in ADAP if the Department learns that the enrolled individual:
1. Is not following the instructions of the enrolled individual’s primary care provider regarding the use of the restricted drug; or
 2. Has not had additional laboratory analyses performed, as required in R9-6-409(E)(1)(i)(ii), to support continuing use of the restricted drug.
- C.** The Department shall send to an individual or the individual’s representative a written notice of termination setting forth the information required under A.R.S. § 41-1092.03 if the Department terminates:
1. The individual’s enrollment in ADAP, or
 2. Approval of a restricted drug for the individual.

R9-6-407, R9-6-409, Drug Prescription and Distribution Requirements

- A.** The primary care provider shall write each drug prescription for an applicant or enrolled individual for the quantity of the drug packaged in the original container by the manufacturer.
- B.** The Department shall purchase a prescribed drug and provide the drug to the enrolled individual’s pharmacy in a quantity sufficient to meet the therapeutic regimen prescribed by the enrolled individual’s primary care provider.
- C.** The Department shall provide a drug in original, unopened containers as packaged by the manufacturer.
- D.** If an enrolled individual changes primary care providers, the original primary care provider shall notify the Department in writing within seven days after the change. The original primary care provider shall provide the following information in the written notice:
1. The name and address of the enrolled individual;
 2. The name and business address and telephone number of the new primary care provider; and
 3. A release signed by the enrolled individual authorizing the Department to contact and exchange information with the new primary care provider.
- E.** Failure to comply with subsection (D) may cause an interruption in or termination of support.

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- A.** A primary care provider shall:
 - 1.** Issue a prescription order:
 - a. For each drug from the ADAP formulary prescribed for an applicant or enrolled individual by the primary care provider;
 - b. For dispensing up to a 30-day supply of the drug; and
 - c. To authorize no more than a six-month supply of the drug, including the original prescription order and all refills;
 - 2.** Submit:
 - a. A written prescription order or copy of a written prescription order to the Department as specified in R9-6-404(A)(3); and
 - b. A written or oral prescription order to the vendor pharmacy when:
 - i. Prescribing a drug for a newly enrolled individual;
 - ii. Prescribing a new drug for an enrolled individual; or
 - iii. Authorizing an additional six-month supply of a drug for an enrolled individual; and
 - 3.** Notify the vendor pharmacy when discontinuing a drug for an enrolled individual.
- B.** The Department shall forward a written prescription order submitted to the Department as specified in subsection (A)(2)(a) to the vendor pharmacy within three business days of approving an individual for initial enrollment.
- C.** The vendor pharmacy shall:
 - 1.** Maintain a supply of the drugs on the ADAP formulary available for dispensing;
 - 2.** Receive prescription orders issued by an enrolled individual's primary care provider;
 - 3.** Before dispensing drugs, verify:
 - a. With an enrolled individual or the enrolled individual's representative the address to which the enrolled individual or the enrolled individual's representative wants the drugs delivered, and
 - b. An individual's enrollment status;
 - 4.** Dispense up to a 30-day supply of a drug to an enrolled individual:
 - a. Upon receipt of a:
 - i. Prescription order as specified in subsection (C)(2), or
 - ii. Request from the enrolled individual or the enrolled individual's representative for a refill of the drug;
 - b. To the address identified, as specified in subsection (C)(3)(a); and
 - c. So the drug is dispensed to the enrolled individual no later than three business days after the vendor pharmacy:
 - i. Receives a prescription order or request for refill, as specified in subsection (C)(4)(a);
 - ii. Has verified the address to which the drug is to be delivered, as specified in subsection (C)(3)(a); and
 - iii. Has verified the individual's enrollment status, as specified in subsection (C)(3)(b); and
 - 5.** Notify the Department upon receiving a request for dispensing a drug for an individual who is neither enrolled nor provisionally enrolled in ADAP.
- D.** The Department may authorize replacement of a drug when:
 - 1.** The drug has been dispensed by the vendor pharmacy to an enrolled individual, and
 - 2.** The enrolled individual or the enrolled individual's representative claims the dispensed drug was lost, stolen, or damaged.
- E.** The primary care provider of an enrolled individual may request approval of a restricted drug for the enrolled individual by:
 - 1.** Completing a Department-provided form for each requested restricted drug that contains the following information:
 - a. The name, business address, and telephone number of the primary care provider;
 - b. The date of the request;
 - c. The enrolled individual's name and date of birth;
 - d. The indications for the use of the restricted drug;
 - e. The most recent results of laboratory analyses to support the request and the dates of the laboratory analyses;
 - f. A justification for use of the restricted drug by the enrolled individual;
 - g. An attestation by the primary care provider that:
 - i. To the best of the primary care provider's knowledge and belief, the information presented in the request is accurate and complete; and
 - ii. The primary care provider understands that the primary care provider is required to provide instructions to the enrolled individual regarding the use of the restricted drug and monitor the enrolled individual's use of the restricted drug;
 - h. The dated signature of the primary care provider;
 - i. An attestation by the enrolled individual or the enrolled individual's representative that the enrolled individual or the enrolled individual's representative understands that the enrolled individual is required to:
 - i. Follow the instructions of the enrolled individual's primary care provider regarding the use of the restricted drug; and
 - ii. Have periodic laboratory analyses performed to support continuing use of the restricted drug; and

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- j. The dated signature of the enrolled individual or the enrolled individual’s representative;
- 2. Issuing a written or oral prescription order for the restricted drug to the vendor pharmacy; and
- 3. Submitting to the Department:
 - a. The completed drug-specific form specified in subsection (E)(1), and
 - b. Copies of the results of the most recent laboratory analyses to support the request for the restricted drug.
- F. If the restricted drug requested under subsection (E) is approved by the Department for an enrolled individual, the enrolled individual’s primary care provider shall:
 - 1. Provide instructions to the enrolled individual regarding the use of the restricted drug; and
 - 2. Monitor the enrolled individual’s use of and clinical response to the restricted drug.
- G. When the Department receives a drug-specific form requesting a restricted drug for an enrolled individual, the Department shall:
 - 1. Review the documents submitted according to subsection (E)(3);
 - 2. Determine whether the information submitted to the Department:
 - a. Is complete; and
 - b. Substantiates that the enrolled individual’s use of the restricted drug is indicated; and
 - 3. Notify the following of the Department’s decision within five business days after receiving the request:
 - a. The enrolled individual or the enrolled individual’s representative;
 - b. The enrolled individual’s primary care provider; and
 - c. The vendor pharmacy.
- H. If the Department denies a request for approval of a restricted drug for an enrolled individual, the Department shall send to the enrolled individual or the enrolled individual’s representative a written notice of denial setting forth the information required under A.R.S. § 41-1092.03.
- I. The Department shall only authorize the distribution of drugs that are included on the ADAP formulary.

~~R9-6-409.~~ **R9-6-410. Confidentiality**

~~The Department considers ADAP application materials and all information received or maintained by the Department in connection with ADAP application and subsequent actions to be confidential medical information, as defined in 9 A.A.C. 1, Article 3. The Department shall comply with 9 A.A.C. 1, Article 3 with regard to disclosing these materials and this information. In administering ADAP, the Department shall comply with all applicable federal and state laws relating to confidentiality of information.~~

NOTICE OF FINAL RULEMAKING

TITLE 9. HEALTH SERVICES

**CHAPTER 22. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM
ADMINISTRATION**

[R07-327]

PREAMBLE

- | | |
|------------------------------------|---------------------------------|
| <u>1. Sections Affected</u> | <u>Rulemaking Action</u> |
| R9-22-101 | Amend |
| R9-22-102 | Repeal |
| R9-22-201 | Repeal |
| R9-22-201 | New Section |
| R9-22-202 | New Section |
| R9-22-217 | Amend |
- 2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**
- Authorizing statute: A.R.S. § 36-2903.01(F)
 - Implementing statute: A.R.S. §§ 36-2901(6)(ii); 36-2903.03(D) and (F)

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3. The effective date of the rules:

November 10, 2007

4. A list of all previous notices appearing in the Register addressing the proposed rule:

Notice of Rulemaking Docket Opening: 12 A.A.R. 1099, April 7, 2006

Notice of Proposed Rulemaking: 13 A.A.R. 1306, April 13, 2007

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Mariaelena Ugarte

Address: AHCCCS

Office of Legal Assistance
701 E. Jefferson, Mail Drop 6200
Phoenix, AZ 85034

Telephone: (602) 417-4693

Fax: (602) 253-9115

E-mail: AHCCCSrules@azahcccs.gov

6. An explanation of the rule, including the agency's reasons for initiating the rule:

The rule has been updated to comply with a recent Consent Decree regarding the coverage of emergency dialysis services for members of the Federal Emergency Services Program (FES). In addition, for easier reference and management of the rules related to the Article, the related definition Section has been moved to the beginning of Article 2, and the rules that existed in the beginning of Article 2 were moved to the next available Section.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on in its evaluation of or justification for the rule or did not 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:

No study was reviewed during this rulemaking and the Agency does not anticipate reviewing any studies.

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

Not applicable

9. The summary of the economic, small business, and consumer impact:

It is anticipated that there will be a minimal economic impact, since the emergency dialysis services have been covered for several years as a result of this lawsuit.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

In addition to the change agreed upon from public comment received, the Administration made the rules more clear, concise, and understandable by making grammatical, verb tense, punctuation, and structural changes throughout the rules.

11. A summary of the comments made regarding the rule and the agency response to them:

Commenter Sally Hart from William E. Morris Institute For Justice submitted a comment to the Administration requesting Section R9-22-217(D) be modified to read "Prior authorization for outpatient dialysis services is met when the treating physician has completed and signed a monthly certification as described in subsection (B)."

The Administration has agreed to modify the rule as suggested.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

None

13. Incorporations by reference and their location in the rules:

None

14. Was this rule previously adopted as an emergency rule?

No

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 22. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM
ADMINISTRATION

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ARTICLE 1. DEFINITIONS

Section

R9-22-101. Location of Definitions

R9-22-102. ~~Scope of Services-related Definitions~~ Repealed

ARTICLE 2. SCOPE OF SERVICES

Section

R9-22-201. ~~General Requirements~~ Scope of Services-related Definitions

R9-22-202. ~~Repealed~~ General Requirements

R9-22-217. Services Included in the Federal Emergency Services Program

ARTICLE 1. DEFINITIONS

R9-22-101. Location of Definitions

A. Location of definitions. Definitions applicable to this Chapter are found in the following:

Definition	Section or Citation
“Accommodation”	R9-22-701
“Act”	R9-22-101
“ADHS”	R9-22-102 <u>R9-22-101</u>
“Administration”	A.R.S. § 36-2901
“Adverse action”	R9-22-101
“Affiliated corporate organization”	R9-22-101
“Aged”	42 U.S.C. 1382c(a)(1)(A) and R9-22-1501
“Aggregate”	R9-22-701
“AHCCCS”	R9-22-101
“AHCCCS inpatient hospital day or days of care”	R9-22-701
“AHCCCS registered provider”	R9-22-101
“Ambulance”	A.R.S. § 36-2201
<u>“Ancillary department”</u>	<u>R9-22-701</u>
<u>“Ancillary service”</u>	<u>R9-22-701</u>
<u>“Anticipatory guidance”</u>	<u>R9-22-201</u>
“Annual enrollment choice”	R9-22-117
“APC”	R9-22-701
“Appellant”	R9-22-101
“Applicant”	R9-22-101
“Application”	R9-22-101
<u>“Assessment”</u>	<u>R9-22-1101</u>
“Assignment”	R9-22-101
“Attending physician”	R9-22-101
“Authorized representative”	R9-22-101
<u>“Authorization”</u>	<u>R9-22-201</u>
“Auto-assignment algorithm”	R9-22-117
<u>“AZ-NBCCEDP”</u>	<u>R9-22-2001</u>
“Baby Arizona”	R9-22-1401
“Behavior management services”	R9-22-1201
“Behavioral health adult therapeutic home”	R9-22-1201
“Behavioral health therapeutic home care services”	R9-22-1201
“Behavioral health evaluation”	R9-22-1201
“Behavioral health medical practitioner”	R9-22-1201

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“Behavioral health professional”	R9-22-1201
“Behavioral health recipient”	R9-22-102 <u>R9-22-201</u>
“Behavioral health service”	R9-22-1201
“Behavioral health technician”	R9-22-1201
“BHS”	R9-22-1401
“Billed charges”	R9-22-701
“Blind”	R9-22-1501
“Burial plot”	R9-22-1401
<u>“Business agent”</u>	<u>R9-22-701 and R9-22-704</u>
<u>“Calculated inpatient costs”</u>	<u>R9-22-712.07</u>
“Capital costs”	R9-22-701
“Capped fee-for-service”	R9-22-101
“Caretaker relative”	R9-22-1401
“Case management”	R9-22-1201
“Case record”	R9-22-101
“Case review”	R9-22-101
“Cash assistance”	R9-22-1401
“Categorically-eligible”	R9-22-101
<u>“CCR”</u>	<u>R9-22-712</u>
“Certified psychiatric nurse practitioner”	R9-22-1201
<u>“Charge master”</u>	<u>R9-22-712</u>
<u>“Child”</u>	<u>R9-22-1503 and R9-22-1603</u>
“Children’s Rehabilitative Services” or “CRS”	R9-22-102 <u>R9-22-201</u>
<u>“Claim”</u>	<u>R9-22-1101</u>
<u>“Claims paid amount”</u>	<u>R9-22-712.07</u>
“Clean claim”	A.R.S. § 36-2904
“Clinical supervision”	R9-22-102 <u>R9-22-201</u>
“CMDP”	R9-22-117
“CMS”	R9-22-101
“Continuous stay”	R9-22-101
“Contract”	R9-22-101
“Contractor”	A.R.S. § 36-2901
<u>“Copayment”</u>	<u>R9-22-701, R9-22-711 and R9-22-1603</u>
<u>“Cost avoid”</u>	<u>R9-22-1201</u>
“Cost-To-Charge Ratio”	R9-22-701
“Covered charges”	R9-22-701
“Covered services”	R9-22-102 <u>R9-22-101</u>
“CPT”	R9-22-701
<u>“Creditable coverage”</u>	<u>R9-22-2003 and 42 U.S.C. 300gg(c)</u>
“Critical Access Hospital”	R9-22-701
<u>“CRS”</u>	<u>R9-22-1401</u>
“Cryotherapy”	R9-22-2001
<u>“Customized DME”</u>	<u>R9-22-212</u>
<u>“Date of eligibility posting”</u>	<u>R9-22-701</u>
“Day”	R9-22-101 <u>and R9-22-1101</u>
<u>“Date of the Notice of Adverse Action”</u>	<u>R9-22-1441</u>
“DBHS”	R9-22-102 <u>R9-22-201</u>

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“DCSE”	R9-22-1401
“De novo hearing”	42 CFR 431.201
“Dentures” and “Denture services”	R9-22-102 <u>R9-22-201</u>
“Department”	A.R.S. § 36-2901
“Dependent child”	A.R.S. § 46-101
“DES”	R9-22-101
“Diagnostic services”	R9-22-102 <u>R9-22-101</u>
“Director”	R9-22-101
“Disabled”	R9-22-1501
“Discussion”	R9-22-101
“Disenrollment”	R9-22-117
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B. General definitions. In addition to definitions contained in A.R.S. § 36-2901, the words and phrases in this Chapter have the following meanings unless the context explicitly requires another meaning:

“Act” means the Social Security Act.

“ADHS” means the Arizona Department of Health Services.

“Adverse action” means an action taken by the Department or Administration to deny, discontinue, or reduce medical assistance.

“Affiliated corporate organization” means any organization that has ownership or control interests as defined in 42 CFR 455.101, and includes a parent and subsidiary corporation.

“AHCCCS” means the Arizona Health Care Cost Containment System, which is composed of the Administration, contractors, and other arrangements through which health care services are provided to a member.

“AHCCCS registered provider” means a provider or noncontracting provider who:

Enters into a provider agreement with the Administration under R9-22-703(A), and

Meets license or certification requirements to provide covered services.

“Appellant” means an applicant or member who is appealing an adverse action by the Department or Administration.

“Applicant” means a person who submits or whose authorized representative submits, a written, signed, and dated application for AHCCCS benefits.

“Application” means an official request for AHCCCS medical coverage made under this Chapter.

“Assignment” means enrollment of a member with a contractor by the Administration.

“Attending physician” means a licensed allopathic or osteopathic doctor of medicine who has primary responsibility for providing or directing preventive and treatment services for a Fee-For-Service member.

“Authorized representative” means a person who is authorized to apply for medical assistance or act on behalf of another person.

“Capped fee-for-service” means the payment mechanism by which a provider of care is reimbursed upon submission of a valid claim for a specific covered service or equipment provided to a member. A payment is made in accordance with an upper, or capped, limit established by the Director. This capped limit can be either a specific dollar amount or a percentage of billed charges.

“Case record” means an individual or family file retained by the Department that contains all pertinent eligibility information, including electronically stored data.

“Case review” means the Administration’s evaluation of an individual’s or family’s circumstances and case record in a review month.

“Categorically-eligible” means a person who is eligible under A.R.S. §§ 36-2901(6)(a)(i), (ii), or (iii) or 36-2934.

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“CMS” means the Centers for Medicare and Medicaid Services.

“Continuous stay” means a period during which a member receives inpatient hospital services without interruption beginning with the date of admission and ending with the date of discharge or date of death.

“Contract” means a written agreement entered into between a person, an organization, or other entity and the Administration to provide health care services to a member under A.R.S. Title 36, Chapter 29, and this Chapter.

“Covered services” means the health and medical services described in Articles 2 and 12 of this Chapter as being eligible for reimbursement by AHCCCS.

“Day” means a calendar day unless otherwise specified.

“DES” means the Department of Economic Security.

“Diagnostic services” means services provided for the purpose of determining the nature and cause of a condition, illness, or injury.

“Director” means the Director of the Administration or the Director’s designee.

“Discussion” means an oral or written exchange of information or any form of negotiation.

“DME” means durable medical equipment, which is an item or appliance that can withstand repeated use, is designed to serve a medical purpose, and is not generally useful to a person in the absence of a medical condition, illness, or injury.

“Enumeration” means the assignment of a nine-digit identification number to a person by the Social Security Administration.

“Equity” means the county assessor full cash value or market value of a resource minus valid liens, encumbrances, or both.

“Experimental services” means services that are associated with treatment or diagnostic evaluation and that are not generally and widely accepted as a standard of care in the practice of medicine in the United States unless:

The weight of the evidence in peer-reviewed articles in medical journals published in the United States supports the safety and effectiveness of the service; or

In the absence of peer-reviewed articles, for services that are rarely used, novel, or relatively unknown in the general professional medical community, the weight of opinions from specialists who provide the service attests to the safety and effectiveness of the service.

“Facility” means a building or portion of a building licensed or certified by the Arizona Department of Health Services as a health care institution under A.R.S. Title 36, Chapter 4, to provide a medical service, a nursing service, or other health care or health-related service.

“FBR” means Federal Benefit Rate, the maximum monthly Supplemental Security Income payment rate for a member or a married couple.

“Fee-For-Service” or “FFS” means a method of payment by the AHCCCS Administration to a registered provider on an amount-per-service basis for a member not enrolled with a contractor.

“FES member” means a person who is eligible to receive emergency medical and behavioral health services through the FESP under R9-22-217.

“FESP” means the federal emergency services program under R9-22-217 which covers services to treat an emergency medical or behavioral health condition for a member who is determined eligible under A.R.S. § 36-2903.03(D).

“FQHC” means federally qualified health center.

“GSA” means a geographical service area designated by the Administration within which a contractor provides, directly or through a subcontract, a covered health care service to a member enrolled with the contractor.

“Hospital” means a health care institution that is licensed as a hospital by the Arizona Department of Health Services under A.R.S. Title 36, Chapter 4, Article 2, and certified as a provider under Title XVIII of the Social Security Act, as amended, or is currently determined, by the Arizona Department of Health Services as the CMS designee, to meet the requirements of certification.

“Interested party” means an actual or prospective offeror whose economic interest may be directly affected by the issuance of an RFP, the award of a contract, or by the failure to award a contract.

“Legal representative” means a custodial parent of a child under 18, a guardian, or a conservator.

“License” or “licensure” means a nontransferable authorization that is granted based on established standards in law by a state or a county regulatory agency or board and allows a health care provider to lawfully render a health care service.

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“Mailing date” when used in reference to a document sent first class, postage prepaid, through the United States mail, means the date:

Shown on the postmark;

Shown on the postage meter mark of the envelope, if no postmark; or

Entered as the date on the document if there is no legible postmark or postage meter mark.

“Medical record” means a document that relates to medical or behavioral health services provided to a member by a physician or other licensed practitioner of the healing arts and is kept at the site of the provider.

“Medically necessary” means a covered service is provided by a physician or other licensed practitioner of the healing arts within the scope of practice under state law to prevent disease, disability, or other adverse health conditions or their progression, or to prolong life.

“Medicare claim” means a claim for Medicare-covered services for a member with Medicare coverage.

“Medicare HMO” means a health maintenance organization that has a current contract with Centers for Medicare and Medicaid Services for participation in the Medicare program under 42 CFR 417 Subpart L.

“Offeror” means an individual or entity that submits a proposal to the Administration in response to an RFP.

“Physician” means a person licensed as an allopathic or osteopathic physician under A.R.S. Title 32, Chapter 13 or Chapter 17.

“Practitioner” means a physician assistant licensed under A.R.S. Title 32, Chapter 25, or a registered nurse practitioner certified under A.R.S. Title 32, Chapter 15.

“Prescription” means an order to provide covered services that is signed or transmitted by a provider authorized to prescribe the services.

“Primary care provider” or “PCP” means an individual who meets the requirements of A.R.S. § 36-2901(12) or (13), and who is responsible for the management of a member’s health care.

“Prior authorization” means the process by which the Administration or contractor, whichever is applicable, authorizes, in advance, the delivery of covered services contingent on the medical necessity of the services.

“Prior period coverage” means the period prior to the member’s enrollment during which a member is eligible for covered services. PPC begins on the first day of the month of application or the first eligible month, whichever is later, and continues until the day the member is enrolled with a contractor.

“Proposal” means all documents, including best and final offers, submitted by an offeror in response to an RFP by the Administration.

“Radiology” means professional and technical services rendered to provide medical imaging, radiation oncology, and radioisotope services.

“Referral” means the process by which a member is directed by a primary care provider or an attending physician to another appropriate provider or resource for diagnosis or treatment.

“Rehabilitation services” means physical, occupational, and speech therapies, and items to assist in improving or restoring a person’s functional level.

“Responsible offeror” means an individual or entity that has the capability to perform the requirements of a contract and that ensures good faith performance.

“Responsive offeror” means an individual or entity that submits a proposal that conforms in all material respects to an RFP.

“Review” means a review of all factors affecting a member’s eligibility.

“Review month” means the month in which the individual’s or family’s circumstances and case record are reviewed.

“RFP” means Request for Proposals, including all documents, whether attached or incorporated by reference, that are used by the Administration for soliciting a proposal under 9 A.A.C. 22, Article 6.

“Service location” means a location at which a member obtains a covered service provided by a physician or other licensed practitioner of the healing arts under the terms of a contract.

“Service site” means a location designated by a contractor as the location at which a member is to receive covered services.

“SOBRA” means Section 9401 of the Sixth Omnibus Budget Reconciliation Act, 1986, amended by the Medicare Catastrophic Coverage Act of 1988, 42 U.S.C. 1396a(a)(10)(A)(i)(IV), 42 U.S.C. 1396a(a)(10)(A)(i)(VI), and 42 U.S.C. 1396a(a)(10)(A)(i)(VII).

“Specialist” means a Board-eligible or certified physician who declares himself or herself as a specialist and practices a specific medical specialty. For the purposes of this definition, Board-eligible means a physician who meets all the

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requirements for certification but has not tested for or has not been issued certification.

“Spouse” means a person who has entered into a contract of marriage recognized as valid by this state.

“SSN” means Social Security number.

“Standard of care” means a medical procedure or process that is accepted as treatment for a specific illness, injury, or medical condition through custom, peer review, or consensus by the professional medical community.

“Subcontract” means an agreement entered into by a contractor with any of the following:

A provider of health care services who agrees to furnish covered services to a member;

A marketing organization; or

Any other organization or person who agrees to perform any administrative function or service for the contractor specifically related to securing or fulfilling the contractor’s obligation to the Administration under the terms of a contract.

R9-22-102. ~~Scope of Services related Definitions Repealed~~

In addition to definitions contained in A.R.S. § 36-2901, the words and phrases in this Chapter have the following meanings unless the context explicitly requires another meaning:

~~“ADHS” means the Arizona Department of Health Services.~~

~~“Behavioral health recipient” means a Title XIX or Title XXI acute care member who is eligible for, and is receiving, behavioral health services through ADHS/DBHS.~~

~~“Children’s Rehabilitative Services” or “CRS” means the program within ADHS that provides covered medical services and covered support services in accordance with A.R.S. § 36-261.—~~

~~“Clinical supervision” means a Clinical Supervisor under 9 A.A.C. 20, Article 2 reviews the skills and knowledge of the individual supervised and provides guidance in improving or developing the skills and knowledge.~~

~~“Covered services” means the health and medical services described in Articles 2 and 12 of this Chapter as being eligible for reimbursement by AHCCCS.~~

~~“DBHS” means the Division of Behavioral Health Services within the Arizona Department of Health Services.~~

~~“Dentures” and “Denture services” mean a partial or complete set of artificial teeth and related services that are determined to be medically necessary and the primary treatment of choice, or an essential part of an overall treatment plan, and designed to alleviate a medical condition as determined by the primary care provider in consultation with the dental service provider.~~

~~“Diagnostic services” means services provided for the purpose of determining the nature and cause of a condition, illness, or injury.~~

~~“DME” means durable medical equipment, which is an item or appliance that can withstand repeated use, is designed to serve a medical purpose, and is not generally useful to a person in the absence of a medical condition, illness, or injury.~~

~~“Emergency behavioral health condition for the non-FES member” means a condition manifesting itself by acute symptoms of sufficient severity, including severe pain, such that a prudent layperson who possesses an average knowledge of health and medicine could reasonably expect the absence of immediate medical attention to result in:~~

- ~~1. Placing the health of the person, including mental health, in serious jeopardy;~~
- ~~2. Serious impairment to bodily functions;~~
- ~~3. Serious dysfunction of any bodily organ or part; or~~
- ~~4. Serious physical harm to another person.~~

~~“Emergency behavioral health services for the non-FES member” means those behavioral health services provided for the treatment of an emergency behavioral health condition.~~

~~“Emergency medical condition for the non-FES member” means treatment for a medical condition, including labor and delivery, that manifests itself by acute symptoms of sufficient severity, including severe pain, such that a prudent layperson who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in:~~

- ~~1. Placing the member’s health in serious jeopardy;~~
- ~~2. Serious impairment to bodily functions; or~~
- ~~3. Serious dysfunction of any bodily organ or part.~~

~~“Emergency medical services for the non-FES member” means services provided for the treatment of an emergency medical condition.~~

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“Fee For Service” or “FFS” means a method of payment by the AHCCCS Administration to a registered provider on an amount per service basis for a member not enrolled with a contractor.

“FES member” means a person who is eligible to receive emergency medical and behavioral health services through the FESP under R9-22-217.

“Hearing aid” means an instrument or device designed for, or represented by the supplier as, aiding or compensating for impaired or defective human hearing, and includes any parts, attachments, or accessories of the instrument or device.

“Home health services” means services and supplies that are provided by a home health agency that coordinates in-home intermittent services for curative, rehabilitative care, including home health aide services, licensed nurse services, and medical supplies, equipment, and appliances.

“IMD” or “Institution for Mental Diseases” means an Institution for Mental Diseases as described in 42 CFR 435.1010 and licensed by ADHS.

“Medical supplies” means consumable items that are designed specifically to meet a medical purpose.

“Non-FES member” means an eligible person who is entitled to full AHCCCS services.

“Occupational therapy” means medically prescribed treatment provided by or under the supervision of a licensed occupational therapist, to restore or improve an individual’s ability to perform tasks required for independent functioning.

“Pharmaceutical service” means medically necessary medications that are prescribed by a physician, practitioner, or dentist under R9-22-209.

“Physical therapy” means treatment services to restore or improve muscle tone, joint mobility, or physical function provided by or under the supervision of a registered physical therapist.

“Physician” means a person licensed as an allopathic or osteopathic physician under A.R.S. Title 32, Chapter 13 or Chapter 17.

“Post stabilization services” means covered services related to an emergency medical or behavioral health condition provided after the condition is stabilized.

“Practitioner” means a physician assistant licensed under A.R.S. Title 32, Chapter 25, or a certified nurse practitioner licensed under A.R.S. Title 32, Chapter 15.

“Prescription” means an order to provide covered services that is signed or transmitted by a provider authorized to prescribe the services.

“Primary care provider” or “PCP” means an individual who meets the requirements of A.R.S. § 36-2901(12) and (13), and who is responsible for the management of a member’s health care.

“Primary care provider services” means healthcare services provided by and within the scope of practice, as defined by law, of a licensed physician, certified nurse practitioner, or licensed physician assistant.

“Prior authorization” means the process by which the Administration or contractor, whichever is applicable, authorizes, in advance, the delivery of covered services contingent on the medical necessity of the services.

“Psychosocial rehabilitation services” means services that provide education, coaching, and training to address or prevent residual functional deficits and may include services that may assist a member to secure and maintain employment. Psychosocial rehabilitation services may include:

- Living skills training;
- Cognitive rehabilitation;
- Health promotion;
- Supported employment; and
- Other services that increase social and communication skills to maximize a member’s ability to participate in the community and function independently.

“Radiology” means professional and technical services rendered to provide medical imaging, radioisotope services, and radiation oncology.

“RBHA” or “Regional Behavioral Health Authority” means the same as in A.R.S. § 36-3401.

“Rehabilitation services” means physical, occupational, and speech therapies, and items to assist in improving or restoring a person’s functional level.

“Residual functional deficit” means a member’s inability to return to a previous level of functioning, usually after experiencing a severe psychotic break or state of decompensation.

“Respiratory therapy” means treatment services to restore, maintain, or improve respiratory functions that are pro-

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vided by, or under the supervision of, a respiratory therapist licensed according to A.R.S. Title 32, Chapter 35.

“Scope of services” means the covered, limited, and excluded services under Articles 2 and 12 of this Chapter.

“Specialist” means a Board-eligible or certified physician who declares himself or herself as a specialist and practices a specific medical specialty. For the purposes of this definition, Board-eligible means a physician who meets all the requirements for certification but has not tested for, or has not been issued certification.

“Speech therapy” means medically prescribed diagnostic and treatment services provided by, or under the supervision of, a certified speech therapist.

“Sterilization” means a medically necessary procedure, not for the purpose of family planning, to render an eligible person or member barren in order to:

Prevent the progression of disease, disability, or adverse health conditions; or

Prolong life and promote physical health.

“Substance abuse” means the chronic, habitual, or compulsive use of any chemical matter that, when introduced into the body, is capable of altering human behavior or mental functioning and, with extended use, may cause psychological dependence and impaired mental, social or educational functioning. Nicotine addiction is not considered substance abuse for adults who are 21 years of age or older.

R9-22-201. General Requirements Scope of Services-related Definitions

A. For the purposes of this Article, the following definitions apply:

1. “Authorization” means written or verbal authorization by:
 - a. The Administration for services rendered to a fee-for-service member or
 - b. The contractor for services rendered to a prepaid capitated member.
2. Use of the phrase “attending physician” applies only to the fee-for-service population.

B. In addition to other requirements and limitations specified in this Chapter, the following general requirements apply:

1. Only medically necessary, cost effective, and federally-reimbursable and state-reimbursable services are covered services.
2. Covered services for the federal emergency services program (FESP) are under R9-22-217.
3. The Administration or a contractor may waive the covered services referral requirements of this Article.
4. Except as authorized by the Administration or a contractor, a primary care provider, attending physician, practitioner, or a dentist shall provide or direct the member’s covered services. Delegation of the provision of care to a practitioner does not diminish the role or responsibility of the primary care provider.
5. A contractor shall offer a female member direct access to preventive and routine services from gynecology providers within the contractor’s network without a referral from a primary care provider.
6. A member may receive behavioral health evaluation services without a referral from a primary care provider. A member may receive behavioral health treatment services only under referral from the primary care provider, or upon authorization by the contractor or the contractor’s designee.
7. A member may receive treatment that is considered the standard of care, or that is approved by the AHCCCS Chief Medical Officer after appropriate input from providers who are considered experts in the field by the professional medical community.
8. AHCCCS or a contractor shall provide services under the Section 1115 Waiver as defined in A.R.S. § 36-2901.
9. An AHCCCS registered provider shall provide covered services within the provider’s scope of practice.
10. In addition to the specific exclusions and limitations otherwise specified under this Article, the following are not covered:
 - a. A service that is determined by the AHCCCS Chief Medical Officer to be experimental or provided primarily for the purpose of research;
 - b. Services or items furnished gratuitously; and
 - c. Personal care items.
11. Medical or behavioral health services are not covered services if provided to:
 - a. An inmate of a public institution;
 - b. A person who is in residence at an institution for the treatment of tuberculosis; or
 - c. A person age 21 through 64 who is in an IMD, unless provided under Article 12 of this Chapter.

C. The Administration or a contractor may deny payment of non-emergency services if prior authorization is not obtained as specified in this Article and Article 7 of this Chapter. The Administration or a contractor shall not reimburse services that require prior authorization unless the provider documents the diagnosis and treatment.

D. Services under A.R.S. § 36-2908 provided during the prior period coverage do not require prior authorization.

E. Prior authorization is not required for services necessary to evaluate and stabilize an emergency medical condition. The Administration or a contractor shall not reimburse services that require prior authorization unless the provider documents the diagnosis and treatment.

F. A service is not a covered service if provided outside the GSA unless one of the following applies:

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1. A member is referred by a primary care provider for medical specialty care outside the GSA. If a member is referred outside the GSA to receive an authorized medically necessary service, the contractor shall also provide all other medically necessary covered services for the member;
 2. There is a net savings in service delivery costs as a result of going outside the GSA that does not require undue travel time or hardship for a member or the member's family;
 3. The contractor authorizes placement in a nursing facility located out of the GSA; or
 4. Services are provided during prior period coverage.
- G.** If a member is traveling or temporarily residing outside of the GSA, covered services are restricted to emergency care services, unless otherwise authorized by the contractor.
- H.** A contractor shall provide at a minimum, directly or through subcontracts, the covered services specified in this Chapter and in contract.
- I.** The Administration shall determine the circumstances under which a FFS member may receive services, other than emergency services, from service providers outside the member's county of residence or outside the state. Criteria considered by the Administration in making this determination shall include availability and accessibility of appropriate care, and cost effectiveness.
- J.** The restrictions, limitations, and exclusions in this Article do not apply to the following:
1. Public and private employers selecting AHCCCS as a health care option for their employees according to 9 A.A.C. 27; and
 2. A contractor electing to provide noncovered services:
 - a. The Administration shall not consider the costs of providing a noncovered service to a member in the development or negotiation of a capitation rate.
 - b. A contractor shall pay for noncovered services from administrative revenue or other contractor funds that are unrelated to the provision of services under this Chapter.

In addition to definitions contained in A.R.S. § 36-2901, the words and phrases in this Chapter have the following meanings unless the context explicitly requires another meaning:

"Anticipatory guidance" means a person responsible for a child receives information and guidance of what the person should expect of the child's development and how to help the child stay healthy.

"Behavioral health recipient" means a Title XIX or Title XXI acute care member who is eligible for, and is receiving, behavioral health services through ADHS/DBHS.

"Children's Rehabilitative Services" or "CRS" means the program within ADHS that provides covered medical services and covered support services in accordance with A.R.S. § 36-261.

"Clinical supervision" means a Clinical Supervisor under 9 A.A.C. 20, Article 2 reviews the skills and knowledge of the individual supervised and provides guidance in improving or developing the skills and knowledge.

"DBHS" means the Division of Behavioral Health Services within the Arizona Department of Health Services.

"Dentures" and "Denture services" mean a partial or complete set of artificial teeth and related services that are determined to be medically necessary and the primary treatment of choice, or an essential part of an overall treatment plan, and designed to alleviate a medical condition as determined by the primary care provider in consultation with the dental service provider.

"Emergency behavioral health condition for the non-FES member" means a condition manifesting itself by acute symptoms of sufficient severity, including severe pain, such that a prudent layperson who possesses an average knowledge of health and medicine could reasonably expect the absence of immediate medical attention to result in:

Placing the health of the person, including mental health, in serious jeopardy;

Serious impairment to bodily functions;

Serious dysfunction of any bodily organ or part; or

Serious physical harm to another person.

"Emergency behavioral health services for the non-FES member" means those behavioral health services provided for the treatment of an emergency behavioral health condition.

"Emergency medical condition for the non-FES member" means treatment for a medical condition, including labor and delivery, that manifests itself by acute symptoms of sufficient severity, including severe pain, such that a prudent layperson who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in:

Placing the member's health in serious jeopardy.

Serious impairment to bodily functions, or

Serious dysfunction of any bodily organ or part.

"Emergency medical services for the non-FES member" means services provided for the treatment of an emergency

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medical condition.

“Hearing aid” means an instrument or device designed for, or represented by the supplier as aiding or compensating for impaired or defective human hearing, and includes any parts, attachments, or accessories of the instrument or device.

“Home health services” means services and supplies that are provided by a home health agency that coordinates in-home intermittent services for curative, rehabilitative care, including home-health aide services, licensed nurse services, and medical supplies, equipment, and appliances.

“IMD” or “Institution for Mental Diseases” means an Institution for Mental Diseases as described in 42 CFR 435.1010 and licensed by ADHS.

“Medical supplies” means consumable items that are designed specifically to meet a medical purpose.

“Non-FES member” means an eligible person who is entitled to full AHCCCS services.

“Occupational therapy” means medically prescribed treatment provided by or under the supervision of a licensed occupational therapist, to restore or improve an individual’s ability to perform tasks required for independent functioning.

“Pharmaceutical service” means medically necessary medications that are prescribed by a physician, practitioner, or dentist under R9-22-209.

“Physical therapy” means treatment services to restore or improve muscle tone, joint mobility, or physical function provided by or under the supervision of a registered physical therapist.

“Post-stabilization services” means covered services related to an emergency medical or behavioral health condition provided after the condition is stabilized.

“Primary care provider services” means healthcare services provided by and within the scope of practice, as defined by law, of a licensed physician, certified nurse practitioner, or licensed physician assistant.

“Psychosocial rehabilitation services” means services that provide education, coaching, and training to address or prevent residual functional deficits and may include services that may assist a member to secure and maintain employment. Psychosocial rehabilitation services may include:

Living skills training.

Cognitive rehabilitation.

Health promotion.

Supported employment, and

Other services that increase social and communication skills to maximize a member’s ability to participate in the community and function independently.

“RBHA” or “Regional Behavioral Health Authority” means the same as in A.R.S. § 36-3401.

“Residual functional deficit” means a member’s inability to return to a previous level of functioning, usually after experiencing a severe psychotic break or state of decompensation.

“Respiratory therapy” means treatment services to restore, maintain, or improve respiratory functions that are provided by, or under the supervision of, a respiratory therapist licensed according to A.R.S. Title 32, Chapter 35.

“Scope of services” means the covered, limited, and excluded services under Articles 2 and 12 of this Chapter.

“Speech therapy” means medically prescribed diagnostic and treatment services provided by or under the supervision of a certified speech therapist.

“Sterilization” means a medically necessary procedure, not for the purpose of family planning, to render an eligible person or member barren in order to:

Prevent the progression of disease, disability, or adverse health conditions; or

Prolong life and promote physical health.

“Substance abuse” means the chronic, habitual, or compulsive use of any chemical matter that, when introduced into the body, is capable of altering human behavior or mental functioning and, with extended use, may cause psychological dependence and impaired mental, social or educational functioning. Nicotine addiction is not considered substance abuse for adults who are 21 years of age or older.

R9-22-202. ~~Repealed~~ General Requirements

A. For the purposes of this Article, the following definitions apply:

- I. “Authorization” means written or verbal authorization by:
 - a. The Administration for services rendered to a fee-for-service member, or
 - b. The contractor for services rendered to a prepaid capitated member.

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2. Use of the phrase “attending physician” applies only to the fee-for-service population.
- B.** In addition to other requirements and limitations specified in this Chapter, the following general requirements apply:
 1. Only medically necessary, cost effective, and federally-reimbursable and state-reimbursable services are covered services.
 2. Covered services for the federal emergency services program (FESP) are under R9-22-217.
 3. The Administration or a contractor may waive the covered services referral requirements of this Article.
 4. Except as authorized by the Administration or a contractor, a primary care provider, attending physician, practitioner, or a dentist shall provide or direct the member’s covered services. Delegation of the provision of care to a practitioner does not diminish the role or responsibility of the primary care provider.
 5. A contractor shall offer a female member direct access to preventive and routine services from gynecology providers within the contractor’s network without a referral from a primary care provider.
 6. A member may receive behavioral health evaluation services without a referral from a primary care provider. A member may receive behavioral health treatment services only under referral from the primary care provider or upon authorization by the contractor or the contractor’s designee.
 7. A member may receive treatment that is considered the standard of care or that is approved by the AHCCCS Chief Medical Officer after appropriate input from providers who are considered experts in the field by the professional medical community.
 8. AHCCCS or a contractor shall provide services under the Section 1115 Waiver as defined in A.R.S. § 36-2901.
 9. An AHCCCS registered provider shall provide covered services within the provider’s scope of practice.
 10. In addition to the specific exclusions and limitations otherwise specified under this Article, the following are not covered:
 - a. A service that is determined by the AHCCCS Chief Medical Officer to be experimental or provided primarily for the purpose of research;
 - b. Services or items furnished gratuitously, and
 - c. Personal care items except as specified under R9-22-212.
 11. Medical or behavioral health services are not covered services if provided to:
 - a. An inmate of a public institution;
 - b. A person who is in residence at an institution for the treatment of tuberculosis; or
 - c. A person age 21 through 64 who is in an IMD, unless the service is covered under Article 12 of this Chapter.
- C.** The Administration or a contractor may deny payment of non-emergency services if prior authorization is not obtained as specified in this Article and Article 7 of this Chapter. The Administration or a contractor shall not reimburse services that require prior authorization unless the provider documents the diagnosis and treatment.
- D.** Services under A.R.S. § 36-2908 provided during the prior period coverage do not require prior authorization.
- E.** Prior authorization is not required for services necessary to evaluate and stabilize an emergency medical condition. The Administration or a contractor shall not reimburse services that require prior authorization unless the provider documents the diagnosis and treatment.
- F.** A service is not a covered service if provided outside the GSA unless one of the following applies:
 1. A member is referred by a primary care provider for medical specialty care outside the GSA. If a member is referred outside the GSA to receive an authorized medically necessary service, the contractor shall also provide all other medically necessary covered services for the member;
 2. There is a net savings in service delivery costs as a result of going outside the GSA that does not require undue travel time or hardship for a member or the member’s family;
 3. The contractor authorizes placement in a nursing facility located out of the GSA; or
 4. Services are provided during prior period coverage.
- G.** If a member is traveling or temporarily residing outside of the GSA, covered services are restricted to emergency care services, unless otherwise authorized by the contractor.
- H.** A contractor shall provide at a minimum, directly or through subcontracts, the covered services specified in this Chapter and in contract.
- I.** The Administration shall determine the circumstances under which a FFS member may receive services, other than emergency services, from service providers outside the member’s county of residence or outside the state. Criteria considered by the Administration in making this determination shall include availability and accessibility of appropriate care and cost effectiveness.
- J.** The restrictions, limitations, and exclusions in this Article do not apply to the following:
 1. Public and private employers selecting AHCCCS as a health care option for their employees according to 9 A.A.C. 27; and
 2. A contractor electing to provide noncovered services.
 - a. The Administration shall not consider the costs of providing a noncovered service to a member in the development or negotiation of a capitation rate.
 - b. A contractor shall pay for noncovered services from administrative pay revenue or other contractor funds that are

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unrelated to the provision of services under this Chapter.

R9-22-217. Services Included in the Federal Emergency Services Program

- A. Definition. For the purposes of this Section, an emergency medical or behavioral health condition for a FES member means a medical condition or a behavioral health condition, including labor and delivery, manifesting itself by acute symptoms of sufficient severity, including severe pain, such that the absence of immediate medical attention could reasonably be expected to result in:
 - 1. Placing the member’s health in serious jeopardy,
 - 2. Serious impairment to bodily functions,
 - 3. Serious dysfunction of any bodily organ or part, or
 - 4. Serious physical harm to another person.
- B. Services. Emergency services for a FES member mean those medical or behavioral health services provided for the treatment of an emergency condition. Emergency services include outpatient dialysis services for an FES member with End Stage Renal Disease (ESRD) where a treating physician has certified that in his opinion the absence of receiving dialysis at least three times per week would reasonably be expected to result in:
 - 1. Placing the patient’s health in serious jeopardy; or
 - 2. Serious impairment of bodily function; or
 - 3. Serious dysfunction of a bodily organ or part.
- C. Covered services. Services are considered emergency services if all of the criteria specified in subsection (A) are satisfied at the time the services are rendered and timely notification as specified in subsection (E) is given. The Administration shall determine whether an emergency condition exists on a case-by-case basis.
- D. Prior authorization. A provider is not required to obtain Prior authorization is not required for emergency services for FES members. Prior authorization for outpatient dialysis services is met when the treating physician has completed and signed a monthly certification as described in subsection (B).
- E. Notification. A provider shall notify the Administration no later than 72 hours after a FES member receiving emergency medical or behavioral health services presents to a hospital for inpatient services. The Administration may deny payment for failure to provide timely notice.

NOTICE OF FINAL RULEMAKING

TITLE 17. TRANSPORTATION

**CHAPTER 4. DEPARTMENT OF TRANSPORTATION
TITLE, REGISTRATION, AND DRIVER LICENSES**

[R07-328]

PREAMBLE

- | | |
|-------------------------------------|----------------------------------|
| <u>1. Sections Affected:</u> | <u>Rulemaking Action:</u> |
| R17-4-701 | Amend |
| R17-4-702 | Amend |
| R17-4-705 | Amend |
| R17-4-712 | New Section |
- 2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**
 Authorizing statute: A.R.S. § 28-366
 Implementing statute: A.R.S. § 28-3103
 - 3. The effective date of the rules:**
 November 10, 2007
 - 4. A list of all previous notices appearing in the Register addressing the final rules:**
 Notice of Rulemaking Docket Opening: 13 A.A.R. 162, January 19, 2007
 Notice of Proposed Rulemaking: 13 A.A.R. 1983, June 8, 2007
 - 5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:**
 Name: Janette M. Quiroz
 Address: Administrative Rules Unit

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Department of Transportation,
Motor Vehicle Division
1801 W. Jefferson, MD 530M
Phoenix, AZ 85007

Telephone: (602) 712-8996
Fax: (602) 712-3081
E-mail: jmquiroz@azdot.gov

Please visit the ADOT web site to track progress of this rule and any other agency rulemaking matters at www.dot.state.az.us/about/rules/index.htm.

6. An explanation of the rules, including the agency's reasons for initiating the rulemaking:

In accordance with 49 CFR 1572 and A.R.S. § 28-3103, the Motor Vehicle Division (Division) has created rules requiring that an applicant transferring a driver license from another state to Arizona successfully pass a Security Threat Assessment (STA), conducted by the Transportation Security Administration, before the Division will issue a Hazardous Materials Endorsement (HME).

7. A reference to any study relevant to the rules that the agency reviewed and either relied on in its justification for the rules or did not rely on in its evaluation of or justification for the rules, 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 Division did not review nor rely upon any study relevant to this rulemaking.

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

Not applicable

9. The summary of the economic, small business, and consumer impact:

The Division promulgated rules in accordance with 49 CFR 1572 and A.R.S. § 28-3103 last year regulating original and renewal applicants for HME. The Division proposes to add individuals applying to transfer an existing HME to this state.

The federal requirement governing the hauling of hazardous materials was an unfunded mandate. Therefore, ADOT incurred all cost associated with implementing the federal regulations.

The initial costs to ADOT in adopting these rules for original and renewal applicants which were substantial included: System programming, driver notification, public and industry education, and other associated costs.

However, as the Division has worked for some time in implementing rules for original and renewal applicants, the anticipated cost to include regulations for transfer applicants is minimal.

The cost to commercial drivers wishing to transfer an HME is minimal. Those drivers who have yet to successfully pass a STA will be required to pay an additional \$94 fee for fingerprint and background services obtained through a federal third party, as well as minimal costs for fees related to testing required under 28-3002.

These rules enhance the state's ability to identify and deter the shipment and use of hazardous materials by terrorists. Drivers who have been determined to pose a security threat will not be issued a hazardous materials endorsement.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

Minor technical changes were made at the suggestion of the Governor's Regulatory Review Council staff.

11. A summary of the comments made regarding the rules and the agency response to them:

No comments were received from the public.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

None

13. Incorporations by reference and their location in the rules:

None

14. Was this rule previously adopted as an emergency rule?

No

15. The full text of the rules follows:

TITLE 17. TRANSPORTATION

CHAPTER 4. DEPARTMENT OF TRANSPORTATION

TITLE, REGISTRATION, AND DRIVER LICENSES

ARTICLE 7. HAZARDOUS MATERIALS ENDORSEMENTS

Section

- R17-4-701. Definitions
- R17-4-702. Scope
- R17-4-705. Required Testing
- R17-4-712. Transfer Applicants

ARTICLE 7. HAZARDOUS MATERIALS ENDORSEMENTS

R17-4-701. Definitions

In addition to the definitions contained in 49 CFR 1572.3, the following words and phrases apply to this Article:

1. "Applicant" means an individual who applies to obtain an original or renewal HME.
2. "CDL" means Commercial Driver License.
3. "HME" means Hazardous Materials Endorsement.
4. "Transfer applicant" means an individual with an existing HME issued by another state, applying to the state of Arizona for an HME.
- 4-5. "TSA" means the U.S. Transportation Security Administration.
- 5-6. "STA" means a Security Threat Assessment conducted by the TSA that includes a fingerprint-based criminal history records check, an intelligence-related background check, and final disposition.

R17-4-702. Scope

This Article applies to commercial drivers who are applying for an original HME or ~~renewal~~ to renew or transfer an existing HME, in accordance with 49 CFR Part 1572 (November 24, 2004) incorporated by reference, on file with the Arizona Department of Transportation and available from the U.S. Government Printing Office's web page at www.gpo.gov. This incorporation by reference contains no future additions or amendments.

R17-4-705. Required Testing

- A.** Original and renewal applicants shall successfully complete the testing requirements under A.R.S. § 28-3223.
- B.** A transfer applicant with an existing HME shall be required to comply with HME knowledge test requirements under A.R.S. 28-3223, and pay applicable fee under R17-4-706.

R17-4-712. Transfer Applicant

- A.** Applicability. A transfer applicant shall comply with the provisions of this Article except otherwise required by this Section.
- B.** Existing TSA approval.
 1. Upon application by a transfer applicant who has an existing HME and has who successfully passed a STA prior to application in Arizona, the Division shall:
 - a. Issue a five-year Arizona CDL with an HME.
 - b. Validate the CDL with an HME upon verification of TSA approval, and the transfer applicant shall not be required to return to a designated CDL office unless otherwise required, and
 - c. Consider an applicant who has been subject to any action under R17-4-708(B) an original applicant and shall require applicant to undergo a new STA and testing requirements under R17-4-705.
 2. The Division shall not require that a transfer applicant who has received STA approval undergo an additional STA prior to expiration of existing TSA approval, unless required under federal or state law or these rules.
 3. If the Division is unsuccessful in verifying successful completion of STA, the Division shall immediately cancel the HME, and require that the applicant return to designated CDL office to have HME removed from license.
 4. The Division shall mail to the transfer applicant a Notice of Action that the applicant has 15 days from the notice date to visit a designated CDL office to have the HME removed.
- C.** No existing TSA approval.
 1. Upon application by a transfer applicant with an existing HME, who has not undergone a STA prior to application in Arizona, the Division shall:
 - a. Require that the transfer applicant successfully undergo a STA; and
 - b. Upon verification of successful completion of STA, issue an Arizona CDL with an HME.
 2. If a transfer applicant fails to successfully complete a STA or the Division is unsuccessful in verifying successful completion of STA, the Division shall deny the application for HME.
 3. If the applicant fails to comply with the Division's Notice of Action, the Division shall cancel the applicant's Arizona Driver License privilege.
- D.** CDL eligibility. The Division may grant an application for a CDL, if an applicant is otherwise qualified to hold CDL.