

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.

Editor's Note: The following Notice of Final Rulemaking was originally published at 8 A.A.R. 1953, April 26, 2002. The Office of the Secretary of State is republishing the Notice here because of printing errors in the original publication.

NOTICE OF FINAL RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 6. DEPARTMENT OF HEALTH SERVICES COMMUNICABLE DISEASES

PREAMBLE

1. Sections Affected

Rulemaking Action

R9-6-101	Amend
R9-6-102	Amend
R9-6-103	Amend
R9-6-104	Repeal
R9-6-308	Amend
R9-6-309	Amend
R9-6-323	Amend
R9-6-330	Amend
R9-6-331	Amend
R9-6-360	Amend
Article 4	Amend
R9-6-401	Renumber
R9-6-401	New Section
R9-6-402	Renumber
R9-6-402	Amend
R9-6-403	Renumber
R9-6-403	Amend
R9-6-404	Renumber
R9-6-404	Amend
R9-6-405	Renumber
R9-6-405	Amend
R9-6-406	Renumber
R9-6-406	Amend
R9-6-407	Repeal
R9-6-407	Renumber
R9-6-407	Amend
R9-6-408	Renumber
R9-6-408	New Section
R9-6-409	Renumber
R9-6-409	Amend
Exhibit A	Renumber
Exhibit B	Renumber
R9-6-410	Renumber
Article 9	New Article
R9-6-901	New Section
R9-6-902	Renumber
R9-6-902	Amend
Exhibit A	Renumber
Exhibit A	Amend

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Exhibit B	Renumber
Exhibit B	Amend
R9-6-903	Renumber
R9-6-903	Amend

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

Authorizing statutes: A.R.S. §§ 36-136(A)(7), 36-136(F)

Implementing statutes: A.R.S. §§ 8-341(O), 13-1210, 13-1415, 32-1483, 36-136(H)(1), 36-136(H)(11), 36-136(H)(12), 36-136(L), 36-663, 36-664(K)

3. The effective date of the rules:

April 3, 2002

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

Notice of Rulemaking Docket Opening: 7 A.A.R. 1385, March 30, 2001

Notice of Proposed Rulemaking: 7 A.A.R. 5546, December 21, 2001

Notice of Proposed Rulemaking: 8 A.A.R. 336, January 25, 2002 (republished to correct publishing errors in Exhibits A and B)

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

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or

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

In December 1999, the Department completed a five-year review report for 9 A.A.C. 6. The five-year review report was approved by the Governor's Regulatory Review Council in March 2000. As a result of the review process, the Department identified a number of changes that needed to be made in 9 A.A.C. 6. The Department also determined that those changes should be made in three separate rule packages. This is the first of those rule packages.

This rule package amends the general definitions Section within Article 1 and the definitions Sections for Articles 2 and 3, which shall remain in Article 1 until the third rule package, to implement the changes recommended in the five-year review report. This rule package also repeals the definitions Section for Article 4 that is currently located in Article 1 and replaces it with a new definitions Section within Article 4.

In Article 3, this rule package amends the Sections that pertain to sexually transmitted diseases by describing required treatment; eliminating use of the terms "suspect case," "suspect carrier," and "special control measure"; eliminating the requirement to obtain a waiver when a parent refuses administration of antibiotic eye ointment to a newborn to prevent gonorrheal ophthalmia; updating the material incorporated by reference in R9-6-331; clarifying the rules; and conforming the rules to current rulemaking format and style requirements. In addition, the Department is eliminating the requirement that local health agencies obtain identification and assure notification of individuals who may have been exposed to chlamydia infection or gonorrhea through sexual contact with a case. Rather, the diagnosing health care provider shall counsel the case about the importance of notifying individuals of possible exposure and of the need to seek treatment. Then, if one of the individuals seeks treatment from the local health agency, the local health

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agency shall offer or arrange for treatment. The Department is changing the notification requirement to a counseling requirement because of the number of annual cases of chlamydia infection and gonorrhea. In a typical year, more than 11,000 cases of chlamydia infection and more than 4,000 cases of gonorrhea are reported in the state of Arizona. Local health agencies have been unable to comply with the rules as written, because to do so would be overly burdensome. For the same reasons, the rules eliminate the requirement that the local health agency conduct an epidemiologic investigation of each case of chlamydia infection or gonorrhea. To ensure that follow-up is provided where needed, the chlamydia infection and gonorrhea rules add a requirement that the Department review each case report for completeness, accuracy, and the need for follow-up.

The Department is removing the parental waiver requirement in the gonorrhea rule because it is not really a case control measure, but rather serves to protect the individual attending a birth from liability. Thus, it is more appropriate to leave the issue of obtaining a waiver to the discretion of the individual attending a birth.

This rule package divides the current Article 4 into 2 Articles. The revised Article 4 includes only the rules pertaining to the AIDS Drug Assistance Program (ADAP), and the new Article 9 includes only the rules pertaining to HIV-related testing. Article 4 is thus redesignated "AIDS Drug Assistance Program (ADAP)," and the new Article 9 is named "HIV-Related Testing."

The rules for ADAP are revised to clarify the rules; to update the program due to changes in drug therapy, HIV-related testing, and other areas; to add time-frames for the application process; and to conform to current rulemaking format and style requirements.

The rules concerning HIV-related testing, which are moved from Article 4 to the new Article 9, are amended to reflect statutory change; to update information in the Exhibits; to reflect changes in HIV-related testing; to clarify the rules; and to conform to current rulemaking format and style changes.

7. A reference to any study that the agency relied on in its evaluation of or justification for the proposed rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study, and other supporting material:

Not applicable

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:

As used in this summary, minimal means less than \$1,000, moderate means between \$1,000 and \$9,999, and substantial means \$10,000 or greater.

The Department anticipates that the proposed rule changes in Article 3 will substantially benefit local health agencies and minimally benefit and minimally burden health care providers. Specifically, the changes to the rules for chlamydia infection and gonorrhea should benefit local health agencies. The current rules require local health agencies to notify all identified individuals potentially exposed through sexual contact with a case and to offer or arrange for treatment. The proposed rules do not require local health agencies to provide this notification. Instead, the proposed rules require the diagnosing health care provider to counsel the case about the importance of notifying individuals who may have been exposed through sexual contact of possible exposure and of the need to seek medical treatment. The current rules also require the local health agency to conduct an epidemiologic investigation of each reported case of chlamydia infection or gonorrhea. The proposed rules eliminate this requirement as well. Because there are more than 11,000 cases of chlamydia and more than 4,000 cases of gonorrhea reported in a typical year, the changes in the chlamydia rule should result in a substantial benefit and the changes in the gonorrhea rule should result in a substantial benefit to local health agencies.

Diagnosing health care providers should incur a minimal cost per case as a result of the new requirement to counsel each case of chlamydia infection or gonorrhea about the importance of notifying individuals who may have been exposed through sexual contact of exposure and of the need to seek treatment. The Department believes that this information is likely already provided by diagnosing health care providers. But, even for those diagnosing health care providers who do not already provide this information, the new requirement will result in only a few additional moments spent counseling each case.

The Department will incur at most a minimal cost per case as a result of the requirement to review each case report of chlamydia infection or gonorrhea for completeness, accuracy, and the need for follow-up. In reality, although not required to do so by the rules, the Department has been conducting reviews of these case reports for some time.

In addition, the proposed rules will no longer require a physician or other individual attending a birth to obtain a parental waiver if a parent refuses administration of antibiotic eye ointment to the newborn to prevent gonorrheal ophthalmia. This could result in a minimal benefit for each health care provider or midwife who attends births, because these individuals will no longer be required to take the time to have the waiver completed. Realistically, however, the Department anticipates that, due to liability concerns, many of these individuals may choose to obtain a waiver even if it is not required.

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The proposed changes to the counseling requirements for a case with herpes genitalis may result in a minimal additional burden per case for diagnosing health care providers. The proposed rules require that a case be informed of treatment options and chemoprophylaxis and other measures to prevent transmission. This may take several minutes more than was spent previously in counseling a case. It is likely, however, that this information was already being provided in spite of its not being required by the rules.

In the proposed HIV rule, ethnicity is added as a field of epidemiological information to be collected from individuals who opt for anonymous testing. The addition of this field should result in a minimal burden for anonymous testing subjects, who will have to check an additional box on a form. The change may also result in a minimal burden for each anonymous testing site, because the forms currently used may have to be changed to add ethnicity.

In addition, the proposed HIV rule updates the material incorporated by reference as the standard for school district personnel who handle blood or bodily fluids. The new reference costs \$27 in hard copy or \$12 in microfiche. Each school district will thus be minimally impacted by the need to purchase at least one copy of the reference.

The renaming of Article 4 should minimally benefit each individual interested in the AIDS Drug Assistance Program (ADAP) because the rules will be easier to find.¹ Previously, the name of the program itself did not appear in the rules, and the rules for ADAP were combined in an Article that also included HIV-related testing provisions and Exhibits.

[¹ In June 2001, ADAP had 1,025 enrolled individuals, provided services to 716 enrolled individuals, and enrolled 44 individuals. The average amount ADAP expended for each of the 716 individuals was \$745. These numbers fluctuate from month to month, and individuals cycle into and out of ADAP as their eligibility changes. It is impossible to estimate how many additional individuals might be interested in applying for ADAP.]

The proposed rules for Article 4 revise the ADAP rules by eliminating the waiting list for ADAP, which should result in a minimal-to-moderate benefit to the Department due to a savings in administrative time spent maintaining the waiting list. Additionally, the proposed rules will benefit individuals who may have believed that they were ineligible for ADAP because the current rules state specific dollar amounts for maximum income and specific HIV-related conditions or test results necessary to be eligible. The proposed rules reflect the eligibility standards currently used by ADAP for income and HIV status: 300% of the federal poverty level and a medical diagnosis of HIV disease or infection.

The proposed rules also reflect the changes made to ADAP as the result of a July 2000 policy issued by the United States Department of Health & Human Services, HIV/AIDS Bureau, requiring Ryan White CARE Act grant recipients to provide benefits to American Indians or Alaska Natives who are otherwise eligible for program benefits even if those individuals could obtain the same benefits through Indian Health Services. The economic impact of these changes is not the result of the rules, but rather is the result of the federal policy.

Each ADAP applicant or enrolled individual may also realize a minimal benefit from the use of the term "primary care provider" rather than "physician" for purposes of diagnosis, completion of forms, and prescription of drugs for ADAP participation. The proposed rules reflect the Department's awareness that an individual's primary care provider is not always a physician, but may be a registered nurse practitioner or a physician assistant.

The proposed ADAP rules also require the primary care provider portion of the follow-up application to be completed only after every 24 months of continuous enrollment, rather than every six months as is currently required. This could save each individual enrolled for a continuous 24-month period three special trips to the primary care provider just to complete follow-up applications and would also save each primary care provider the time of doing that portion of the follow-up application on those three occasions, resulting in a minimal benefit to the primary care provider for each patient enrolled in ADAP and to each individual enrolled in ADAP. Additionally, the proposed rules allow submission of the most recent HIV-related tests rather than requiring submission of specific HIV-related tests. This may minimally benefit each individual applying for or enrolled in ADAP who thus may not pay for a test that was previously required for ADAP but that otherwise would not have been ordered.

Also, rather than having an eligibility determination last for only one year, the proposed ADAP rules have an eligibility determination last indefinitely, based on submission of a follow-up application and current proof of income after every six months and of the primary care provider portion of the follow-up application after every 24 continuous months. This will result in a minimal benefit to each enrolled individual and a minimal-to-moderate benefit to the Department, because less paperwork will be required to remain eligible for and to administer ADAP. In the same vein, the proposed rules will no longer limit a prescription to a one-month supply with five refills. Rather, the proposed rules do not limit the number of refills and require that the prescription be written for the quantity in the manufacturer's original packaging. This should be more convenient for each primary care provider and enrolled individual and for the Department and should minimally benefit each.

Finally, the proposed ADAP rules add a time-frames Section and expressly require ADAP to comply with the Administrative Procedure Act (APA) rather than the appeals Section, which is being repealed. The addition of time-frames will result in a moderate burden on the Department. ADAP has not always provided notice in writing and will now do so. The repeal of the appeals Section should not burden any party, because ADAP was already following the APA for appeals.

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The creation of a new Article 9 for HIV-Related Testing should minimally benefit individuals who seek to use these rules. It was difficult to find the rules in Article 4 because they were located at the end of the Article, which primarily dealt with ADAP, not HIV-related testing. The proposed rule changes to the consent Section and to the Exhibits should not result in any economic impact other than the need for individuals who order HIV-related tests to copy and use the revised Exhibits. This cost should be minimal for each individual who orders tests.

The changes to the Section on court-ordered HIV-related testing should result in a minimal economic benefit to clinical laboratories that run HIV-related tests, to health care providers that order HIV-related tests, and to individuals who pay for HIV-related tests. Rather than requiring use of the enzyme immunoassay test, a retest of reactive blood in duplicate, and a test of repeatedly reactive blood with the Western blot test, the proposed rules allow use of any licensed test for HIV screening and require retesting of a repeatedly reactive sample with a licensed supplemental or confirmatory test or as recommended by the original test manufacturer's package insert. This gives health care providers who order HIV-related tests and clinical laboratories that run HIV-related tests a great deal of freedom in the tests that are used and should also allow the individuals paying for HIV-related tests some choice in the tests used. Additionally, the proposed rule will allow testing of bodily substances other than blood, thereby permitting use of additional tests and of new technologies as they are licensed by the FDA.

The Department will incur the costs of the rulemaking process, which are moderate.

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

In R9-6-103(8), the Department changed the Centers for Disease Control's May 1994 *HIV Counseling, Testing, and Referral Standards and Guidelines* to the Centers for Disease Control's November 2001 *Revised Guidelines for HIV Counseling, Testing, and Referral*. This does not represent a substantial change, because the counseling and testing sites that this change affects are already required by contract to comply with the new *Guidelines*.

In R9-6-902(B)(1), the Department added two fields of permissible information, to be consistent with current practice.

Throughout the rules, the Department made minor changes to make the rules more clear, concise, and understandable.

11. A summary of the principal comments and the agency response to them:

Although the Department held three oral proceedings on the rules, only one individual attended. That individual did not have any comments on the rules themselves and merely asked several questions to clarify whether the rule changes would impact the operations of that individual's organization. The Department answered the questions.

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 rules:

R9-6-103(8): Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, *Revised Guidelines for HIV Counseling, Testing, and Referral* (November 2001), published in Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, Pub. No. RR-19, 50 *Morbidity and Mortality Weekly Report* (November 9, 2001)

R9-6-331: Elizabeth A. Bolyard et al., *Guideline for Infection Control in Health Care Personnel*, 1998 (1998)

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

No

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

**CHAPTER 6. DEPARTMENT OF HEALTH SERVICES
COMMUNICABLE DISEASES**

ARTICLE 1. DEFINITIONS

Section

- R9-6-101. ~~General~~ Definitions
- R9-6-102. Communicable Disease Reporting
- R9-6-103. Control Measures for Communicable Diseases
- R9-6-104. ~~Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS)~~ Repealed

ARTICLE 3. CONTROL MEASURES FOR COMMUNICABLE AND PREVENTABLE DISEASES

Section

- R9-6-308. Chancroid (*Haemophilus ducreyi*)
- R9-6-309. Chlamydia Infection

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- R9-6-323. Gonorrhea
- R9-6-330. Herpes Genitalis
- R9-6-331. Human Immunodeficiency Virus (HIV) Infection and Related Disease
- R9-6-360. Syphilis

ARTICLE 4. ~~HUMAN IMMUNODEFICIENCY VIRUS (HIV) / ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)~~ AIDS DRUG ASSISTANCE PROGRAM (ADAP)

Section

- R9-6-401. Definitions.
- ~~R9-6-401~~R9-6-402. Limitations and Termination of Program
- ~~R9-6-402~~R9-6-403. Eligibility Requirements
- ~~R9-6-403~~R9-6-404. Application Process
- ~~R9-6-404~~R9-6-405. Eligibility Determination and Enrollment Process
- ~~R9-6-405~~R9-6-406. Period of Eligibility Continuing Enrollment
- ~~R9-6-407. Appeal~~
- ~~R9-6-406~~R9-6-407. Distribution Requirements
- R9-6-408. Time-frames
- ~~R9-6-408~~R9-6-409. Confidentiality
 - Exhibit A. ~~Consent for HIV-Related Testing~~ Renumbered
 - Exhibit B. ~~Consentimiento para la Prueba de VIH~~ Renumbered
- R9-6-410. ~~Human Immunodeficiency Virus Testing~~ Renumbered

ARTICLE 9. HIV-RELATED TESTING

Section

- R9-6-901. Definitions
- ~~R9-6-409~~R9-6-902. Consent for HIV-related Testing
 - ~~Exhibit A~~Exhibit A. Consent for HIV Testing
 - ~~Exhibit B~~Exhibit B. Consentimiento Para la Prueba de VIH
- ~~R9-6-410~~R9-6-903. Human Immunodeficiency Virus Court-ordered HIV-related Testing

ARTICLE 1. DEFINITIONS

R9-6-101. General Definitions

In this Chapter, unless the context otherwise requires specified:

1. "AIDS" means Acquired Immunodeficiency Syndrome.
- ~~1-2.~~ No change
- ~~2-3.~~ No change
4. "Body fluid" means semen, vaginal secretion, tissue, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, amniotic fluid, urine, blood, or saliva.
- ~~3-5.~~ "Carrier" means an infected person who harbors an infectious agent in the absence of clinical disease and who serves as a potential source of infection individual with an asymptomatic infection that can be transmitted to a susceptible individual.
- ~~4-6.~~ "Case" means a person an individual with a clinical syndrome of a communicable disease whose condition is documented:
 - ~~a.~~ By laboratory results which that support the presence of the causative agent;
 - ~~b.~~ or by By a physician's health care provider's diagnosis based on clinical observation;
 - ~~c.~~ By epidemiologic associations with communicable disease, the causative agent, or its toxic products.
- ~~5-7.~~ "Communicable disease" means an illness caused by an infectious agent or its toxic products which that arises through the transmission of that agent or its products to a susceptible host, either directly or indirectly.
- ~~6-8.~~ No change
9. "Dentist" means an individual licensed under A.R.S. Title 32, Chapter 11, Article 2.
10. "Department" means the Arizona Department of Health Services.
- ~~7-11.~~ No change
- ~~8-12.~~ "Epidemiologic investigation" means the application of scientific methods to verify the a diagnosis, identify risk factors for the a disease, determine the potential for spread, institute appropriate control measures, and complete requisite communicable disease and case investigation reports.
- ~~9-13.~~ No change
- ~~10-14.~~ No change
- ~~11-15.~~ No change
16. "Health care provider" means a physician, physician assistant, registered nurse practitioner, or dentist.
17. "HIV" means Human Immunodeficiency Virus.

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18. "HIV-related test" has the same meaning as in A.R.S. § 36-661.
~~12-19.~~No change
- ~~13-20.~~"Local health agency" means a county ~~public~~ health department, a public health services district, a tribal health unit, or a United States Public Health Service Indian Health Service Unit.
- ~~14-21.~~No change
22. "Physician" means an individual licensed as a doctor of:
- a. Allopathic medicine under A.R.S. Title 32, Chapter 13;
 - b. Naturopathic medicine under A.R.S. Title 32, Chapter 14;
 - c. Osteopathic medicine under A.R.S. Title 32, Chapter 17; or
 - d. Homeopathic medicine under A.R.S. Title 32, Chapter 29.
23. "Physician assistant" has the same meaning as in A.R.S. § 32-2501.
~~15-24.~~No change
25. "Registered nurse practitioner" has the same meaning as in A.R.S. § 32-1601.
- ~~16.~~ "Syndrome" means a pattern of signs and symptoms characteristic of a specific disease.
~~17-26.~~No change
27. "Subject" means an individual whose blood or other body fluid has been tested or is to be tested.
18. "Suspect carrier" means a person without clinical symptoms of disease but who tests positive for HIV by culture, antigen, antibodies to the virus, or viral genetic sequence detection.
- ~~19-28.~~"Suspect case" means ~~a person~~ an individual whose medical history, signs, or symptoms indicate that ~~person~~ the individual may have or is developing a communicable disease.
29. "Syndrome" means a pattern of signs and symptoms characteristic of a specific disease.

R9-6-102. Communicable Disease Reporting

In Article 2, unless ~~the context~~ otherwise requires specified:

- 1. No change
- 2. "Health care provider" means any physician, nurse, aide, therapist, dentist, or dental hygienist, whether paid or a volunteer.
- ~~3-2.~~ No change

R9-6-103. Control Measures for Communicable Diseases

In Article 3, unless ~~the context~~ otherwise requires specified:

- 1. No change
- 2. No change
- ~~3.~~ "Body fluid" means semen, vaginal secretion, tissue, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, amniotic fluid, urine, blood, or saliva.
- 3. "Blood bank" means a facility where human whole blood or a blood component is collected, prepared, tested, processed, or stored, or from which human whole blood or a blood component is distributed.
- 4. "Blood center" means a mobile or stationary facility that procures human whole blood or a blood component that is transported to a blood bank.
- 5. "Blood component" means any part of a single donor unit of blood separated by physical or mechanical means.
- ~~4-6.~~ "Concurrent disinfection" means the application of disinfective measures to inanimate objects or surfaces after the discharge of blood or body fluids from the body of an infected ~~person~~, individual or after the contamination of articles with blood or body fluids.
- 5. "Contact precautions" means, in addition to Standard precautions, the use of barriers to prevent infection spread by direct contact.
- ~~6-7.~~ "Contaminated" means to have come in contact with a disease-causing agent or toxin.
- ~~7-8.~~ "Counseling and testing site" means a health facility offering clients HIV counseling and HIV-related testing which ~~that~~ meets the standards established in the "HIV Counseling, Testing, and Referral, Standards and Guidelines," May 1994, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, Revised Guidelines for HIV Counseling, Testing, and Referral (November 2001), published in Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, Pub. No. RR-19, 50 Morbidity and Mortality Weekly Report (November 9, 2001), incorporated by reference, on file with the Department and the Office of the Secretary of State, and available at <http://www.cdc.gov/mmwr/> or <ftp://ftp.cdc.gov/pub/Publications/mmwr/> or from Centers for Disease Control, 1600 Clifton Road, N.E., Atlanta, GA 30333, ~~incorporated by reference and on file with the Department and Office of the Secretary of State.~~ This incorporation by reference contains no future editions or amendments.
- ~~8-9.~~ No change
- ~~9-10.~~No change
- ~~10-11.~~No change
- 12. "Drug" means a chemical substance licensed by the United States Food and Drug Administration.

- 44-13. "Follow-up" means the practice of investigating and monitoring cases, carriers, contacts, or suspect cases; to detect, treat, or prevent disease.
14. "Guardian" means an individual who is invested with the authority and charged with the duty of caring for a minor by a court of competent jurisdiction.
15. "Identified individual" means an individual named by a case as an individual who may have been exposed through sexual contact with the case and for whom a case provides information that enables the local health agency to locate the individual.
16. "Midwife" has the same meaning as in A.R.S. § 36-751.
17. "Milk bank" means a facility that procures, processes, stores, or distributes human breast milk.
18. "Organ bank" means a facility that procures, processes, stores, or distributes human kidneys, livers, hearts, lungs, or pancreases.
19. "Parent" means a natural or adoptive mother or father.
20. "Plasma center" means a facility where the process of plasmapheresis or another form of apheresis is conducted.
21. "Pupil" means a student attending a school, as defined in A.R.S. § 15-101.
22. "School district personnel" means individuals who work for a school district, as defined by A.R.S. § 15-101, whether within a classroom or other setting and whether as employees, contractors, or volunteers.
23. "Sexual contact" means vaginal intercourse, anal intercourse, fellatio, or cunnilingus.
- ~~12-24.~~ No change
25. "Tissue bank" means a facility that procures, processes, stores, or distributes corneas, bones, semen, or other specialized human cells for the purpose of injecting, transfusing, or transplanting the cells into a human body.
26. "Whole blood" means human blood from which plasma, erythrocytes, leukocytes, and thrombocytes have not been separated.

R9-6-104. Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS) Repealed

In Article 4, unless the context otherwise requires:

1. "AHCCCS" means the Arizona Health Care Cost Containment System.
2. "Clinical trial study" means the Treatment IND (investigative new drug) trial of zidovudine conducted by Burroughs-Wellcome Company between October 11, 1986, and April 30, 1987.
3. "Enrolled" means eligible for and being provided therapeutic assistance by the Department.
4. "Family" means a group of two or more persons related by birth, marriage, or adoption who reside together; all such related persons are considered members of one family. If a household includes more than one family and/or more than one unrelated individual, the poverty guidelines are applied separately to each family and/or unrelated individual, and not to the household as a whole.
5. "Family unit of size one" means an unrelated individual, that is, a person 15 years old or older (other than an inmate of an institution) who is not living with relatives. An unrelated individual may be the sole occupant of a housing unit, or may be residing in a housing unit, including a rooming house, in which one or more persons also reside who are not related to the individual in question by birth, marriage, or adoption.
6. "Income" means the total annual cash receipts before taxes from all sources; it may consist of data for the most recent 12 months or an annualized figure derived by computation from less than 12 months' data. Income includes money, wages and salaries before any deductions, but does not include food or rent received in lieu of wages. Income also includes net receipts from nonfarm or farm self-employment, net of business or farm expenses. Income includes regular payments from social security, railroad retirement, unemployment compensation, workers' compensation, strike benefits from union funds, veterans' benefits, public assistance (including Aid to Families with Dependent Children, Supplemental Security Income, and non-Federally-funded General Assistance or General Relief money payments), training stipends, alimony, child support, and military family allotments or other regular support from an absent family member or someone not living in the household, private and government employee pensions, and regular insurance or annuity payments, and income from dividends, interest, rents, royalties, or periodic receipts from estates or trusts. For eligibility purposes, income does not include: capital gains, any assets drawn down as withdrawals from a bank, proceeds from the sale of property, a house, or a car; tax refunds, gifts, lump-sum inheritances, one-time insurance payments, or compensation for injury. Also excluded are noncash benefits, such as the employer-paid or union-paid portion of health insurance and other employee fringe benefits; the value of food and fuel produced and consumed on farms, the imputed value of rent from owner-occupied nonfarm or farm housing, and federal programs such as Medicare, Medicaid, food stamps, school lunches, and public housing.
7. "SSI" means Supplemental Security Income, a program of the Social Security Administration.
8. "Symptomatic HIV infection" means illness either within the case definition of the Centers for Disease Control for acquired immunodeficiency syndrome (AIDS) or generally recognized as AIDS related complex (ARC). Incorporated by reference herein and on file with the Office of the Secretary of State is Morbidity and Mortality Weekly Report: Revision of the CDC Surveillance Case Definition for Acquired Immunodeficiency Syndrome, Centers for Disease Control, Atlanta, Georgia, Vol. 36, No. 15, August 14, 1987.

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9. ~~“Therapeutic agents” means drugs determined by the United States Food and Drug Administration to prolong the life of individuals with symptomatic HIV infection.~~
10. ~~“Zidovudine” means azidothymidine (AZT).~~

ARTICLE 3. CONTROL MEASURES FOR COMMUNICABLE AND PREVENTABLE DISEASES

R9-6-308. Chancroid (*Haemophilus ducreyi*)

A. Case control measures:

1. ~~The A~~ diagnosing health care provider or authorized representative shall treat prescribe drugs to render a case noninfectious and counsel or arrange for a the case to be counseled:
 - a. ~~to~~ To abstain from sexual contact until lesions are healed during drug treatment and for at least seven days after drug treatment is completed; and
 - b. About the following:
 - i. The characteristics of chancroid.
 - ii. The syndrome caused by chancroid.
 - iii. Measures to reduce the likelihood of transmitting chancroid to another, and
 - iv. The need to notify individuals with whom the case has had sexual contact within a time period determined based upon the stage of the disease; and
2. The local health agency shall conduct an epidemiologic investigation of each reported case, confirming the stage of the disease.

B. Contact control measures: The local health agency shall:

1. ~~notify sexual contacts of exposure and~~ Notify each identified individual of exposure;
2. ~~offer~~ Offer or arrange for treatment of each identified individual; and
3. Counsel each identified individual about the following:
 - a. The characteristics of chancroid.
 - b. The syndrome caused by chancroid.
 - c. Measures to reduce the likelihood of transmitting chancroid to another, and
 - d. The need to notify individuals with whom the identified individual has had sexual contact within a time period determined based upon the stage of the disease.

R9-6-309. Chlamydia Infection

~~**A. Reports:** Suspect cases include clinically diagnosed cases of nongonococcal urethritis and epididymitis in men under age 35 years, and pelvic inflammatory disease and nongonococcal mucopurulent cervicitis in women.~~

~~**A.**~~ **Case control measures:**

1. ~~The A~~ diagnosing health care provider or authorized representative shall:
 - a. Prescribe drugs to render a case noninfectious.
 - b. ~~counsel a~~ Counsel or arrange for the case to be counseled to abstain from sexual contact ~~until~~ during drug treatment and for at least seven days after drug treatment is complete completed, and
 - c. Counsel or arrange for the case to be counseled about the importance of notifying individuals who may have been exposed through sexual contact of exposure and of the need to seek medical treatment.
2. The Department shall review each case report for completeness, accuracy, and need for follow-up.

~~**B.**~~ **Contact control measures:** ~~The~~ If an individual who may have been exposed through sexual contact with a case seeks treatment from the local health agency, the local health agency shall notify identified sexual contacts and offer or arrange for treatment.

~~**D.**~~ **Special control measures:** ~~The local health agency shall conduct or direct an epidemiologic investigation of each reported case.~~

R9-6-323. Gonorrhea

A. Case control measures:

1. ~~The A~~ diagnosing health care provider shall:
 - a. Prescribe drugs to render a case noninfectious.
 - b. ~~counsel~~ Counsel or arrange for the case to be counseled to abstain from sexual contact during drug treatment and for 7 at least seven days after drug treatment is completed, and
 - c. Counsel or arrange for the case to be counseled about the importance of notifying individuals who may have been exposed through sexual contact of exposure and of the need to seek medical treatment.
2. The Department shall review each case report for completeness, accuracy, and need for follow-up.
3. For the prevention of gonorrheal ophthalmia, a health care provider or midwife attending the birth of an infant in Arizona shall treat the eyes of the infant immediately after the birth with one of the following, unless treatment is refused by the parent or guardian:
 - a. Erythromycin ophthalmic ointment 0.5%, or
 - b. Tetracycline ophthalmic ointment 1%.

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B. Contact control measures: ~~The~~ If an individual who may have been exposed through sexual contact with a case seeks treatment from the local health agency, the local health agency shall assure identification and notification and shall offer or arrange for treatment to sexual contacts.

C. Special control measures:

1. ~~For the prevention of gonorrheal ophthalmia, the physician or person attending the birth of any newborn in Arizona shall treat the eyes of the baby immediately after the birth with 1 of the following medications:~~
 - a. ~~Erythromycin ophthalmic ointment 0.5%,~~
 - b. ~~Tetraeycline ophthalmic ointment 1%,~~
 - e. ~~Silver nitrate aqueous solution 1%.~~
2. ~~A parent or guardian may refuse the treatment set forth in subsection (C)(1) by signing a written statement, witnessed by the physician or person attending the birth, stating that the parent or guardian has been informed of the potential risks and benefits of waiving the prescribed treatment and is refusing to allow its application. The physician or person attending the birth shall maintain a copy of the written refusal in the newborn's medical record.~~
3. ~~The local health agency shall conduct or direct an epidemiologic investigation of each reported case.~~

R9-6-330. Herpes Genitalis

Case control measures: ~~The~~ A diagnosing health care provider or authorized representative shall counsel or arrange for a case to be counseled:

1. ~~to~~ To abstain from sexual contact until lesions are healed,
2. About available treatment, and
3. About chemoprophylaxis and other measures to prevent transmission.

R9-6-331. Human Immunodeficiency Virus (HIV) Infection and Related Disease

A. Reports: ~~As directed by Article 2, a person shall report a case, suspect case, or suspect carrier except for the suspect carrier requesting anonymity pursuant to subsection (D)(4).~~

B. ~~A.~~ Case control measures:

1. ~~A health care provider or operator of a blood bank, blood center, plasma center, tissue bank, organ bank, or milk bank shall not utilize use donated blood or blood components, plasma, milk, body organs, sperm semen, or other tissue from a case, suspect case, or suspect carrier for transfusion, transplantation, or consumption.~~
2. A health care provider or operator of a blood bank, blood center, plasma center, tissue bank, organ bank, or milk bank who orders or administers a test for HIV or HIV antibodies and receives a test result that the health care provider or operator interprets as positive for HIV or HIV antibodies shall notify the subject or arrange for the subject to be notified of the test result within 30 days after receiving the test result.
3. A health care provider or operator of a blood bank, blood center, plasma center, tissue bank, organ bank, or milk bank shall provide or arrange for subject counseling at the time of notification that includes the following information:
 - a. The characteristics of HIV;
 - b. The syndrome caused by HIV and its symptoms;
 - c. The measures that are effective in reducing the likelihood of transmitting HIV to another;
 - d. The need to notify individuals, including a spouse, with whom the subject has had sexual contact or has shared needles of exposure to HIV; and
 - e. The availability of assistance from local health agencies in notifying those individuals described in subsection (A)(3)(d).
4. The local health agency shall conduct an epidemiologic investigation of each reported case or carrier within 30 days after receiving a report. Upon completion of the epidemiologic investigation, the local health agency shall not retain any personal identifying information about the case or carrier.
5. A counseling and testing site supervised by the Department or by a local health agency shall offer anonymous testing. The Department or local health agency shall collect the following epidemiologic information about each individual opting for anonymous testing:
 - a. Age.
 - b. Race and ethnicity.
 - c. Sex.
 - d. County of residence, and
 - e. HIV-associated risk behaviors.
6. The Department shall confidentially notify an identifiable third party reported to be at risk of HIV infection under A.R.S. § 36-664(K) if all of the following conditions are met:
 - a. The Department receives the report of risk in a document that includes the following:
 - i. The name and address of the identifiable third party,
 - ii. The name and address of the individual placing the identifiable third party at risk,
 - iii. The name and address of the individual making the report, and
 - iv. The type of exposure placing the identifiable third party at risk;

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- b. The individual making the report is in possession of confidential HIV-related information; and
 - c. The Department determines that the information provided in the report is accurate and sufficient to warrant notification of the identifiable third party.
7. As authorized under A.R.S. § 36-136(L), a local health agency shall notify the superintendent of a school district, as defined in A.R.S. § 15-101, in a confidential document that a pupil of the school district is a case or carrier of HIV if the following criteria are met:
- a. The local health agency determines by consulting with the Department that the pupil places others in the school setting at risk for HIV infection; and
 - b. The school district has an HIV policy that includes the following provisions:
 - i. That a school shall not exclude an infected pupil from attending school or school functions or from participating in school activities solely due to HIV infection;
 - ii. That the school district shall establish a group to determine on a case-by-case basis whether an infected pupil should be permitted to attend school by considering the risks and benefits to the pupil and to others if the pupil attends school;
 - iii. That the group described in subsection (A)(7)(b)(ii) shall include the superintendent of the school district, the parents or guardians of a minor pupil, the pupil if the pupil is not a minor or is emancipated, the pupil's physician, and the local health officer, and may include a school administrator, a school nurse, and a teacher or counselor of the pupil;
 - iv. That school district personnel who are informed of the pupil's HIV infection shall keep that information confidential;
 - v. That the school district shall provide HIV education programs to pupils, parents or guardians of pupils, and school district personnel through age-appropriate curricula, workshops, or in-service training sessions; and
 - vi. That school district personnel who handle blood or body fluids shall comply with Elizabeth A. Bolyard et al., Guideline for Infection Control in Health Care Personnel, 1998 (1998), incorporated by reference, on file with the Department and the Office of the Secretary of State, and available from National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. This incorporation by reference includes no future editions or amendments.

~~C.B.~~ Environmental control measures: The diagnosing An employer, as defined under A.R.S. § 23-401, or health care provider or authorized representative shall ensure concurrent disinfection of equipment or other surfaces contaminated with blood, semen, vaginal fluids, or other body fluids containing visible blood of cases, suspect cases, or suspect carriers comply with 29 CFR 1910.1030 (1999), as required by A.R.S. § 23-403 and A.A.C. R20-5-602.

~~D.~~ Special control measures:

- 1. Any physician, hospital administrator, or other person, including operators of blood or plasma centers, tissue or sperm banks, who orders, administers or interprets as positive a test for HIV or antibodies to the virus shall, in addition to meeting the reporting requirements specified, use all reasonable means to notify the person on whom the test was performed within 30 days of receiving the test result.
- 2. At the time of notification, the physician, hospital administrator or other person shall provide or arrange for counseling which includes factual information regarding the virus, the syndrome and its symptoms, measures which are effective in reducing the likelihood of transmitting the virus to others, the need to notify sex and/or needle-sharing partners of their exposure to the virus and the availability of assistance from local health agencies in partner notification procedures.
- 3. The local health agency shall conduct or direct an epidemiologic investigation of each reported case, suspected case, or suspect carrier within 30 days of the initial report. Upon completion of the epidemiologic investigation, the local health department shall not retain any personal identifying information on the case, suspect case, or suspect carrier.
- 4. Counseling and testing sites supervised by the Department or by local health agencies shall offer an anonymous testing option. Epidemiologic information including age, race, sex, county of residence, and associated risk behaviors shall be collected on individuals opting for anonymous testing.
- 5. The Department shall confidentially notify an identifiable 3rd party reported to be at risk of HIV infection pursuant to A.R.S. § 36-664(K) if all of the following conditions are met:
 - a. The report of risk is made to the Department in writing and includes the name and address of the identifiable 3rd party, the name and address of the person placing the identifiable 3rd party at risk, the type of exposure placing the identifiable 3rd party at risk, and the name and address of the person making the report;
 - b. The report is made by a person in possession of confidential HIV-related information;
 - c. The Department determines that the above information is both accurate and sufficient to warrant notification of the 3rd party at risk.
- 6. The local health department shall notify the school district superintendent in a writing which shall be kept confidential that a school district pupil is reported as a case, suspect case, or suspect carrier of HIV infection when all of the following criteria are met:

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- a. ~~The infected pupil places others in the school setting at risk for HIV infection. The local health department shall make this determination in consultation with the Department.~~
- b. ~~The school district has established a communicable disease policy which consists of the following criteria:~~
 - i. ~~A school shall not exclude an infected pupil from school or school functions solely due to HIV infection.~~
 - ii. ~~The school district superintendent, the pupil, or parents or legal guardians of a minor pupil, the pupil's physician, and the local health officer shall make decisions regarding the educational setting for HIV-infected pupils on a case-by-case basis. In addition to the aforementioned individuals, the school district superintendent may also include the following individuals in this decision-making process: the school administrator, school nurse, and principal teacher or counselor. In making this decision, these individuals shall consider the risks and benefits to the pupil and others of maintaining the pupil in the school setting.~~
 - iii. ~~School district personnel informed of the pupil's HIV infection shall maintain that information as confidential.~~
 - iv. ~~School district personnel who handle blood or body fluids shall comply with the "Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health Care Settings", June 1988, Centers for Disease Control, 1600 Clifton Road, N.E., Atlanta, GA 30333, incorporated by reference and no other amendments and on file with the Office of the Secretary of State.~~
 - v. ~~AIDS educational programs shall be made available to pupils, parents, and staff through age-appropriate curricula, workshops, or in-service training sessions.~~

R9-6-360. Syphilis

A. Case control measures:

- 1. A diagnosing health care provider shall prescribe drugs to render a case noninfectious and counsel or arrange for the case to be counseled:
 - a. To abstain from sexual contact during drug treatment and for at least seven days after drug treatment is completed; and
 - b. About the following:
 - i. The characteristics of syphilis.
 - ii. The syndromes caused by syphilis.
 - iii. Measures to reduce the likelihood of transmitting syphilis to another, and
 - iv. The need to notify individuals with whom the case has had sexual contact within a time period determined based upon the stage of the disease.
- 2. A case shall be subject to obtain serologic testing at 3 three months and 6 six months following after initiation of initiating drug treatment.
- 3. A health care provider or operator of a blood bank, blood center, or plasma center, tissue bank, or organ bank shall not utilize use blood, plasma blood components, sperm, body organs, or tissue from a case for injection, transfusion, or transplantation. The diagnosing health care provider or authorized representative shall counsel the case to abstain from sexual contact for 7 days after completion of treatment.
- 4. An operator of a blood bank, blood center, plasma center, tissue bank, or organ bank who interprets as positive a test for the syphilis antigen or antibody shall notify the subject of the test within 30 days after interpreting the test.
- 5. The local health agency shall conduct an epidemiologic investigation of each reported case, confirming the stage of the disease.

B. Contact control measures: The local health agency shall;

- 1. identify Notify each identified individual of exposure;
- 2. and offer Offer or arrange for serologic testing and treatment of each identified individual to sexual contacts; and
- 3. Counsel each identified individual about the following:
 - a. The characteristics of syphilis.
 - b. The syndromes caused by syphilis.
 - c. Measures to reduce the likelihood of transmitting syphilis to another, and
 - d. The need to notify individuals with whom the identified individual has had sexual contact within a time period determined based upon the stage of the disease.

C. Special control measures:-

- 1. ~~Any person operating a blood or plasma center who interprets a positive test for the syphilis antigen or antibody shall, in addition to meeting the reporting requirements specified, notify or cause to be notified the person on whom the test was performed within 30 days of interpreting the test.~~
- 2. ~~The local health agency shall conduct or direct an epidemiologic investigation of each reported case.~~

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ARTICLE 4. ~~HUMAN IMMUNODEFICIENCY VIRUS (HIV) / ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)~~ AIDS DRUG ASSISTANCE PROGRAM (ADAP)

R9-6-401. Definitions

In this Article, unless otherwise specified:

1. "ADAP" means the AIDS Drug Assistance Program.
2. "AHCCCS" means the Arizona Health Care Cost Containment System.
3. "Applicant" means an individual who submits an application for ADAP to the Department.
4. "Diagnosis" means an identification of a disease by an individual authorized by law to make the identification.
5. "Drug" means a chemical substance determined by the United States Food and Drug Administration to be useful in the treatment of individuals with HIV infection.
6. "Earned income" means payments received by an individual as a result of work performed, 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.
7. "Family income" means the combined gross earned income and unearned income of all individuals within the family unit.
8. "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.
9. "Outpatient" means in an ambulatory setting.
10. "Poverty level" means the annual income for a family unit of a particular size included in the poverty guidelines updated annually in the Federal Register by the United States Department of Health and Human Services.
11. "Primary care provider" means a physician, registered nurse practitioner, or physician assistant who is treating an applicant or enrolled individual for HIV disease or HIV infection.
12. "Public assistance" means a government program that provides benefits to individuals based on need, such as Aid to Families with Dependent Children, SSI, or non-federally funded general assistance.
13. "Resident" means an individual who has a place of habitation in Arizona and lives in Arizona as other than a tourist.
14. "SSI" means Supplemental Security Income, a program of the Social Security Administration.
15. "Unearned income" means non-gift payments received by an individual that are unrelated to work performed by the individual, including:
 - a. Unemployment insurance;
 - b. Workers' compensation;
 - c. Disability payments;
 - d. Social security payments;
 - e. Public assistance payments;
 - 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 or other regular support payments from a relative or other individual not residing in the household;
 - m. Investment income;
 - n. Royalty payments;
 - o. 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.

~~R9-6-401.~~R9-6-402. Limitations and Termination of Program

- ~~A:~~ This program shall provide zidovudine and any other drug which has been determined by the FDA to prolong the life of a person with AIDS or related conditions to the extent of funding made available for that purpose.
- ~~B:~~ Therapeutic assistance shall be available only to certain low income individuals not covered under AHCCCS or by any third-party payor.

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- ~~C.~~ Therapeutic assistance shall be allocated to the maximum number of eligible persons derived by dividing the available funds by the cost of treatment for one person with zidovudine or other life-prolonging drug for a period concurrent with and ending in accordance with the fiscal year for which such funds are authorized. All others shall be placed on a waiting list; the Department may revise the maximum number of persons upward or downward, according to its actual experience with the availability of the therapeutic agent. Those on the waiting list shall have therapeutic assistance afforded them only if the maximum number of persons is raised or one or more persons receiving assistance leave the program. Upon the occurrence of such vacancy, the person at the top of the waiting list shall be enrolled for the period of time remaining in the fiscal year.
- ~~D.~~ All therapeutic assistance shall terminate upon the exhaustion or termination of available funding expressly authorized for this purpose. ADAP ceases to provide drugs when available funding is exhausted or terminated. This program shall ADAP is not constitute an entitlement program for any person or and does not create a right to assistance absent continued available funding.

~~R9-6-402~~**R9-6-403. Eligibility Requirements**

- A. To establish financial eligibility, an applicant shall comply with the following An individual is eligible to participate in ADAP if the individual:
 1. Provide a copy of one of the following Applies for enrollment in AHCCCS and possesses one of the following:
 - a. Application A letter from AHCCCS stating that an application for eligibility determination as filed with AHCCCS or SSI, bearing their stamp of the date processed, for which a determination of eligibility has not yet been made; is pending, or
 - b. Letter A letter from AHCCCS denying eligibility under AHCCCS or SSI;
 2. Certify that Has no or inadequate health insurance is in effect for the applicant which covers to cover the cost of the therapeutic agents drugs that are or may become available under this Article 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. To establish financial eligibility for HIV/AIDS therapy assistance, income shall not exceed the following allowable family income levels: Has annual family income that is less than or equal to 300% of the poverty level;

ALLOWABLE INCOME LIMITS

Size of Family Unit	Upper Limit Annual Income
1	\$13,240
2	\$17,760
3	\$22,280
4	\$26,800
5	\$31,320
6	\$35,840
7	\$40,360
8	\$44,880

- ~~B.~~ To establish medical eligibility, an applicant 13 years of age or over shall have one of the following conditions:
 1. A medical history of cytologically confirmed Pneumocystis carinii pneumonia, or
 2. A diagnosis of HIV infection which includes serologic or virologic evidence of HIV infection and an absolute CD4 (T4 helper/inducer) lymphocyte count of less than 500/mm³ in the peripheral blood before the initiation of therapy.
- ~~C.~~ To establish medical eligibility, an applicant more than three months but less than 13 years of age shall have one of the following conditions:
 1. A diagnosis of HIV-related illness, or
 2. A diagnosis of HIV infection with laboratory values indicating HIV-related immunosuppression.
 4. Is ineligible for Veterans' Administration benefits;
 5. Has a medical diagnosis of HIV disease or HIV infection; and
- ~~D.~~ 6. The applicant shall be 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.

~~R9-6-403~~**R9-6-404. Application Process**

- A. Application shall be made on a form prescribed by An applicant shall submit to the Department containing the following documents:
 1. ~~Personal and other information.~~ An application completed by the applicant, on a form provided by the Department, including the following:
 - a. Name The applicant's name, date of birth, and sex;

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- b. Address The applicant's address;
 - c. Telephone The applicant's telephone number;
 - d. Number of persons in household The number of individuals in the applicant's family unit;
 - e. Income The applicant's annual family income; and
 - f. The identification number, if a subject in the clinical trial study of zidovudine; 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. Medical information: An application completed by the applicant's primary care provider, on a form provided by the Department, including the following:
- a. A medical history of cytologically confirmed Pneumocystis carinii pneumonia The applicant's name; or
 - b. A confirmed diagnosis of symptomatic HIV infection, and evidence that the applicant's CD4 (T4 helper/inducer) lymphocyte count is above or below 400/mm³ in the peripheral blood prior to the initiation of therapy, the date of testing, and the name and address of the laboratory performing the testing The primary care provider's name and business address, telephone number, and facsimile number; and
 - c. The name, address and telephone number of the applicant's physician. 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
 - g. The signature of the primary care provider and the date of signature;
3. Certification statements:
- a. The applicant, or the applicant's parent, if the applicant is a minor, or legal guardian shall certify the following:
"I, _____, certify that to the best of my knowledge and belief, all statements made herein regarding personal and other nonmedical information are true and accurate. I certify that I am or my child or ward is not covered by any health insurance plan that would provide the support for which I am or my child or ward is applying. I understand that eligibility does not guarantee that the Arizona Department of Health Services will be able to provide support and that such support, if begun, may be terminated without notice."
 - b. The applicant's physician shall sign the certificate attesting to the following:
"I certify that to the best of my knowledge and belief all medical information presented by me in this application is true and accurate."
 - e. Failure by the applicant or the physician to provide the certification shall result in a denial of eligibility by the Department.
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;
 - c. A letter describing any monetary award received by a student to cover non-tuition expenses;
 - d. A letter describing each public assistance award; and

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- e. Documentation showing the amount and source of any other income.
- B.** As a part of, and appended to the prescribed application form, the applicant shall present documentation for benefits from AHCCCS or SSI pursuant to R9-6-402(A)(1).

R9-6-404, R9-6-405. Eligibility Determination and Enrollment Process

- A.** The Department shall review each completed application for completeness, for the certifications by both the applicant and the physician, and the application for benefits from either AHCCCS or SSI. The Department may seek to verify any and all information submitted in or in support of the application prior to or after a determination of eligibility. Applicants shall be required, upon request by the Department, to produce any reasonable documentation relating to eligibility. Failure to provide such documentation or provision of false or inaccurate information shall be grounds for denial of eligibility. If all portions are determined to be accurate, true and complete, if the certifications are present, and if the eligibility standards set forth in R9-6-402 are met, the applicant shall be declared eligible. received and determine enrollment based on applicant eligibility, the date on which the application is completed, and the availability of funds.
- B.** All applications shall be reviewed, and have an eligibility determination made, if all necessary documentation is included, at the time of receipt by the Department. If a slot is available for enrollment and support, the eligible person shall be enrolled. If none is available, the eligible person shall be placed on the waiting list. Enrollment or placement on the waiting list shall be in the order the applications are received, except that clinical trial study subjects shall be given priority over other eligible persons. An applicant shall execute any consent forms or releases of information necessary for the Department to verify eligibility.
- C.** The Department shall notify, in writing, both the applicant and the physician of the declaration of or denial of eligibility. The time-frames for approving or denying an application are described in R9-6-408.

R9-6-405, R9-6-406. Period of Eligibility Continuing Enrollment

- A.** Eligibility shall continue for one year subject to a six-month review from the date of determination; The Department shall review eligibility every six months after enrollment unless one of the following events occur ending the occurs within the six-month period to end eligibility period immediately:
1. Death of the eligible person The enrolled individual dies;
 2. Use of the therapeutic agent is halted The enrolled individual stops using the drug or drugs on the advice of the physician a primary care provider;
 3. Determination of eligibility and enrollment The enrolled individual is determined eligible and enrolled to receive medical services through either AHCCCS or SSI another third-party payor other than Indian Health Services;
 4. Increase in The enrolled individual's annual family income increases to an amount above the allowable 300% of the poverty level; or
 5. Establishment of residence The enrolled individual establishes residency outside Arizona.
- B.** The eligible person enrolled individual or the person's physician enrolled individual's primary care provider shall notify the Department within 30 days of after the occurrence of any of these the events listed in subsection (A) occurs.
- B.C.** The review at six months shall be based upon the submission of a follow-up application by the eligible person on a form prescribed by the Department. Failure to provide the follow-up application shall result in a denial of further eligibility by the Department. 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:
 1. Name The enrolled individual's name, address, and telephone number;
 2. The enrolled individual's race and ethnicity, date of birth, sex, and social security number;
 3. The enrolled individual's residency;
 4. The number of individuals in the enrolled individual's family unit;
 5. The enrolled individual's employment status;
 2. Status of the application made to SSI or to AHCCCS since the Department's determination of eligibility;
 3. f. Current 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;
 4. k. Recertification utilizing the statement specified in R9-6-403(A)(3)(a) 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;

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- 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;
 - 5. ii. Physician's A statement by the primary care provider that treatment with the therapeutic agent drug or drugs is still appropriate; and
 - 6. iii. The results and dates of the most recent HIV-related tests for the enrolled individual, if available;
 - iv. A recertification by the physician with the statement specified in R9-6-403(A)(3)(b) 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.

R9-6-407. Appeal

- A.** ~~The provisions of this Section shall be applicable to applicants and eligible persons adversely affected by an action regarding eligibility.~~
- B.** ~~An applicant may seek review of any decision regarding eligibility by filing a written appeal with the assistant director of the Division of Disease Prevention no more than 20 days from the date of receipt of the eligibility decision.~~
- C.** ~~The assistant director shall review the eligibility decision and, within ten days of the filing of the appeal, shall mail the written determinations to the applicant. The determination shall include a statement regarding the right of the applicant to appeal to the Director, within 20 days of receipt of the assistant director's written determination, pursuant to A.A.C. R9-1-111 through R9-1-126.~~
- D.** ~~Any appeal made to the Director following the review by the assistant director shall constitute a waiver of the applicant's confidentiality, but solely for the purpose of the administrative proceeding.~~

~~**R9-6-406.**~~**R9-6-407. Distribution Requirements**

- A.** ~~The physician primary care provider shall submit to the Department an order on the physician's prescription form for one month's supply of the therapeutic agent for each enrolled person who is under the care of the physician. Each prescription shall be refillable a maximum of five times~~ 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 the therapeutic agent a prescribed drug and provide it the drug to the enrolled person's physician individual's pharmacy in quantities a quantity sufficient to meet the therapeutic regimen prescribed by the physician enrolled individual's primary care provider.~~
- C.** ~~The Department shall provide the therapeutic agent a drug in original, unopened containers as supplied packaged by its vendor the manufacturer.~~
- D.** ~~In the event the care of If an enrolled person is transferred to another physician individual changes primary care providers, the original physician primary care provider shall notify the Department in writing within five working seven days of after the transfer change. The following information original primary care provider shall be provided provide the following information in the written notice:~~
 - 1. ~~Name~~ The name and address of the enrolled person individual;
 - 2. ~~Name~~ The name; and business address; and telephone number of physician to whom care is transferred the new primary care provider; and
 - 3. ~~A release signed by the patient enrolled individual authorizing the Department to contact and exchange information with the physician to whom care is transferred new primary care provider.~~
- E.** ~~Failure to comply with subsection (D) may cause an interruption in or termination of support.~~

R9-6-408. Time-frames

- 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.

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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.
 - c. 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

~~R9-6-408~~R9-6-409. Confidentiality

The Department considers ADAP application materials and all information received or maintained by the Department in connection with ADAP application for support and subsequent actions shall to be considered as confidential medical information, as defined in 9 A.A.C. 1, Article 3. The provisions of A.A.C. R9-1-311 et seq. shall govern the Department Department shall comply with 9 A.A.C. 1, Article 3 with regard to disclosing these materials and this information.

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Exhibit A. ~~Consent for HIV-Related Testing~~ Renumbered

Consent for HIV Testing

Information on HIV

The Human Immunodeficiency Virus (HIV) is the virus that causes Acquired Immune Deficiency Syndrome (AIDS). HIV is spread through the exchange of blood (including transfusion), sexual fluids (semen and vaginal secretions) and sometimes through breast milk. HIV can be transmitted from mother to baby during pregnancy or childbirth.

HIV Testing

There are several laboratory tests for HIV. The most common is the antibody test, which is a blood test that detects antibodies produced by the body in response to infection with HIV.

A positive antibody test consists of a repeatedly reactive (the same specimen testing positive twice) enzyme immunoassay (EIA) and a reactive Western blot (supplementary test). A positive antibody test means that an individual is infected with HIV; however, this does not always mean that the individual has AIDS. Research indicates that early and regular medical care is important to the health of a person with HIV. Certain treatments are now available to delay HIV associated illnesses.

A negative antibody test indicates that no detectable antibodies are present in the blood. An individual may not have antibodies because the individual is not infected with HIV or because detectable antibodies have not yet been made in response to infection. The production of these antibodies could take 3 months or longer. Therefore, in certain cases, an individual may be infected with HIV and yet test negative. Individuals with a history of HIV risk behaviors within the past 3 to 6 months should consider retesting.

Like any test, HIV testing is not 100% reliable and may occasionally produce both false positive and false negative results.

Means to Reduce Risk for Contracting or Spreading HIV

Risk of contracting or spreading HIV can be reduced by avoiding or decreasing contact with blood and sexual fluids (semen and vaginal secretions). Some methods of decreasing the risk of contracting or spreading HIV include abstaining from sexual intercourse, using methods that limit exposure to body fluids during intercourse (such as the proper use of condoms), not engaging in injecting drug use, not sharing needles, or using bleach and water to clean needles and syringes. The use of certain medications by a HIV-infected woman during pregnancy may reduce the chances of HIV transmission from mother to child.

Disclosure of Test Results

I understand that if the HIV test results are positive, the physician or facility representative conducting the test will make reasonable efforts to notify me of the results at the address or phone number I have provided, and will provide or arrange for counseling as required by Arizona state laws and regulations regarding (1) the HIV (2) AIDS and (3) appropriate precautions to reduce the likelihood of transmission of the virus to others. I agree to assume all risks that may result if I cannot be contacted.

I understand that Arizona law and regulations require that if my test results are positive, they will be submitted to local and state health departments. Information received by these health departments may only be released (1) if there is written authorization from the person being tested; (2) for statistical purposes without individual identifying information, or as otherwise required or allowed by law.

Identifying Information

I also understand that the physician or facility may report to the Arizona Department of Health Services identifiable 3rd parties such as a spouse or sex partner who may be at risk of contracting the virus if I do not release this information. Finally, I understand that the test results may be placed in a medical record kept by the facility or person administering the test and that persons involved in providing or paying for my health care may have access to that information.

Additional Sources of Information on HIV

Additional information regarding testing for HIV is available through your county health department and, in the Phoenix metropolitan area, (602) 234-2752, the Tucson metropolitan area, (520) 326-2437, or outside the Phoenix area, 1-800-334-1540. National Hotline: English, 1-800-342-2437; Spanish, 1-800-344-7432; TTY/TDD, 1-800-243-7012.

Consent

I have been given the opportunity to ask questions regarding this information and have had my questions answered to my satisfaction. I understand that this test can be performed anonymously at a public health agency. I also understand that I may withdraw my consent at any time before a blood sample is taken in order to conduct a test, and that I may be asked to put my decision to withdraw my consent in writing if I have signed this consent. I also understand that this is a voluntary test and that I have a right to refuse to be tested.

My signature below indicates that I have received and understand the information I have been given and I voluntarily consent to and request HIV testing.

Patient/Subject Name (Printed)

Patient/Subject or Legal Representative Signature

Date

Witness

NOTICE

The Arizona Department of Health Services does not discriminate on the basis of disability in the administration of its programs and services as prescribed by Title II of the Americans with Disabilities Act of 1990 and Section 504 of the Rehabilitation Act of 1973. If you need this publication in an alternative format, please contact the ADHS Office of HIV/STD Services at (602) 230-5819 or 1-800-367-8939 (state TDD/TTY Relay).

**Exhibit B. Consentimiento para la Prueba de VIH
Renumbered**

Consentimiento Para la Prueba de VIH

Información sobre el VIH

El virus de Inmunodeficiencia Humana (VIH) es el virus que causa el Síndrome de Inmunodeficiencia Adquirida (SIDA). VIH se transmite a través del contacto con sangre (incluyendo la transfusión), fluidos sexuales (semen y secreciones vaginales) y en algunas ocasiones a través de la leche materna. VIH puede ser transmitido de la madre al bebé durante el embarazo o al momento del parto.

La prueba del VIH

Existen pruebas de laboratorio para saber si una persona está infectada con el VIH. La más común es la prueba de anticuerpos. Esta es un examen de sangre que detecta los anticuerpos producidos por el cuerpo al reaccionar contra la infección por VIH.

Un examen de anticuerpos positivo consiste de una prueba por inmunoanálisis enzimático (EIA) (realizada dos veces en cada espécimen) y una prueba reactiva por Western Blot u otras pruebas confirmatorias. El resultado positivo a la prueba de anticuerpos quiere decir que el individuo está infectado con el VIH; sin embargo, esto no siempre quiere decir que el individuo tenga el SIDA. Investigaciones médicas señalan que atención médica temprana y continua es importante para la salud de una persona con el VIH. Hoy en día se dispone de tratamientos para retardar las enfermedades asociadas con el SIDA.

Un examen de anticuerpos negativo indica que no se han detectado anticuerpos en la sangre. Un individuo puede no tener anticuerpos por que el individuo no está infectado(a) o porque aún no se han producido suficientes anticuerpos contra la infección. Estos anticuerpos pueden tardar tres meses o más para ser producidos. De tal manera, en ciertos casos, un individuo puede estar infectado con el VIH y su prueba resultar negativa. Los individuos que han tenido comportamiento de alto riesgo en los últimos tres a seis meses deberían pensar en repetir la prueba.

Como cualquier prueba, la prueba del VIH no es 100% segura y en alguna ocasión puede producir resultados falsos ya sea positivos o negativos.

Maneras de reducir el riesgo de infección o transmisión del VIH

El riesgo de contraer o transmitir el VIH se puede reducir al evitar contacto con la sangre y fluidos sexuales (semen y secreciones vaginales). Algunos métodos para disminuir el riesgo de infección o transmisión del VIH incluyen: abstinencia sexual, usar métodos que limitan el contacto de fluidos corporales durante la relaciones sexuales (como el uso correcto de condones), no usar drogas intravenosas, no compartir agujas, y usar "cloro" (blanqueador) y agua para limpiar las jeringas y las agujas. En mujeres infectadas con VIH, el uso de ciertos medicamentos durante el embarazo, puede reducir el riesgo de la transmisión del VIH de madre a hijo.

El resultado de la prueba

Entiendo que si el resultado de la prueba del VIH es positivo, el doctor o el representante de la institución que hizo el examen va a hacer esfuerzos suficientes para notificarme del resultado a la dirección (domicilio) o al teléfono que he proporcionado y que me dará información, cumpliendo con los requisitos de la ley estatal de Arizona, sobre (1) el VIH, (2) el SIDA, y (3) las precauciones necesarias para reducir la posibilidad de transmisión del virus a otras personas. Estoy de acuerdo en asumir todos los riesgos que resultarán de no poder contactarme.

Entiendo que la ley estatal de Arizona exige que si el resultado de mi prueba es positivo, éste se reportará a los departamentos de salud local y estatal. La información que estos departamentos reciben solamente puede ser revelada a otras personas: (1) si hay una

Identifying Information/Datos de Identidad

autorización por escrito de la persona que se ha hecho la prueba; (2) por razones de estudios estadísticos sin revelar la identidad del individuo, o por cualquier otra razón que la ley permita.

También entiendo que el doctor o la institución puede reportar al Departamento de Salud del Estado de Arizona, la identidad de terceras personas como: los esposos(as) o los compañeros(as) sexuales que pueden estar en riesgo de contraer con el virus si decido no darles esta información. Por último, entiendo que el resultado de la prueba puede guardarse con el resto de mi información médica en la agencia o por la persona que hizo el examen; y que las personas encargadas de proveer o pagar por el cuidado de mi salud pueden tener acceso a esta información.

Otras fuentes de información sobre el VIH

Información adicional sobre el examen del VIH está disponible a través del departamento de salud de su condado. En el área metropolitana de Phoenix llame al (602) 234-2752, en el área metropolitana de Tucson (520) 326-2437, y en el resto de Arizona 1-800-334-1540. Líneas telefónicas a nivel nacional son: en inglés 1-800-342-2437; en español 1-800-344-7432. (TTY/TDD) Transmisión de voz 1-800-243-7012.

Consentimiento

Se me ha dado la oportunidad de hacer preguntas respecto a esta información y me han sido contestadas satisfactoriamente. Entiendo que este examen se puede hacer de forma anónima en una agencia de salud pública. También entiendo que puedo retirar mi consentimiento en cualquier momento antes de que me saquen la sangre para hacer la prueba y que me pueden pedir que ponga por escrito mi decisión de retirar mi consentimiento si ya había firmado este permiso. Entiendo también que este examen es voluntario y que tengo el derecho a negarme a que se me haga la prueba.

Mi firma indica que he recibido y he entendido la información que se me ha proporcionado y que voluntariamente autorizo y solicito la prueba del VIH.

Nombre del paciente (letra imprenta)

Firma del paciente o de su representante legal

Fecha

Testigo

AVISO

El Departamento de Salud del Estado de Arizona no discrimina basado en los impedimentos de las personas en la administración de los programas y servicios ordenado por la ley de 1990: Americanos con Impedimentos, Título II y la Sección 504 de la ley de Rehabilitación de 1973. Si usted necesita esta publicación por otros medios de comunicación, favor ponerse en contacto con el Departamento de Salud del Estado de Arizona, Oficina de Servicios de VIH/ETS al 1-800-842-4681 (transmisión de voz estatal) or 1-800-367-8939 (transmisión TDD/TYY estatal).

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R9-6-410. ~~Human Immunodeficiency Virus Testing~~ Renumbered

A blood test performed pursuant to A.R.S. § 13-1415 for antibodies to HIV shall use an enzyme immunoassay test and shall be licensed by the Food and Drug Administration (FDA). Blood that is reactive according to the manufacturer's recommendations shall be retested in duplicate, diluting from the original specimen. Repeatedly reactive blood shall be tested with an FDA-licensed Western blot test. Western blot band patterns shall be interpreted according to the recommendations, "Interpretation and Use of the Western Blot Assay for Serodiagnosis of Human Immunodeficiency Virus Type 1 Infections", Morbidity and Mortality Weekly Report, July 21, 1989, vol. 38, No. S-7, Centers for Disease Control, 1600 Clifton Road, N.E., Atlanta, GA 30333, incorporated herein by reference and no other amendments and on file with the Office of the Secretary of State. Test results shall be reported directly to the Department.

ARTICLE 9. HIV-RELATED TESTING

R9-6-901. Definitions

In this Article, unless otherwise specified:

1. "Health professional" has the same meaning as "health care provider" in A.R.S. § 36-661.
2. "Hospital" means a health care institution licensed by the Department as a general hospital, a rural general hospital, or a special hospital under 9 A.A.C. 10.
3. "Informed consent" means permission to conduct an HIV-related test obtained from a subject who has capacity to consent or an individual authorized by law to consent for a subject without capacity to consent after an explanation that complies with A.R.S. § 36-663(B).

~~R9-6-409~~R9-6-902. Consent for HIV-related Testing

- A. ~~A person~~ An individual ordering a ~~an~~ HIV-related test shall obtain consent for the test, unless the test has been ordered by the a court under A.R.S. §§ 8-341, 13-1210, or 13-1415(B) or falls under A.R.S. § 36-663(D).
1. If the test is ordered in a hospital, the individual ordering the test shall obtain specific written informed consent as specified in subsection (B).
 2. If the test is ordered outside a hospital by a physician licensed pursuant to A.R.S. Title 32, Chapter 13, 17, or 29, a registered nurse practitioner certified pursuant to A.R.S. Title 32, Chapter 15, or a physician's assistant certified pursuant to A.R.S. Title 32, Chapter 25, the individual ordering the test shall obtain consent shall be either written informed consent as specified in subsection (B) or oral informed consent.
 3. If the test is ordered outside a hospital by a health professional licensed under A.R.S. Title 32, but not listed in subsection (A)(2), who is authorized to provide HIV-related tests within the health professional's scope of practice, the individual ordering the test shall obtain written informed consent as specified in subsection (B).
 4. If the HIV-related test is performed anonymously, then the individual ordering the test shall obtain oral consent is required and no record shall be made with not make a record containing personal identifying information on about the patient subject.
- B. ~~Written consent shall be on~~ An individual obtaining written, informed consent for an HIV-related test shall use the form shown in Exhibit A (English) or Exhibit B (Spanish).
1. ~~Individuals and facilities~~ Except as described in subsection (A)(4), an individual using the consent form may add ~~or affix~~ the following ~~additional~~ information in the Identifying Information section of the form:
 - a. ~~patient/subject's~~ The subject's name and identifying number,
 - b. ~~facility~~ Facility identifying information,
 - c. ~~facility~~ Facility processing codes,
 - d. The subject's race and ethnicity.
 - e. The subject's address, and
 - f. ~~patient/subject's~~ The subject's date of birth and sex.
 2. This form may be reproduced to accommodate a multiple copy or carbonless form.

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Exhibit A. Consent for HIV Testing EXHIBIT A. CONSENT FOR HIV-RELATED TESTING

Consent for HIV-related Testing

Information on HIV

The Human Immunodeficiency Virus (HIV) is the virus that causes Acquired ~~Immune Deficiency~~ Immunodeficiency Syndrome (AIDS). HIV is spread through the exchange of blood (including transfusion), or sexual fluids (semen and vaginal secretions) and sometimes through breast milk. HIV can be transmitted from mother to baby during pregnancy or childbirth.

HIV-related Testing

There are several laboratory tests for HIV. The most common is the antibody test, which is a blood test that detects antibodies produced by the body in response to infection with HIV.

A positive antibody test consists of a repeatedly reactive (the same specimen testing positive twice) enzyme immunoassay (EIA) and a reactive Western blot (or other supplementary confirmatory test). A positive antibody test means that an individual is infected with HIV; however, this does not always mean that the individual has AIDS.

Research indicates that early and regular medical care is important to the health of a person an individual with HIV. Certain treatments are now available to delay treat HIV-associated illnesses.

A negative antibody test indicates that no detectable antibodies are present in the blood. An individual may not have antibodies because the individual is not infected with HIV or because detectable antibodies have not yet been made in response to infection. The production of these antibodies could take 3 months or longer. Therefore, in certain cases, an individual may be infected with HIV and yet test negative. Individuals with a history of HIV risk behaviors within the past 3 to 6 months should consider retesting.

Like any test, HIV-related testing is not accurate 100% reliable of the time and may occasionally produce both false positive and false negative results.

Means to Reduce Risk for Contracting or Spreading HIV

Risk of contracting or spreading HIV can be reduced by avoiding or decreasing contact with blood and sexual fluids (semen and vaginal secretions). Some methods of decreasing the risk of contracting or spreading HIV include abstaining from sexual intercourse, using methods that limit exposure to body fluids during intercourse (such as the proper use of condoms), not engaging in injecting drug use, not sharing needles, or using bleach and water to clean needles and syringes. The use of certain medications by a an HIV-infected woman during pregnancy may reduce the chances of HIV transmission from mother to child.

Disclosure of Test Results

I understand that if the HIV test results are positive, the physician or facility representative conducting the test will make reasonable efforts to notify me of the results at the address or phone number I have provided, and will provide or arrange for counseling as required by Arizona state laws and regulations regarding (1) ~~the~~ HIV, (2) AIDS, and (3) appropriate precautions to reduce the likelihood of transmission of the virus to others. I agree to assume all risks that may result if I cannot be contacted.

I understand that Arizona law and regulations require that if my test results are positive, they will be submitted to local and state health departments. Information received by these health departments may only be released: (1) if there is written authorization from the person individual being tested; (2) for statistical purposes without individual identifying information, or (3) as otherwise required or allowed by law.

Identifying Information

I also understand that the physician or facility may report to the Arizona Department of Health Services identifiable 3rd parties such as a spouse or sex partner who may be at risk of contracting the virus if I do not release this information. Finally, I understand that the test results may be placed in a medical record kept by the facility or person administering the test and that persons involved in providing or paying for my health care may have access to that information.

Additional Sources of Information on HIV

Additional information regarding testing for HIV is available through your county health department and, in the Phoenix metropolitan area, (602) 234-2752, the Tucson metropolitan area, (520) 326-2437 791-7676, or outside the Phoenix area, 1-800-334-1540. National Hotline: English, 1-800-342-2437; Spanish, 1-800-344-7432; TTY/TDD, 1-800-243-7012.

Consent

I have been given the opportunity to ask questions regarding this information and have had my questions answered to my satisfaction. I understand that this test can be performed anonymously at a public health agency. I also understand that I may withdraw my consent at any time before a blood sample is taken in order to conduct a test, and that I may be asked to put my decision to withdraw my consent in writing if I have signed this consent. I also understand that this is a voluntary test and that I have a right to refuse to be tested. My signature below indicates that I have received and understand the information I have been given and I voluntarily consent to and request HIV-related testing.

Patient/Subject Name (Printed)

Patient/Subject or Legal Representative Signature

Date

Witness

NOTICE

The Arizona Department of Health Services does not discriminate on the basis of disability in the administration of its programs and services as prescribed by Title II of the Americans with Disabilities Act of 1990 and Section 504 of the Rehabilitation Act of 1973. If you need this publication in an alternative format, please contact the ADHS Office of HIV/STD Services at (602) 230-5819 or 1-800-367-8939 (state TDD/TTY Relay).

Exhibit B. Consentimiento Para La Prueba De VIH EXHIBIT B. CONSENTIMIENTO PARA LA PRUEBA DE VIH

Consentimiento Para la Prueba de VIH

Información sobre el VIH

El virus de Inmunodeficiencia Humana (VIH) es el virus que causa el Síndrome de Inmunodeficiencia Adquirida (SIDA). VIH se transmite a través del contacto con sangre (incluyendo la transfusión), o fluidos sexuales (semen y secreciones vaginales) y en algunas ocasiones a través de la leche materna. VIH puede ser transmitido de la madre al bebé durante el embarazo o al momento del parto.

La prueba del VIH

Existen pruebas de laboratorio para saber si una persona está infectada con el VIH. La más común es la prueba de anticuerpos. Esta es un examen de sangre que detecta los anticuerpos producidos por el cuerpo al reaccionar contra la infección por VIH.

Un examen de anticuerpos positivo consiste de una prueba por inmunoanálisis enzimático (EIA) (realizada dos veces en cada espécimen) y una prueba reactiva por Western Blot u otras pruebas confirmatorias. El resultado positivo a la prueba de anticuerpos quiere decir que el individuo está infectado con el VIH; sin embargo, esto no siempre quiere decir que el individuo tenga el SIDA. Investigaciones médicas señalan que atención médica temprana y continua es importante para la salud de una persona con el VIH. Hoy en día se dispone de tratamientos para retardar las enfermedades asociadas con el SIDA.

Un examen de anticuerpos negativo indica que no se han detectado anticuerpos en la sangre. Un individuo puede no tener anticuerpos por que el individuo no está infectado(a) o porque aún no se han producido suficientes anticuerpos contra la infección. Estos anticuerpos pueden tardar tres meses o más para ser producidos. De tal manera, en ciertos casos, un individuo puede estar infectado con el VIH y su prueba resultar negativa. Los individuos que han tenido comportamiento de alto riesgo en los últimos tres a seis meses deberían pensar en repetir la prueba.

Como cualquier prueba, la prueba del VIH no es 100% segura y en alguna ocasión puede producir resultados falsos ya sea positivos o negativos.

Maneras de reducir el riesgo de infección o transmisión del VIH

El riesgo de contraer o transmitir el VIH se puede reducir al evitar contacto con la sangre y fluidos sexuales (semen y secreciones vaginales). Algunos métodos para disminuir el riesgo de infección o transmisión del VIH incluyen: abstinencia sexual, usar métodos que limitan el contacto de fluidos corporales durante la relaciones sexuales (como el uso correcto de condones), no usar drogas intravenosas, no compartir agujas, y usar "cloro" (blanqueador) y agua para limpiar las jeringas y las agujas. En mujeres infectadas con VIH, el uso de ciertos medicamentos durante el embarazo, puede reducir el riesgo de la transmisión del VIH de madre a hijo.

El resultado de la prueba

Entiendo que si el resultado de la prueba del VIH es positivo, el doctor o el representante de la institución que hizo el examen va a hacer esfuerzos suficientes para notificarme del resultado a la dirección (domicilio) o al teléfono que he proporcionado y que me dará información, cumpliendo con los requisitos de la ley estatal de Arizona, sobre (1) el VIH, (2) el SIDA, y (3) las precauciones necesarias para reducir la posibilidad de transmisión del virus a otras personas. Estoy de acuerdo en asumir todos los riesgos que resultarán de no poder contactarme.

Entiendo que la ley estatal de Arizona exige que si el resultado de mi prueba es positivo, éste se reportará a los departamentos de salud local y estatal. La información que estos departamentos reciben solamente puede ser revelada a otras personas: (1) si hay una autorización por escrito de la persona que se ha hecho la prueba; (2) por razones de estudios estadísticos sin revelar la identidad del individuo, o (3) por

Identifying Information/Datos de Identidad

cualquier otra razón que la ley permita.

También entiendo que el doctor o la institución puede reportar al Departamento de Salud del Estado de Arizona, la identidad de terceras personas como: los esposos(as) o los compañeros(as) sexuales que pueden estar en riesgo de contraer con el virus si decido no darles esta información. Por último, entiendo que el resultado de la prueba puede guardarse con el resto de mi información médica en la agencia o por la persona que hizo el examen; y que las personas encargadas de proveer o pagar por el cuidado de mi salud pueden tener acceso a esta información.

Otras fuentes de información sobre el VIH

Información adicional sobre el examen del VIH está disponible a través del departamento de salud de su condado. En el área metropolitana de Phoenix llame al (602) 234-2752, en el área metropolitana de Tucson (520) 326-2437 791-7676, y en el resto de Arizona 1-800-334-1540. Líneas telefónicas a nivel nacional son: en inglés 1-800-342-2437; en español 1-800-344-7432. (TTY/TDD) Transmisión de voz 1-800-243-7012.

Consentimiento

Se me ha dado la oportunidad de hacer preguntas respecto a esta información y me han sido contestadas satisfactoriamente. Entiendo que este examen se puede hacer de forma anónima en una agencia de salud pública. También entiendo que puedo retirar mi consentimiento en cualquier momento antes de que me saquen la sangre para hacer la prueba y que me pueden pedir que ponga por escrito mi decisión de retirar mi consentimiento si ya había firmado este permiso. Entiendo también que este examen es voluntario y que tengo el derecho a negarme a que se me haga la prueba.

Mi firma indica que he recibido y he entendido la información que se me ha proporcionado y que voluntariamente autorizo y solicito la prueba del VIH.

Nombre del paciente (letra imprenta)

Firma del paciente o de su representante legal

Fecha

Testigo

AVISO

El Departamento de Salud del Estado de Arizona no discrimina basado en los impedimentos de las personas en la administración de los programas y servicios ordenado por la ley de 1990: Americanos con Impedimentos, Título II y la Sección 504 de la ley de Rehabilitación de 1973. Si usted necesita esta publicación por otros medios de comunicación, favor ponerse en contacto con el Departamento de Salud del Estado de Arizona, Oficina de Servicios de VIH/ETS al 1-800-842-4681 (transmisión de voz estatal) or 1-800-367-8939 (transmisión TDD/TYY estatal.).

ADHS2002

~~R9-6-410, R9-6-903. Human Immunodeficiency Virus~~ Court-ordered HIV-related Testing

- A.** ~~A~~ An individual who tests a specimen of blood or another body fluid to detect HIV antibody test performed pursuant to under court order issued under A.R.S. §§ 8-341 or 13-1415 for antibodies to HIV shall use an enzyme immunoassay a test and shall be licensed by the United States Food and Drug Administration (FDA) for use in HIV screening. Blood that If a specimen is reactive two or more times according to the test manufacturer's recommendations, the individual shall be retested in duplicate, diluting from the original specimen retest the specimen using a licensed supplemental or confirmatory assay or as recommended by the original test manufacturer's package insert. Repeatedly reactive blood shall be tested with an FDA-licensed Western blot test. Western blot band patterns shall be interpreted according to the recommendations, "Interpretation and Use of the Western Blot Assay for Serodiagnosis of Human Immunodeficiency Virus Type 1 Infections", Morbidity and Mortality Weekly Report, July 21, 1989, vol. 38, No. S-7, Centers for Disease Control, 1600 Clifton Road, N.E., Atlanta, GA 30333, incorporated herein by reference and no other amendments and on file with the Office of the Secretary of State.
- B.** ~~Test results~~ The individual shall be reported report each test result for each subject directly to the Department.