CHAPTER 11
ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

FINANCIAL ASSISTANCE TO ELIGIBLE HIV-INFECTED PATIENTS

Rescinded IAB 12/8/93, effective 1/12/94

641—11.1 to **11.15** Reserved.

CERTIFICATION OF LABORATORIES FOR HIV TESTING

641—11.16(141) Purpose. To describe the certification procedures and standards for laboratories that desire to perform HIV testing services.

641—11.17(141) Definitions. For the purpose of rules 641—11.16(141) to 641—11.34(141), the following definitions shall apply:

"AAB" means American Association of Bioanalysts.

"AABB" means American Association of Blood Banks.

"AOA" means American Osteopathic Association.

"Blood bank" means a facility for the collection, processing, or storage of human blood or blood derivatives, or from which or by means of which human blood or blood derivatives are distributed or otherwise made available.

"CAP" means College of American Pathologists.

"CDC" means Centers for Disease Control and Prevention.

"CLIA" means Clinical Laboratories Improvement Act as administered by HCFA for HIV testing.

"Clinical laboratory" means a facility for the microbiological, serological, chemical, hematological, radiobioassay, cytological, immunohematological, pathological or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or assessment of a medical condition.

"Confirmatory test" means an additional more specific test designed to validate the results of a screening test.

"Department" means Iowa department of public health.

"FDA" means Food and Drug Administration.

"HCFA" means Health Care Financing Administration.

"HIV" means "human immunodeficiency virus."

"HIV testing" means laboratory analysis of a specimen for the purpose of detecting HIV infection.

"JCAHO" means Joint Commission on Accreditation of Healthcare Organizations.

"Laboratory" means a clinical or public health laboratory or a blood bank inside or outside the boundaries of Iowa.

"Medicare" means Medicare laboratories certified by HCFA under 42 CFR 482.27, effective September 15, 1986, (Conditions of Participation for Hospitals) or 42 CFR 405.1310 et seq., effective January 1, 1966 (Conditions for Coverage of Services of Independent Laboratories).

"Physician" means a person currently licensed pursuant to Iowa Code chapters 148, 150 or 150A.

"Public health laboratory" means a laboratory operated by an agency of city, county or state government for purposes of supporting disease control activities.

"Screening test" means the initial test performed to detect antibodies to HIV.

"Specimen" means a human body fluid or tissue sample.

641—11.18(141) Responsibilities of the department.

11.18(1) The department shall consider for certification those laboratories that desire to perform HIV testing services.

11.18(2) An application package is available from the Iowa Department of Public Health, Division of Health Protection, Lucas State Office Building, Des Moines, Iowa 50319-0075.

11.18(3) The application package shall include:

a. A copy of these rules, and

b. An "Application to Perform HIV Testing."

11.18(4) To determine laboratory compliance with the standards established pursuant to these rules, the department, at the department's discretion, may conduct periodic inspections of:

a. Laboratory facilities,

b. Methods,

c. Procedures,

d. Materials (including reagents),

e. Staff, and

f. Equipment.

NOTE: The department may delegate this authority to the State Hygienic Laboratory pursuant to the provisions of Iowa Code chapter 141.

11.18(5) The department shall issue a written notice for each certified laboratory that clearly identifies the laboratory and the certification period. The notice shall also specify whether the laboratory is certified to perform screening only, or can perform both screening and confirmatory HIV testing services.

11.18(6) The department shall maintain and furnish upon request a current list of all HIV testing laboratories certified by the department. The list shall also specify whether the laboratories are certified to perform screening only, or can perform both screening and confirmatory HIV testing services.

641—11.19(141) Initial application and certification requirements.

11.19(1) Laboratories desiring to perform HIV testing services shall apply to the department.

11.19(2) Laboratories requesting certification to perform HlV testing shall provide to the department:

a. A completed "Application to Perform HIV Testing."

b. Proof of current accreditation, certification or licensure by AOA, CAP, CLIA, FDA, JCAHO or Medicare.

c. A copy of the documents that describe the interpretive basis for positive, negative and indeterminate screening and confirmatory test results.

NOTE: Recommended guidelines for interpreting test results are those published by the Committee on HIV Testing, Association of State and Territorial Public Health Laboratory Directors, 6728 Old McLean Village Drive, McLean, Virginia 22101, or other guidelines approved by the department.

d. Proof of current enrollment in an HIV proficiency testing program. Proficiency testing programs include, but are not limited to, those administered by AAB, AABB, CAP or CDC.

11.19(3) Acceptable performance must be maintained during the 12-month certification period in all appropriate areas of HIV proficiency testing. Laboratories shall send copies of their proficiency testing results to the State Hygienic Laboratory on a quarterly basis for the purpose of ongoing monitoring and evaluation of performance. The address is: State Hygienic Laboratory, University of Iowa, Oakdale Hall, Iowa City, Iowa 52242.

11.19(4) Acceptable proficiency testing performance is stipulated below:

a. For laboratories providing screening tests, four out of five survey specimens must be interpreted accurately with a minimum of five survey specimens analyzed per quarter.

b. For laboratories providing confirmatory tests, no unacceptable results are permitted for five out of five survey specimens with a minimum of five survey specimens analyzed per quarter.

641—11.20 Reserved.

641—11.21(141) Renewal of laboratory certification. Certification to continue HIV testing must be renewed annually. To renew certification, laboratories must submit the following information to the department at least 60 days before their current certification expires:

1. Proof of continued accreditation, certification or licensure by AOA, CAP, CLIA, FDA, JCAHO or Medicare.
2. Proof of continued enrollment in a recognized HIV proficiency testing program.

641—11.22(141) Reinstatement of certification. A laboratory whose certification has been limited, suspended, or revoked may be reinstated, provided the department receives (within 90 days) documentation that corrective actions have been taken that satisfy the reason(s) for limitation, suspension, or revocation.

641—11.23(141) Application fees and inspection costs.

11.23(1) Each laboratory at the time of application shall remit to the department the appropriate application fee. All fees shall be made payable to the "Iowa Department of Public Health" as follows:

a. Annual certification. A fee of $100 is required the first time a laboratory applies for annual certification.

b. Renewal. A fee of $100 is required for laboratories desiring to renew their annual certification.

c. Reinstatement. A fee of $100 is required for laboratories desiring to reinstate their certification. If, however, the reinstatement occurs with less than 2 months remaining in the 12-month certification period, the $100 fee shall be waived.

NOTE: A reinstatement does not alter a laboratory's previously established certification period.

11.23(2) Inspection costs. Reimbursement for actual expenses shall be assessed only to those laboratories where an on-site inspection is considered necessary. Expenses shall be reimbursed to the State Hygienic Laboratory for the actual costs incurred for personnel time and travel expenses consistent with state of Iowa travel reimbursement limitations.

641—11.24(141) Requirements for laboratory personnel.

11.24(1) Laboratory directors shall meet the qualifications specified by AOA, CAP, CLIA, FDA, JCAHO or Medicare.

11.24(2) Laboratory supervisors shall meet the qualifications specified by CLIA or Medicare.

641—11.25(141) Laboratory procedures and procedure manual requirements.

11.25(1) All laboratories shall have written procedures and a procedure manual which encompasses all current aspects of the HIV testing process including, but not limited to:

a. Specimen acquisition.
b. Specimen and report security.
c. Test performance.
d. Reporting of results.
e. Confirmation of positive test results.
f. Confidentiality.

11.25(2) Procedure manuals shall be readily available for review during any on-site inspection.

11.25(3) Positive and negative controls shall be used each time a test is performed.

11.25(4) Laboratories shall develop criteria for the rejection of specimens.

641—11.26(141) Notification of certain changes during a certification period. Any of the following changes that occur during a certification period shall be reported to the department within ten working days from the date the changes take place:

1. Change in accreditation, certification or licensure.
2. Change in address.
3. Change in method used for screening or confirmatory tests.
4. Change in laboratory used to perform confirmatory tests.
5. Change in laboratory director.
6. Change in laboratory ownership.

641—11.27(141) Testing methodologies and confirmation of positive test results.

11.27(1) Screening tests. The screening test shall be the enzyme-linked immunosorbent assay (ELISA) test or an equivalent test as determined by the department.

11.27(2) Confirmatory tests. Specimens which are reactive as a result of the screening test shall be confirmed by the enzyme-linked immunoelectrotransfer blot (Western blot) test or an equivalent test as determined by the department before being reported by the laboratory to the department as a confirmed positive test result.

11.27(3) Specimens requiring confirmation that cannot be tested by the laboratory performing the screening test shall be referred to a laboratory capable of performing confirmatory testing which has been certified by the department.

11.27(4) Confirmed positive specimens shall be retained at or below minus 20 degrees centigrade for at least six months.

641—11.28(141) Record maintenance and documentation of the testing process. The following information shall be retained for at least two years:

1. Test results of all specimens.
2. Relevant quality control documentation that includes the identification and lot number of the kit or reagents used for each batch.

641—11.29(141) Reporting of test results to the department.

11.29(1) Each laboratory shall ensure that:

a. Written procedures have been established for reporting test results and release of information.

b. All test results are reviewed by the director, or a qualified designee, prior to reporting.

c. All test results are clearly identified and that appropriate interpretive information is included with the HIV test report.

11.29(2) Within seven days of the receipt of a person's confirmed positive test result indicating HIV infection, the director of a blood plasma center, blood bank, clinical laboratory or public health laboratory that performed the test or that requested the confirmatory test shall make a report to the department on a form provided by the department. The report shall include:

a. The person's age, race, marital status and other information deemed necessary by the department for epidemiological purposes or as much of that information as the director may possess, but shall not include the person's name or address without the written authorization of the person.

b. The name, address and telephone number of the blood plasma center, blood bank, clinical laboratory or public health laboratory that performed or requested the test.

c. The address of the physician or other health care practitioner that requested the test. This paragraph, however, shall not apply to a blood plasma center or blood bank.

NOTE: Iowa Code requires the performance of a confirmatory test for any screening test result which is reactive. However, only confirmatory test results that are positive are to be reported to the department.

641—11.30(141) Complaints or noncompliance.

11.30(1) The department shall accept complaints of alleged problems or noncompliance, provided they relate to the laboratory's HIV testing performance. The complainant shall state in as specific a manner as possible the basis for the complaint. The complaint shall be presented in writing or in person to the Iowa Department of Public Health, Division of Health Protection, Lucas State Office Building, Des Moines, Iowa 50319-0075.

11.30(2) Within 20 working days following the department's receipt of the complaint, the department shall communicate with the laboratory director for initial evaluation of the specific matters alleged in the complaint.

11.30(3) Based upon the nature of the complaint, the department may request technical assistance from the State Hygienic Laboratory in order to properly assess the alleged problem.

11.30(4) The laboratory shall receive a written report of the department's findings relating to the complaint investigation and the complainant shall be informed of any action taken by the department.

11.30(5) Upon a determination by the department that a laboratory has violated these rules, the department may immediately move to limit, suspend, revoke or deny that laboratory's certification.

641—11.31(141) Adverse actions and the appeal process.

11.31(1) Laboratories shall receive written notice by certified mail, return receipt requested, setting forth the reason(s) for any limitation, suspension, revocation or denial of certification.

11.31(2) The adverse action shall become effective 30 days after the aggrieved party has received the department's notice unless the aggrieved party, within 30 days, gives written notice to the department requesting a hearing. In that event, the notice shall be deemed to be suspended.

11.31(3) Contested cases. The procedures for contested cases, as set out in Iowa Code chapter 17A and the rules adopted by the department in 641—Chapter 173, shall be followed in all cases where proper notice has been made to the department of the intent to formally contest any limitation, suspension, revocation or denial of certification.

Rules 641—11.16(141) to 641—11.31(141) are intended to implement Iowa Code section 141.7.

641—11.32 to **11.34** Reserved.

TRAINING PROGRAMS

641—11.35(141) Purpose. The purpose is to describe what constitutes an approved training program, the required content of acquired immune deficiency syndrome training programs and to identify the groups of personnel involved.

11.35(1) *Nonemergency personnel.* All supervisory and patient care personnel of any agency listed below shall complete a minimum of two hours of training concerning acquired immune deficiency syndrome-related conditions:

a. A licensed hospice,

b. A homemaker-home health aide provider agency which receives state homemaker-home health aide funds, or

c. An agency which provides respite care services and receives funds.

NOTE: New employees shall complete the training within six months of their initial employment. Existing employees shall complete the training on or before January 1, 1989. AIDS education programs conducted on or after January 1, 1987, shall count as satisfying the two-hour requirement when attendance and course content can be verified.

11.35(2) *Content.* Training programs must address the following topics:

a. HIV disease processes,

b. Signs and symptoms,

c. Transmission,

d. High-risk activities,

e. Prevention recommendations, and

f. Universal precautions according to the following Morbidity and Mortality Weekly Reports published by the U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Atlanta, Georgia 30333:

(1) Volume 36, Number 2S, Supplement, dated August 21, 1987, entitled "Recommendations for Prevention of HIV Transmission in Health-Care Settings," and

(2) Volume 37, Number 24, dated June 24, 1988, entitled "Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings."

11.35(3) *Emergency and law enforcement personnel.* All emergency medical services personnel, firefighters, and law enforcement personnel shall complete a minimum of two hours of training concerning acquired immune deficiency syndrome-related conditions and the prevention of human immunodeficiency virus infection.

11.35(4) *Content.* Training programs must address the following topics:

a. HIV disease processes,

b. Signs and symptoms,

c. Transmission,

d. High-risk activities,

e. Prevention recommendations, and

f. Universal precautions according to the following Morbidity and Mortality Weekly Reports published by the U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Atlanta, Georgia 30333:

(1) Volume 36, Number 2S, Supplement, dated August 21, 1987, entitled "Recommendations for Prevention of HIV Transmission in Health-Care Settings," and

(2) Volume 37, Number 24, dated June 24, 1988, entitled "Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings."

This rule is intended to implement Iowa Code sections 135.11, 135.39, 139B.1(2)*"f"* and 141.1 to 141.10.

641—11.36 to **11.39** Reserved.

DIRECT NOTIFICATION OF AN IDENTIFIABLE THIRD PARTY

641—11.40(141) Purpose. To establish, as a part of the partner notification program, a procedure for the notification by a physician or the department of an identifiable third party who is a sexual partner of or who shares intravenous equipment with a person who has tested positive for the human immunodeficiency virus.

11.40(1) This procedure shall be used only when both of the following situations exist:

a. A physician for the infected person is of the good faith opinion that the nature of the continuing contact through sexual intercourse or the sharing of intravenous equipment poses an imminent danger of human immunodeficiency virus infection transmission to the third party.

b. When the physician believes in good faith that the infected person, despite strong encouragement, has not and will not warn the third party and will not participate in the voluntary partner notification program.

11.40(2) A physician may reveal the identity of a person who has tested positive for the human immunodeficiency virus infection pursuant to this rule only to the extent necessary to protect a third party from the direct threat of transmission. Notification of a person pursuant to this rule shall be made confidentially. Nothing in this rule shall be interpreted to create a duty to warn third parties of the danger of exposure to human immunodeficiency virus through contact with a person who tests positive for the human immunodeficiency virus infection.

11.40(3) When the physician is of the good faith opinion and belief that third-party notification should be performed, notification of a person pursuant to this rule shall be made:

a. Directly by the physician according to the procedures stated in subrules 11.40(4), 11.40(5) and 11.40(10), or

b. By the department at the request of the physician according to subrules 11.40(6) to 11.40(10).

11.40(4) Notification by the physician. Prior to notification of a third party by an infected person's physician, the physician shall make reasonable efforts to inform, in writing, the person who has tested positive for the human immunodeficiency virus infection. The written information shall state that due to the nature of the person's continuing contact through sexual intercourse or the sharing of intravenous equipment with a third party, and the physician's belief that the infected person, despite strong encouragement, has not and will not warn the third party and will not participate in the voluntary partner notification program, the physician is forced to take action to provide notification to the third party. The physician, when reasonably possible, shall provide the following information to the person who has tested positive for the human immunodeficiency virus infection:

a. The nature of the disclosure and the reason for the disclosure.

b. The anticipated date of disclosure.

c. The name of the party or parties to whom disclosure is to be made.

NOTE: Reasonable efforts to inform, in writing, the person who has tested positive for the human immunodeficiency virus infection shall be deemed satisfied when the physician delivers the written notice in person or directs a written notice to the person's last-known address by restricted certified mail, return receipt requested, at least five days prior to the anticipated date of disclosure to the third party.

11.40(5) When performed by the infected person's physician, notification of the third party and any disclosure concerning the purpose of that notification shall be made in person. The third party may be requested by telephone or by ordinary mail to arrange to meet with the physician at the earliest opportunity to discuss an important health matter. The nature of the health matter to be discussed shall not be revealed in the telephone call or letter.

11.40(6) Notification by the department. When referring to the department, the infected person's physician shall first make reasonable efforts to inform the infected person by delivering a written notice in person or by directing a written notice to the person's last-known address by restricted certified mail, return receipt requested, at least five days prior to the anticipated date of referral to the department. The notice shall state that due to the nature of the person's continuing contact through sexual intercourse or the sharing of intravenous equipment with a third party, and the physician's belief that the infected person, despite strong encouragement, has not and will not warn the third party and will not participate in the voluntary partner notification program, the physician is forced to take action by requesting that the department notify the third party. The notice shall also state that the following information is being reported to the department for purposes of third-party notification:

a. The infected person's name and address.

b. The third party's name, address, telephone number and any other locating information known to the physician.

NOTE: A copy of the letter provided to the infected person pursuant to this subrule shall accompany the physician's request for third-party notification by the department.

11.40(7) A physician's request to the department to notify a third party shall be made by certified mail, return receipt requested. The department's address for this purpose is: Iowa Department of Public Health, Division of Disease Prevention, AIDS Prevention Program, Lucas State Office Building, Des Moines, Iowa 50319-0075. The request shall include:

a. The infected person's name and address.

b. The third party's name, address, telephone number and any other locating information known to the physician.

c. A statement of the facts and circumstances which satisfy the requirements of subrule 11.40(1).

11.40(8) It shall be the department's responsibility prior to making a third-party notification, when reasonably possible, to provide, in writing, the following information to the person who has tested positive for the human immunodeficiency virus infection:

a. The nature of the disclosure and the reason for the disclosure.

b. The anticipated date of disclosure.

c. The name of the third party or parties to whom disclosure is to be made.

NOTE: Reasonable efforts to inform, in writing, the person who has tested positive for the human immunodeficiency virus infection shall be deemed satisfied when the department directs a written notice to the person's last-known address by restricted certified mail, return receipt requested, at least five days prior to the anticipated date of disclosure to the third party.

11.40(9) When performed by the department, notification of the third party and any disclosure concerning the purpose of that notification shall be made in person. The third party may be requested by telephone or by restricted certified mail, return receipt requested, to arrange to meet with a department representative at the earliest opportunity to discuss an important health matter. The nature of the matter to be discussed shall not be revealed in the telephone call or letter.

11.40(10) Confidentiality. The infected person's physician and the department shall protect the confidentiality of the third party and the infected person. The identity of the infected person shall remain confidential unless it is necessary to reveal it to the third party so that the third party may

avoid exposure to the human immunodeficiency virus infection. If the identity of the infected person is revealed, the third party shall be presented with a statement in writing at the time of disclosure which includes the following or substantially similar language: "Confidential information revealing the identity of a person infected with the human immunodeficiency virus has been disclosed to you. The confidentiality of this information is protected by state law. State law prohibits you from making any further disclosure of the information without the specific written consent of the person to whom it pertains. Any breach of the required confidential treatment of this information subjects you to legal action and civil liability for monetary damages. A general authorization for the release of medical or other information is not sufficient for this purpose."

This rule is intended to implement Iowa Code sections 135.11, 135.39, 139B.1(2)*"f,"* 141.1 to 141.10 and 141.22A(17).

641—11.41 to **11.44** Reserved.

EMERGENCY CARE PROVIDERS
EXPOSED TO CONTAGIOUS OR
INFECTIOUS DISEASES

641—11.45(139B,141) Purpose. The purpose of these rules is to implement Iowa Code sections 139B.1(2)*"f"* and 141.22A(17), relating to emergency care providers who are exposed to contagious or infectious diseases.

641—11.46(139B,141) Definitions. For the purpose of rules 641—11.45(139B,141) to 641—11.53(139B,141) the following definitions shall apply:

"AIDS" means acquired immunodeficiency syndrome.

"Contagious or infectious disease" means blood-borne viral hepatitis, meningococcal disease, tuberculosis, and any other disease with the exception of AIDS or HIV infection as defined in Iowa Code section 141.21, determined to be life-threatening to a person exposed to the disease as established by the department based upon a determination by the state epidemiologist and in accordance with guidelines of the Centers for Disease Control of the U.S. Department of Health and Human Services.

"Department" means the Iowa department of public health.

"Designated officer" means a person who is designated by a department, agency, division, or service organization to act as an infection control liaison officer.

"Emergency care provider" means a person who renders direct emergency aid without compensation or a person who is trained and authorized by federal or state law to provide emergency medical assistance or treatment, for compensation or in a voluntary capacity including, but not limited to, all of the following:

1. A basic emergency medical care provider as defined in Iowa Code section 147.1.
2. An advanced emergency medical care provider as defined in Iowa Code section 147A.1.
3. A health care provider as defined in this rule.
4. A firefighter.
5. A peace officer.
6. Any other person who is not part of an emergency care provider service who renders direct emergency aid without compensation.

"Exposure" means the risk of contracting disease.

"Health care provider" means a person licensed or certified under Iowa Code chapter 148, 148C, 150, 150A, 152, or 153 to provide professional health care services to a person during the person's medical care, treatment or confinement.

"HIV infection" means human immunodeficiency virus infection as defined in Iowa Code section 141.21.

"Infectious body fluids" means body fluids capable of transmitting HIV infection as listed in "Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public-Safety Workers," found in Morbidity and Mortality Weekly Report, dated

June 23, 1989, Volume 38, Number S-6, published by the U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Atlanta, Georgia 30333, or subsequent Centers for Disease Control statements on this topic. To prevent HIV and blood-borne viral hepatitis B disease transmission, this reference indicates that universal precautions should be followed for exposure to the following infectious body fluids: blood, amniotic fluid, pericardial fluid, peritoneal fluid, pleural fluid, synovial fluid, cerebrospinal fluid, semen, vaginal secretions, and saliva contaminated with blood. HIV and hepatitis B disease transmission has not occurred from feces, nasal secretions, sputum, sweat, tears, urine, vomitus, and saliva when it is not contaminated with blood.

"Report of exposure to infectious disease" means the report form provided by the department and is the only form authorized for the reporting of an exposure to blood-borne hepatitis B or the reporting of a significant exposure to HIV. The report form may be incorporated into the Iowa prehospital care report, the Iowa prehospital advanced care report, or a similar report used by an ambulance, rescue, or first responder service or law enforcement agency.

"Significant exposure" means the risk of contracting HIV infection by means of exposure to a person's infectious body fluids in a manner capable of transmitting HIV infection as determined by the Centers for Disease Control of the U.S. Department of Health and Human Services. Exposure includes contact with blood or other infectious body fluids to which universal precautions apply through percutaneous inoculation or contact with an open wound, nonintact skin, or mucous membranes during the performance of normal job duties. Significant exposures for HIV reportable to the hospital, or to the office or clinic of a health care provider to initiate the notification procedure regarding an exposure to an infectious body fluid are:

1. Transmission of blood or bloody fluids of the patient onto a mucous membrane (mouth, nose, or eyes) of the emergency care provider.
2. Transmission of blood or bloody fluids onto an open wound or lesion with significant breakdown in the skin barrier, including a needle puncture with a needle contaminated with blood.

641—11.47(139B,141) General provisions.

11.47(1) A hospital licensed under Iowa Code chapter 135B shall have written policies and procedures for notification of an emergency care provider who renders assistance or treatment to a patient when in the course of admission, care, or treatment of that patient, the patient is diagnosed or is confirmed as having a contagious or infectious disease.

11.47(2) If a patient is diagnosed or confirmed as having a contagious or infectious disease, the hospital shall notify the designated officer of an emergency care provider service who shall notify persons involved in attending or transporting the patient. For blood-borne contagious or infectious diseases, notification shall only take place upon the filing of a report form with the hospital.

11.47(3) The person who renders direct emergency aid without compensation as identified in rule 641—11.46(139B,141), "emergency care provider," paragraph "6," who is exposed to a patient who has a contagious or infectious disease shall also receive notification from the hospital when the hospital has received a report form.

11.47(4) The notification shall advise the emergency care provider of possible exposure to a particular contagious or infectious disease and recommend that the provider seek medical attention. The notification shall be provided as soon as reasonably possible following determination that the patient has a contagious or infectious disease.

11.47(5) The emergency care provider shall file exposure and significant exposure reports with the hospital or health care provider as soon as reasonably possible following the exposure.

11.47(6) The hospital shall maintain a record of all exposure or significant exposure reports it receives and shall retain each report for a period of five years.

11.47(7) The report form "Report of Exposure to Infectious Disease" is a confidential record pursuant to Iowa Code section 141.22A.

11.47(8) The employer of an emergency care provider who submits a report form pursuant to these rules shall pay the cost of HIV counseling and testing for the emergency care provider and testing of the patient pursuant to subrule 11.50(1) or 11.51(2). The department shall provide HIV counseling and

testing at alternate testing sites for an emergency care provider who has rendered direct emergency aid without compensation as identified in rule 11.46(139B,141), "emergency care provider," paragraph "6."

641—11.48(139B,141) Contagious or infectious diseases, not including HIV—hospitals.

11.48(1) Notification for blood-borne viral hepatitis shall take place only upon the filing of an exposure report form with the hospital.

11.48(2) Notification shall take place whether or not an exposure report form has been filed for the following contagious or infectious diseases if the identity of the emergency care provider or the designated officer is known:

a. Meningococcal meningitis.

b. Tuberculosis (communicable). Tuberculosis may require six to ten weeks for disease confirmation.

11.48(3) These rules do not require a hospital to administer a test for the express purpose of determining the presence of a contagious or infectious disease.

11.48(4) The notification shall not include the name of the patient with the contagious or infectious disease unless the patient gives written consent.

11.48(5) These rules do not preclude a hospital from providing notification to an emergency care provider or health care provider under circumstances in which the hospital's policy provides for notification of the hospital's own employees of an exposure to a disease that is not life-threatening. The exposure report shall not reveal the patient's name unless the patient gives written consent.

11.48(6) A hospital's duty of notification under these rules is not continuing. It is limited to a diagnosis of a contagious or infectious disease made in the course of admission, care, and treatment following the rendering of emergency assistance or treatment for which the notification requirements of these rules apply.

641—11.49(139B,141) Contagious or infectious diseases, not including HIV—health care providers.

11.49(1) A health care provider may provide the notification required of hospitals in these rules to emergency care providers if a patient who has a contagious or infectious disease is transported by an emergency care provider to the office or clinic of a health care provider.

11.49(2) These rules do not require a health care provider to administer a test for the express purpose of determining the presence of a contagious or infectious disease.

11.49(3) Notification shall not include the name of the patient who has the contagious or infectious disease unless the patient gives written consent.

11.49(4) A health care provider's duty of notification under these rules is not continuing, but is limited to a diagnosis of a contagious or infectious disease made in the course of care and treatment following the rendering of emergency assistance or treatment for which the notification requirements of these rules apply.

641—11.50(139B,141) HIV infection—hospitals.

11.50(1) These rules do not require or permit a hospital to administer a test for the express purpose of determining the presence of HIV infection except that testing may be performed if the patient consents and if the requirements of Iowa Code section 141.22 are satisfied.

11.50(2) Following submission of a significant exposure report by the emergency care provider to the hospital and a determination that the exposure reported was a significant exposure as defined in rule 11.46(139B,141), and a diagnosis or confirmation by the attending physician that the patient has HIV infection, a hospital shall provide notification of possible exposure to HIV pursuant to subrule 11.50(3) to the designated officer of the emergency care provider who provided assistance or treatment to the patient.

11.50(3) Notification to the emergency care provider of exposure to HIV infection shall be made in accordance with both of the following:

a. The hospital shall inform the patient, when the patient's condition permits, that a significant exposure occurred to an emergency care provider and that a significant exposure report has been filed.

b. The patient may provide consent for HIV testing or voluntarily disclose HIV status to the hospital and consent to the provision of notification.

11.50(4) Notwithstanding subrule 11.50(3), notification shall be made when the patient denies consent for or consent is not reasonably obtainable for serological testing, and in the course of admission, care, and treatment of the patient, the patient is diagnosed or is confirmed as having HIV infection.

11.50(5) The hospital shall notify the designated officer of the emergency care provider service. The designated officer shall notify those emergency care providers who submitted a significant exposure report and attended or transported the patient. The identity of the designated officer shall not be revealed to the patient.

11.50(6) The designated officer shall advise the emergency care providers who are notified to seek immediate medical attention and of the provisions of confidentiality under rule 641—11.53(139B,141).

11.50(7) The designated officer shall inform the hospital of the names of the emergency care providers to whom notification was made.

11.50(8) Hospitals shall inform the patient that they have a record of the names of the emergency care providers to whom notification was provided and, if requested by the patient, the hospital shall inform the patient of those names.

11.50(9) A person who renders direct emergency aid without compensation as identified in rule 11.46(139B,141), "emergency care provider," paragraph "6," who is exposed to a patient who has HIV infection, shall receive notification directly from the hospital in accordance with the procedures established in subrules 11.50(1) to 11.50(4).

11.50(10) The process for notification under these rules shall be initiated as soon as reasonably possible consistent with protocols for postexposure prophylaxis, according to "Public Health Service Statement on Management of Occupational Exposure to Human Immunodeficiency Virus, Including Considerations Regarding Zidovudine Postexposure Use," found in the Morbidity and Mortality Weekly Report, dated January 26, 1990, Volume 39, Number RR-1, published by the U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Atlanta, Georgia 30333, or subsequent Centers for Disease Control statements on this topic.

11.50(11) A hospital's duty of notification under these rules is not continuing. It is limited to the diagnosis of HIV infection made in the course of admission, care, and treatment following the rendering of emergency assistance or treatment of the patient with the disease.

11.50(12) Notwithstanding subrule 11.50(11), if, following discharge or completion of care or treatment, a patient, for whom a report form was submitted that did not result in notification, wishes to provide information regarding the patient's HIV infection status to the emergency care provider, the hospital shall provide a procedure for notifying the emergency care provider.

641—11.51(139B,141) HIV infection—health care providers.

11.51(1) A health care provider, with written consent of the patient, may provide the notification required of hospitals in these rules to emergency care providers if a patient who has HIV infection is transported by an emergency care provider to the office or clinic of the health care provider. Notification shall take place only upon submission of a significant exposure report by the emergency care provider to the health care provider and after determination by the health care provider that a significant exposure has occurred.

11.51(2) These rules do not require or permit a health care provider to administer a test for the express purpose of determining the presence of HIV infection except that testing may be performed if the patient consents and if the requirements of Iowa Code section 141.22 are satisfied.

641—11.52(139B,141) Immunity. Hospitals, health care providers, or other persons participating in good faith in making a report under these rules, upon filing of a report form or a report under similar

procedures to notify their own employees or in failing to make a report under these rules are immune from any liability, civil or criminal, which may otherwise be incurred or imposed.

641—11.53(139B,141) Confidentiality.

11.53(1) Notifications made pursuant to these rules shall not disclose the identity of the patient who is diagnosed or confirmed as having HIV infection unless the patient provides a specific written release as provided in Iowa Code section 141.23, subsection 1, paragraph *"a."*

11.53(2) If during these notification procedures an emergency care provider determines the identity of a patient with confirmed HIV infection, the identity of the patient shall be confidential information and shall not be disclosed by the emergency care provider to any other person unless a specific written release is obtained from the patient.

11.53(3) The procedures followed under rules 641—11.50(139B,141) to 641—11.51(139B,141) shall provide for the anonymity of the patient and all documentation shall be maintained in a confidential manner.

Rules 641—11.45(139B,141) to 641—11.53(139B,141) are intended to implement Iowa Code sections 139B.1(2)*"f"* and 141.22A(17).

641—11.54 to **11.69** Reserved.

HIV-RELATED TEST FOR CONVICTED OR ALLEGED SEXUAL-ASSAULT OFFENDERS AND THE VICTIMS

641—11.70(709B) Purpose. The purpose of these rules is to describe procedures to follow for testing of a convicted or alleged offender for the human immunodeficiency virus pursuant to 1998 Iowa Acts, House File 2369, and 1998 Iowa Acts, House File 2527, and to establish procedures to follow to provide for counseling, health care, and support services to the victim.

641—11.71(709B) Definitions. For the purpose of these rules, the following definitions shall apply:

"AIDS" means acquired immune deficiency syndrome as defined by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services.

"Alleged offender" means a person who has been charged with the commission of a sexual assault or a juvenile who has been charged in juvenile court with being a delinquent as a result of actions that would constitute a sexual assault.

"Authorized representative" means an individual authorized by the victim to request an HIV test of a convicted or alleged offender who is any of the following:

1. The parent, guardian, or custodian of the victim if the victim is a minor.
2. The physician of the victim.
3. The victim counselor or person requested by the victim who is authorized to provide the counseling required pursuant to Iowa Code section 141.22.
4. The victim's spouse.
5. The victim's legal counsel.

"Convicted offender" means a person convicted of a sexual assault or a juvenile who has been adjudicated delinquent for an act of sexual assault.

"Department" means the Iowa department of public health.

"Division" means the crime victims assistance division of the office of the attorney general.

"HIV" means the human immunodeficiency virus identified as the causative agent of AIDS.

"HIV test" means a positive result for the HIV antibody, a positive result for HIV nucleic acid, a positive result for p24 antigen, or a positive result for HIV virus isolation.

"Petitioner" means a person who is the victim of a sexual assault which resulted in alleged significant exposure, or the parent, guardian, or custodian of a victim if the victim is a minor, for whom the county attorney files a petition with the district court to require the convicted offender to undergo an HIV test.

"Sexual assault" means sexual abuse as defined in Iowa Code section 709.1, or any other sexual offense by which a victim has allegedly had sufficient contact with a convicted or an alleged offender to be deemed a significant exposure.

"Significant exposure" means contact of the victim's ruptured or broken skin or mucous membranes with the blood or body fluids, other than tears, saliva, or perspiration, of the convicted or alleged offender. "Significant exposure" is presumed to have occurred when there is a showing that there was penetration of the convicted or alleged offender's penis into the victim's vagina or anus, contact between the mouth and genitalia, or contact between the genitalia of the convicted or alleged offender and the genitalia or anus of the victim.

"Victim" means a petitioner or a person who is the victim of a sexual assault which resulted in significant exposure, or the parent, guardian, or custodian of such a victim if the victim is a minor, for whom the victim or the peace officer files an application for a search warrant to require the alleged offender to undergo an HIV test. "Victim" includes an alleged victim.

"Victim counselor" means a person who is engaged in a crime victim center as defined in Iowa Code section 236A.1, who is certified as a counselor by the crime victim center, and who has completed at least 20 hours of training provided by the Iowa coalition against sexual assault or a similar agency.

641—11.72(709B) HIV test—convicted or alleged sexual assault offender.

11.72(1) Unless a petitioner chooses to be represented by private counsel, the county attorney shall represent the victim's interest in all proceedings under Iowa Code chapter 709B.

11.72(2) If a person is convicted of sexual assault or adjudicated delinquent for an act of sexual assault, the county attorney, if requested by the petitioner, shall petition the court for an order requiring the convicted offender to submit to an HIV test, provided that all of the following conditions are met:

a. The sexual assault for which the offender was convicted or adjudicated delinquent included sufficient contact between the victim and the convicted offender to be deemed a significant exposure pursuant to 641—11.71(709B).

b. The authorized representative of the petitioner, the county attorney, or the court sought to obtain written informed consent to the testing from the convicted offender.

c. Written informed consent was not provided by the convicted offender.

11.72(3) If a person is an alleged offender, the county attorney, if requested by the victim, shall make application to the court for the issuance of a search warrant, in accordance with Iowa Code chapter 808, for the purpose of requiring the alleged offender to submit to an HIV test, if all of the following conditions are met:

a. The applicant states that the victim believes that the sexual assault for which the alleged offender is charged included sufficient contact between the victim and the alleged offender to be deemed a significant exposure pursuant to 641—11.71(709B) and states the factual basis for the belief that a significant exposure exists.

b. The authorized representative of the victim, the county attorney, or the court sought to obtain written informed consent to the testing from the alleged offender.

c. Written informed consent was not provided by the alleged offender.

11.72(4) Upon receipt of the petition or application, the court shall:

a. Prior to the scheduling of a hearing, refer the victim for counseling by a victim counselor or a person requested by the victim who is authorized to provide the counseling required pursuant to Iowa Code section 141.22, regarding the nature, reliability and significance of the HIV test and of any test results of the convicted offender. The counselor shall have a certificate of attendance from the department of public health-sponsored workshop on HIV serologic test counseling.

b. Schedule a hearing to be held as soon as is practicable.

c. Cause written notice to be served on the convicted or alleged offender who is the subject of the proceeding, in accordance with the Iowa Rules of Civil Procedure relating to the service of original notice, or if the convicted or alleged offender is represented by legal counsel, provide written notice to the convicted or alleged offender and the convicted or alleged offender's legal counsel.

d. Provide for the appointment of legal counsel for a convicted or alleged offender if the convicted or alleged offender desires but is financially unable to employ counsel.

e. Furnish legal counsel with copies of the petition or application, written informed consent, if obtained, and copies of all other documents related to the petition or application, including, but not limited to, the charges and orders.

11.72(5) A hearing under these rules shall be conducted in an informal manner consistent with orderly procedure and in accordance with the Iowa Rules of Evidence.

a. The hearing shall be limited in scope to the review of questions of fact only as to the issue of whether the sexual assault for which the offender was convicted or adjudicated delinquent or for which the alleged offender was charged provided sufficient contact between the victim and the convicted or alleged offender to be deemed a significant exposure, and to questions of law.

b. In determining whether the contact should be deemed a significant exposure for a convicted offender, the court shall base the determination on the testimony presented during the proceedings on the sexual assault charge, the minutes of the testimony or other evidence included in the court record, or if a plea of guilty was entered, based upon the complaint or upon testimony provided during the hearing. In determining whether the contact should be deemed a significant exposure for an alleged offender, the court shall base the determination on the application and the factual basis provided in the application for the belief of the applicant that a significant exposure exists.

c. The victim may testify at the hearing, but shall not be compelled to testify. The court shall not consider the refusal of a victim to testify at the hearing as material to the court's decision regarding issuance of an order or search warrant requiring testing.

d. The hearing shall be in camera unless the convicted or alleged offender and the petitioner or victim agree to a hearing in open court and the court approves. The report of the hearing proceedings shall be sealed and no report of the proceeding shall be released to the public, except with the permission of all parties and the approval of the court.

e. Stenographic notes or electronic or mechanical recording shall be taken of all court hearings unless waived by the parties.

11.72(6) Following the hearing, the court shall require a convicted or alleged offender to undergo an HIV test only if the petitioner or victim proves all of the following by a preponderance of evidence.

a. The sexual assault constituted a significant exposure.

b. An authorized representative of the petitioner, the county attorney, or the court sought to obtain written informed consent from the convicted or alleged offender.

c. Written informed consent was not provided by the convicted or alleged offender.

11.72(7) A convicted offender who is required to undergo an HIV test may appeal to the court for review of questions of law only, but may appeal questions of fact if the findings of fact are clearly erroneous.

641—11.73(709B) Medical examination costs. The cost of a medical examination for the purpose of gathering evidence and the cost of treatment for the purpose of preventing venereal disease shall be paid from the victim compensation fund as established in Iowa Code chapter 709B, and 1998 Iowa Acts, House File 2527, section 55. Information is available from the department of justice, crime victim assistance program, telephone (515)281-5044.

641—11.74(709B) Testing, reporting, and counseling—penalties.

11.74(1) The physician or other practitioner who orders the test of a convicted or alleged offender for HIV under Iowa Code chapter 709B shall disclose the results of the test to the convicted or alleged offender, and to the victim counselor or a person requested by the victim who is authorized to provide the counseling required pursuant to Iowa Code section 141.22, who shall disclose the results to the petitioner.

11.74(2) All testing under this chapter shall be accompanied by pretest and posttest counseling as required under Iowa Code section 141.22. The department of public health may be contacted for brochures that may assist in meeting the requirements of Iowa Code section 141.22.

11.74(3) Subsequent testing arising out of the same incident of exposure shall be conducted in accordance with the procedural and confidentiality requirements of 641—11.70(709B) to 641—11.74(709B).

11.74(4) Results of a test performed under 641—11.70(709B) to 641—11.74(709B), except as provided in subrule 11.74(6), shall be disclosed only to the physician or other practitioner who orders the test of the convicted or alleged offender, the convicted or alleged offender, the victim, the victim counselor or person requested by the victim who is authorized to provide the counseling required pursuant to Iowa Code section 141.22, the physician of the victim if requested by the victim, the parent, guardian, or custodian of the victim, if the victim is a minor, and the county attorney who filed the petition for the HIV testing under 641—11.70(709B) to 641—11.74(709B), who may use the results to file charges of criminal transmission of HIV. Results of a test performed under these rules shall not be disclosed to any other person without the written, informed consent of the convicted or alleged offender. A person to whom the results of a test have been disclosed under 641—11.70(709B) to 641—11.74(709B) is subject to the confidentiality provision of Iowa Code section 141.23, and shall not disclose the results to another person except as authorized by Iowa Code section 141.23, subsection 1.

11.74(5) If HIV testing is ordered under 641—11.70(709B) to 641—11.74(709B), the court shall also order periodic testing of the convicted offender during the period of incarceration, probation, or parole or of the alleged offender during a period of six months following the initial test if the physician or other practitioner who ordered the initial test of the convicted or alleged offender certifies that, based upon prevailing scientific opinion regarding the maximum period during which the results of an HIV test may be negative for a person after being HIV-infected, additional testing is necessary to determine whether the convicted or alleged offender was HIV-infected at the time the sexual assault or alleged sexual assault was perpetrated. The results of the test conducted pursuant to subrule 11.74(6) shall be released only to the physician or other practitioner who orders the test of the convicted or alleged offender, the convicted or alleged offender, the victim counselor or person requested by the victim who is authorized to provide the counseling required pursuant to Iowa Code section 141.22, who shall disclose the results to the petitioner, the physician of the victim if requested by the victim and the county attorney who may use the results as evidence in the prosecution of the sexual assault or in the prosecution of the offense of criminal transmission of HIV.

11.74(6) The court shall not consider the disclosure of an alleged offender's serostatus to an alleged victim, prior to conviction, as a basis for a reduced plea or reduced sentence.

11.74(7) The fact that an HIV test was performed under 641—11.70(709B) to 641—11.74(709B) and the results of the tests shall not be included in the convicted offender's medical or criminal record unless otherwise included in department of corrections records.

11.74(8) The fact that an HIV test was performed under 641—11.70(709B) to 641—11.74(709B) and the results of the test shall not be used as a basis for further prosecution of a convicted offender in relation to the incident which is the subject of the testing, to enhance punishments, or to influence sentencing.

11.74(9) If the serologic status of a convicted offender, which is conveyed to the victim, is based upon an HIV test other than a test which is authorized as a result of the procedures established in 641—11.70(709B) to 641—11.74(709B), legal protections which attach to such testing shall be the same as those which attach to an initial test under 641—11.70(709B) to 641—11.74(709B), and the rights to a predisclosure hearing and to appeal provided under 1998 Iowa Acts, House File 2527, section 35, shall apply.

11.74(10) HIV testing required under 641—11.70(709B) to 641—11.74(709B) shall be conducted by the state hygienic laboratory.

11.74(11) Notwithstanding the provision of these rules requiring initial testing, if a petition is filed with the court under 1998 Iowa Acts, House File 2527, section 35, requesting an order for testing and the order is granted, and if a test has previously been performed on the convicted offender while under the control of the department of corrections, the test results shall be provided in lieu of the performance of an initial test of the convicted offender, in accordance with 641—11.70(709B) to 641—11.74(709B).

11.74(12) Test results shall not be disclosed to a convicted offender who elects against disclosure.

11.74(13) In addition to the counseling received by a victim, referral to appropriate health care and support services shall be provided. Referral information is available at state alternate test sites. Alternate test site information is available from the Iowa department of public health, STD/HIV prevention program, telephone (515)281-4936.

11.74(14) In addition to persons to whom disclosure of the results of a convicted or alleged offender's HIV test results is authorized under these rules, the victim may also disclose the results to the victim's spouse, persons with whom the victim has engaged in vaginal, anal, or oral intercourse subsequent to the sexual assault, or members of the victim's family within the third degree of consanguinity.

11.74(15) A person to whom disclosure of a convicted offender's HIV test results is authorized under these rules shall not disclose the results to any other person for whom disclosure is not authorized under these rules. A person who intentionally or recklessly makes an unauthorized disclosure in violation of this subrule is subject to a civil penalty of $1000. The attorney general or the attorney general's designee may maintain a civil action to enforce these rules. Proceedings maintained under this subrule shall provide for the anonymity of the test subject, and all documentation shall be maintained in a confidential manner.

These rules are intended to implement 1998 Iowa Acts, House File 2527, and 1998 Iowa Acts, House File 2369.

641—11.75 to **11.79** Reserved.

HIV HOME COLLECTION

641—11.80(126) Purpose. The purpose of these rules is to implement Iowa Code section 126.25(1) as amended by 1997 Iowa Acts, Senate File 300.

641—11.81(126) Definitions. For the purpose of these rules, the following definitions shall apply:

"CLIA" means the Clinical Laboratories Improvement Act as administered by the Health Care Financing Administration.

"FDA" means the U.S. Food and Drug Administration.

"HIV" means the human immunodeficiency virus identified as the causative agent of AIDS.

"HIV home collection kit" means a product for human immunodeficiency virus testing that provides for the specimen to be collected by an individual and then submitted to a laboratory, for determination of test results.

"HIV home testing kit" means a product for human immunodeficiency virus testing that provides for specimen collection and determination of test results by an individual without the utilization of a laboratory.

"Laboratory" means a laboratory meeting the CLIA requirements for HIV testing.

"Specimen" means a human body fluid or tissue sample.

641—11.82(126) HIV home testing kit. An HIV home testing kit shall not be advertised for sale, offered for sale, or sold in this state.

641—11.83(126) HIV home collection kit. An HIV home collection kit approved by the FDA may be advertised for sale, offered for sale, or sold in this state.

AIDS DRUG ASSISTANCE PROGRAM (ADAP)

641—11.84(141A) Definitions. For purposes of these rules, the following definitions shall apply:

"ADAP advisory committee" means the committee appointed by the bureau of HIV, STD, and hepatitis to provide advice and technical assistance to the department regarding ADAP.

"ADAP formulary" means the list of drugs approved for use in ADAP by the bureau upon recommendation of the ADAP advisory committee.

"AIDS" means acquired immune deficiency syndrome as defined by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services.

"AIDS drug assistance program" or *"ADAP"* means the Iowa AIDS drug assistance program administered by the bureau of HIV, STD, and hepatitis within the department and includes two components, the medication assistance program and the health insurance assistance program.

"Bureau" means the bureau of HIV, STD, and hepatitis within the department.

"Deductible" means an amount of money that an insured person must pay out of pocket before any benefits from the health insurance policy can be used.

"Department" means the Iowa department of public health.

"Director" means the director of the Iowa department of public health.

"Health insurance assistance program" means a component of ADAP that purchases health insurance and pays insurance premiums, copayments for medications, and deductibles for eligible enrollees in ADAP.

"HIV" means the human immunodeficiency virus identified as the causative agent of AIDS.

"Household" means a group of individuals residing together who are related by birth, marriage, or adoption; or an individual who does not reside with any other individual to whom the individual is related by birth, marriage, or adoption.

"Household income" means the combined gross earned and unearned income of all individuals within the household.

"Medication assistance program" means a component of ADAP that provides medications directly to eligible enrollees in ADAP.

"Payer of last resort" means a requirement to coordinate services and seek payment from all other sources before Ryan White funds are used.

[**ARC 0755C**, IAB 5/29/13, effective 7/3/13]

641—11.85(141A) Purpose. The AIDS drug assistance program is a state-administered program that provides certain HIV/AIDS medications to eligible low-income individuals diagnosed with HIV if adequate funding is available for administration of the program. There are two components to the Iowa AIDS drug assistance program: the medication assistance program and the health insurance assistance program. The AIDS drug assistance program is authorized under Part B of Title XXVI of the Public Health Service (PHS) Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87). This legislation requires that the Ryan White program, including the AIDS drug assistance program, be the payer of last resort for HIV-related services. ADAP is not an entitlement program and does not create a right to assistance. In the event that funding is exhausted or terminated or there are changes in state or federal guidelines, programs, or regulations that impact funding available to ADAP, the department reserves the right to close enrollment, cease to provide medication assistance or health insurance assistance, or alter eligibility criteria until such time that funding is again sufficient.

[**ARC 0755C**, IAB 5/29/13, effective 7/3/13]

641—11.86(141A) Ensuring payer of last resort. To ensure that ADAP is the payer of last resort, the Iowa Medicaid enterprise shall grant the department access to client-level information for persons enrolled in Medicaid.

[**ARC 0755C**, IAB 5/29/13, effective 7/3/13]

641—11.87(141A) Eligibility requirements.

11.87(1) An applicant is eligible to participate in the ADAP Medication assistance program if the applicant:

a. Applies for enrollment in ADAP on a form provided by the department;

b. Has no health insurance to cover the cost of the drugs that are or may become available from ADAP;

c. Is currently being prescribed a drug on the ADAP formulary;

d. Has an annual gross household income that is less than or equal to 200 percent of the poverty level as determined by the most recent federal poverty guidelines published annually by the United States

Department of Health and Human Services for the size of the household (this income shall be determined after a $500 work-related allowance is deducted from the monthly gross salary of an employed person with HIV/AIDS);

e. Has a medical diagnosis of HIV infection or AIDS or is an unborn infant or an infant under 18 months of age who has an HIV-infected mother; and

f. Is a resident of Iowa.

11.87(2) An applicant is eligible to participate in the ADAP health insurance assistance program if the applicant:

a. Applies for enrollment in ADAP on a form provided by the department;

b. Has creditable health insurance coverage;

c. Is currently being prescribed a drug on the ADAP formulary;

d. Has an annual gross household income that is less than or equal to 400 percent of the poverty level as determined by the most recent federal poverty guidelines published annually by the United States Department of Health and Human Services for the size of the household;

e. Has a medical diagnosis of HIV infection or AIDS or is an unborn infant or an infant under 18 months of age who has an HIV-infected mother; and

f. Is a resident of Iowa.

11.87(3) For purposes of paragraphs 11.87(1)*"d"* and 11.87(2)*"d,"* an individual may report annual household income by using actual household income for the most recent 12 months or by using estimated annual household income determined by multiplying the current monthly household income by 12.
[**ARC 0755C**, IAB 5/29/13, effective 7/3/13]

641—11.88(141A) Enrollment process.

11.88(1) The department shall review each completed application and shall determine enrollment based upon applicant eligibility, the date on which the application was completed, and the availability of funds. When the department determines that an applicant is eligible for enrollment, the applicant may be enrolled for six months commencing with the date of the determination or may be enrolled for a shorter time period at the discretion of the department.

11.88(2) An applicant shall provide the department with all requested information and shall execute any consent forms or releases of information necessary for the department to verify eligibility.
[**ARC 0755C**, IAB 5/29/13, effective 7/3/13]

641—11.89(141A) Discontinuation of services.

11.89(1) The department shall review eligibility semiannually after enrollment unless one of the following events occurs within the six-month period to end eligibility:

a. The enrolled individual dies;

b. The enrolled individual is determined eligible and enrolled to fully receive medical services through a third-party payer and is able to fully pay the insurance deductibles and copayments;

c. The enrolled individual's annual household income increases to an amount above the respective ADAP component's income guidelines;

d. The enrolled individual establishes residency outside the state of Iowa;

e. The enrolled individual does not request drugs within a 90-day period; or

f. The enrolled individual is placed in an institution such as a nursing home, state prison, or jail for more than 30 days.

11.89(2) An applicant must submit renewal documentation on a semiannual basis, accompanied by all information requested by the department.
[**ARC 0755C**, IAB 5/29/13, effective 7/3/13]

641—11.90(141A) Distribution requirements.

11.90(1) Enrolled individuals shall be eligible to receive financial assistance only for drugs that:

a. Have received Food and Drug Administration approval to treat HIV or prevent the deterioration of health due to HIV, coinfections or opportunistic infections; and

b. Are on the ADAP formulary.

11.90(2) The primary care provider shall write each drug prescription for an applicant or enrolled individual.

11.90(3) The enrolled individual must obtain the approved drug from the department's contracted pharmacy unless an exception to this requirement is granted by the department.
[**ARC 0755C**, IAB 5/29/13, effective 7/3/13]

641—11.91(141A) ADAP waiting list.

11.91(1) If an applicant is eligible for ADAP and sufficient funds are available to provide services to the applicant, the department shall enroll the applicant. If the applicant is eligible for ADAP and sufficient funds are not available to provide services to the applicant, the department shall place the applicant's name on the ADAP waiting list in the order provided for in this rule.

11.91(2) The department shall place names on the waiting list in chronological order based upon the date of receipt of a completed application by the department.

11.91(3) To verify that applicants on the waiting list continue to meet ADAP eligibility requirements, the department shall require applicants on the waiting list to submit reapplication forms semiannually.

11.91(4) The department shall remove applicants from the waiting list in the chronological order in which their completed applications were approved, provided all updates were received by the department.
[**ARC 0755C**, IAB 5/29/13, effective 7/3/13]

641—11.92(141A) Appeals. The department shall cause an applicant to be notified of the department's decision to approve or deny an application or to place an applicant on the ADAP waiting list. In the event an applicant is dissatisfied with the department's decision, the applicant may submit a formal appeal in writing to the ADAP advisory committee. Such request shall be delivered in person or shall be mailed by certified mail, return receipt requested, to ADAP Advisory Committee, Iowa Department of Public Health, Lucas State Office Building, 321 E. 12th Street, Des Moines, Iowa 50319. Upon receipt of such an appeal, the ADAP advisory committee shall review the case and issue a written determination within 15 days of receipt of the request. The decision shall refer to the applicant by initials or other nonidentifying means. The ADAP advisory committee's decision shall be final and binding. This appeal process does not constitute a contested case proceeding as defined in Iowa Code chapter 17A.
[**ARC 0755C**, IAB 5/29/13, effective 7/3/13]

641—11.93(141A) Confidentiality. The ADAP application and all information received or maintained by the department in connection with ADAP shall be considered confidential information in accordance with Iowa Code section 141A.9.
[**ARC 0755C**, IAB 5/29/13, effective 7/3/13]

These rules are intended to implement Iowa Code section 141A.3(1).

[Filed emergency 9/18/87—published 10/7/87, effective 9/18/87]
[Filed 9/26/88, Notice 8/10/88—published 10/19/88, effective 11/23/88]
[Filed emergency 1/11/89—published 2/8/89, effective 1/11/89]
[Filed 11/9/89, Notice 10/4/89—published 11/29/89, effective 1/3/90]
[Filed emergency 1/10/90—published 2/7/90, effective 1/10/90]
[Filed emergency 9/28/90—published 10/17/90, effective 10/1/90]
[Filed emergency 11/9/90—published 11/28/90, effective 11/9/90]
[Filed 3/15/91, Notice 11/28/90—published 4/3/91, effective 5/8/91]
[Filed emergency 5/10/91—published 5/29/91, effective 6/1/91]
[Filed emergency 3/11/92—published 4/1/92, effective 4/1/92]
[Filed 3/13/92, Notice 2/5/92—published 4/1/92, effective 5/6/92]
[Filed 11/15/93, Notice 8/4/93—published 12/8/93, effective 1/12/94]
[Filed 11/15/93, Notice 9/1/93—published 12/8/93, effective 1/12/94]
[Filed 7/14/94, Notice 6/8/94—published 8/3/94, effective 9/7/94]
[Filed 7/11/97, Notice 6/4/97—published 7/30/97, effective 9/3/97]
[Filed 9/18/98, Notice 7/15/98—published 10/7/98, effective 11/11/98]
[Filed 9/10/04, Notice 8/4/04—published 9/29/04, effective 11/3/04]

[Filed emergency 1/9/08—published 1/30/08, effective 1/9/08]
[Filed 3/13/08, Notice 1/30/08—published 4/9/08, effective 5/14/08]
[Filed ARC 0755C (Notice ARC 0650C, IAB 3/20/13), IAB 5/29/13, effective 7/3/13]