

**64CSR64**

**TITLE 64  
LEGISLATIVE RULE  
DIVISION OF HEALTH  
DEPARTMENT OF HEALTH AND HUMAN RESOURCES**

**SERIES 64  
AIDS-RELATED MEDICAL TESTING AND CONFIDENTIALITY**

**§64-64-1. General.**

1.1. Scope. -- This legislative rule establishes specific standards and procedures concerning AIDS-related medical testing; record confidentiality and disclosure; consent for testing by a legal representative; exclusion from schools; reporting requirements for physicians, laboratories and other health care providers; the approval of laboratories for HIV testing; and other matters pertinent and necessary for the implementation of the AIDS-Related Medical Testing and Records Confidentiality Act, W. Va. Code §16-3C-1 et seq.

This rule supplements the AIDS-Related Medical Testing and Records Confidentiality Act, W. Va. Code §16-3C-1 et seq., and should be read in conjunction with the Act.

1.2. Authority. -- W. Va. Code §§16-3C-8, 16-1-7 and 16-5J-3.

1.3. Filing Date. -- April 13, 2000.

1.4. Effective Date. -- May 15, 2000.

1.5. Supersession and Repeal of Former Rules - This rule repeals and replaces "AIDS-Related Medical Testing and Confidentiality," 64 CSR 64, effective April 26, 1996.

**§64-64-2. Application and Enforcement.**

2.1. Application. -- This rule applies to:

2.1.1. Health facilities;

2.1.2. Health care providers;

2.1.3. Funeral service providers and personnel;

2.1.4. Persons issuing marriage licenses;

2.1.5. Persons with access to or in charge of medical records or other sources of information regarding AIDS-related testing information;

2.1.6. Laboratories seeking approval to conduct AIDS-related tests to be utilized in this State;

2.1.g. Medical or emergency responders and their employers; and

2.1.h. Spouses, sexual contacts and intravenous (IV) drug contacts who may be at risk of having acquired the HIV infection as a result of the possible exchange of body fluids.

2.2. Enforcement. -- This rule is enforced by the commissioner of the bureau of public health or his or her lawful designee.

**§64-64-3. Definitions.**

The following definitions of terms are in addition to the definitions of terms in W. Va. Code §16-3C-1.

3.1. Anonymous HIV Testing. -- HIV testing performed on a voluntary patient by a health provider with no knowledge of the person's identity.

3.2. Body Fluids. -- Substances that have been implicated in the transmission of HIV that include:

3.2.a. Blood, semen, vaginal secretions or other body fluids contaminated with visible blood; and

3.2.b. Cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids, which have an undetermined risk for transmitting HIV.

3.3. Bureau of Public Health. -- Division of health.

3.4. CLIA-88. -- Clinical Laboratory Improvement Amendments of 1988 (Public Law 100-578) to Section 353 of the Public Health Service Act (Title 42 United States Code Section 263a).

3.5. Commissioner of the Bureau of Public Health. -- Director of the division of health.

3.6. Confidential HIV Testing. -- HIV testing performed by a health provider identifying the patient by name. The use of test results is limited by law.

3.7. Contact. --When used as a noun, a sexual or needle-sharing partner.

3.8. Convicted. -- Pleas of guilty and pleas of nolo contendere accepted by the court having jurisdiction of the criminal prosecution, a finding of guilty following a jury trial to a court, and a juvenile delinquent or status offender as defined in W. Va. Code §49-1-4.

3.9. Director. -- The director of the division of health of the department of health and human resources or his or her lawful designee.

3.10. Division. -- The division of health of the state department of health and human resources.

3.11. Funeral Director. -- Any person engaged, or holding himself or herself out as engaged, in the business of funeral directing as defined in W. Va. Code §30-6-4, and who uses in connection with his or her name or business the words or terms "funeral director," "undertaker," "mortician," or any other word, term, or title to imply or designate himself or herself as a funeral director, undertaker, or mortician.

3.12. Funeral Establishment. -- A place of business maintained and operated by a person, partnership, association, corporation, or other organization, conducted in a building, or series of buildings, or a separate portion of a building having a specific street address or location, and devoted to activities incident, convenient, or related to the preparation and arrangements, financial and otherwise, for the embalming, funeral, transportation, burial or other disposition of dead human bodies.

3.13. HIV-Infected Person. -- A person who has been diagnosed with AIDS or ARC or who has a positive confirmatory test for HIV.

3.14. Legal Representative. -- A person from whom substituted consent may be obtained as provided for in W. Va. Code §16-3C-4 for HIV-related testing or for the authorization of the release of test results.

3.15. Physician. -- A person licensed under Chapter 30 of the W. Va. Code to practice medicine and surgery.

3.16. Post-Exposure Care. -- Care including an initial HIV test following exposure and United States centers for disease control and prevention currently recommended follow-up HIV testing, counseling, medical evaluation and provision for post-exposure prophylactic treatment.

3.17. Source Patient. -- Any person whose body fluids have been the source of a significant exposure to a medical or emergency responder or other person.

**§64-64-4. Testing.**

4.1. Voluntary Consent.

4.1.a. The HIV-related testing provided for in W. Va. Code §§16-3C-2(a) through (d) may also be requested by a health care provider acting within the scope of his or her professional license.

4.1.b. The provisions of W. Va. Code §§16-3C-2(b) through (d) shall also be followed when a patient, without a request from a physician, dentist, other health care provider acting within the scope of his or her professional license, or the division, voluntarily seeks an HIV test from any physician, dentist, other health care provider, or from the division.

4.1.c. Nothing in this rule shall be construed to provide grounds for any physician, dentist, other health care provider or the director to refuse to treat a patient, nor shall the testing provisions of this rule be used by health care providers to screen patients.

4.2. Consent Not Required.

4.2.a. No consent for testing is required and the provisions of W. Va. Code §16-3C-2(b) and Subsection 4.1 of this rule do not apply for the performance of an HIV test:

4.2.a.1. On a human body part as provided in W. Va. Code §16-3C-2(e)(1). If a test is required of the donor or recipient of the human body part, reasonable efforts shall be made to obtain consent and otherwise follow the procedures of W. Va. Code §§16-3C-2(b) through (d).

4.2.a.1.A. All confidentiality restrictions contained in Section 9 of this rule and in W. Va. Code §16-3C-3 apply to information obtained through the testing of human body parts, tissue, blood, blood products, or semen;

4.2.a.1.B. Consent for HIV-related testing is required for donors of routine blood transfusions, and the provisions of W. Va. Code §16-3C-2(e)(1) do not apply to those transfusions;

4.2.a.2. In documented bona fide medical emergencies as provided for in W. Va. Code §16-3C-2(e)(2) and as determined by a treating physician taking into account the nature and extent of the exposure to another person, whether the source patient's blood is to be obtained or is already available: Provided, That:

4.2.a.2.A. The source patient is unable or unwilling to grant or withhold consent, and if the

source patient is unable to grant or withhold consent, substituted consent is not obtained after a reasonable attempt (such as telephoning or personal contact) is made to obtain consent from a legal representative of the source patient in accordance with W. Va. Code §16-3C-4;

4.2.a.2.B. The test results are necessary for medical diagnostic purposes to provide appropriate emergency care or treatment, and the HIV testing for a source patient is conducted only after a health care provider, as qualified in Subsection 8.1 of this rule, documents in the medical record of a medical or emergency responder or another person who has come into contact with a source patient that there has been a significant exposure of the responder or person and that in the medical judgement of the above described health care provider the results are medically necessary to determine the course of treatment for the exposed responder or person; and

4.2.a.2.B.1. Attempts to counsel the source patient for obtaining consent for the performance of the test and release of the results are documented on a form provided by the division and reported to the division in a confidential envelope;

4.2.a.2.B.2. A reasonable attempt, such as telephoning or personal contact, is made to contact the source patient, or the source patient's legal representative if the source patient is unable to grant or withhold consent, to inform him or her that the test will be performed using a pseudonym;

4.2.a.2.B.3. The test results are offered to the source patient, and any refusal of acceptance is documented only in the medical record of the exposed medical or emergency responder or other exposed person;

4.2.a.2.B.4. Post-test counseling is provided in accordance with W. Va. Code §16-3C-2(d). Necessary treatment shall not be withheld pending HIV test results; and

4.2.a.2.B.5. None of the activities set forth in this Subsection are documented in the source patient's medical record. Confidentiality shall be maintained by the health care facility and the medical or emergency responder. If any improper disclosure occurs, the source patient may invoke the remedies and penalties of W.Va. Code §16-3C-5; and

4.2.a.3. For the purpose of research in accordance with W. Va. Code §16-3C-2(e)(3).

4.2.b. For a test performed under the authority of W. Va. Code §16-3C-2(f)(9), the director may, at his or her discretion, release the test result to the physician or other health care provider who requested the test: Provided, That the provisions of Section 9 of this rule and W. Va. Code §16-3C-3 regarding confidentiality and disclosure apply. The director may establish a list of health care providers who are approved to authorize HIV testing in emergency medical aid circumstances.

#### 4.3. Mandated HIV Testing of Sexual Offenders and Management of Victims.

4.3.a. The testing of persons convicted of a sex-related crime as specified in W. Va. Code §16-3C-2(f) is under the direction of the court having jurisdiction of the criminal prosecution.

4.3.b. The director shall recommend guidelines for courts to follow in referring convicted sexual offenders for medical testing, sharing HIV test results of convicted sex offenders with victims, and advising victims or alleged victims of HIV counseling and testing services.

4.3.c. The director shall request access to all convicted sex offenders who test HIV positive for the purposes of contact notification consultation under the direction of the director. Contact notification information obtained from the convicted sex offender is protected information and shall be used by the

director solely for referring individuals with a potential HIV exposure to HIV counseling and testing sources.

4.3.d. The director shall set the level of reimbursement the division shall pay for the mandated HIV testing and counseling and pre- and post-conviction HIV-related testing and counseling for which it is responsible pursuant to the provisions of W. Va. Code §16-3C-2(f).

**§64-64-5. Cease and Desist Orders.**

5.1. A cease and desist order issued under the authority of W. Va. Code §16-3C-2(f)(4) shall be in writing, and shall set forth the name of the person to be restricted, and the initial period of time during which the order remains effective, the terms of the restrictions and other conditions that are warranted to protect the public health.

5.2. If any person violates a cease and desist order issued pursuant to this rule and the person is a danger to others, the director shall apply to the circuit court of Kanawha County to enforce the cease and desist order by imposing any restrictions upon the person that are necessary to prevent the specific conduct which endangers the health of others.

**§64-64-6. Review of Marriage License.**

The division shall periodically review marriage licenses in order to determine compliance with the requirements of W. Va. Code §16-3C-2(g) regarding documentation of the provision of information concerning AIDS and HIV-related testing and counseling.

**§64-64-7. Charting Information.**

Health care providers may only enter the results of an HIV-related test in the chart of a patient if the statement in W. Va. Code §16-3C-3(c) is printed on the test report in the chart.

**§64-64-8. Post-Exposure Care and Treatment.**

8.1. A health facility shall have access to a knowledgeable trained health care provider to assess the HIV exposure risk of medical or emergency responders or others during all working hours, including nights and weekends. The assessment of HIV exposure risk and initiation of basic post-exposure care regimen requires knowledge or experience in clinical epidemiology, infection control, occupational health, or the clinical treatment of HIV. Consultation on the facility's currently accepted practice, when prescribing post-exposure prophylaxis, is strongly encouraged.

8.2. A health facility shall have a written post-exposure HIV management plan patterned after current recommendations of the United States centers for disease control and prevention.

8.3. A laboratory shall not determine a test result to be positive, and a health care provider shall not reveal a positive test result to any person, without corroborating or confirmatory testing being conducted. However, a laboratory may release preliminary test results to the health care provider assessing the significant exposure for the purposes of determining post-exposure management of the medical or emergency responder or other person.

8.4. Health care providers shall report all confirmed positive test results to the division in compliance with Section 13 of this rule.

8.5. The employer of a medical or emergency responder who was exposed while performing a duty of his

or her employment shall bear the costs of HIV tests of blood samples of the source patient and the responder, unless a workers' compensation or other benefit program affords coverage for the testing. For a responder who tested negative for HIV antibodies immediately following the exposure, the employer shall also bear the costs of the United States centers for disease control and prevention's recommended initial prophylactic treatment and additional HIV testing at three and six months after exposure, unless a workers' compensation or other job-related employee benefit program affords coverage for the treatment and testing.

8.6. Relative to the management of source patient medical information, the medical or emergency responder reporting a significant exposure is subject to the requirements of the disclosure statement contained in W. Va. Code §16-3C-3(c) and to the remedies and penalties specified in W. Va. Code §16-3C-5.

**§64-64-9. Confidentiality.**

9.1. Any laboratory performing an HIV-related test in West Virginia shall have the statement of confidentiality in W. Va. Code §16-3C-3(c) appear on the report form or as an attachment to the report form returned to the health care provider or facility.

9.2. No person who obtains information protected by the provisions of W. Va. Code §16-3C-1 et seq. and this rule may convey the protected information to any other person except in strict compliance with W. Va. Code §16-3C-1 et seq. and this rule. Unauthorized disclosure will subject the person to all of the penalties available.

9.3. The victims or alleged victims of sexual crimes are eligible for HIV counseling and testing at public health HIV testing sites in West Virginia. The provisions of this rule and W. Va. Code W. Va. Code §16-3C-1 et seq. regarding voluntary testing and counseling apply to testing and counseling these individuals. All victim testing information is subject to the confidentiality requirements of this rule and W. Va. Code §16-3C-1 et seq. for voluntary testing.

9.4. An agent or employee of a health facility or health care provider has a need to know HIV test results under the provisions of W. Va. Code §16-3C-3(a)(4) when the information is medically necessary to protect the individual from a significant risk of transmission or will have an impact on the treatment modality.

9.5. HIV test results may be disclosed to medical or emergency responders who have been subject to a significant exposure during the course of medical practice or in the performance of professional duties. The medical or emergency responder is subject to the requirements of the disclosure statement contained in W. Va. Code §16-3C-3(c) and to the remedies and penalties provided in W. Va. Code §16-5C-5.

**§64-64-10. Contact Notification.**

10.1. Notification made by the director under W. Va. Code §16-3C-3(d) shall include an explanation of exposure to HIV, HIV prevention messages and information on accessibility to HIV counseling and testing services to the contact with a reported HIV exposure. The confidentiality rules that apply to the names of HIV-infected persons shall apply to the names of their contacts.

10.2. In contact notification situations, the division recommends that private health care providers refer contact notification activities to the division rather than attempt notification themselves. The division has an established program for notifying partners of persons with infectious conditions.

**§64-64-11. Consent by Legal Representative.**

11.1. Substituted consent for HIV-related testing or for the authorization of the release of test results shall be obtained in accordance with W. Va. Code §16-3C-4 and this rule.

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11.2. Minors shall be treated as established under W. Va. Code §16-4-10.

**§64-64-12. School Exclusion.**

School exclusions shall be in accordance with W. Va. Code §16-3C-6. If the student is under the jurisdiction of a protection or advocacy agency, a representative from that agency may be included in consultation. The provisions of this rule and of W. Va. Code §16-3C-1 et seq. regarding the confidentiality and the release of information are applicable in the school setting.

**§64-64-13. Requirement for All Health Care Providers to Report Positive Serologic and Other Tests for the Human Immunodeficiency Virus.**

13.1. All health care providers in West Virginia who perform, or cause to have performed, serologic or other tests for HIV shall make a report of all HIV infection associated with laboratory tests that are positive or results that are indicative of the HIV infection to the director on forms provided by the director for that purpose as follows:

13.1.1. All positive (reactive) laboratory test results; and

13.1.2. All clinical status data.

13.2. These health care provider reports shall include:

13.2.1. The name and full address of the laboratory;

13.2.2. The name of the tests performed, the date each test was performed and the results of the tests;

13.2.3. The legibly printed or typed name and location of the health care provider reporting the positive HIV laboratory results;

13.2.4. The name of the confidentially-tested or the identification code of the anonymously-tested individual;

13.2.5. Patient demographic information including the patient's age, sex, race and address, unless the patient requests anonymous reporting;

13.2.6. Social and risk factor information of the patient relative to HIV infection; and

13.2.7. Other information concerning HIV infection judged necessary by the director.

13.3. Reports of HIV shall be submitted within thirty (30) days of the receipt of positive (reactive) test results.

13.4. Health care providers performing anonymous HIV testing on individuals shall use confidential reporting of HIV infection for patients revealing their identity in HIV infection consultation. If an individual who has been tested anonymously, either makes his or her identity known to the provider or rescinds the request for anonymity, the provider shall report the name to the director.

13.5. The director shall work with an individual's health care provider in any follow-up of reported positive laboratory tests or HIV infection.

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13.6. Health care providers who provide HIV care to patients on the basis of a medical or a self referral shall submit an HIV infection report form to the division.

13.7. The reports of all HIV infection submitted in compliance with this rule are protected and are exempt from public disclosure under the exemption for medical records contained in W. Va. Code §29B-1-1 et seq., the Freedom of Information Act: Provided, That the reports are subject to the provisions of W. Va. Code §16-3C-1 et seq. This information shall not be used except as is necessary to enforce State public health laws and rules and to analyze the magnitude of HIV infection in the State for assisting in the development of adequate safeguards against its spread.

**§64-64-14. Requirement for Laboratories to Report Positive Serologic and Other Tests for the Human Immunodeficiency Virus.**

14.1. All laboratories conducting HIV testing in West Virginia or providing HIV testing results for use in this State shall make a report on the first and fifteenth days of each month of all laboratory tests that are positive or results that are indicative of the HIV infection to the director on forms provided by the director for that purpose as follows:

14.1.1. All positive (reactive) serologic antibody tests for HIV;

14.1.2. All positive (reactive) laboratory tests for the identification of HIV;

14.1.3. All CD4+ test results on peripheral blood with counts less than 200/mm<sup>3</sup> or less than fourteen per cent (14%); and

14.1.4. All other positive laboratory test results which identify the presence of HIV or the progression of an HIV infection.

14.2. These reports shall include:

14.2.1. The name and full address of the laboratory;

14.2.2. The name of the test, the date performed, and the result;

14.2.3. The name and location of the health care provider who submitted the specimen;

14.2.4. The name of the patient, if known, or an identification code, if the name is not known, and the patient's sex, age and address, if available;

14.2.5. Other information concerning HIV infection management and control judged necessary by the director; and

14.2.6. The signature of the supervisor of the laboratory.

14.3. The laboratory shall submit the results of the laboratory reports related to Subdivisions 14.1.a through 14.1.d of this rule on the first and fifteenth days of each month.

14.4. If no reportable tests are performed during a reporting period, a statement to this effect shall be submitted by the supervisor of the laboratory.

14.5. The director shall work with an individual's health care provider in any follow-up of the reports of positive laboratory tests.

14.6. The reports of all positive tests submitted in compliance with this rule are protected and are exempt from public disclosure under the exemption for medical records contained in W. Va. Code §29B-1-1 et seq., the Freedom of Information Act: Provided, That the reports are subject to the provisions of W. Va. Code §16-3C-1 et seq. The information shall not be used except as is necessary to enforce State public health laws and rules and to analyze the magnitude of HIV infection in the State for assisting in the development of adequate safeguards against its spread.

**§64-64-15. Quality Control of Laboratories Conducting HIV Tests.**

15.1. Laboratories Required to be Approved.

15.1.1. All laboratories conducting HIV testing in this State or providing HIV testing results for use in this State shall be approved by the division.

15.1.2. A laboratory located in West Virginia and seeking approval shall:

15.1.2.a. Show that it complies with the applicable requirements of W. Va. Code §16-3C-1 et seq. and this rule;

15.1.2.b. Complete application forms when seeking initial approval or when there is a change of ownership, the laboratory administrator, or location; and

15.1.2.c. Be certified for moderate or high complexity tests under CLIA-88.

15.1.3. A laboratory located outside of West Virginia is eligible for approval only if it is approved for high complexity testing by the federal government regulations promulgated pursuant to CLIA-88 (42 CFR Part 493, Laboratory Requirements, as amended in the April 24, 1995, edition of the Federal Register (60 FR 20035)).

15.2. Laboratory Director and Personnel Qualifications.

The laboratory director and personnel shall meet the qualifications set forth by the federal government pursuant to CLIA for certification of laboratories for participation in Medicare, and the relevant provisions of the October 1, 1994, edition of 42 CFR Part 493, Laboratory Requirements, as amended in the April 24, 1995, edition of the Federal Register (60 FR 20035), are hereby incorporated by reference.

15.3. Quality Control Standards.

A laboratory requesting approval shall demonstrate that a quality control program acceptable to the division is in effect for verification and assessment of accuracy, measurement of precision, and detection of error. The demonstration shall be evidenced, when applicable, in part by:

15.3.1. Selection of test methods appropriate to the needs of those served by the laboratory;

15.3.2. Use of controls and calibrating standards;

15.3.3. Recording of the acceptable limits and the results of controls and calibrating standards;

15.3.4. Recording of maintenance and calibration of equipment and instruments;

15.3.5. Labeling and dating of all reagents, solutions, standards, and control materials; and

15.3.6. Maintaining a manual containing all procedures and policies currently in use, which shall include action to be taken when control results are outside the acceptable limits and the procedure for reporting positive HIV test results to the division.

15.4. Proficiency Testing.

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Laboratories shall participate in a proficiency testing program approved by the division. The testing shall be conducted on a regular basis and satisfactory performance by the laboratory is mandatory. The laboratory is responsible for forwarding proficiency testing survey results to the division.

### 15.5. On-site Inspection.

The director may conduct an on-site inspection to determine compliance with this rule initially prior to approval, and thereafter as frequently as the director considers necessary to insure compliance with this subsection. The division has the right of entry upon proper identification at times judged necessary during operating hours in order to conduct the inspections.

### 15.6. Certificate of Approval; Revocation.

15.6.1. The director shall issue certificates of approval for a laboratory to perform HIV testing upon initial approval and on an annual basis thereafter pursuant to the conditions listed in this rule. Certificates issued shall contain the name and location of the laboratory, a laboratory code number, the name of the laboratory director and the date of expiration of the certificate.

15.6.2. Laboratories shall notify the division when there is a change in ownership, laboratory director, technical personnel or location of the laboratory.

15.6.3. The director may revoke or suspend a laboratory's approval if the laboratory:

15.6.3.a. Performs unsatisfactorily in on-site inspections;

15.6.3.b. Fails to comply with this rule and all applicable provisions of W. Va. Code §16-3C-1 et seq.;

15.6.3.c. Fails to report positive test results to the division according to W. Va. Code §16-3C-8B and this rule; or

15.6.3.d. Closes.

### **§64-64-160 Banking Blood.**

Banking of blood is permitted in accordance with W. Va. Code §16-3C-9.

### **§64-64-170 Administrative Due Process.**

Those persons adversely affected by the enforcement of this rule desiring a contested case hearing to determine any rights, duties, interests or privileges shall do so in a manner prescribed in the Rules of Procedure for Contested Case Hearings and Declaratory Rulings, 64 CSR 1.