

**WEST VIRGINIA**  
**SECRETARY OF STATE**  
**KEN HECHLER**  
**ADMINISTRATIVE LAW DIVISION**

Form #6

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OFFICE OF WEST VIRGINIA  
SECRETARY OF STATE

**NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED  
BY THE WEST VIRGINIA LEGISLATURE.**

AGENCY: Division of Health TITLE NUMBER: 64

AMENDMENT TO AN EXISTING RULE: YES\_\_\_, NO X

IF YES, SERIES NUMBER OF RULE BEING AMENDED: \_\_\_\_\_

TITLE OF RULE BEING AMENDED: \_\_\_\_\_

IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED: 64

TITLE OF RULE BEING PROPOSED: AIDS-Related Medical Testing and  
Confidentiality

THE ABOVE RULE HAS BEEN AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE.

AUTHORIZATION IS CITED IN (house or senate bill number) SB243

SECTION §64-5-2(m), PASSED ON 3-10-90

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON  
THE FOLLOWING DATE: April 6, 1990

Tanja Willis Miller  
Tanja Willis Miller, Secretary  
Dept. of Health and Human Resources



[PROPOSED]  
LEGISLATIVE RULES  
DEPARTMENT OF HEALTH  
AIDS-RELATED MEDICAL TESTING AND CONFIDENTIALITY

64 CSR 64

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[PROPOSED]  
TITLE 64  
WEST VIRGINIA LEGISLATIVE RULES  
DIVISION OF PUBLIC HEALTH  
SERIES 64  
AIDS-RELATED MEDICAL TESTING AND CONFIDENTIALITY

FILED

1988 NOV 17 AM 9:24

§64-64-1. General

OFFICE OF WEST VIRGINIA  
SECRETARY OF STATE

1.1. Scope - This legislative rule establishes specific standards and procedures concerning AIDS-related medical testing; record confidentiality and disclosure; substituted consent for testing; 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.

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 Code.

1.2. Authority - §16-3C-8 of the West Virginia Code. Related - §16-3C-1 et seq. of the West Virginia Code.

1.3. Filing Date -

1.4. Effective Date -

1.5. Final Approval - This rule was approved by the Administrator of the Division of Public Health on August 31, 1988.

1.6. Supersession and Repeal of Former Rules - None.

§64-64-2. Application and Enforcement

2.1. Application - This rule shall apply to:

- (a) health facilities;
- (b) health care providers;
- (c) funeral service providers and personnel;
- (d) persons issuing marriage licenses;
- (e) persons with access to or in charge of medical records or other sources of information regarding AIDS-related testing information; and

(f) laboratories seeking approval to conduct AIDS-related tests to be utilized in this State.

2.2. Enforcement - This rule shall be enforced by the Administrator of the Division of Public Health.

§64-64-3. Definitions

3.1. "Administrator" means the Administrator of the Division of Public Health or his or her lawful designee.

3.2. "AIDS" means acquired immunodeficiency syndrome.

3.3. "ARC" means AIDS-related complex.

3.4. "Division" means the Division of Public Health of the State Department of Health and Human Resources.

3.5. "Funeral director" means any person engaged, or holding himself out as engaged, in the business of funeral directing as defined in Article 6, Chapter 30 of the West Virginia Code, and who uses in connection with his name or business the words or terms "funeral director," "undertaker," "mortician," or any other word, term, or title to imply or designate him as a funeral director, undertaker, or mortician.

3.6. "Funeral establishment" means 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 such activities as are 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.

3.7. "Health facility" means a hospital, nursing home, clinic, blood bank, blood center, sperm bank, laboratory or other health care institution.

3.8. "Health care provider" means any physician, dentist, nurse, paramedic, psychologist or other person providing medical, dental, nursing, psychological or other health care services of any kind.

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

3.10. "HIV-infected person" means a person who has been diagnosed with AIDS or ARC or who has a positive confirmatory test for HIV.

3.11. "HIV-related illness" means a diagnosis of AIDS or ARC.

3.12. "HIV-related test" means a test for the HIV antibody or antigen or any future valid test approved by the Division, the Federal Drug Administration or the Centers for Disease Control.

3.13. "Person" includes any natural person, partnership,

association, joint venture, trust, public or private corporation or health facility.

3.14. "Release of test results" means a written authorization for disclosure of HIV-related test results which is signed, dated and which specifies to whom disclosure is authorized and the time period during which the release is to be effective.

#### §64-64-4. Testing

4.1(a) A physician, dentist, or the Administrator may request that a person consider voluntarily consenting to an HIV-related test when there is medical evidence providing reasonable cause to believe that: (1) the person may have a positive HIV test; (2) the presence of HIV infection would affect medical decisions concerning the type of patient care recommended; or (3) knowledge of a test result is necessary for effective counseling about behavior change.

(b) The requesting physician, dentist or the Administrator shall provide the person with information in the form of a booklet or printed information prepared or approved by the Division or, in the case of persons who are unable to read, shall either show a video or film prepared or approved by the Division to the patient or read or cause to be read to the patient the information prepared or approved by the Division which contains the following specifics:

(1) An explanation of the test, including its purpose, potential uses, limitations, the meaning of its results and any special relevance to pregnancy and prenatal care; and

(2) An explanation of the procedures to be followed; and

(3) An explanation that the test is voluntary and may be obtained anonymously; and

(4) An explanation that the consent for the test may be withdrawn at any time prior to drawing the sample for the test and that such withdrawal of consent may be given orally if the consent was given orally, or shall be in writing if the consent was given in writing; and

(5) An explanation of the nature and current knowledge of asymptomatic HIV infection, ARC and AIDS and the relationship between the test result and those diseases; and

(6) Information about behaviors known to pose risks for transmission of HIV infection.

(c) The provisions of Section 4.1(b) of this rule must also be followed when a patient, without a request from a physician, dentist, or the Division, voluntarily seeks an HIV test from any physician, dentist, or other health care provider, or from the

Division.

(d) A person seeking an HIV-related test who wishes to remain anonymous has the right to do so, and to provide written, informed consent through use of a coded system with no linking or individual identity to the test requests or results. Such a coded system may be used by a private health care provider as well as by public facilities. A health care provider who does not provide HIV-related tests on an anonymous basis shall refer such a person to a test site which does provide anonymous testing, or to any local or county health department which provides for performance of an HIV-related test and counseling or to any Division-designated HIV counseling and testing site. Local or county health departments shall provide access or referral to designated sites or to private clinics which provide anonymous HIV testing for persons residing within their jurisdiction.

(e) At the time of learning of an HIV test result, the subject of the test shall be provided with post-test counseling or referral for post-test counseling including assistance in coping with the emotional consequences of learning a test result. This may be done by brochure or personally, or both.

(f) Nothing in the rule shall be construed to provide a ground for any physician, dentist, or the Administrator 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. No consent for testing is required and the provisions of Section 4.1 of this rule do not apply for the performance of an HIV test:

(a) on a human body part (including tissue and blood or blood products and semen) or the donor or the recipient when the health care provider or health facility procures, processes, distributes or uses a human body part for a purpose specified under the uniform anatomical gift act, or for transplant recipients, or for the purpose of artificial insemination: Provided, That 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 Section 4.1 of this rule.

Further, all confidentiality restrictions contained in Section 7 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.

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 such transfusions.

(b) in documented bona fide medical emergencies: Provided, That

(1) The subject of the test is unable to grant or withhold consent; and

(2) Substituted consent has been sought but has been refused; and

(3) The test results are necessary for medical diagnostic purposes to provide appropriate emergency care or treatment; and

(4) Post-test counseling is provided.

Necessary treatment shall not be withheld pending HIV test results.

(c) for the purpose of research: Provided, That the testing is performed in a manner by which the identity of the test subject is not known and may not be retrieved by the researcher or any other person.

4.3(a) The testing of persons convicted of a crime specified in W.Va. Code §16-3C-2(f)(2) shall be accompanied by pre-test and post-test counseling. All statutory provisions as to the confidentiality of HIV test results shall apply to this testing program.

(b) If the Administrator has evidence to support the belief that a person could be infected with HIV and that the blood or other bodily fluids of that person may have exposed another person receiving or rendering emergency medical aid or in the performance of their work to a significant risk for transmission of HIV, the Administrator may, upon request by a physician or at his or her discretion, request said person to consent to HIV-related testing: Provided, That if the person believed by the Administrator to be infected refuses to consent, or if substituted consent is refused in the case of a person unable to grant or withhold consent, the Administrator may require an HIV test if information from such a test is believed by the Administrator to be necessary to protect the life or health of the person who may have been exposed to HIV. The Administrator shall establish a list of health care providers who are approved to authorize HIV testing in emergency medical aid circumstances.

4.4. Nothing in Section 4 of this rule is applicable to any insurer regulated under Chapter 33 of the W.Va. Code.

**§64-64-5. Review of Marriage License** - The Division will periodically review marriage licenses in order to determine compliance with the requirements of W. Va. Code §16-3C-2(h) regarding documentation of the provision of information concerning AIDS and HIV-related testing and counseling.

**§64-64-6. Charting Information** - Health care providers shall be permitted to enter in a patient's medical chart a diagnosis of an HIV-related illness, but may only enter the results of an HIV-

related test in the chart of a patient if the following statement is printed on the test report in the chart: "This information has been disclosed to you from records whose confidentiality 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, or as otherwise permitted by law. A general authorization for the release of medical or other information is NOT sufficient for this purpose."

#### §64-64-7. Confidentiality

7.1. Any laboratory performing an HIV-related test in West Virginia shall have the following statement of confidentiality appear on the report form or as an attachment to the report form returned to the health care provider or facility: "This information has been disclosed to you from records whose confidentiality 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, or as otherwise permitted by law. A general authorization for the release of medical or other information is NOT sufficient for this purpose."

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

7.3. HIV test results may be disclosed to agents or employees of funeral establishments or of health care providers or facilities if the agent or employee provides patient care or handles or possesses specimens of body fluids or tissues and the agent or employee has a need to know such information. A person shall be deemed to have a need to know HIV test results under the provisions of W. Va. Code §16-3C-3(a)(3) and this subsection of this rule where the information is medically necessary to protect the individual from a significant risk of transmission or will have an impact on the treatment modality.

#### §64-64-8. Contact Notification

3.1. When a health care provider of an HIV-infected person notifies the Division of a sexual or intravenous (IV) drug contact that has not been advised of their exposure, the Administrator shall review the identifying, locating and related epidemiologic information and specify follow-up recommendations. Contact notification shall be initiated by the Administrator when the Administrator has reason to believe that contacts may be unknowingly at risk for HIV infection. Notification will include an explanation of exposure to HIV, HIV prevention messages and information on accessibility to HIV counseling and testing services to the person with a reported HIV exposure. The name or

identity of the person whose HIV test result was positive shall remain confidential. The confidentiality rules that apply to the names of HIV-infected persons shall apply to the names of their contacts.

8.2. 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.

**§64-64-9. Substituted Consent**

9.1. If the person whose consent is necessary under the provisions of Article 3C, Chapter 16 of the West Virginia Code or this rule for HIV-related testing or for the authorization of the release of test results is unable to give such consent or authorization because of mental incapacity or incompetency, the consent or authorization shall be obtained from another person in the following order of preference:

(a) A person holding a durable power of attorney for health care decisions;

(b) The person's duly appointed legal guardian or guardian ad litem; or

(c) The person's next-of-kin in the following order of preference: spouse, parent, adult child, sibling, uncle or aunt, grandparent.

9.2. The person's inability to consent shall not be permitted to result in delay or denial of necessary medical treatment.

9.3. The information and pre- and post-test counseling required to be provided to the person pursuant to W. Va. Code §16-3C-2(b) and §16-3C-2(d) shall be provided to the person giving substituted consent.

9.4. Minors will be treated as established under W. Va. Code §16-4-10.

**§64-64-10. School Exclusion** - Exclusion of an HIV-infected student from school or participation in school sponsored activities will be determined on a case by case basis through consultation with a committee which may include the student's parents or guardians, medical care provider, health authorities, school or institution administrators or medical advisors in accordance with policies and guidelines which may have been established by the entities. The exclusion must be based on the student representing an unacceptable risk for transmission of the HIV infection. If the student is under the jurisdiction of a protection or advocacy agency, a representative from that agency may be included. Any finding of unacceptable risk by the local committee must be

approved by the Administrator as an unacceptable risk for the transmission of HIV to others because of the stage or nature of the illness prior to the student's exclusion. The provisions of this rule and of W.Va. Code §16-3C-1 et seq. regarding the confidentiality of and the release of information are applicable in the school setting.

**§64-64-11. Requirement for All Health Care Providers to Report Positive Serologic and Other Tests for the Human Immunodeficiency Virus**

11.1. 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 laboratory tests that are positive or results that are indicative of the HIV infection to the Administrator on forms provided by the Administrator for that purpose as follows:

(a) All positive (reactive) serologic antibody tests for HIV;

(b) All positive (reactive) laboratory tests for the identification of HIV; and

(c) All other positive laboratory test results which identify the presence of HIV.

11.2. These reports shall include:

(a) The name and full address of the laboratory;

(b) The name of the test, the date performed and the result;

(c) The legibly printed or typed name and location of the health care provider reporting the positive HIV laboratory results;

(d) The name or identification code of the individual tested and, if available, his or her sex, age and address; and

(e) The signature of the health care provider.

11.3. Reports of the above named laboratory tests shall be submitted within fifteen (15) days of the receipt of such test results.

11.4. The Administrator shall work with an individual's health care provider for any follow-up of the reports of positive laboratory tests.

11.5. The reports of all positive tests submitted in compliance with this rule are deemed confidential and are exempt from public disclosure under the exemption for medical records

contained in Chapter 29B of the West Virginia Code, the Freedom of Information Act: Provided, That the reports shall be subject to the provisions of Article 3C, Chapter 16 of the West Virginia Code. Such 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.

**\$64-64-12. Requirement for Laboratories to Report Positive Serologic and Other Tests for the Human Immunodeficiency Virus**

12.1. All laboratories conducting HIV testing in West Virginia or providing HIV testing results for use in this State shall make a report of all laboratory tests that are positive or results that are indicative of the HIV infection to the Administrator on forms provided by the Administrator for that purpose as follows:

(a) All positive (reactive) serologic antibody tests for HIV;

(b) All positive (reactive) laboratory tests for the identification of HIV; and

(c) All other positive laboratory test results which identify the presence of HIV.

12.2. These reports shall include:

(a) The name and full address of the laboratory;

(b) The name of the test, the date performed, and the result;

(c) The name and location of the health care provider who submitted the specimen;

(d) The name of the patient (or identification code) and (if available) the patient's sex, age and address;

(e) The signature of the supervisor of the laboratory.

12.3. Reports of the above named laboratory tests shall be submitted on the first and fifteenth days of each month.

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

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

12.6. The reports of all positive tests submitted in com-

pliance with this rule are deemed confidential and are exempt from public disclosure under the exemption for medical records contained in Chapter 29B of the West Virginia Code, the Freedom of Information Act: Provided, That the reports shall be subject to the provisions of Article 3C, Chapter 16 of the West Virginia Code. Such 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.

#### §64-64-13. Quality Control of Laboratories Conducting HIV Tests.

##### 13.1. Laboratories Required to be Approved

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

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

(a) Show that it complies with the applicable requirements of Article 3C, Chapter 16 of the West Virginia Code and this rule; and

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

13.1.3. A laboratory located outside the boundaries of West Virginia will be eligible for approval only if it is licensed by the Federal Government under the Clinical Laboratories Improvement Act (CLIA) of 1967.

##### 13.2. Quality Control

13.2.1. Laboratory Director and Personnel Qualifications- The laboratory director and personnel shall meet the qualifications set forth by the Federal Government under the conditions of Coverage of Services of Independent Laboratories (for participation in Medicare), found at 42 CFR 405.1310 through 405.1315, 1987, inclusive, and the aforesaid qualifications are hereby adopted by reference.

13.3. Quality Control Standards - A laboratory requesting approval must 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. Such demonstration shall be evidenced, when applicable, in part by:

(a) Selection of test method(s) appropriate to the needs of those served by the laboratory;

(b) Use of controls and calibrating standards;

(c) Recording of the acceptable limits and the results of controls and calibrating standards;

(d) Recording of maintenance and calibration of equipment and instruments;

(e) Labeling and dating of all reagents, solutions, standards, and control materials; and

(f) 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.

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

13.5. On-site Inspection - An on-site inspection to determine compliance with this rule shall be conducted initially prior to approval, and on an annual basis thereafter. The Division shall have the right of entry upon proper identification at such times as deemed necessary during operating hours in order to conduct such inspections.

#### 13.6. Certificate of Approval; Revocation

13.6.1. Certificates of approval for the performance of HIV testing shall be issued upon initial approval and on an annual basis thereafter pursuant to the conditions listed herein. Certificates issued will 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.

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

13.6.3. Approval may be revoked or suspended upon:

(a) Unsatisfactory performance in on-site inspections;

(b) Failure to comply with this rule and all applicable provisions of Article 3C, Chapter 16 of the West Virginia Code;

(c) Failure to report positive test results to the Division according to W. Va. Code §16-3C-8B and this rule; or

(d) Closure of the laboratory.

**§64-64-14. Banking Blood** - The health care provider or a private, public, or nonprofit blood bank shall, upon request, store and bank a person's blood and the health care provider shall use such blood in the elective surgery or medical procedure to the extent such blood is available.

**§64-64-15. 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 WV CSR 1.

**§64-64-16. Severability** - The provisions of this rule are declared to be severable. If any provision of this rule shall be held invalid, the remaining provisions shall remain in effect.

KEN HECHLER  
Secretary of State

MARY P. RATLIFF  
Deputy Secretary of State

ROBERT E. WILKINSON  
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Charleston 25305

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Director, Corporations

SHEREE COHEN  
Special Assistant

(Plus all the volunteer  
help we can get)

Judy Smith

AGENCY: Division of Health

FROM: JUDY COOPER, DIRECTOR ADMINISTRATIVE LAW DIVISION

DATE: January 29, 1991

THE ATTACHED RULE RECENTLY FILED BY YOUR AGENCY HAS BEEN ENTERED INTO OUR COMPUTER SYSTEM. PLEASE REVIEW, PROOF AND RETURN IT WITH ANY CORRECTIONS. IF THERE ARE NO CORRECTIONS, PLEASE SIGN THIS MEMO AND RETURN IT TO THIS OFFICE. YOU WILL BE SENT A FINAL VERSION OF YOUR RULE FOR YOUR RECORDS.

PLEASE RETURN EITHER THE CORRECTED RULE OR THIS FORM WITHIN TEN (10) WORKING DAYS OF THE DATE YOU RECEIVED THIS REQUEST. CALL IF YOU HAVE ANY QUESTIONS.

SERIES: 64 TITLE Aids Related Medical Testing & Confidentiality

\* THE ATTACHED RULE HAS BEEN REVIEWED AND IS CORRECT.

SIGNED: Kay Howard

TITLE OF PERSON SIGNING: Director, Regulatory Development

DATE: 5/13/91

\*\*\*\*\*

\* THE ATTACHED RULE HAS BEEN REVIEWED AND NEEDS CORRECTING. THE CORRECTIONS HAVE BEEN MARKED.

SIGNED: \_\_\_\_\_

TITLE OF PERSON SIGNING: \_\_\_\_\_

DATE: \_\_\_\_\_