

**WEST VIRGINIA
SECRETARY OF STATE**

KEN HECHLER

ADMINISTRATIVE LAW DIVISION

Form #2

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SEP 17 9 09 AM '98

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

Division of Health

AGENCY: Department of Health & Human Resources TITLE NUMBER: 64

RULE TYPE: Legislative; CITE AUTHORITY W. Va. Code §§ 16-3C-2(e)(2),
16-3C-8 & 16-1-7

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 64

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

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: _____

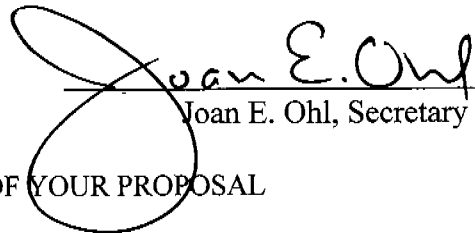
TITLE OF RULE BEING PROPOSED: _____

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON October 23, 1998 AT 4:30 p.m.

ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS.

L. Arnold, Office of General Counsel
Department of Health & Human Resources
Capitol Complex - Building 3, Room 265
Charleston, WV 25305

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.


Joan E. Ohl, Secretary

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

\$7.60

AIDS-Related Medical Testing and Confidentiality, 64CSR64

BRIEF SUMMARY OF THE RULE

The proposed amendments to this rule address AIDS/HIV-related medical testing, including: the authorization for treating physicians to determine bona fide medical emergencies when HIV-related testing for medical diagnostic purposes is necessary; and spousal notification regarding contact with a source patient who tested positive for HIV; confidentiality; costs associated with testing; documentation; post-test counseling; post-exposure prophylaxis; and other matters.

When health care providers do not provide spousal/contact notification, they are required to notify the Division of Public Health so the Division can provide the notice.

The rule has been renumbered in accordance with the Secretary of State's current numbering system and to accommodate new material.

AIDS-Related Medical Testing and Confidentiality, 64CSR64

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE PROPOSED RULE

Since during the 1998 legislative session amendments were made to W. Va. Code Chapter 16, Article 3C, AIDS-Related Medical Testing and Records Confidentiality Act, changes are necessitated in the corresponding rule, 64CSR64.

The proposed amendments to this rule will be used by health care facilities throughout the State in writing their internal plans to ensure appropriate post-exposure care for health care workers and emergency medical responders exposed while performing a duty of their employment.

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period, Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: September 14, 1998

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

Division of Health

FROM: (Agency name, Address & Phone No.) Department of Health and Human Resources

State Capitol Complex, Building 3, Room 265, Charleston, WV 25305

Telephone: (304) 558-3223

LEGISLATIVE RULE TITLE: AIDS-Related Medical Testing and Confidentiality

64 CSR 64

1. Authorizing statute(s) citation: WV Code §§ 16-3C-2(e)(2), 16-3C-8 & 16-1-7

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

September 17, 1998

b. What other notice, including advertising, did you give of the hearing?

The proposed rule will be sent to the West Virginia Hospital Association, hospital administrators, hospital infection control personnel and the Insurance Commission, among others.

c. Date of Public Hearing(s) or Public Comment Period ended:

October 23, 1998.

- d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached N/A No comments received N/A

- e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing (be exact):

N/A

- f. Name, title, address and phone/fax/e-mail numbers of agency person(s) to receive all written correspondence regarding this rule (please type):

Larry Arnold, Attorney, Office of General Counsel

Department of Health and Human Resources

Building 3 Room 265, Capitol Complex

558-3223 FAX: 558-1130 LArnold@WVDHHR.ORG

- g. IF DIFFERENT FROM ITEM 'f', please give Name, title, address and phone number(s) of agency person(s) who wrote and/or has responsibility for the contents of this rule (please type):

Loretta Haddy, Director, Division of Surveillance and Disease Control

1422 Washington Street, East

Charleston, West Virginia 25301

Phone: 558-5358 or 1-800-423-1271

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

- a. Give the date upon which you filed in the State Register a notice of the time and place a hearing for the taking of evidence and a general

description of the issues to be decided.

N/A

b. Date of hearing or comment period:

N/A

d. On what date did you file in the State Register the findings and determinations required together with the reasons therefore?

N/A

d. Attach findings and determinations and reasons:

Attached N/A

FISCAL NOTE FOR PROPOSED RULES

Rule Title: AIDS-Related Medical Testing and Confidentiality, 64 CSR 64

Type of Rule: **Legislative** **Interpretive** **Procedural**

Agency: Division of Health
Department of Health and Human Resources

Address: Building 3, Capitol Complex
Charleston, W. Va. 25305

1. Effect of the Proposed Rule	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
Estimated Total Cost	\$	\$	\$ 0	\$ 0	\$0
Personal Services					
Current Expense					
Repairs & Alterations					
Equipment					
Other					
Revenue					

2. Explanation of above estimates.

No new funding is required to implement this rule.

3. Objectives of this rule:

These rule amendments address AIDS/HIV-related medical testing, including: the authorization for treating physicians to determine bona fide medical emergencies when HIV-related testing for medical diagnostic purposes is necessary; confidentiality; costs associated with testing; documentation; post-test counseling; post-exposure prophylaxis; and spousal notification regarding contact with a source patient who tested positive for HIV.

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

None anticipated.

B. Economic Impact on Political Subdivisions; Specific Industries; Specific Groups of Citizens.

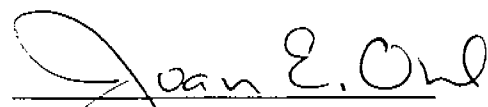
Costs for testing, counseling and initial prophylactic treatment for the first six months after the significant exposure of a medical or emergency responder will be the responsibility of the responder's employer. It is unknown how many medical or emergency responders will be significantly exposed to need such post-exposure services.

C. Economic Impact on Citizens/Public at Large.

Good Samaritans responding in an emergency situation may incur the costs for testing the source patients of their exposure.

Date: 9/3/98

Signature of Agency Head or Authorized Representative



Joan E. Ohl, Secretary
Department of Health and Human Resources

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

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

PROPOSED RULE FOR COMMENT

64 CSR 64

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

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

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TITLE 64
LEGISLATIVE RULES
DIVISION OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

OFFICE OF THE CLERK OF THE SENATE
SECRETARY OF STATE

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. Related -- W. Va. Code § 16-3C-1 et seq. §§16-3C-2(e)(2), 16-3C-8 and 16-1-7.~~

1.3. Filing Date. --

1.4. Effective Date. --

~~1.5. Supersession and Repeal of Former Rules -- This rule amends and reenacts AIDS-Related Medical Testing and Confidentiality, 64 CSR 64, 1990.~~

§64-64-2. Application and Enforcement.

2.1. Application. -- This rule applies to:

- 2.1.a. Health facilities;
- 2.1.b. Health care providers;
- 2.1.c. Funeral service providers and personnel;
- 2.1.d. Persons issuing marriage licenses;
- 2.1.e. Persons with access to or in charge of medical records or other copies of

information regarding AIDS-related testing information; and

2.1.f. 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 possible exchange of body fluids.

2.2. Enforcement. -- This rule is enforced by the director of the division of health or his or her lawful designee.

§64-64-3. Definitions.

3.1. AIDS. -- Acquired immunodeficiency syndrome.

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

3.3. ARC. -- AIDS-related complex.

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

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

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

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

3.6. 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).

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

3.8. Confidential HIV Reporting. -- The reporting of an HIV infection by name of the person identified as being HIV infected. The use of information is limited by law.

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

- 3.10. Contact. -- When used as a noun, a sexual or needle-sharing partner.
- 3.11. 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 an adjudicated juvenile offender as defined in W. Va. Code § 49-5b-3.
- 3.12. Director. -- The director of the division of health of the department of health and human resources or his or her lawful designee.
- 3.13. Division. -- The division of health of the state department of health and human resources.
- 3.14. 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.
- 3.15. 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.
- 3.16. Health Facility. -- A hospital, nursing home, clinic, blood bank, blood center, sperm bank, laboratory or other health care institution.
- 3.17. Health Care Provider. -- Any physician, dentist, nurse, paramedic, psychologist or other person providing medical, dental, nursing, psychological or other health care services of any kind.
- 3.18. HIV. -- The human immunodeficiency virus identified as the causative agent of AIDS.
- 3.19. HIV-Infected Person. -- A person who has been diagnosed with AIDS or ARC or who has a positive confirmatory test for HIV.
- 3.20. HIV-Related Illness. -- A diagnosis of AIDS or ARC.
- 3.21. HIV-Related Test. -- 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.
- 3.22. Legal Representative. --

64 CSR 64

3.22.a. A guardian, temporary guardian or limited guardian appointed pursuant to the West Virginia Guardianship and Conservatorship Act, W. Va. Code, § ~~44-1-1 et seq.~~, 44A-1-1 et seq., within the limits set by the order;

3.22.b. An individual appointed as committee or guardian prior to June 9, 1994, within the limits set by the appointing order and W. Va. Code § 44A-1-2(d);

3.22.c. A person having a medical power of attorney pursuant to the West Virginia Medical Power of Attorney Act, W. Va. Code §§ 16-30A-1 et seq., within the limits set by the law and the appointment;

3.22.d. A surrogate decision-maker appointed pursuant to the West Virginia Health Care Surrogate Act, W. Va. Code § 16-30B-1 et seq., or the West Virginia Do Not Resuscitate Act, § 16-30C-1 et seq., within the limits set by the appointment;

3.22.e. An individual having a durable power of attorney pursuant to W. Va. Code § 39-4-1, or a power of attorney under common law, within the limits of the appointment; or

3.22.f. A person lawfully appointed in a similar or like relationship of responsibility under the laws of this State, or another State or legal jurisdiction, within the limits of the applicable statute and appointing authority.

3.23. Medical or Emergency Responders. -- Paid or volunteer firefighters, law-enforcement officers, emergency medical technicians, paramedics, or other emergency service personnel, providers or entities acting within the usual course of their duties; good Samaritans and other nonmedical and nonemergency personnel providing assistance in emergencies; funeral directors; health care providers; the director; and all employees thereof and volunteers associated therewith.

3.24. Patient or Test Subject or Subject of the Test. -- The person upon whom a HIV test is performed, or the person who has legal authority to make health care decisions for the test subject.

3.25. Person. -- Any natural person, partnership, association, joint venture, trust, public or private corporation or health facility.

3.26. 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.

3.27. Release of Test Results. -- 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.

3.28. Significant Exposure. --

3.28.a. Exposure to blood or body fluids through needlestick, instruments, sharps, surgery or traumatic events; or

3.28.b. Exposure of mucous membranes to visible blood or body fluids, to which universal precautions apply according to the national centers for disease control and prevention, and laboratory specimens that contain HIV (e.g., suspensions of concentrated virus); or

3.28.c. Exposure of skin to visible blood or body fluids, when the exposed skin is chapped, abraded or afflicted with dermatitis or the contact is prolonged or involving an extensive area.

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

3.30. Victim. -- The person or persons to whom transmission of bodily fluids from the perpetrator of the crimes of sexual abuse, sexual assault, incest or sexual molestation occurred or was likely to have occurred in the commission of such crimes.

§64-64-4. Testing.

4.1. Voluntary Consent.

4.1.a. A physician, dentist, other health care professional acting within the scope of his or her professional license, or the director may request that a person consider voluntarily consenting to an HIV-related test when there is medical evidence providing reasonable cause to believe that:

4.1.a.1. The person may have a positive HIV test;

4.1.a.2. The presence of HIV infection would affect medical decisions concerning the type of patient care recommended; or

4.1.a.3. Knowledge of a test result is necessary for effective counseling about behavior change; or

4.1.a.4. The results of HIV-testing of samples of blood or body fluids from a source patient could provide information important in the care of medical or emergency responders: *Provided*, That the source patient whose blood or body fluids is being tested pursuant to this section must have come into contact with a medical or emergency responder or other person in such a way that a significant exposure has occurred.

4.1.b. The requesting physician, dentist, other health care professional acting within the

scope of his or her professional license, or the director shall make arrangements to 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:

4.1.b.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;

4.1.b.2. An explanation of the procedures to be followed;

4.1.b.3. An explanation that the test is voluntary and may be obtained anonymously;

4.1.b.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 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;

4.1.b.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

4.1.b.6. Information about behaviors known to pose risks for transmission of HIV infection.

4.1.c. The provisions of Section 4.1.2 of this rule shall also be followed when a patient, without a request from a physician, dentist, other health care professional 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.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 of individual identity to the test requests or results. 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 the 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.

4.1.e. At the time the health care provider learns of an HIV test result, he or she shall provide the subject of the test with post-test counseling or referral for post-test counseling, including assistance in coping with the emotional consequences of learning the test result. This may be done by brochure or personally, or both.

4.1.f. Nothing in this rule shall be construed to provide a ground for any physician, dentist, 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 Section 4.1 of this rule do not apply for the performance of an HIV test:

4.2.a.1. 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~~ section 8 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;

4.2.a.2. In documented bona fide medical emergencies, as determined by a treating physician taking into account the nature and extent of the exposure to another person: Provided, That:

4.2.a.2.A. The subject of the test is unable or unwilling to grant or withhold consent;

4.2.a.2.B. ~~Consent by the subject's legal representative has been sought but has been refused;~~ If the subject of the test is unable to grant or withhold consent, consent is not obtained after a reasonable attempt is made to contact and obtain consent from the subject's legal representative;

4.2.a.2.C. 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 an assessing clinician, as described in section 8.1 of this rule, documents in the medical record of any exposed medical or emergency responder that there has been a significant exposure and that in the clinician's medical judgement the information is medically necessary to determine the course of treatment for the exposed medical or emergency responder.

4.2.a.2.D. 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.E. A reasonable attempt is made to contact the source patient and legal representative, if any, and inform them that the test will be performed using a pseudonym;

4.2.a.2.F. 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;

4.2.a.2.G. Post-test counseling is provided. Necessary treatment shall not be withheld pending HIV test results; and

4.2.a.2.H. None of the above activities 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 has the right to invoke the remedies and penalties of W.Va. Code §16-3C-5.

4.2.a.3. 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.

4.2.b. If the director 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 his or her work, or in other medically recognized exposure situations or settings to a significant risk for transmission of HIV, the director may, upon request by a physician, other health care provider acting within the scope of his or her professional license, or at his or her discretion, request that person to consent to HIV-related testing: Provided, That if the person believed by the director to be infected refuses to consent, or if, in the case of a person unable to grant or withhold consent, the person's legal representative refuses to consent, the director may require an HIV test if information from the test is believed by the director to be necessary to protect the life or health of the person who may have been exposed to HIV. The director may, at his or her discretion, release the test result to the physician or other health care provider: Provided, That the provisions of ~~Sections 8.1 through 8.4~~ sections 9.1 through 9.4 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 over 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 will 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 § 16-2-(f). All restitution funds collected by the court from persons convicted of prostitution, sexual abuse, sexual assault, incest or sexual molestation for the cost of HIV testing and counseling and held in the State treasury are to be available to the director to facilitate the provision of HIV-related testing and counseling conducted pursuant to W. Va. Code § 16-3C-1 et seq.

4.4. Applicability to Insurers.

Nothing in Section 4 of this rule is applicable to any insurer regulated under W. Va. Code § 33-1-1 et seq.

§64-64-5. Cease and Desist Orders.

If the director is presented with information that a person known to be HIV-infected is involved in a behavior that potentially endangers the health of others the director may, after assuring that the person has been provided with reasonable opportunities for counseling, if he or she judges it necessary to promote appropriate conduct for preventing the transmission of HIV, initiate a public health cease and desist order. The cease and desist order shall be in writing, and shall set forth the name of the person to be restricted, and the initial period of time, not to exceed three (3) months, during which the order shall remain effective, the terms of the restrictions and such other conditions as may be warranted to protect the public health.

If a 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 such restrictions upon the person as 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(h) regarding documentation of the provision of

information concerning AIDS and HIV-related testing and counseling.

§64-64-7. 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."

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

8.1. A health facility shall have access to a knowledgeable trained clinician to assess the HIV exposure risk of medical or emergency responders during all working hours, including nights and weekends. The assessment of HIV exposure risk and initiation of basic post-exposure prophylaxis regimen necessitates 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. No test result shall be determined as positive and no positive test result shall be revealed to any person without corroborating or confirmatory testing being conducted. However, preliminary test results may be released to the clinician assessing the significant exposure for the purposes of determining post-exposure management of the medical or emergency responder.

8.4. All confirmed positive test results shall be reported to the division in compliance with section 13 of this rule.

8.5. Costs of any HIV test of a blood sample, performed with or without the consent of the source patient and the exposed medical or emergency responder, and the counseling and initial prophylactic treatment shall be borne by the employer of the medical or emergency responder who was exposed while performing a duty of his or her employment. However, costs of subsequent treatment and post-exposure HIV-related testing beyond six months are not required to be borne by the employer.

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 section 7 of this rule 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 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."

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 full 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. 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 the information. A person shall be judged to have a need to know HIV test results under the provisions of W. Va. Code § 16-3C-3(a)(3) and this Subsection 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.

§64-64-10. Contact Notification.

10.1. When a health care provider of an HIV-infected person notifies the division of a spouse, sexual contact or intravenous (IV) drug contact that has not been advised of his or her exposure, the director shall review the identifying, locating and related epidemiologic information, specify follow-up recommendations and make a good faith effort to inform a spouse, sexual contact or intravenous (IV) drug contact that they may be at risk of having acquired the HIV infection as a result of possible exchange of body fluids. The division has no notification obligations when the division determines that there has been no likely exposure of

such persons to HIV from the infected test subject within the ten-year period immediately prior to the diagnosis of the infection. Contact notification shall be initiated by the director when the director has reason to believe that contacts may be unknowingly at risk for HIV infection. Notification 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 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.

10.2. Spouses, sexual contacts, or intravenous (IV) drug contacts may be tested anonymously at the division's designated test sites, or at their own expense by a health care provider or an approved laboratory of their choice.

10.3. 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. If the person whose consent is necessary under the provisions of W. Va. Code § 16-3C-1 et seq. or this rule for HIV-related testing or for the authorization of the release of test results is unable to give consent or authorization because of mental incapacity or incompetency, the consent or authorization shall be obtained from the person's legal representative.

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

11.3. 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's legal representative.

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

§64-64-12. School Exclusion.

A school principal or other appropriate authority shall make a decision to exclude an HIV-infected student from school or participation in school-sponsored activities 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 any policies and guidelines which may have been established by the educational system authorities having jurisdiction over the school proposing to exclude the student. The exclusion shall 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. The director shall approve of any finding of unacceptable risk by the local committee 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 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.a. All positive (reactive) laboratory test results; and

13.1.b. All clinical status data.

13.2. These health care provider reports shall include:

13.2.a. The name and full address of the laboratory;

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

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

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

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

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

13.2.g. 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 a 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.

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

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

14.1.c. All CD4+ test results on peripheral blood with counts less than 200/mm³ or less than fourteen per cent (14%); and

14.1.d. 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.a. The name and full address of the laboratory;

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

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

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14.2.d. 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.e. Other information concerning HIV infection management and control judged necessary by the director; and

14.2.f. The signature of the supervisor of the laboratory.

14.3. The laboratory shall submit the results of the laboratory reports related to Sections 13.1.1 through 13.1.4 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.a. 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.b. A laboratory located in West Virginia and seeking approval shall:

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

15.1.b.2. Complete application forms when seeking initial approval or when there is a change of ownership, the laboratory administrator, or location; and

15.1.b.3. Be certified for moderate or high complexity tests under CLIA-88.

15.1.c. A laboratory located outside of West Virginia is be eligible for approval only if it is approved for high complexity testing by the federal government rules and 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.a. Selection of test method(s) appropriate to the needs of those served by the laboratory;

15.3.b. Use of controls and calibrating standards;

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

15.3.d. Recording of maintenance and calibration of equipment and instruments;

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

15.3.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.

15.4. Proficiency Testing.

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 shall be 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 deems necessary to insure compliance with this subsection. The division shall have 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.a. 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.b. Laboratories shall notify the division when there is a change in ownership, laboratory director, technical personnel or location of the laboratory.

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

15.6.c.1. Performs unsatisfactorily in on-site inspections;

15.6.c.2. Fails to comply with this rule and all applicable provisions of W. Va. Code § 16-3C-1 et seq.;

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

15.6.c.4. Closes.

§64-64-16. 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 the blood in the elective surgery or medical procedure to the extent the blood is available.

§64-64-17. 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.

§64-64-18. Severability.

The provisions of this rule are severable. If any provision of this rule is held invalid, the remaining provisions remain in effect.