

WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #4

Do Not Mark In this Box

FILED

JAN 23 2 47 PM '96

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: Division of Health TITLE NUMBER: 64

CITE AUTHORITY W. Va. Code §16-3C-8

AMENDMENT TO AN EXISTING RULE: YES NO

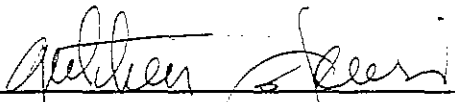
IF YES, SERIES NUMBER OF RULE BEING AMENDED: 64

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

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

TITLE OF RULE BEING PROPOSED: _____

THE ABOVE PROPOSED LEGISLATIVE RULE, FOLLOWING REVIEW BY THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE IS HEREBY MODIFIED AS A RESULT OF REVIEW AND COMMENT BY THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE. THE ATTACHED MODIFICATIONS ARE FILED WITH THE SECRETARY OF STATE.



Gretchen O. Lewis, Secretary

580

**PROPOSED RULE - TITLE 64
WEST VIRGINIA ADMINISTRATIVE RULES
DIVISION OF HEALTH**

SERIES 64

AIDS-RELATED MEDICAL TESTING AND CONFIDENTIALITY

**Modified Rule Approved by the Legislative
Rule-Making Review Committee**

WEST VIRGINIA ADMINISTRATIVE RULES
DIVISION OF HEALTH
AIDS-RELATED MEDICAL TESTING AND CONFIDENTIALITY
64 CSR 64

Table of Contents

§ 64-64-1. General	1
§ 64-64-2. Application and Enforcement	1
§ 64-64-3. Definitions	2
§ 64-64-4. Testing	4
<u>§ 64-64-5. Cease and Desist Orders</u>	8
§ 64-64-6. Review of Marriage License	8
§ 64-64-7. Charting Information	8
§ 64-64-8. Confidentiality	9
§ 64-64-9. Contact Notification	9
§ 64-64-10. Substituted <u>Consent by Legal Representative</u>	10
§ 64-64-11. School Exclusion	10
§ 64-64-12. Requirement for All Health Care Providers to Report Positive Serologic and Other Tests for the Human Immunodeficiency Virus	11
§ 64-64-13. Requirement for Laboratories to Report Positive Serologic and Other Tests for the Human Immunodeficiency Virus	12
§ 64-64-14. Quality Control of Laboratories Conducting HIV Tests	13
§ 64-64-15. Banking Blood	15
§ 64-64-16. Administrative Due Process	16
§ 64-64-17. Severability	16

PROPOSED RULE - TITLE 64
 WEST VIRGINIA LEGISLATIVE RULES JAN 23 2 47 PM '96
 DEPARTMENT OF HEALTH AND HUMAN RESOURCES
 SERIES 64
 AIDS-RELATED MEDICAL TESTING AND CONFIDENTIALITY

OFFICE OF WEST VIRGINIA
 SECRETARY OF STATE

Ed. Note: This rule has been renumbered according to the format prescribed by the Secretary of State.

§ 64-64-1. General.

1.1. **Scope** - This legislative rule establishes specific standards and procedures concerning AIDS-related medical testing; record confidentiality and disclosure; substituted 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 ~~Code~~ Act.

1.2. **Authority** - W. Va. Code § 16-3C-8. Related - W. Va. Code § 16-3C-1 et seq.

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 ~~shall apply~~ 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; and

2.1.6. Laboratories seeking approval to conduct AIDS-related tests to be uti-

lized in this State.

~~2.2. Enforcement - This rule shall be enforced by the Administrator of the Division of Public Health. This rule is enforced by the director of the division of health or his or her lawful designee.~~

§ 64-64-3. Definitions.

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

3.1. **AIDS** - means 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** - means AIDS-related complex.

3.4. **Bureau of Public Health** - Division of health.

3.5. **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).

3.6. **Commissioner of the Bureau of Public Health** - Director of the division of health.

3.7. **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.

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

3.9. **Contact** - A sexual or needle-sharing partner.

3.10. **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.

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

3.12. **Division** - ~~means~~ The division of Public health of the state department of health and human resources.

3.13. **Funeral Director** - ~~means~~ 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.

3.14. **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.

3.15. **Health Facility** - ~~means~~ A hospital, nursing home, clinic, blood bank, blood center, sperm bank, laboratory or other health care institution.

3.16. **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.

3.17. **HIV** - ~~means~~ The human immunodeficiency virus identified as the causative agent of AIDS.

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

3.19. **HIV-Related Illness** - ~~means~~ A diagnosis of AIDS or ARC.

3.20. **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.

3.21. Legal Representative

3.21.1. 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., within the limits set by the order;

3.21.2. 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);

3.21.3. 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;

3.21.4. 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:

3.21.5. 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

3.21.6. 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;

3.22. **Person** - ~~includes~~ Any natural person, partnership, association, joint venture, trust, public or private corporation or health facility.

3.23. **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.

3.24. **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. ~~Testing~~ Voluntary Consent.

4.1.1. A physician, dentist, other health care professional acting within the scope of his or her professional license, or the ~~Administrator~~ 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:

4.1.1.a. The person may have a positive HIV test;

4.1.1.b. The presence of HIV infection would affect medical decisions concerning the type of patient care recommended; or

4.1.1.c. Knowledge of a test result is necessary for effective counseling about behavior change.

4.1.2. The requesting physician, dentist, other health care professional acting within the scope of his or her professional license, or the ~~Administrator~~ 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:

64 CSR 64

4.1.2.a. 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~~

4.1.2.b. An explanation of the procedures to be followed; ~~and~~

4.1.2.c. An explanation that the test is voluntary and may be obtained anonymously; ~~and~~

4.1.2.d. 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~~

4.1.2.e. 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

4.1.2.f. Information about behaviors known to pose risks for transmission of HIV infection.

4.1.3. The provisions of Section ~~4.1.b.~~ 4.1.2 of this rule ~~must~~ 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, ~~or~~ other health care provider, or from the division.

4.1.4. 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~~ of 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 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.

4.1.5. At the time ~~of learning~~ the health care provider learns of an HIV test result, he or she shall ~~shall~~ provide 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 the test result. This may be done by brochure or personally, or both.

4.1.6. Nothing in ~~the~~ this rule shall be construed to provide a ground for any physician, dentist, or the ~~Administrator~~ director to refuse to treat a patient, nor shall the test-

ing provisions of this rule be used by health care providers to screen patients.

4.2. Consent Not Required.

4.2.1. 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:

4.2.1. 4.2.1.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;

4.2.2 4.2.1.b. In documented bona fide medical emergencies, : Provided, That:

4.2.2.e. 4.2.1.b.A. The subject of the test is unable to grant or withhold consent; and

4.2.2.b. 4.2.1.b.B. Substituted Consent by the subject's legal representative has been sought but has been refused; and

4.2.2.e. 4.2.1.b.C. The test results are necessary for medical diagnostic purposes to provide appropriate emergency care or treatment; and

4.2.2.d. 4.2.1.b.D. Post-test counseling is provided.

Necessary treatment shall not be withheld pending HIV test results; or

4.2.3. 4.2.1.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.

4.2.2. 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 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. ~~Testing of Persons~~ Mandated HIV Testing of Sexual Offenders and Management of Victims.

4.3.1. 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, 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.

4.3.2. 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.

4.3.3. 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.

4.3.4. 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.

4.3.5 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. Applicability to Insurers.

Nothing in Section 4 of this rule is applicable to any insurer regulated under Chapter 33 of the West Virginia Code 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, provisions for the person, 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 ~~will~~ 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. Confidentiality.

8.1. 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."

8.2. No person who obtains information protected by the provisions of W. Va. Code § 16-3C-1 et seq. and this rule may convey ~~such~~ 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 ~~such~~ the person to full penalties available.

8.3. 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.

8.4. 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 ~~such~~ the information. A person shall be ~~deemed~~ 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 ~~of this rule where~~ 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.

§ 64-64-9. Contact Notification.

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

HIV counseling and testing services to the person 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.

9.2. 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.

§ 64-64-10. Substituted Consent by Legal Representative.

10.1. 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 ~~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:~~ the person's legal representative.

~~10.1.1. A person holding a durable power of attorney for health care decisions;~~

~~10.1.2. The person's duly appointed legal guardian or guardian ad litem; or~~

~~10.1.3. The person's next of kin in the following order of preference: spouse, parent, adult child, sibling, uncle or aunt, grandparent.~~

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

10.3. 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~~ person's legal representative.

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

§ 64-64-11. School Exclusion.

A school principal or other appropriate authority shall make a decision to exclude ~~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 any policies and guidelines which may have been established by the entities educational system authorities having jurisdiction over the school proposing to exclude the student. The exclusion ~~must~~ 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 repre-

sentative from that agency may be included. ~~The director shall approve of~~ 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.

§ 64-64-12. Requirement for All Health Care Providers to Report Positive Serologic and Other Tests for the Human Immunodeficiency Virus.

12.1. 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 ~~Administrator~~ director on forms provided by the ~~Administrator~~ director for that purpose as follows:

12.1.1. All positive (reactive) ~~serologic antibody tests for HIV~~ laboratory test results; and

12.1.2. ~~All positive (reactive) laboratory tests for the identification of HIV;~~ and All clinical status data.

~~11.1.(e) All other positive laboratory test results which identify the presence of HIV;~~

12.2. These health care provider reports shall include:

12.2.1. The name and full address of the laboratory;

12.2.2. The name of the ~~test~~ tests performed, the date each test was performed and the ~~result~~ results of the tests;

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

12.2.4. The name of the confidentially tested or the identification code of the anonymously tested individual; ~~tested and, if available, his or her, sex, age and address; and~~

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

12.2.6. ~~The signature of the health care provider.~~ Social and risk factor information of the patient relative to HIV infection; and

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

64 CSR 64

12.3. Reports of HIV infection ~~the above named laboratory tests~~ shall be submitted within ~~fifteen (15)~~ thirty (30) days of the receipt of such positive (reactive) test results.

12.4. 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.

12.5. The ~~Administrator~~ director shall work with an individual's health care provider in ~~for~~ any follow-up of reported ~~the reports of~~ positive laboratory tests or HIV infection.

12.6. 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.

12.7. The reports of all ~~positive tests~~ HIV infection submitted in compliance with this rule are ~~deemed confidential~~ protected and are exempt from public disclosure under the exemption for medical records contained in ~~Chapter 29B of the West Virginia Code~~ W. Va. Code § 29B-1-1 et seq., the Freedom of Information Act: Provided, That the reports ~~shall be~~ are subject to the provisions of W. Va. Code § 16-3C-1 et seq. ~~Such~~ 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.

§ 64-64-13. Requirement for Laboratories to Report Positive Serologic and Other Tests for the Human Immunodeficiency Virus.

13.1. 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 ~~Administrator~~ director on forms provided by the ~~Administrator~~ director for that purpose as follows:

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

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

and

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

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

13.2. These reports shall include:

64 CSR 64

13.2.1. The name and full address of the laboratory;

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

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

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

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

13.2.6. The signature of the supervisor of the laboratory.

~~13.3. Reports of the above named laboratory tests shall be submitted on the first and fifteenth days of each month. 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.~~

~~13.4~~ 13.4. If no reportable tests are performed during a reporting period, a statement to this effect shall be submitted by the supervisor of the laboratory.

~~13.5~~ 13.5. The ~~Administrator~~ director shall work with an individual's health care provider in any follow-up of the reports of positive laboratory tests.

13.6. The reports of all positive tests submitted in compliance with this rule are ~~deemed confidential~~ protected and are exempt from public disclosure under the exemption for medical records contained in ~~Chapter 29B of the West Virginia Code~~ W. Va. Code § 29B-1-1 et seq., the Freedom of Information Act: ~~Provided, That the reports shall be~~ are subject to the provisions of W. Va. Code § 16-3C-1 et seq. ~~Such~~ 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.

§ 64-64-14. Quality Control of Laboratories Conducting HIV Tests.

14.1. Laboratories Required to be Approved.

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

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

14.1.2.a. Show that it complies with the applicable requirements of W.

Va. Code § 16-3C-1 et seq. and this rule; and

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

14.1.2.c. Be certified for high complexity tests under CLIA-88.

14.1.3. A laboratory located outside of West Virginia ~~will~~ is be eligible for approval only if it is ~~licensed~~ approved for high complexity testing by the federal government under the ~~Clinical Laboratories Improvement Act (CLIA) of 1967~~ 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)).

14.2. 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 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.~~

14.3. Quality Control Standards.

A laboratory requesting approval ~~must~~ 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. ~~Such~~ The demonstration shall be evidenced, when applicable, in part by:

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

14.3.2. Use of controls and calibrating standards;

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

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

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

14.3.6. 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.

14.4. Proficiency Testing

Laboratories shall participate in a proficiency testing program approved by the division. ~~Such~~ 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.

14.5. On-site Inspection

~~The director may conduct~~ an on-site inspection to determine compliance with this rule ~~shall be conducted~~ initially prior to approval, and ~~on an annual basis~~ 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 ~~such~~ as deemed ~~judged~~ necessary during operating hours in order to conduct ~~such~~ the inspections.

14.6. Certificate of Approval; Revocation.

14.6.1. ~~The director shall issue~~ certificates of approval for ~~the performance of~~ a laboratory to perform HIV testing ~~shall be issued~~ upon initial approval and on an annual basis thereafter pursuant to the conditions listed ~~herein~~ in this rule. Certificates issued ~~will~~ 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.

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

14.6.3. ~~The director may revoke or suspend a laboratory's approval may be revoked or suspended upon~~ if the laboratory:

14.6.3.a. ~~Performs unsatisfactory performance~~ unsatisfactorily in on-site inspections;

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

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

14.6.3.d. ~~Closure of the laboratory~~ Closes.

§ 64-64-15. Banking Blood.

The health care provider or a private, public, or nonprofit blood bank shall, upon

64 CSR 64

request, store and bank a person's blood and the health care provider shall use ~~such~~ the blood in the elective surgery or medical procedure to the extent ~~such~~ the blood is available.

§ 64-64-16. 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.

§ 64-64-17. Severability.

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



FILED

JAN 19 2 13 PM '96

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

West Virginia Legislature
Legislative Rule-Making Review Committee

Room MB47-State Capitol
Charleston, West Virginia 25305
(304) 347-4840

Senator Mike Ross, Co-Chair
Delegate Vicki Douglas, Co-Chair

January 9, 1996

Debra A. Graham, Counsel
Joe Altizer, Associate Counsel
Marie Nickerson, Admr. Assistant

RECONSIDERED

NOTICE OF ACTION TAKEN BY LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

TO: Ken Hechler, Secretary of State, State Register
TO: Ms. Gretchen G. Lewis, Secretary
Dept. of Health and Human Resources
Capitol Complex, Bldg. 3
Charleston, WV 25305

FROM: Legislative Rule-Making Review Committee

PROPOSED RULE: AIDS - Related Medical Testing and Confidentiality

The Legislative Rule-Making Review Committee recommends that the West Virginia Legislature:

- 1. Authorize the agency to promulgate the Legislative Rule
 - (a) as originally filed
 - (b) as modified by the agency
- 2. Authorize the agency to promulgate part of the Legislative rule; a statement of reasons for such recommendation is attached.
- 3. Authorize the agency to promulgate the Legislative rule with certain amendments; amendments and a statement of reasons for such recommendation is attached.
- 4. Authorize the agency to promulgate the Legislative rule as modified with certain amendments; amendments and a statement of reasons for such recommendation is attached.
- 5. Recommends that the rule be withdrawn; a statement of reasons for such recommendation is attached.

 X

Pursuant to Code 29A-3-11(c), this notice has been filed in the State Register and with the agency proposing the rule.

cc: Kay Howard
Regulatory Development

64-64