

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

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OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

Form #3

**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE
AND
FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE**

AGENCY: Division of Health, Dept. of Health & Human Resources TITLE NUMBER: 64

CITE AUTHORITY W. Va. Code §§16-3C-2(e)(2), 16-3C-8 and 16-1-7

AMENDMENT TO AN EXISTING RULE: YES NO

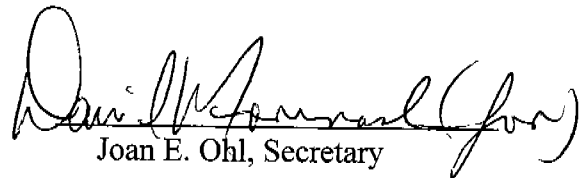
IF YES, SERIES NUMBER OF RULE BEING AMENDED: 64

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

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: _____

TITLE OF RULE BEING PROPOSED: _____

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE FOR THEIR REVIEW.


Joan E. Ohl, Secretary

\$12.30

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: November 16, 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 was 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 X No comments received _____

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

12/1/98

- 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

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.

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.

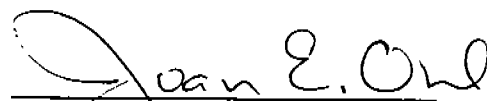
Costs for testing, counseling and initial prophylactic treatment for the first six months after the significant exposure of a medical or emergency responder will be the responsibility of the responder's employer. It is unknown how many medical or emergency responders will be significantly exposed to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

64CSR64

AIDS-Related Medical Testing and Confidentiality

Commenters

Betty Hicks, Bluefield Regional Medical Center, 500 Cherry Street, Bluefield, WV 24701

Sharon Self, Infection Control Practitioner, City Hospital, Dry Run Road, Martinsburg, WV 25402

Cynthia Rinaldi, Correctional Medical Services< Mount Olive Correctional Complex, 1 Mountainside Way, Mount Olive, WV 25185

Linda Roach, Plateau Medical Center, 430 Main Street, Oak Hill, WV 25901

Rose Anne Michaels, Plateau Medical Center, 430 Main Street, Oak Hill, WV 25901

Brian Henry, Advocacy Group, P.O. Box 6162, Charleston, WV 25362-0162

Martha Hardman, Infection Control Practitioner, Roane General Hospital, 200 Hospital Drive, Spencer, WV 25276

Plateau Medical Center Home Care Services Staff, 430 Main Street, Oak Hill, WV 25901

Kathleen Martin, Beckley Appalachian Regional Hospital, Beckley, WV 25801

Number of Pages
(Including Cover Sheet)

Fax to number:
558-1130

HERE'S THE FAX!

Attention: Loretta Haddy, Director Division of Surveillance and Disease Control
Jerry Arnold, Office of Gen Counsel
Business: Dept of HHS

Message: Comments Concerning Proposed
Legislative Rule 64 CSR 64
pg 8 + page 10 (see copy comments)

From: Betty Hicks Infection Control BLMC

CONFIDENTIALITY NOTICE: Unless otherwise indicated or obvious from the nature of the transmittal, the information contained in this facsimile message is confidential and is intended solely for the use of the individual or entity named above. If the reader of this message is not the intended recipient, or the employee or agent responsible to deliver it to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please immediately notify the sender by telephone and return the original message to the sender. Thank you.

If this copy is illegible or incomplete, please call (304) 327-1178



Betty Hicks
INFECTION CONTROL PRACTITIONER
(304) 327-1723

500 CHERRY STREET • BLUEFIELD, WEST VIRGINIA 24701
(304) 327-1100 • FAX (304) 327-7293

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64 CSR 64

ation concerning AIDS and HIV-related testing and counseling.

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."

*Is this defined as m.d.'s facility
wants JCP to do followup.
would this be acceptable?
for house supervisors*

§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.

*why to
hospital
or
representative?
professional*

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

64 CSR 64

? nuclear?

such as
by
William

ance of the test and release of the results are documented on a form provided by the
on 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 in the criminal
prosecution.



HEALTHCARE
EXCELLENCE
IN A
CARING
ENVIRONMENT

October 20, 1998

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

Re: Amendment to WV AIDS-Related Medical Testing and Records Confidentiality Act

Dear Mr. Arnold,

Please consider the following regarding the proposed rule amendments:

1. Rule 64-64-3. Definitions.

3.3. Page 2: Deleting this definition as "ARC" is an obsolete term and may cause confusion.

3.21. Page 3: Replacing the term "ARC" with "opportunistic infection related to HIV immunosuppression."

3.28.b. Page 5: Replacing "universal" precautions with "standard" precautions, as "universal" is considered an obsolete term. The most recent CDC recommendations use the language "standard" and "transmission-based precautions."

2. Rule 64-64-4. Testing.

4.2.a.2.C. Page 7: Please consider replacing "assessing clinician" with "Health Care Provider" in lines three and five.

Requiring an assessing clinician (i.e., physician, NP, PA) to complete an assessment of the injury and document that there has been a significant exposure prior to beginning the process to obtain a source patient result, will greatly increase the time involved in providing Post Exposure Prophylaxis (PEP) to an injured employee in an emergent situation in which all involved are trying to work within a two hour time frame. As the decision to administer PEP is most efficiently provided within two hours, it would benefit the exposed worker if the decision to request HIV testing from a source patient could be made within minutes by an assessing Health Care Provider as defined in 3.17.

This would allow a decision on the need for source patient HIV testing to be made immediately after the event by persons such as an Employee Health Practitioner, or an Infection Control Coordinator, etc. This Health Care Provider could also complete the necessary documentation on the exposed employee treatment record.

This course of action does not negate the need for a clinician, as the primary care giver, to diagnose or prescribe treatment, but rather simply assists with the assessment of the injury and decreases the amount of time necessarily used in obtaining a source patient HIV result

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when that result may be critical in the treatment decision. (At CHI a laboratory technician must be called in, stat, between 4 pm and 8am to complete source patient HIV testing. Requiring a clinician to first assess and document prior to implementing the process to obtain those results, or completing the testing, will do little more than delay the availability of the results.)

This Health Care Provider could/would also be responsible for documenting the efforts made to obtain consent from the source patient, complete the required state form, and report the results to the division in a confidential envelope.

3. Rule 64-64-8. Post-Exposure Care and Treatment.

8.1. Page 10: Consider revising line one to include: "...a knowledgeable trained Health Care Provider and/or clinician to assess the HIV exposure risk of medical or emergency responders during all working hours, including nights and weekends." Again, this inclusion would allow for the assessment to be assisted or completed by a health care provider other than the clinician whose time is most at a premium.

8.5. Page 10: Consider amending to the following to clarify: "Costs of.....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 when no coverage is afforded by a Workers' Compensation or similar job-related employee benefit program. However, costs of subsequent treatment and post-exposure HIV-related testing beyond six months are not required to be borne by the employer when the employee tests negative for HIV antibodies at the time of injury and up to and including the CDC recommended six month post-exposure HIV antibody screening subsequent to the work related exposure event."

Thank you for considering these comments regarding the proposed rules.

Sincerely,



Sharon L. Self, RN, MS, CIC
Infection Control Coordinator

cc: P. Mulford
S. Cleaver
N. Gain

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HHS
10 OCT 22 11:11 AM '98

10 OCT 22 11:11 AM '98

CLERK

Correctional Medical Services
Mount Olive Correctional Complex
1 Mountainside Way
Mount Olive, WV 25185
304-442-2250 Phone
304-442-2766 Fax

**CORRECTIONAL
MEDICAL SERVICES**

Fax

LARRY ARNOLD

To: ~~Loretta Haddy~~ From: Cynthia Rinaldi
Fax: ~~304 558-6335~~ Pages: 4
Phone: 558-1130 Date: ~~8/31/98~~ 10-23-91
Re: CC:

Urgent For Review Please Comment Please Reply Please Recycle

Loretta, 8/31/98
Comments/questions on final draft
of HIV Legislative Rule
Cynthia

9/9/98
Hard copy - same material that
was faxed to you on 8/31/98.
If you have questions, call me
Cynthia

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

*you've already defined "body fluids" in 3.4A+B
I don't think this is...*

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;

4.2.a.2.C. The test results are necessary for medical diagnostic purposes to provide appropriate emergency care or treatment; and

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 shall be 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 any 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. Unless written consent is obtained, None of the above activities will be documented in the source patient's medical record. Confidentiality will 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

medically necessary to determine the course of treatment for the exposed medical or emergency responder.

8.4. 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.

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

8.6. 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, the counseling and initial prophylactic treatment shall be borne by the employer of the medical or emergency responder. However, costs of subsequent treatment and post-exposure HIV-related testing beyond six months shall not be borne by the employer.

*WC
Who pays
for volun-
& good
 Samaritans
?*

8.7. 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.

9.2

*Shouldn't reference
be to section 9.2, not
7?*

§ 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.

SENT BY:PMC

3044698605
:10-23-98 : 9:04 : Plateau Medical →

304 558 1130:# 2/ 3

**Plateau Medical
Center, Inc.**

430 Main Street

Oak Hill, WV 25901

Phone (304) 469-8600

Fax (304) 469-8605

An Affiliate of
Heritage Health
System, Inc.

Larry Arnold, Attorney, Office of General Counsel
Department of Health and Human Resources
Building 3 Room 265, Capitol Complex
Charleston, WV 25301

October 23, 1998

Changes to Legislative Rule Title 64, Series 64 - "Aids-Related Medical Testing and Confidentiality"

I would like to submit the following comments in regards to the above mentioned proposed rule.

1. In 4.2.a.2 a "treating physician" is required to determine exposure. Many facilities have an alternative healthcare professional already functioning in this capacity. Can this wording be amended.
2. Define "assessing clinician" in 4.2.a.2.C. Is this the same physician listed in 4.2.a.2 or can this be another healthcare professional.
3. I believe Section 4.2 should specifically address the testing, without consent, of source specimen if blood is already available in the laboratory. In speaking with members of the Panel that reviewed the changes, other states have this type of situation defined specifically in their laws. I believe, from the standpoint of a lay person trying to interpret what is meant in this rule, it would be very beneficial to have this spelled out.
4. What is considered a "reasonable attempt" (4.2.a.2.B and 4.2.a.2.E) when you are working under very strict time factors to offer an employee post-exposure prophylaxis within hours of an incident?
5. Without documentation in the source patient's medical record, it would become very difficult to provide the source with a copy of that record at a later date. If all of the information is in the employee file, the source would have to know the employee name for us to track their records. Given the fact that the patient record is already protected by 64-64-7 and 64-64-9 we believe is an unfair burden on the facility to develop a more elaborate tracking method.

SENT BY:PMC

3044698605
:10-23-98 : 9:05 : Plateau Medical →

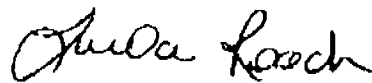
304 558 1130:# 3/ 9

6. Section 8.5 requires the employer to pay for testing and treatment for six months post-exposure. The CDC only recommends prophylaxis for four weeks post-exposure. Therefore, any treatment regimens recommended by a physician beyond this period should be considered experimental and not our responsibility.

7. I would have been totally unaware of these changes had it not been for attending an Association for Professionals in Infection Control and Epidemiology (APIC) meeting on September 18 where two members of the review Panel were present. I called the Health Department, Aids Surveillance Division, to obtain the address to send comments and was told to wait until my Administrator received a notice. No notice has been sent to our facility to date. I obtained your fax number from one of the above Panel members. Per my discussion with her, she tried to get it from WV-AHA and was told they had not been notified. She eventually got it from her regional AIDS Surveillance contact person. I would hope in the future when such changes are being presented, that more effort is put into distributing the materials to the appropriate persons in a timely fashion.

Thank you for your time in reviewing these comments.

Respectfully,



Linda Roach BSMT(ASCP) CIC
Infection Control Coordinator

cc: Hank Woodson, COO

SENT BY:PMC

3044598605

:10-23-98 : 10:45 : Plateau Medical →

304 558 1130:# 2/ 3

Larry Arnold, Attorney, Office of General Counsel
Department of Health and Human Resources
Building 3 Room 265, Capitol Complex
Charleston, WV 25301

October 23, 1998

Changes to Legislative Rule Title 64, Series 64 - "Aids-Related Medical Testing and Confidentiality"

As the Employee Health Nurse for Plateau Medical Center, I am concerned about all aspects of the above topic. Please review the following points for consideration

1. In 4.2.a.2 a "treating physician" is required to determine exposure. Many facilities have an alternative healthcare professional already functioning in this capacity, such as me, the Employee Health Nurse.
2. Define "assessing clinician" in 4.2.a.2.C. Is this the same physician listed in 4.2.a.2 or can this be another healthcare professional. Same as above, an Employee Health Nurse is competent to assess.
3. I believe Section 4.2 should specifically address the testing, without consent, of source specimen if blood is already available in the laboratory. In speaking with members of the Panel that reviewed the changes, other states have this type of situation defined specifically in their laws. I believe, from the standpoint of a lay person trying to interpret what is meant in this rule, it would be very beneficial to have this spelled out.
4. What is considered a "reasonable attempt" (4.2.a.2.B and 4.2.a.2.E) when we are working under very strict time factors to offer an employee post-exposure prophylaxis within hours of an incident?
5. Without documentation in the source patient's medical record, it would become very difficult to provide the source with a copy of that record at a later date. If all of the information is in the employee file, the source would have to know the employee name for us to track their records. Given the fact that the patient record is already protected by 64-64-7 and 64-64-9 we believe is an unfair burden on the facility to develop a more elaborate tracking method.

98-2111 88 100 86

CLARENCE

Larry Arnold, Attorney, Office of General Counsel
Department of Health and Human Resources
Building 3 Room 265, Capitol Complex
Charleston, WV 25301

October 23, 1998

Changes to Legislative Rule Title 64, Series 64 - "Aids-Related Medical Testing and Confidentiality"

As the Employee Health Nurse for Plateau Medical Center, I am concerned about all aspects of the above topic. Please review the following points for consideration

1. In 4.2.a.2 a "treating physician" is required to determine exposure. Many facilities have an alternative healthcare professional already functioning in this capacity, such as me, the Employee Health Nurse.
2. Define "assessing clinician" in 4.2.a.2.C. Is this the same physician listed in 4.2.a.2 or can this be another healthcare professional. Same as above, an Employee Health Nurse is competent to assess.
3. I believe Section 4.2 should specifically address the testing, without consent, of source specimen if blood is already available in the laboratory. In speaking with members of the Panel that reviewed the changes, other states have this type of situation defined specifically in their laws. I believe, from the standpoint of a lay person trying to interpret what is meant in this rule, it would be very beneficial to have this spelled out.
4. What is considered a "reasonable attempt" (4.2.a.2.B and 4.2.a.2.E) when we are working under very strict time factors to offer an employee post-exposure prophylaxis within hours of an incident?
5. Without documentation in the source patient's medical record, it would become very difficult to provide the source with a copy of that record at a later date. If all of the information is in the employee file, the source would have to know the employee name for us to track their records. Given the fact that the patient record is already protected by 64-64-7 and 64-64-9 we believe is an unfair burden on the facility to develop a more elaborate tracking method.

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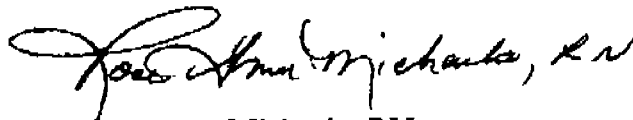
11

- 6. Section 8.5 requires the employer to pay for testing and treatment for six months post-exposure. The CDC only recommends prophylaxis for four weeks post-exposure. Therefore, any treatment regimens recommended by a physician beyond this period should be considered experimental and not our responsibility.

As the Employee Health Nurse for this facility, my main objective is to provide prompt, quality care to any employee who suffers an exposure. Only realistic and fair laws will allow me to do this.

Thank you for your time in reviewing these comments.

Sincerely,



Rose Anne Michaels, RN

cc: Cyndy Sundstrom, RNC Dir. QA/Risk Management, Home Health

RECEIVED
 HEALTH SERVICES
 DIVISION
 10/23/98

98 OCT 23 AM 12:33

RECEIVED

10.22.1998

To: L. Arnold

Office of General Counsel, WV DHHS Bldg. 3, room 265

From: Brian Henry PO box 6162 25362 -0162

Re: Comments on a amendment to HIV Legislative Rules in W.Va.

The panel process itself which drafted the amendments was disappointing, though not surprising. In typical fashion the state catered to the medical community while disregarding and disrespecting the concerns of people with HIV and/or people perceived to have HIV. Any discussion on the Partner notification component was unwelcomed.

Regarding HIV antibody testing and Post Exposure Prophylaxis, I disagree with testing anyone without their consent as this is a clear violation of the "source patients" constitutional right to privacy and a breach of their confidentiality when the testing results are provided to others without consent.

This seems unnecessary, as any health care worker, EMT, private citizen, etc. who experiences a significant blood exposure in a health care setting can and should get baseline HIV ab testing and counseling and proceed with post exposure prophylaxis, regardless of the source patients known or perceived HIV status or their willingness to consent to testing.

Thank you

RECEIVED
OCT 23 11:01 AM '98

Martha Hardman
104 Deerfield Road
Spencer, WV 25276

October 23, 1998

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

Mr. Arnold:

As an infection control professional, I am glad to see that the West Virginia AIDS-Related Medical Testing and Confidentiality Rule is being amended to address health care worker exposure and HIV testing without patient consent following exposure. I also anticipate many questions related to the Rule and would like to comment on the following sections that I feel need clarification:

- **4.2 Consent Not Required**

I think it is important to clarify that testing without consent will be done on a blood sample that is already available. For example, in a draft of the Florida law, language addressing testing without consent includes the phrase "and where a blood sample is taken from that individual voluntarily by medical personnel for other purposes" and "If the individual cannot be found, an HIV test may be conducted on the available sample." (Emphasis added). Even the OSHA Bloodborne Pathogen law (*Federal Register* Vol. 56, No. 235; December 6, 1991) says:

When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented. (Emphasis added).

Including this language may help avoid questions about what recourse to follow when a sample is not available. Is the intent to refer to paragraph 4.2.b where the director "may require an HIV test?"

- **Process to Follow for an Unconscious Patient**

The CDC guidelines (Public Health Service Guidelines for the Management of Health-Care Worker Exposures to HIV and Recommendations for Postexposure Prophylaxis; *MMWR*, May 15, 1998) say that "If consent cannot be obtained (e.g., patient is unconscious), procedures should be followed for testing source persons according to applicable state and local laws." The Rule should address the unconscious patient specifically and make clear that the law covers this issue.

Martha Hardman
104 Deerfield Road
Spencer, WV 25276
October 23, 1998 Page 2

- **Source Patient Transferred**
In the event a source patient is transferred to another facility before attempts at counseling and consent can be made, is the original hospital enabled by the Rule to test an available blood sample? If the source patient is contacted through the receiving hospital and refuses to give consent, can the requirements in 4.2.a.2D, 4.2.a.2E, and 4.2.a.2F be met?
- **Confidentiality**
The section on confidentiality should include a statement saying that HIV test results of the source patient may be given to the exposed person. The Florida law has done this by saying that no person may disclose test results, "except to the following persons:"
 - Medical personnel who have been subject to a significant exposure during the course of medical practice or in the performance of professional duties, or individuals who are the subject of the significant exposure...The OSHA Bloodborne Pathogen law says:
 - Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

Thank you for the opportunity to make comments on the Rule and for your consideration.

Sincerely,

Martha Hardman
Martha Hardman, BSMT (ASCP), CIC
Director of Infection Control and Safety
Roane General Hospital
200 Hospital Drive
Spencer, WV 25276
927-4444 Fax 927-6367
E-mail martha.hardman@pihn.org

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OCT 23 1998

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OSWALDEN

Larry Arnold, Attorney, Office of General Counsel
 Department of Health and Human Resources
 Building 3 Room 265, Capitol Complex
 Charleston, WV 25301

October 23, 1998

Changes to Legislative Rule Title 64, Series 64 - "Aids-Related Medical Testing and Confidentiality"

The members of the nursing staff at PMC Home Care Services would like to express our views related to the above mentioned proposed rule. We feel that any legislation related to this subject directly affects Home Health and are obliged to voice our opinion.

1. In 4.2.a.2 a "treating physician" is required to determine exposure. Many facilities have an alternative healthcare professional already functioning in this capacity. Can this wording be amended to the term used by OSHA, LICENSED HEALTHCARE PROFESSIONAL?
2. Define "assessing clinician" in 4.2.a.2.C. Is this the same physician listed in 4.2.a.2 or can this be another healthcare professional.
3. We believe Section 4.2 should specifically address the testing, without consent, of source specimen if blood is already available in the laboratory.
4. What is considered a "reasonable attempt" (4.2.a.2.B and 4.2.a.2.E) when you are working with a home health patient some distance from the main facility under very strict time factors to offer an employee post-exposure prophylaxis within hours of an incident?

Thank you for your attention to this issue.

PMC HOME CARE SERVICES STAFF

Cynda Sundstrom, RNC, Administrator
Theresa Dain, RN
Ann Michalek, RN
Rosie Kelly, RN
Mina Logan, RN

cc: Cynda Sundstrom, RNC, Dir. QA/Risk Mgmt, Dir. Home Health

Grand Selye
Gail Settem, RN, MSN
Patricia King, RN
Debra Beck, RN
Debra McCallister, RN
Terry Rineard, RN

From: Kathy Martin <kmartin@arh.org>
To: ""Larry Arnold <|Arnold@WVDHHR.org>"" <Larry Arno...
Date: Fri, Oct 23, 1998 11:48 AM
Subject: Comment

Mr. Arnold,

I would like to make a couple of comments on the proposed rule AIDS-Related Medical Testing and Confidentiality 64CSR64. I have been employed in Infection Control and Employee Health for several years and have dealt frequently with employee exposures.

3.28.c - Does this definition include open cuts? We have had employees get blood or body fluids splashed into open cuts that I have followed-up as exposures.

Add out to list

4.2.a.1.F-H - I am concerned by where we are to document the post-test counseling, and the test results of the source patient, particularly if they are positive. Physicians, healthcare workers, and funeral homes have a need to know if the patient's HIV is positive so that they can protect themselves and others, try to prevent its spread to a fetus or child, and suspect, diagnose, and treat the other disease entities that go along with the HIV virus. Could the test results be put in the medical records of both source patient and exposed healthcare worker, and the post-test counseling be documented in the source patient's chart?

Not in language need

Thank you for allowing me to comment.

Kathleen Martin, RN CIC
 Infection Control/Employee Health Coordinator
 Beckley Appalachian Regional Hospital
 Beckley, WV 25801

and how to chart results, etc
from the source patient.
we want to encourage exposure situation
intent for this language is to prevent source patient from any unnecessary disinfecting services are documented
the exposed employees
issues. In an exposure situation
addresses these
the rest of the
If pat is ⊕
this section

Responses to Comments and Changes Made as a Result of the Public Comment Period

A public comment period on the proposed rule, **AIDS-Related Medical Testing and Confidentiality, 64CSR64**, was held beginning September 17, 1998, and ending October 23, 1998.

Comment: Comments were received regarding the statute -- one dealing with privacy rights of the source patient and the other dealing with ARC (AIDS-Related Complex).

Response: This rule cannot change the statute.

Comment: Without documentation in the source patient's medical record, it would become very difficult to provide the source with a copy of that record at a later date. If all of the information is in the employee file, the source would have to know the employee name for us to track their records. Given the fact that the patient record is already protected by 64-64-7 and 64-64-9, we believe it is an unfair burden on the facility to develop a more elaborate tracking method.

Response: It is not understood why the source patient would want or need the information regarding the exposed employee. Therefore, no tracking system should be required of any facility.

§3.28.b. **Comment:** A commenter:

- 1) Questioned the use and interpretation of the definition of the word "body fluids"; and
- 2) requested a change of "universal precautions" to "standard precautions."

Response: 1) The interpretation of body fluids throughout this rule is as defined in §§3.4.a. and 3.4.b; and

2) this change is made.

§3.28.c. **Comment:** Questioning whether the definition of significant exposure includes open cuts.

Response: "Open cuts" are added to the definition.

§4.2 **Comment:** Commenters feel it is important to clarify that testing without consent be done on a blood sample that is "already available."

Response: To make it explicit that the testing authorized in §4.2.a.2 includes the testing of available blood, a statement to that effect is added.

§4.2.a.2. **Comment:** In the event a source patient is transferred to another facility before attempted counseling and treatment, is the original hospital enabled by this rule to test an available blood sample? Also, if the source patient is contacted through the receiving hospital and refuses to give consent, can the requirements in 4.2.a.2.D. , 4.2.a.2.E., and 4.2.a.2.F. be met?

Response: The answer to the first question is yes, without consent of the source patient, if the requirements of §4.2 are met. All the attempts and services outlined in the sections cited will have to be coordinated between the two hospitals, because the receiving hospital may have to counsel the source patient while the original hospital is performing the test, completing the form and making the information available to the receiving hospital to make the results available to the source patient if he or she wants them.

§4.2.a.2. **Comment:** A commenter wants to include a new section regarding process to follow for an unconscious patient.

Response: Section 4.2.a.2. already sets out the process in the case of a subject unable (unconscious) or unwilling to consent.

§4.2.a.2.B. The subparagraph was clarified regarding “a reasonable attempt” to obtain consent from any legal representative of a subject who is unable to grant or withhold consent, and the subparagraph was broken down into §§4.2.a.2.B.1 and 4.2.a.2.B.2.

§4.2.a.2.C. **Comment:** Consider replacing “assessing clinician” with “health care provider.”

Response: The replacement is made in §§4.2.a.2.C and 8.

§ 4.2.a.2.E. **Comment:** The term “reasonable attempt” needs clarification.

Response: The following words are added as an example of a reasonable attempt: “such as telephoning or personal contact.”

4.2.a.2.F-H. **Comment:** A commenter asked whether the HIV test results (especially if positive) could be charted in medical records of both the source patient and exposed health care worker and asked whether the post-test counseling could be documented in the source patient’s chart.

Response: No additional language is needed in this section. If the patient is positive, other sections of the rule address these issues, such as when to chart results, the right to know, etc. In an exposure situation, consent from the source patient is to be

encouraged. The intent of the language is to prevent the source patient from facing any unnecessary discrimination. The exposed employee's services are what need to be documented as they were not addressed in this rule until the new language was added.

§4.2.a.2.H. **Comment:** Add the words "unless written consent is obtained" in front of the first sentence.

Response: It is not necessary to add these words, because if the individual gives consent for testing, the results will be documented in the source patient's medical record under language spelled out in §7, "Charting Information."

§4.2.b. **Comment:** Is the intent of that section to mean the director may require an HIV test?

Response: Yes.

§8. **Comment:** A commenter questions the use of the words "knowledgeable trained clinician" and comments that the commenters' facility wants an infection control practitioner to perform this responsibility.

Response: Since the term "clinician" is not defined in this rule, it is changed to "health care provider" as defined in §3.17. Refer to §8.1 for what this "knowledgeable trained clinician" is supposed to assess.

§8.1. **Comment:** Consider line one to include "health care provider"

Response: The word "clinician" is replaced with the term "health care provider."

§8.5. **Comment:** Suggestion to amend as follows: "Costs of.....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 when no coverage is afforded by a Workers' Compensation or similar job-related employee benefit program. However, costs of subsequent treatment and post-exposure HIV-related testing beyond six months are not required to be borne by the employer when the employee tests negative for HIV antibodies at the time of injury and up to and including the CDC recommended six month post-exposure HIV antibody screening subsequent to the work related exposure event."

Response: The subsection was rewritten incorporating in substance the commenter's suggested language.

§8.5 **Comment:** Regarding the employer paying for six months of treatment, commenters state: "The CDC only recommends prophylaxis for four weeks post-

exposure. Therefore, any treatment regimens recommended by a physician beyond this period should be considered experimental and not our responsibility.”

Response: The comment was taken into account in the rewriting of the subsection.

§8.5. **Comment:** Individuals questioned who pays for the testing and treatment of volunteers and good Samaritans.

Response: This rule does not change the present state of affairs with regard to volunteers; namely, the cost will be borne by the volunteers, the volunteers’ health insurance companies, or health care providers’ charity care or bad debt writeoffs.

§8.6. **Comment:** Questioning the use of disclosure as used in §7 asking if this is a mistake and did we mean §9.2.

Response: No, §7 is the first place in 64CSR64 where the disclosure statement is made; therefore, it is the appropriate reference for the disclosure statement.

§9. **Comment:** Section on confidentiality should include a statement that HIV test results of the source patient may be given to the exposed person.

Response: Agree. A new §9.5 will be added to read as follows: HIV test results may be disclosed to medical or emergency responders who have been subject to a significant exposure during the course of medical practice or in the performance of professional duties. The medical or emergency responder is subject to the requirements of the disclosure statement contained in Section 7 of this rule and to the remedies and penalties provided in W. Va. Code § 16-5C-5.

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

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

**AGENCY APPROVED PROPOSED RULE
FOR REVIEW BY THE
LEGISLATIVE RULE-MAKING REVIEW COMMITTEE**

64 CSR 64

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

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

TABLE OF CONTENTS

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

§64-64-17. Administrative Due Process 17

~~§64-64-18. Severability 18~~

FILED

TITLE 64
LEGISLATIVE RULES
DIVISION OF HEALTH

Dec 1 9 25 AM '98

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 sources 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. --

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 an 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. --

64 CSR 64

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

3.28.b. Exposure of mucous membranes to visible blood or body fluids, to which standard 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 has an open cut, 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 are 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, whether the test subject's blood is to be obtained or is already available: 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, such as telephoning or personal contact, is made to:

4.2.a.2.B.1. Identify and contact the subject's close relatives to determine if the subject has a legal representative; and,

4.2.a.2.B.2. Contact and obtain consent from the legal representative, if any;

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 a health care provider, 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, such as telephoning or personal contact, 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 of the criminal prosecution.

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

4.3.c. The director shall request access to all convicted sex offenders who test HIV positive for the purposes of contact notification consultation under the direction of the director. Contact notification information obtained from the convicted sex offender is protected information and shall be used by the director solely for referring individuals with a potential HIV exposure to HIV counseling and testing sources.

4.3.d. The director shall set the level of reimbursement the division 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 health care provider 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. The employer of a medical or emergency responder who was exposed while performing a duty of his or her employment shall bear the costs of HIV tests of blood samples of the source patient and the responder, unless a workers' compensation or other benefit program

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

8.6. Relative to the management of source patient medical information, the medical or emergency responder reporting a significant exposure is subject to the requirements of the disclosure statement contained in 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.

9.5. HIV test results may be disclosed to medical or emergency responders who have been subject to a significant exposure during the course of medical practice or in the performance of

professional duties. The medical or emergency responder is subject to the requirements of the disclosure statement contained in Section 7 of this rule and to the remedies and penalties provided in W. Va. Code § 16-5C-5.

§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 ad-

dress, 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 HIV infection consultation. If an individual who has been tested anonymously, either makes his or her identity known to the provider or rescinds the request for anonymity, the provider shall report the name to the director.

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

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

64 CSR 64

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 the specimen;

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 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.

64 CSR 64

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.~~