WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

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OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

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

AGENCY: Division of Health TITLE NUMBER: 64

CITE AUTHORITY §16-3C-8

AMENDMENT TO AN EXISTING RULE: YES___ NO X

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

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

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

THE ABOVE 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.

George W. Lilley, Jr., Ed.D.
Acting Administrator

WEST VIRGINIA DEPARTMENT OF HUMAN SERVICES

Building 6, Capitol Complex

Gaston Caperton
Governor

Charleston, WV 25305

Telephone (304) 348-2400

Taunja Willis Miller
Commissioner

August 14, 1989

George W. Lilley, Jr., Ed.D.
Acting Administrator
Division of Health
Building 3, Room 206
Charleston, West Virginia 25305

Re: Proposed Rule - AID Related
Medical Testing and Confidentiality

Dear Dr. Lilley:

As Secretary of the Department of Health and Human Resources, I hereby approve the attached rules, described above. You may submit a copy of this approval letter to the Legislative Rule-Making Committee.

Very truly yours,

Taunja Willis Miller
Secretary
Department of Health
and Human Resources

TWM/jah

Attachment

FISCAL NOTE FOR PROPOSED RULES

Rule Title: AIDS-Related Medical Testing and Confidentiality

Type of Rule: X Legislative _____ Interpretive _____ Procedural

Agency Health Address 1800 Washington Street, East
Charleston, West Virginia 25305

1. Effect of Proposed Rule	ANNUAL Increase	ANNUAL Decrease	FISCAL YEAR Current	FISCAL YEAR Next	FISCAL YEAR Thereafter
Estimated Total Cost	$	$	$	$ 308,000	$ 301,000
Personal Services				138,200	143,000
Current Expense				149,800	155,000
Repairs and Alterations					
Equipment				20,000	3,000
Other					

2. Explanation of above estimates.

The estimated cost of rule implementation and maintaining support activities includes personnel funding for a coordinator, a field investigator, a lab technician, two health educators, a secretary and a data entry person. Current expenses reflect monies for travel ($12,000), supplies ($13,000), a contracted expense for HIV testing and associated counseling and follow-up ($100,000) and other expense costs of $22,800 for such costs as postage ($2,000), printing ($3,000), office space ($8,300), telephone ($500) and utilities ($3,000), etc. Equipment estimate includes laboratory and office needs.

3. Objectives of these rules:

- Ensure appropriate notification and education of persons having an HIV test.
- Monitor physician and laboratory reporting of positive HIV tests.
- Provide public health follow-up on persons infected with HIV.
- Ensure quality control of laboratories conducting HIV tests.
- Ensure confidentiality of HIV records.
- Implementation generally of the provisions of House Bill 303 (1988).

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

The implementation and maintenance of the rules associated with House Bill 303 will require more than $300,000 a year in State funding. These funds will support the laboratory quality assurance system and the HIV laboratory and health care provider reporting and follow-up program. The statute also requires educational programs and materials for medical providers and patients.

B. Economic Impact on Political Subdivisions; Specific Industries; Specific groups of citizens.

Laboratories seeking approval for HIV testing will incur an annual cost of $300 for proficiency testing.

C. Economic Impact on Citizens/Public at Large.

NONE

Date September 30, 1988

Signature of Agency Head or Authorized Representative

David K. Heydinger, M.D.
Director of Health

WEST VIRGINIA BOARD OF HEALTH
RULE ABSTRACT

Title: AIDS-Related Medical Testing and Confidentiality

CSR Title and Series: 64 CSR 64 Type: Legislative

Summary: This legislative rule establishes specific standards and procedures concerning AIDS-related medical testing; record confidentiality and disclosure; substituted consent for testing; exclusion from schools; reporting requirements for physicians, laboratories and other health care providers; the approval of laboratories for HIV testing; and other matters pertinent and necessary for the implementation of the AIDS-Related Medical Testing and Records Confidentiality Act.

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

For further information contact: Regulatory Development Section, telephone 348-3223 or Loretta Haddy, Director, Division of Surveillance and Disease Control, telephone 348-5358, Health Department, 1800 Washington Street, East, Charleston, WV 25305.

[PROPOSED]

TITLE 64
LEGISLATIVE RULES

AIDS-RELATED MEDICAL TESTING AND CONFIDENTIALITY

SERIES 64

199_

For Filing With the
Legislative Rule-Making Review Committee

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

64 CSR 64

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[PROPOSED]
TITLE 64
WEST VIRGINIA LEGISLATIVE RULES
DEPARTMENT OF HEALTH
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; substituted consent for testing; exclusion from schools; reporting requirements for physicians, laboratories and other health care providers; the approval of laboratories for HIV testing; and other matters pertinent and necessary for the implementation of the AIDS-Related Medical Testing and Records Confidentiality Act.

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

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

1.3. **Filing Date** -

1.4. **Effective Date** -

1.5. **Final Approval** - This rule was approved by the Director of the State Department of Health on August 31, 1988.

1.6. **Supersession and Repeal of Former Rules** - None.

§64-64-2. Application and Enforcement

2.1. **Application** - This rule shall apply to:

(a) health facilities;

(b) health care providers;

(c) funeral service providers and personnel;

(d) persons issuing marriage licenses;

(e) persons with access to or in charge of medical records or other sources of information regarding AIDS-related testing information; and

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

2.2. **Enforcement** - This rule shall be enforced by the Director of the State Department of Health.

§64-64-3. Definitions

3.1. "AIDS" means acquired immunodeficiency syndrome.

3.2. "ARC" means AIDS-related complex.

3.3. "Department" means the State Department of Health.

3.4. "Director" means the Director of the State Department of Health or his or her lawful designee.

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

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

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

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

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

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

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

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

3.13. "Person" includes any natural person, partnership, association, joint venture, trust, public or private corporation or health facility.

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

§64-64-4. Testing

4.1(a) A physician, dentist, or the 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: (1) the person may have a positive HIV-test; or (2) when the presence of HIV infection would affect medical decisions concerning the type of patient care recommended or (3) when knowledge of a test result is believed necessary for effective counseling about behavior change.

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

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

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

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

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

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

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

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

(d) A person seeking an HIV-related test who wishes to

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

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

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

(a) on a human body part (including tissue and blood or blood products and semen) or the donor or the recipient when the health care provider or health facility procures, processes, distributes or uses a human body part for a purpose specified under the uniform anatomical gift act, or for transplant recipients, or for the purpose of artificial insemination: Provided, That if a test is required of the donor or recipient of the human body part, reasonable efforts shall be made to obtain consent and otherwise follow the procedures of Section 4.1 of this rule.

Further, all confidentiality restrictions contained in Section 7 of this rule and in W. Va. Code §16-3C-3 apply to information obtained through the testing of human body parts, tissue, blood, blood products, or semen.

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

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

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

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

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

(4) Post-test counseling is provided.

Necessary treatment shall not be withheld pending HIV test results.

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

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

(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 their work to a significant risk for transmission of HIV, the Director may, upon request by a physician or at his or her discretion, request said person to consent to HIV-related testing: Provided, That if the person believed by the Director to be infected refuses to consent, or if substituted consent is refused in the case of a person unable to grant or withhold consent, the Director may require an HIV test if information from such a 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 shall establish a list of health care providers who are approved to authorize HIV testing in emergency medical aid circumstances.

4.4. Consent to an HIV test shall be in writing unless the person to be tested is unable to give written consent.

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

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

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

related test in the chart of a patient with the permission of the patient if the following statement is printed on the test report and accompanies any other entry of the results of such a test: "This information has been disclosed to you from records whose confidentiality is protected by State law. State law prohibits you from making any further disclosure of the information without the specific written consent of the person to whom it pertains, or as otherwise permitted by law. A general authorization for the release of medical or other information is **NOT** sufficient for this purpose."

§64-64-7. Confidentiality

7.1. Any laboratory performing an HIV-related test in West Virginia shall have the following statement of confidentiality appear on the report form or as an attachment to the report form returned to the health care provider or facility: "This information has been disclosed to you from records whose confidentiality is protected by State law. State law prohibits you from making any further disclosure of the information without the specific written consent of the person to whom it pertains, or as otherwise permitted by law. A general authorization for the release of medical or other information is **NOT** sufficient for this purpose."

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

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

§64-64-8. Contact Notification

8.1. When a health care provider of an HIV-infected person notifies the Department of a sexual or intravenous (IV) drug contact that has not been advised of their exposure, the Director shall review the identifying, locating and related epidemiologic information and specify follow-up recommendations. 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 will include an explanation of exposure, HIV prevention messages and information on accessibil-

ity to HIV counseling and testing services to the person with a reported HIV exposure. The name or identity of the person whose HIV test result was positive shall remain confidential. The confidentiality rules that apply to the names of HIV-infected persons shall apply to the names of their contacts. Further, nothing in this rule shall be construed to require an HIV-infected person to reveal his sexual or IV drug contacts.

8.2. In contact notification situations, the Department recommends that private health care providers refer contact notification activities to the Department rather than attempt notification themselves. The Department has an established program for notifying partners of persons with infectious conditions. Private providers should notify partners only if the provider feels qualified to counsel the partners appropriately and to maintain the index patient's confidentiality.

§64-64-9. Substituted Consent

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

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

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

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

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

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

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

§64-64-10. School Exclusion - Exclusion of an HIV-infected student from school or participation in school sponsored activities will be determined on a case by case basis through consultation with a committee which may include the student's parents or guardians, medical care provider, health authorities, school or

institution administrators or medical advisors in accordance with policies and guidelines which may have been established by the entities. The exclusion must be based on the student representing an unacceptable risk for transmission of the HIV infection. If the student is under the jurisdiction of a protection or advocacy agency, a representative from that agency may be included. Any finding of unacceptable risk by the local committee must be approved by the Director prior to the student's exclusion. The provisions of this rule and of W.Va. Code §16-3C-1 et seq. regarding the confidentiality of and the release of information are applicable in the school setting.

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

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

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

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

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

11.2. These reports shall include:

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

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

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

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

(e) The signature of the health care provider.

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

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

atory tests.

11.5. The reports of all positive tests submitted in compliance with this rule are deemed confidential and are exempt from public disclosure under the exemption for medical records contained in Chapter 29B of the West Virginia Code, the Freedom of Information Act: Provided, That they shall be subject to the provisions of Article 3C, Chapter 16 of the West Virginia Code. Such information shall not be used except as is necessary to enforce State public health laws and rules and to analyze the magnitude of HIV infection in the State for assisting in the development of adequate safeguards against its spread.

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

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

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

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

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

12.2. These reports shall include:

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

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

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

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

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

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

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

12.5. The Director shall work with an individual's health

care provider in any follow-up of the reports of positive laboratory tests.

12.6. The reports of all positive tests submitted in compliance with this rule are deemed confidential and are exempt from public disclosure under the exemption for medical records contained in Chapter 29B of the West Virginia Code, the Freedom of Information Act: Provided, That they shall be subject to the provisions of Article 3C, Chapter 16 of the West Virginia Code. Such information shall not be used except as is necessary to enforce State public health laws and rules and to analyze the magnitude of HIV infection in the State for assisting in the development of adequate safeguards against its spread.

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

13.1. Laboratories Required to be Approved

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

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

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

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

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

13.2. Quality Control

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

13.3. **Quality Control Standards** - A laboratory requesting approval must demonstrate that a quality control program acceptable to the Department is in effect for verification and assessment of accuracy, measurement of precision, and detection of error. Such demonstration shall be evidenced, when applicable, in part by:

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

(b) Use of controls and calibrating standards;

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

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

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

(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 Department.

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

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

13.6. **Certificate of Approval; Revocation**

13.6.1. Certificates of approval for the performance of HIV testing shall be issued upon initial approval and on an annual basis thereafter pursuant to the conditions listed herein. Certificates issued will contain the name and location of the laboratory, a laboratory code number, the name of the laboratory director and the date of expiration of the certificate.

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

13.6.3. Approval may be revoked or suspended upon:

(a) Unsatisfactory performance in on-site inspections;

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

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

(d) Closure of the laboratory.

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

§64-64-15. Administrative Due Process - Those persons adversely affected by the enforcement of this rule desiring a contested case hearing to determine any rights, duties, interests or privileges shall do so in a manner prescribed in the **Rules of Procedure for Contested Case Hearings and Declaratory Rulings**, West Virginia Department of Health Procedural Rules, 64 CSR 1.

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

DATE: August 30, 1989

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: Health Department

LEGISLATIVE RULE TITLE: AIDS-Related Medical Testing and Confidentiality

1. Authorizing statute(s) citation §16-3C-8

2. a. Date filed in State Register with Notice of Hearing:

October 13, 1988

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

Notice was mailed to all hospitals, nursing homes, laboratories, medical schools and various professional organizations and licensing boards

c. Date of hearing (s): November 15, 1988

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)

August 30, 1989

f. Name and phone number of agency person to contact for additional information:

Kay Howard 348-3223

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 of a hearing for the taking of evidence and a general description of the issues to be decided.

      N/A

   b. Date of hearing: N/A

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

      N/A

   d. Attach findings and determinations and reasons:

      Attached N/A

Proposed Rules

Public Hearing Comments Received,

Discussion and Response

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

A public hearing regarding this proposed new rule was held on November 15, 1988. The hearing was attended by twelve (12) persons, five of whom presented comments, representing four (4) organizations. An attendance record is attached. Additionally, seven sets of comments were received by mail or hand delivery (list attached). Copies of comments received are attached.

1. Comment: The American Council of Life Insurance requested the insertion of language into the rule to reflect certain exemptions granted to insurers by the statute.

Response: The Department has added Section 4.5 which restates Chapter 16, Article 3C, Section 2(j) of the W.Va. Code for informational purposes.

2. Comment: Section 4.1. Generally speaking, Section 4.1 received extensive comments.

The West Virginia Medical Association and the West Virginia Dental Association both believe that the language of proposed Section 4.1 extends beyond the intent of the Code. The Dental Association stated that the proposed language of all of Section 4.1 restricts and limits dentists' professional judgements. The Medical Association objected to the language expanding "cause to believe that an HIV test could be positive." They stated: "This is a medical determination, which is subject to continuing change as research in this area progresses, and therefore is completely inappropriate for regulation." The Medical Association further stated that requiring physicians to categorize individuals as being high-risk or as participating in high-risk behavior is inappropriate and may "open them up to multitudinous litigation for categorizations considered possibly defamatory." Both the Medical Association and the Dental Association proposed that 4.1.a should simply restate the language of the Code.

The American Civil Liberties Union (ACLU) stated that the ". . . definition of 'cause to believe that the HIV test could be positive' is deficient, however, because it fails to require medical evidence for these 'causes to believe,'" and the West Virginia Nurses Association concurred. The ACLU further stated that: "It thus allows for the possibility of requests for HIV tests being made of patients simply because a health care provider is curious or, viewed in the worst light, wants to avoid providing treatment to a patient."

With respect to 4.1(b), the Medical Association stated that either a positive or a negative test result could provide information important in the care of the patient, and that the requirement for documented evidence "intrudes into medical decision making" and also carries the risk of litigation. The Medical Association advocated using the exact language of the Code. Primary Health Care Associates asked what the documented evidence of a possibly positive HIV test would be, and how this evidence would be obtained. Primary Health Care Associates also expressed concerns about a "different

type of care" for persons with positive HIV tests and about who would be involved in defining the differences.

Five commenters offered comments about the provisions of 4.1 related to consent. The Medical Association stated that:

> "The proviso added to §4.1 (b) of the proposed rule is gratuitous and irrelevant; unless the provisions of West Virginia Code §16-3C-2 (e) or (f) apply, consents for HIV-related testing must be obtained in any event."

The Charleston AIDS Network stated that:

> "As presently worded, the regulation might be interpreted to mean that the testing in question could proceed in the absence of any consent because getting it is not feasible. Such an interpretation clearly conflicts with the requirement of Section 16-3C-2 of the statute that such testing proceed only on a permissive, as opposed to mandatory, basis. We assume that this is not the interpretation intended by the Department, and that the feasibility language actually refers to the provisions for substituted consent in the statute. If so, the regulation should be clarified."

The Mountain State AIDS Network inquired what would be the procedures in the event consent was not given.

The ACLU, supported by the West Virginia Nurses Association, discussed the consent provisions as follows:

> "Both the rule and the Act provide three alternatives under which HIV testing 'may be requested by a physician, dentist or the director' (substantially identical language in the Act and the proposed rule). But neither the Act nor the proposed rule states anywhere that the 'request' is a request <u>of a person to be tested</u>. Because Sec. 16-3C-2(a) (3) lists 'when any person voluntarily consents to the test' as one example of when a test may be requested, a possible interpretation of this statutory section may be that the 'request' is to a third party not the patient (such as the Department itself) and that such a request might be to perform an HIV-related test on a person <u>without that person's knowledge or consent</u>.
>
> "That this reading is incorrect is made clear by §16-3C-2(b) of the Act, which states unambiguously that the patient shall be provided, <u>inter alia</u>:
>
> (3) An explanation that the test is voluntary and may be obtained anonymously; and
> (4) An explanation that the consent for the test may be withdrawn at any time prior to drawing the sample for the test.
>
> "The only exceptions to this consent provision are enumerated in the Act at §16-3C-2(e) - (g). Thus, the Act does establish that 'voluntary consent' <u>must be given</u> for testing performed under subsection (a). Because of this confusing language, however, it is imperative that the proposed rule explicitly and unambiguously state that no testing under subsection (a) can be performed without the voluntary, informed, consent of the patient.
>
> "In addition, this clarification of the rule is necessary to ensure the legality

of the Act. Without a clarification making clear what 'request' means (and that such a request of a patient requires voluntary, informed, consent prior to testing), the Act would seem to permit the testing of a person's blood without that person's knowledge or consent. Such testing is repugnant to the fourth amendment to the United States Constitution, and to Article III, Section 6 of the West Virginia Constitution, which guarantee each person the right 'to be secure' in his or her 'person' against 'unreasonable searches.' A state-authorized non-consensual 'search' for HIV antibodies or antigen is an unreasonable search. See, e.g., Schmerber v. California, 384 U.S. 757 (1966) (permitting a warrantless non-consensual blood test only upon a showing of probable cause to arrest and where its purpose was to uncover evidence likely to disappear)."

The Medical Association proposed that Sections 4.1.b and 4.1.c should simply restate the applicable Code. The ACLU proposed an overall rewrite of Section 4.1 as follows:

"A physician, dentist, 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 the person may have a positive HIV-related test and (1) when the presence of HIV infection would affect the medical decision concerning the type of patient care recommended or (2) when knowledge of test results is believed to be necessary for effective counseling about behavior change."

In addition to the comments about the text of Section 4.1 as proposed, commenters requested numerous additions and clarifications. Both the ACLU and the West Virginia Nurses Association strongly recommended the restatement and some expansion in Section 4 of the provisions of the Code regarding education, counseling, informed consent, and anonymous testing. The Charleston AIDS Network requested at least a reference to the appropriate Code sections concerning education, counseling and both informed and substituted consent. The West Virginia Hospital Association requested clarification that the provision of information and counseling or referral for counseling are the responsibility of the health care provider and not the facility. The ACLU also suggested adding a new section specifying that all consents should be in writing, unless the person to be tested is unable to give written consent, and that the Department draft a model informed consent form. The ACLU provided specific language to carry out all of their suggestions related to consensual testing.

Response: The intent of the proposed Section 4.1 was to provide what the Department believed was some desirable amplification and clarification of the portions of the Code related specifically to voluntary testing. The Department's intent was to safeguard the rights of individuals and not to suggest that testing should be requested for non-medical reasons. Additionally, the Department believed that the specificity of the Code regarding counseling and education made it unnecessary to restate that portion of the Code.

Due to the comments, we have concluded that the proposed Section 4.1 was inadequate. We have therefore rewritten and expanded Section 4.1. The language of Section 4.1(a) is closer to the original Code and stresses medical judgement and factors in requesting HIV testing. Sections 4.1(b), (d) and (e) restate the Code §16-3C-2(b) through 16-3C-2(d), with clarification that HIV testing and counseling are available at a number of Health Department designated sites rather than at every local health department. Local health departments will provide at a minimum referrals to designated

sites or to private clinics which offer anonymous testing. Section 4.1(c) merely clarifies that an individual may initiate a request to a health care provider to be tested. The Department has developed a model informed consent form.

W.Va. Code §16-3C-6(a) provides for the right to quality health care by stating that:

> "A positive HIV test report, or the diagnosis of AIDS related complex (ARC), or the diagnosis of the AIDS syndrome or disease, may not constitute a basis upon which to deny the individual so diagnosed, access to quality health care: Provided, That this subsection does not apply to insurance."

A new Section 4.1(f) does not require every health care provider to treat HIV infected patients but does clarify that the provisions of the rule may not be construed to permit the refusal of treatment and that the testing provisions of the rule and the Code may not be used to screen patients.

3. Comment: Sections 4.2 and 4.4 (Non-consensual testing). The ACLU, supported by the West Virginia Nurses Association, suggested that parts 4.2 and 4.4 of the proposed rule need substantial clarification in that each relates to situations in which HIV testing can be undertaken without consent. Indeed, the ACLU stated that the related sections of the Code, §16-3C-2(e)(1) and §16-3C-2(e) are "possibly intrusive to the lives of the people of West Virginia" and "violative of their state and federal constitutional rights."

Regarding the testing of donors or recipients of body parts, the ACLU stated that the rule should make clear that it is the human body parts that are to be tested and not the human beings involved. The ACLU states that in the types of situations contemplated by this part of the Code "only the 'human body part' itself can be the route of disease transmission," and that it believes that "the Act does not mean to suggest the irrational need to test either recipients or donors." The ACLU suggested that it is within the discretion of the Department to specify that consent is not required for the testing of body parts but is required for the testing of donors and recipients and that such testing should be accompanied by counseling and education.

Regarding W.Va. Code, §16-3C-2 (e)(2) on HIV-related testing in an emergency situation, the ACLU states:

> "Subsection (e) (2), implemented by Part 4.4, perplexes us. We do not understand how a true medical emergency, that is so urgent that the substituted consent provisions of §16-3C-4 are of no avail, could await the results of HIV-related testing. Indeed, the Act itself seems to recognize this problem by stating quite correctly that 'Necessary treatment may not be withheld pending HIV test results.'
>
> "Nonetheless, the proposed rule should at the very least include the restrictions on such testing which are in the Act, and might also include additional language in an attempt to ameliorate the Act's illogic."

Finally, the ACLU had no objection to W.Va. Code §16-3C-2(e)(3), which authorizes nonconsensual HIV-testing for research purposes when the identity of the test subject remains anonymous but did propose the inclusion of specific language regarding this situation.

Response: The Department agrees with the ACLU that the HIV could not be transmitted from the recipient of a human body part (including tissue, blood or blood products) to the donor. To distinguish between testing the donated "body part" and the donor seems a distinction of little practical value in most situations, however. The Department also agrees that there is no need for non-consensual testing in situations covered by the Uniform Anatomical Gift Act, or in instances of organ transplants or artificial insemination. In such situations, the recipient could simply make testing a condition of receipt. We would also agree that counseling and education should be required if the individual is tested in such situations. However "irrational" the Code may be, we do not agree that the Department has the discretion to correct this situation. The Department does believe that either direct or substituted consent should be obtained, if at all feasible, and notes that according to W.Va. Code §16-3C-2(e)(1), no HIV-related testing is to occur unless "such test is necessary to assure medical acceptability of a recipient of such gift or semen for the purposes intended."

The Department has therefore included in a revision of Section 4.2 expanded text to clarify the use of non-consensual testing in organ transplant and analogous situations and has retained the language clarifying that the provisions of the Code concerning non-consensual testing do not apply to routine blood transfusions. The Department has also accepted the ACLU's suggestion to clarify the use of non-consensual testing in emergency situations. A restatement of the law on non-consensual testing for research purposes has been included in Section 4.2.

4. Comment: Section 4.3. The ACLU, again supported by the West Virginia Nurses Association, provided extensive comments on the mandated testing provisions of the Code. It noted that Section 16-3C-2 (8) mandates the testing of persons convicted of certain crimes or offenses and stated its belief that this section of the Code is "unwise and possibly unconstitutional." The ACLU further stated that:

> ". . . we believe it is incumbent upon the Department pursuant to §16-3C-8(a) to establish procedures for testing these groups of people. Such procedures should explicitly preserve the counseling process of such persons and guarantee their statutory rights to confidentiality protections. The confidentiality provisions of the Act, §16-3C-3, do not include any exception which would allow the results of these mandated tests to be released to any persons outside the Department, including victims, judges, or persons in the Department of Corrections. The Department must make clear to those in the criminal justice system, as well as to its own employees, that the law requiring testing does not authorize any disclosure or the test results except as provided in Sec. 16-3C-3. If confidentiality of these test results were to be breached, we are of the legal opinion that remedies against the Department might lie under §16-3C-5."

The ACLU provided the following comments regarding the law on mandatory testing in conjunction with exposure as a result of rendering emergency medical aid or receiving exposure as a funeral director:

> "Section 16-3C-2(f) (3) is confusing as written, and the proposed rule fails to clarify the language of the Act . . . The wording of the Act establishes no standards for the implementation of this rule. Thus, any emergency medical provider, or person provided emergency medical aid, or funeral director would appear to be able to demand that the Department test third persons at any time and in any circumstances."

The ACLU further stated that Section 4.3 of the proposed rule, which attempts to limit the ability of possibly HIV-exposed person to request testing of other parties, "is a start," but that "it does not go far enough" and continued:

> "Moreover, neither the law nor the proposed rule recognizes the possibility that most times this situation presents itself, the subject of the proposed forced testing will voluntarily consent to be tested if apprised of the circumstances and guaranteed confidentiality. This possibility should be acknowledged in the Department's rule and forced testing reserved only for medically necessary situations where consent cannot be obtained voluntarily. . . Further, neither the law or the proposed rule makes clear that when this type of forced testing is mandated, the information sought can, and should where possible, be transmitted to the third party without the patient's identifier. Finally, as with all the subsections of §16-3C-2(f), post-test counseling is required."

Finally, with respect to the remaining provisions of the Code concerning HIV-related mandated testing and also certain potential restrictions of a person who "is or may be a danger to the public health," the ACLU, supported by the West Virginia Nurses Association, commented as follows:

> "Sections 16-3C-2(f) (4) and (g) of the Act are, we believe, unconstitutional on their face. It is obvious that (f) (4) permits great invasions of the procedural and substantive rights of the people of West Virginia. For example, (f) (4) allows the Director to force a variety of restrictive measures upon an individual based only the Director's 'knowledge' or 'reason to believe' that a person is infected with HIV and that such a person 'is' or 'may be' a danger to the public health. For example, a person could be compelled to submit to a medical examination and to undergo counseling against his will; and, in an even greater restriction of personal freedom, the Director may effectively quarantine a person by directing him to 'cease and desist from specified conduct which endangers health of others.' Thus, without any hearing on the questions of HIV infection or danger to the public health, a person might be deprived of his right to refuse medical treatment or his right to engage in otherwise legal conduct, freedoms basic to the notion of liberty under our constitution."

Although the ACLU reserved comment on whether any rule can "cure the unconstitutionality" of the statute, it believes that the Department has the responsibility to attempt to correct the perceived defects by including "provisions incorporating the minimal requirements of due process." It further proposed that the Department draft and publish for hearing a set of due process procedures.

Response: The Department has accepted with some modification the ACLU's suggestion regarding the testing of persons convicted of prostitution, sexual abuse, sexual assault, incest or molestation and testing related to exposure as a result of rendering emergency aid or in the performance of their work and revised Section 4.3 accordingly. The previous Section 4.4 relating to persons approved to authorize HIV testing in emergency medical aid circumstances has been included as part of 4.3(b).

The Department believes that the rule promulgation process is not the appropriate forum to debate the constitutionality of the Act. Nor is the Department firmly convinced that it is necessary to establish a set of procedural rules in order for the Department to provide appropriate due process protection.

Generally, authority to invoke mandatory testing would only be used in the event that the individuals in question refused to be tested on a voluntary basis. In a situation involving mandatory testing, the question of due process would arise only if the individual in question claimed a right not to be tested. In such cases, the Department believes that it could conduct an administrative hearing relying on §16-1-16, W.Va. Code, related to investigations and hearings and on the Department's procedural rule for contested cases which is referenced in Section 15 of the rule. The Department's rules for contested cases provide due process protection as also do the Administrative Procedures Act and the Constitution. In addition, there are adequate common law remedies which might be invoked by an individual such as claims of unlawful search and seizure or unlawful invasion of privacy.

5. Comment: Section 4. The ACLU suggested that the rule emphasize that consent to HIV-related testing should be in writing whenever possible in order to protect both the provider conducting the test and the test subject in case there is a later claim that the testing was non-consensual.

Response: Agreed. See 4.4.

6. Comment: Section 6. Two commenters raised concerns that Section 6, which relates to charting medical information, is inadequate to protect patient confidentiality generally, if that was the intent of the section. Primary Health Care Associates stated that: "Charting on any patient's record that they have an HIV-related illness poses serious compromise to all aspects of their daily living, including physical, emotional, social and spiritual issues. A general statement printed on the test result is not sufficient to protect the person's confidentiality." The West Virginia Hospital Association stated that a positive HIV test result might appear in more than one place in a medical record and that evidence of the presence of the HIV or of AIDS might occur at a number of different places in the medical record. The Association believes that attainment of the protection of patient confidentiality may be an unworkable goal and that the required attachment of the disclosure statement to the lab test will serve only a limited purpose.

Additionally, the Association requested clarification as to whether the disclosure statement is required for laboratory tests which are performed by out-of-state laboratories.

Finally, C. L. Baldwin, Jr., suggested that the rule should be changed to allow the entry of the results of an HIV-related test in the chart only with the permission of the patient, and that it should retain the requirement for attaching the disclosure statement to the lab results.

Response: The Department believes that every reasonable effort should be made to protect the confidentiality of persons undergoing HIV testing. The potential for unwarranted discrimination against individuals with AIDS is extremely high in all aspects of their lives, including employment and living quarters even though there is no evidence of HIV transmission through casual contact. AIDS is transmitted through sexual contact, sharing unsterilized needles, blood transfusions (extremely unlikely since 1985) and passage of HIV from an infected mother to her newborn during pregnancy at the time of birth.

The Department agrees that Section 6 of the rule should provide stronger protection and has accepted the suggestion to require the permission of a patient in order to enter the results of an HIV-related test in a patient's medical chart. To date, there

has been no evidence of HIV transmission to health care workers who have casual contact with or provide routine care for patients with HIV infection (e.g. non-invasive activities such as taking blood pressures, giving bed baths, feeding patients). In instances where contact with blood or other bodily fluids may occur, appropriate barrier precautions should be used routinely (see A Physician's Guide to AIDS, West Virginia Department of Health, 1988, and other materials available from the State Health Department). Section 6 has also been changed to make it clear that the confidentiality statement must appear anywhere in the patient's chart that the test results appear. Finally, Sections 12.1 and 12.6 make it clear that out-of-state laboratory results used in this state are subject to the confidentiality protections provided by both the Code and the rule.

7. Comment: Section 7.1. The West Virginia Hospital Association suggested language should be added to make it clear that laboratories should attach the mandated disclosure statement to HIV test results returned to health care facilities as well as to health care providers.

Response: Agreed.

8. Comment: Section 7.1. Primary Health Care Associates stated that monitoring by the State of the unlawful disclosure by a laboratory of information about HIV-related testing could have serious financial impact and inquired as to what methods are available for the State to use as follow-up.

Response: The Department will check upon initial approval and annually to see that appropriate protocols are in place and efforts will be made to assure that laboratory personnel are following procedures. Any additional follow-up will be oriented to specific complaints received. The overall cost for the laboratory approval program has been estimated at $30,000. It is anticipated that complaint investigation will account for only a small percentage of this cost. The maximum penalty available to the Department would be withdrawal of the approval of the laboratory to conduct HIV testing. Damages and other civil remedies will require action by the aggrieved individual in the Circuit Court.

9. Comment: Section 7. The ACLU suggested additional language to define the term "need to know" in W.Va. Code §16-3C-3(a)(3) since neither the statute nor the proposed rule defines this "critical phrase."

Response: The Department agrees. Subsection 7.3 has been added to the rule for this purpose.

10. Comment: Section 7. The ACLU proposed additional language to further clarify the circumstances of the release of information on the HIV testing of an individual as follows:

"Secondly, Sec. 16-3C-c(a) (4) provides that certain health care personnel can also be given access to the information if knowledge of test results is 'necessary or useful to provide appropriate care or treatment, in an appropriate manner.' This language, too, needs explanation."

Response: The Department believes that the language of the Code is adequate.

11. Comment: Section 8. The ACLU and the West Virginia Nurses Association expressed similar concerns about the contact notification portion of the proposed rule.

They suggested that the absence of a specific assurance that the names of contacts of HIV-infected persons would be kept confidential would be a deterrent to the reporting of those contacts by the infected individual. Secondly, they suggested an assurance that an HIV-infected person can not be required to reveal the names of his or her sexual or intravenous drug contacts. Thirdly, they suggested a specific limitation of the Director's discretion to initiate contact notification. They proposed specific language to be added.

Response: Agreed. See 8.1.

12. Comment: Section 8. The ACLU expressed the opinion that contact notification would best be handled by the State and that the State should provide guidance to providers:

> "An additional and greater concern is that private health care providers are provided with virtually no guidance in the proposed rule as to the professional and ethical criteria for doing contact notification. Although such providers may elect to notify the Department rather than undertake partner notification themselves, they are not bound to follow that course by the statute. Thus the greatest potential for abuse lies in the vagaries with which hundreds of private providers might seek to do notification."

Response: Agreed. See 8.1 and new Subsection 8.2.

13. Comment: Section 9. Primary Health Care Associates recommended that, because the majority of AIDS victims are seen in the gay community, "significant persons" in the lives of AIDS victims should be involved in the substituted consent decision making process. The comment was not specific as to how this might be accomplished.

Response: Since neither the relevant Code nor any other part of State law recognize any rights of "significant others," the Department believes that it is not feasible to give such individuals any legal standing through a regulation. The Department recognizes that this is a difficult issue, with strong emotional involvements, but believes that the inclusion of persons other than those specifically authorized by law to give substituted consent will have to be left to those same specifically authorized persons.

14. Comment: Section 10. The Mountain State AIDS Network suggested that provisions regarding the confidentiality of HIV-infected students be added.

Response: The Department has no objection to emphasizing that students have the same confidentiality protection as do others.

15. Comment: Primary Health Care Associates asked for a definition of "unacceptable risk" for transmission of the HIV infection and also commented that "since the modes of transmission of the HIV virus do not seem to apply to the school setting, decisions regarding exclusion may need to be addressed in another way."

Response: The Department considers that the exclusion is appropriately addressed in W.Va. Code §16-3C-6(b).

16. Comment: Sections 11 and 12. Several commentors found the use of names and/or addresses in the routine reporting of HIV-positive tests to the Health Department by health care providers and by laboratories to be objectionable (ACLU, American Red Cross, Charleston AIDS Network, Mountain State AIDS Network, West

Virginia Hospital Association, West Virginia Nurses Association). While the legitimate need of data for epidemiological purpose is recognized, commenters believe that the collection of names and addresses: 1) is not needed; 2) is not mandated; 3) will deter individuals from using anything other than testing programs, 4) will create a severe if not impossible task for the state to protect the names from disclosure; and 5) might even be exempt from protection from disclosure by the State under the State Freedom of Information Act (W.Va. Code Chapter 29B) according to criteria established in a 1986 decision by the State Supreme Court (Group Protection Groups v. Cline, 350 S.E.2d 541, W.Va., 1986).

Zip codes and county or community location were suggested as meaningful alternatives for statistical purposes. One commenter suggested the deletion of both Sections 11 and 12 due to the "reactive nature of West Virginia State government." Another suggestion made (West Virginia Hospital Association) was to require the attachment of the disclosure statement found in Section 7.1 of the proposed rule (and in W.Va. Code, §16-3C-3(c)) by health care providers to the reports submitted to the Department.

Response: The Department notes that the Act and the rule clearly give individuals the right to be treated anonymously if they so choose. Therefore, a laboratory will not have an individual's name if anonymous testing is requested.

The Code, however, clearly permits the release without specific authorization of the identity of persons who have been tested for HIV and the results of the test in a manner which permits identification of the individual to the State Department of Health and to the Centers for Disease Control of the United States Public Health Service. The Department is well aware of the need to maintain strict confidentiality of the information in question and believes that it has adequate personnel, procedures and facilities to maintain the confidentiality of any AIDS-related patient information in its possession.

17. Comment: The Mountain State AIDS Network recommended that the rule include a provision for the revocation of laboratory's approval for HIV testing for breach of confidentiality in Section 13.6.3. The ACLU suggested that in order to assure that laboratories comply with the confidentiality and other provisions of the law the phrase "or the applicable requirements of Article 3C, Chapter 16 of the West Virginia Code" be added to Section 13.6.3 (b).

Response: As the ACLU pointed out, Section 13.1.2(a) of the proposed rule requires that a laboratory seeking approval must comply with the rule and "the applicable portions of Article 3C, Chapter 16 of the West Virginia Code." The Department intended that Section 13.6.3(b) would include revocation for failure to comply with all applicable portions of the law, including those related to confidentiality. Since there appears to be some confusion on this point, Section 13.6.3(b) has been changed as suggested. Section 13.6.3 has also been changed to permit rather than mandate the revocation of approval for various violations. This will permit a laboratory to implement corrective action rather than automatically lose approval.

18. Comment: The West Virginia Hospital Association expressed concerns about the legal position of blood banking facilities in situations where an individual who banks his or her own blood for use in surgery or another medical procedure becomes HIV-positive or is diagnosed as having AIDS subsequent to use of the blood. There might arise a question of liability as to whether the individual became infected as a result of some fault on the part of the blood-banking facility or was already infected at the time the

blood was drawn and stored. The Association recommended the addition of language to provide adequate protection for the facilities as follows: "In storing and banking any person's blood for subsequent use, nothing in this section shall be construed to hold the blood banking facility as a warrantor or guarantor of the condition of stored blood. Additionally, nothing in this section shall be construed to categorize blood as a 'product' within the meaning of the Restatement of Torts 2d, §404-A."

Response: Section 14 of the proposed rule is a restatement of part of W.Va. Code §16-3C-9 and was included in the rule for the purposes of information and convenience. The Department believes that it is beyond the scope of this rule to cope with complicated matters of liability and therefore does not accept this suggestion.

PUBLIC HEARING

AIDS-Related Medical Testing & Confidentiality

November 15, 1988 - 9:00 a.m.

NAME	ADDRESS	GROUP REPRESENTED (IF ANY)	DO YOU WISH TO COMMENT (YES/NO)
Richard Stevens	4004 MacCorkle Ave, SE Charleston, WV 25304	WV Dental Assn WV Pharmacists Assn	Yes
Susan Harbur	PO Box 848 Keyser, W.Va 26726	WV TASK Force	No
Melody Simpson	1600 Chas Nat'l Plaza Chas WV 25301	WV State Medical Assoc.	Yes.
Loretta Haddy		WV Dept. Health	No
Sarah Bass		WV Dept. Health – AIDS Prevention Program	No
Cynthia Rinaldi		WVa Dept of Health Aids Prevention Program	No
G.F. Feuchia, Esq	[illegible]	[illegible]	
Felix Daily, III Nora Cutlake	[illegible]	[illegible]	No
Adrian D. Francis	P.O. Box 3465 Chas 25334	Charleston Medical Society	Yes.
Randy Cox	Po Box 273 Charleston, WV	American Council of Life Insurance	No

PUBLIC HEARING

AIDS-Related Medical Testing & Confidentiality
November 15, 1988 - 9:00 a.m.

NAME	ADDRESS	GROUP REPRESENTED (IF ANY)	DO YOU WISH TO COMMENT (YES/NO)
M. D. Scholten	P. O. Box 4106	WV State Med. Assn.	Yes
Dee Ashtiee	"	"	no

COMMENTS ON PROPOSED WEST VIRGINIA DEPARTMENT OF HEALTH LEGISLATIVE RULE ON AIDS-RELATED TESTING AND CONFIDENTIALITY

SUBMITTED BY THE
WEST VIRGINIA CIVIL LIBERTIES UNION
AND
THE AMERICAN CIVIL LIBERTIES UNION AIDS PROJECT
AND
THE HUNTINGTON AIDS TASK FORCE

November 15, 1988

The West Virginia Department of Health has proposed a legislative rule (the "rule") concerning AIDS-Related Medical Testing and Confidentiality as a "supplement" to West Virginia's AIDS-Related Medical Testing and Records Confidentiality Act, W.Va. Code §§16-3C-1, et seq. (the "Act"). The stated purpose of the rule is to provide "specific standards and procedures concerning" those subjects covered by the Act.

The West Virginia Civil Liberties Union, the American Civil Liberties Union's AIDS Project, and the Huntington AIDS Task Force believe that several sections of the proposed rule fall far short of the avowed purpose of establishing such specific standards and procedures, and, additionally, that the rule omits discussion of several important aspects of the Act itself.

These comments are submitted to elucidate our concerns about both the shortcomings and omissions of the proposed rule. Wherever possible, we have suggested language to replace or to augment that proposed by the Department in the rule. Some of our arguments are of a logical nature, others are legal; all flow from our concern that West Virginia's response to the AIDS crisis be a sound public health response. We hope that these suggestions will be of assistance in ensuring that the final rule contains more detailed and complete directions for the implementation of this Act.

SUMMARY OF RECOMMENDATIONS

Our specific recommendations are ordered according to the order of the proposed rule. However, what follows is a summary of what we feel are the most pressing issues in our specific recommendations.

First, §§16-3C-2(f) and (g) of the Act, which permit "mandated [HIV] testing" and enforcement of health department "cease and desist" orders without guarantees of procedural protection, are the most legally offensive sections of the Act and are probably unconstitutional. It is quite dismaying, then, that the proposed rule did not even attempt to establish procedural protections for the implementation of these sections. While we reserve judgment concerning whether carefully tailored regulations could cure the constitutional defects of the Act, we strongly urge the Department to make that attempt. Moreover, among these other recommendations, we suggest that the Department immediately assume the

responsibility delegated to it by the Act for testing persons convicted of certain crimes enumerated therein, and further, assume responsibility for ensuring the confidentiality of such test results and for conducting the counseling of these tested persons as required by the Act. Our specific comments on these sections suggest language and principles which should inform such an effort.

Second, in addition to the "mandated testing" sections, the Act treads on legally precarious ground when its permits HIV-testing without consent, §§16-3C-2(e)(1)-(3). Accordingly, it is, again, of the utmost importance that these sections be implemented with precise and carefully drawn rules. Yet, once again, the proposed rule lends no direction to the implementation of these sections of the Act. The rule should make it clear that, as to (e)(1), it is the blood, tissue, body part, or semen that should be tested, not the human being; and that, as to (e)(2), testing in medical emergencies should be exceptional and should never delay treatment. Our comments on these sections suggest specific language which could be employed to guard against abuses of non-consensual testing.

Third, the voluntary testing section of the Act, §16-3C-2(a), employs ambiguous language by permitting physicians and dentists to "request" HIV tests. This section needs, but is lacking, a specific interpretation by the Department indicating that "request" means a "request" by the physician or dentist of the patient, and not a request by the physician or the dentist of a third party, such as the Department, to test the patient without consent. Such

an interpretation is also necessary to give meaning to those portions of the Act, §§16-3C-2(b), (c), and (d), which set forth the requirements for the voluntary, informed consent which is a prerequisite to this testing. However, these sections are not even mentioned in the proposed rule at present. Our specific comments on these sections set forth a precise rule which could be used to ensure that HIV testing is conducted only with the voluntary, informed consent required by the Act.

Fourth, as to the contact notification sections of the rule, we suggest that the Department clarify (1) that contact notification, if undertaken, preferably should be undertaken by the Department; (2) that participation in a contact notification program by the index case is entirely voluntary; (3) that the names of contacts given by the infected person will be kept confidential; and (4) notification will be undertaken only where medically appropriate.

Fifth, the Department should stress with regard to its name reporting requirements, that such requirements in no way affect the statutorily guaranteed right of individuals in West Virginia to have access to anonymous HIV testing. The name reporting requirements should recognize that health care providers have the option to do anonymous HIV-testing and that access to anonymous testing should be made available in each county in the state.

As stated above, specific language as to each of these recommendations, and others, appears below.

SPECIFIC RECOMMENDATIONS

§64-64-1. General

No comment.

§64-64-2. Application and Enforcement

No comment.

§64-64-3. Definitions

No comment.

§64-64-4. Testing

The language of the proposed rule regarding HIV testing is confusing and provides fewer specific guidelines than the Act itself. The rule, which is aimed at providing more specific guidance in the implementation of a statute, ought to at least reference the requirements of the statute, and, in this instance, the rule should contain more guidance than a simple recitation of the statutory provisions.

Further, the rule is confusing because its sections do not track the provisions of the law. In addition to the substantive comments outlined below, we would recommend fashioning a rule that can be read alongside the law it is implementing. Accordingly, our comments which follow are based on the sequence of these provisions in the Act.

§16-3C-2(a)

Part 4.1 of the proposed rule parallels §16-3C-2(a) of the Act. In two respects, however, we believe the Department needs to clarify ambiguous language in the statute. Failing to use the regulations for this purpose could lead to significant problems of enforcement in the future.

Both the rule and the Act provide three alternatives under which HIV testing "may be requested by a physician, dentist or the director" (substantially identical language in the Act and the proposed rule). But neither the Act nor the proposed rule states anywhere that the "request" is a request of the person to be tested. Because Sec. 16-3C-2(a)(3) lists "when any person voluntarily consents to the test" as one example of when a test may be requested, a possible interpretation of this statutory section may be that the "request" is to a third party not the patient (such as the Department itself) and that such a request might be to perform an HIV-related test on a person without that person's knowledge or consent.

That this reading is incorrect is made clear by §16-3C-2(b) of the Act, which states unambiguously that the patient shall be provided, inter alia:

> (3) An explanation that the test is voluntary and may be obtained anonymously; and
>
> (4) An explanation that the consent for the test may be withdrawn at any time prior to drawing the sample for the test.

The only exceptions to this consent provision are enumerated in the Act at §§16-3C-2(e)-(g). Thus, the Act does establish that "voluntary consent" must be given for testing performed under subsection (a). Because of this confusing language, however, it is imperative that the proposed rule explicitly and unambiguously state that no testing under subsection (a) can be performed without the voluntary, informed, consent of the patient.

In addition, this clarification of the rule is necessary to ensure the legality of the Act. Without a clarification making clear what "request" means (and that such a request of a patient requires voluntary, informed, consent prior to testing), the Act would seem to permit the testing of a person's blood without that person's knowledge or consent. Such testing is repugnant to the fourth amendment to the United States Constitution, and to Article III, section 6 of the West Virginia Constitution, which guarantee each person the right "to be secure" in his or her "person" against "unreasonable searches." A state-authorized non-consensual "search" for HIV antibodies or antigen is an unreasonable search. See, e.g., Schmerber v. California, 384 U.S. 757 (1966) (permitting a warrantless non-consensual blood test only upon a showing of probable cause to arrest and where its purpose was to uncover evidence likely to disappear).

We therefore suggest that the proposed rule to implement §16-3C-2(a) be changed to include subsections 16-3C-2(b),(c), and (d) of the Act verbatim so as to clarify that "request" mean "request of the patient."

A second problem with this section of the proposed rule concerns its interpretation of §16-3C-2(a)(1) of the Act. That section of the Act allows a physician, dentist, or the department to request that the patient consider an HIV-test "when there is cause to believe that the test could be positive." The proposed rule (at Part 4.1(a)) expands on the statutory phrase "cause to believe that the [HIV] test could be positive" by outlining that the bases for such a belief on the part of the requesting party must be:

> from high-risk behavior, or risk-exposure with an HIV-infected individual or exposure to blood products that were reported to be from an individual with a positive HIV-related test.

We believe that this definition of "cause to believe that the HIV test could be positive" is deficient, however, because it fails to require <u>medical</u> evidence for these "causes to believe." It thus allows for the possibility of requests for HIV tests being made of patients simply because a health care provider is curious or, viewed in the worst light, wants to avoid providing treatment to a patient.

We believe that it is ethical for a physician, dentist, or the Director to request that a patient consider an HIV-related test <u>only</u> if that test is related to the health care provided to the

person[1] or is reasonably believed to be necessary to bring about a behavioral change when counseling without the test has proved unsuccessful in achieving change. If the test would have no clinical relevance to the patient's health care, or if the counseling about behavioral change already has been successful, or if testing will not significantly add to the counseling process, testing is not appropriate.

We therefore suggest that Part 4.1 be rewritten as one rule which merges the provisions of §§16-3C-2(a)(1) and (2) to read:

> A physician, dentist, 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 the person may have a positive HIV-related test and (1) when the presence of HIV infection would affect the medical decision concerning the type of patient care recommended or (2) when knowledge of a test result is believed necessary for effective counseling about behavior change.

This paragraph would then be followed by sections §§16-3C-2(b), (c) and (d) of the Act verbatim, as discussed above. In this way, the ambiguity in the Act and the confused language of the proposed rule would be replaced by language that clearly describes of whom the test is "requested," and that all testing that is not "mandated" may only be done with the informed consent of the patient.

Finally, we strongly urge that a new section be added to this

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[1]This concept is included in the next subsection of the Act, §16-3C-2(a)(2), which permits a physician, dentist, or the department to request that a patient consider HIV-testing "When there is cause to believe that the test could provide information important in the care of the patient."

part of the rule. There have been significant problems throughout the nation with health care providers attempting to screen out patients who are infected with HIV. The American Medical Association has adopted as ethical guidance a rule that health care providers should be prohibited from refusing to serve persons with AIDS or HIV infection. We therefore strongly urge the Department to add the following language to the rule:

> **Nothing in this rule or the Act which it supplements 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.**

§16-3C-2(b)

While we believe that the provisions of §16-3C-2(b) of the Act are generally unobjectionable and self-explanatory, we believe that these provisions should nonetheless be embodied in the implementing regulations. As we have redrafted Part 4.1, this section of the Act would be implemented by that part of the rule.

§16-3C-2(c)

We believe that the provisions of §16-3C-2(c) of the Act are extremely important and need to be re-emphasized and elaborated in the implementing regulations. The availability of anonymous testing has been demonstrated to be essential in inducing cooperation with voluntary testing programs by persons in groups at highest risk. L. Fehrs, et al., Trial of Anonymous Versus Confidential Human Immunodeficiency Virus Testing, The Lancet (Aug.

13, 1988) 379-381. We urge the Department to make clear that (1) private health care providers can offer their patients HIV antibody testing which is anonymous as to state agencies (i.e., reporting of test results to the Department can be done with the use of codes); and (2) local health departments have an obligation to provide access to HIV antibody tests on an anonymous basis, to insure that such access is not geographically restricted. As we have redrafted Part 4.1, this section of the Act would be implemented by that part of the rule.

§16-3C-2(d)

While we believe that the provisions of §16-3C-2(d) of the Act are generally unobjectionable and self-explanatory, we believe that these provisions should nonetheless be embodied in the implementing regulations. As we have redrafted Part 4.1, this section of the Act would be implemented by that part of the rule.

In sum, we suggest that §64-64-4 (Part 4.1) be re-written to read as follows :

> **(a) A physician, dentist, 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 the person may have a positive HIV-related test and (1) when the presence of HIV infection would affect the medical decision concerning the type of patient care recommended or (2) when knowledge of test results is believed to be necessary for effective counseling about behavior change.**
>
> **(b) Such a request must be accompanied by information in the form of a booklet or printed information prepared or approved by the Department or, in the case of persons who**

are unable to read, a video or film prepared or approved by the Department, or the requesting physician or dentist must read or cause to be read to the patient the information prepared or approved by the Department which contains the following specifics:

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

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

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

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

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

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

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

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

(e) At the time of learning of any test result, the subject of the test shall be provided with counseling or referral for counseling for coping with the emotional consequences of learning any test result. This may be done by brochure or personally, or both.

(f) Nothing in this rule or the Act which it supplements 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.

§16-3C-2(e)

Part 4.2 of the proposed rule is apparently designed to implement §16-3C-2(e)(1) of the Act and Part 4.4 is apparently designed to implement §16-3C-2(e)(2) of the Act. No part of the rule has been proposed to implement 16-3C-2(e)(3) of the Act. We believe these parts of the proposed rule need substantial clarification. Each relates to instances in which testing can be undertaken without consent. Thus each of these sections of the Act are possibly intrusive to the lives of the people of West Virginia and, we believe, violative of their state and federal constitutional rights. We suggest below language that could be added to the proposed rule to mitigate the intrusiveness of these sections of the Act.

Section 16-3C-2(e) of the Act contains three provisions for non-consensual testing; the sections of the rule should be written to parallel these sections of the Act and our comments are arranged accordingly.

Section §16-3C-2(e)(1), regarding testing of donated blood

and body parts, needs to be clarified in the proposed rule (Part 4.2) to make it clear that it is the human body parts (including tissue and blood or blood products) that are to be tested, and not the human beings involved. HIV (or indeed any infectious disease) cannot be transmitted from the recipient of a "human body part" to its donor, or visa versa; only the "human body part" itself can be the route of disease transmission. We therefore believe that the Act does not mean to suggest the irrational need to test either recipients or donors. It is within the discretion of the Department in implementing this section of the Act to give it a rational meaning. Suggested language is below.

Subsection (e)(2), implemented by Part 4.4, perplexes us. We do not understand how a true medical emergency, that is so urgent that the substituted consent provisions of §16-3C-4 are of no avail, could await the results of HIV-related testing. Indeed, the Act itself seems to recognize this problem by stating quite correctly that "Necessary treatment may not be withheld pending HIV test results."

Nonetheless, the proposed rule should at the very least include the restrictions on such testing which are in the Act, and might also include additional language in an attempt to ameliorate the Act's illogic. Suggested language is below.

We have no objection to §16-3C-2(e)(3), which permits non-consensual HIV-testing for research purposes when the identity of the test subject remains anonymous.

In sum, we suggest that §16-3C-2(e) should be implemented by

a rule which reads as follows:

> 4.2. No consent for testing is required and the provisions of rule 4.1 of these regulations do not apply for the performance of an HIV test:
>
> (a) on a human body part (including tissue and blood or blood products and semen) 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, however, that it is the body part itself which is tested and not the human being.
>
> If a test is desired of the donor or recipient of human body part, tissue, blood, blood product, or semen, the procedures established in Part 4.1 must be followed.
>
> Further, all confidentiality restrictions contained in Part 7 apply to information obtained through the testing of human body parts, tissue, blood, blood products, or semen.
>
> (b) in documented bona fide medical emergencies provided:
>
> (1) that the subject of the test is unable to grant or withhold consent; and
> (2) that substituted consent has been sought but has been refused; and
> (3) that the test results are necessary for medical diagnostic purposes to provide appropriate emergency care or treatment; and
> (4) that post-test counseling is provided; and
> (5) that necessary treatment may not be withheld pending HIV test results.
>
> (c) for the purpose of research, provided that the testing is performed in a manner by which the identity of the test subject is not known and may not be retrieved by the researcher or any other person.

§16-3C-2(f)

Section 16-3C-2(f) of the Act mandates testing of certain persons regardless of their ability to consent. The Act's

provisions fall into three categories: (1) the mandatory testing of persons convicted of certain crimes (prostitution, sexual abuse, sexual assault, incest or molestation), §16-3C-2(f)(2)(i) and (ii); (2) the discretionary non-consensual testing of persons "causing [HIV] exposure" to "a person who was possibly exposed to HIV infected blood or other bodily fluids as a result of receiving or rendering emergency medical aid or who possibly received such exposure as a funeral director," §16-3C-2(f)(3); and (3) the discretionary non-consensual testing of persons who the Department believes may be infected with HIV and "is or may be" a danger to the public health, §16-3C-2(f)(4), and the associated provisions to require such a person to seek counseling and to "cease and desist" from certain conduct, §16-3C-2(g).

The proposed rule contains no regulations elucidating these highly intrusive provisions. The absence of clarifying, defining and limiting regulatory provisions will create needless confusion and lead to numerous implementation problems. We propose language for each of three categories in turn.

§16-3C-2(f)(1)

First, as to the mandatory testing of the classes of convicted criminals described in the Act, despite our belief that this section of the Act is unwise and possibly unconstitutional,[2] we

[2]Nonconsensual testing is an infringement of fourth amendment rights and must be justified by a compelling governmental interest. See, e.g., Glover v. ENCOR, 686 F.Supp. 243 (D.Neb. 1988)(on appeal)(enjoining a program for HIV-testing program of employees at a state home for mentally handicapped persons on the grounds

believe it is incumbent upon the Department pursuant to §16-3C-8(a) to establish procedures for testing these groups of people. Such procedures should explicitly preserve the counseling process for such persons and guarantee their statutory rights to confidentiality protections. The confidentiality provisions of the Act, §16-3C-3, do not include any exception which would allow the results of these mandated tests to be released to any persons outside the Department, including victims, judges, or persons in the Department of Corrections. The Department must make clear to those in the criminal justice system, as well as to its own employees, that the law requiring testing does not authorize any disclosure of the test results except as provided in Sec. 16-3C-3. If confidentiality of these test results were to be breached, we are of the legal opinion that remedies against the Department might lie under §16-3C-5.

We recommend that the following language be added to the proposed rule:

> **Upon notification to the Department that a person has been convicted of a crime specified in Sec. 16-3C-2(f)(2), the Department shall conduct HIV antibody testing for the convicted person. Such testing shall be accompanied by pre-test and post-test counseling. All**

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that such a constitutional infringement was not justified). Given current data on the infrequency of transmission of HIV by prostitutes, for instance, it is unlikely that the government could justify this infringement of the convicted person's fourth amendment rights. Nor is the information useable in court proceedings; the state legislature has correctly maintained the confidentiality of the test results. Thus it is difficult to see what purpose is served by mandatory testing which could not be served by an aggressive program for counseling offenders about behavior changes to prevent HIV transmission.

statutory provisions as to the confidentiality of HIV antibody test results shall apply to this testing program.

§16-3C-2(f)(3)

Section 16-3C-2(f)(3) is confusing as written, and the proposed rule fails to clarify the language of the Act. The section is designed to allow forced testing "for the protection" of persons who may have been exposed to HIV-infected blood or bodily fluids "as a result of receiving or rendering emergency medical aid or . . . as a funeral director." The wording of the Act establishes no standards for the implementation of this rule. Thus, any emergency medical provider, or person provided emergency medical aid, or funeral director, would appear to be able to demand that the Department test third persons at any time and in any circumstances.

The Department has adopted one sentence in its proposed rule (Part 4.3) which attempts to limit the ability of possibly HIV-exposed persons to request testing of other parties: "Exposure must be deemed by the Director to pose a significant risk for transmission of the HIV to the person concerned about infection for a test to be ordered on the individual causing exposure." While this phrase is a start, we believe it does not go far enough.

Moreover, neither the law nor the proposed rule recognizes the possibility that most times this situation presents itself, the subject of the proposed forced testing will voluntarily consent to

be tested if apprised of the circumstances and guaranteed confidentiality. This possibility should be acknowledged in the Department's rule and forced testing reserved only for medically necessary situations where consent cannot be obtained voluntarily. (Compare with §16-3C-2(e)(2) and proposed rule, supra.)

Further, neither the law or the proposed rule makes clear that when this type of forced testing is mandated, the information sought can, and should where possible, be transmitted to the third party without the patient's identifier.

Finally, as with all the subsections of §16-3C-2(f), post-test counseling is required.

In sum, we suggest that the following be added to the proposed rule to clarify and define when the "protection" of such a person justifies a non-consensual HIV-related test:

> The Director may request a person to provide written informed consent for an HIV-related test if the Director has medical evidence to support the belief that the person is 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 a funeral Director to a significant risk for transmission of HIV; provided that if the person believed by the Director to be infected refuses to provide written informed consent, or if substituted consent is refused in the case of a person unable to grant or withhold consent, the Director may require an HIV test if information from such a 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. In no case, however, shall the identity of the person so tested be disclosed.

While this language still permits non-consensual testing of persons who may have exposed emergency workers of funeral directors to HIV,

it provides a preferred consensual mechanism for testing, and preserves the anonymity of persons who are involuntarily tested.

§16-3C-2(f)(4) and §16-3C-2(g)

Sections 16-3C-2(f)(4) and (g) of the Act are, we believe, unconstitutional on their face. It is obvious that (f)(4) permits great invasions of the procedural and substantive rights of the people of West Virginia. For example, (f)(4) allows the Director to force a variety of restrictive measures upon an individual based only the Director's "knowledge" or "reason to believe" that a person is infected with HIV and that such a person "is" or "may be" a danger to the public health. For example, a person could be compelled to submit to a medical examination and to undergo counseling against his will; and, in an even greater restriction of personal freedom, the Director may effectively quarantine a person by directing him to "cease and desist from specified conduct which endangers health of others." Thus, without any hearing on the questions of HIV infection or danger to the public health, a person might be deprived of his right to refuse medical treatment or his right to engage in otherwise legal conduct, freedoms basic to the notion of liberty under our constitution.

The proposed rule should attempt to correct this constitutional defect[3] by including provisions incorporating the minimal requirements of procedural due process. Such protections are undoubtedly required in the enforcement of public health measures such as this Act. Greene v. Edwards, 263 S.E.2d 661 (W.Va. 1980) (finding that West Virginia quarantine statute lacked required procedural protections). In Greene, the Supreme Court of West Virginia decided that the procedural protections required in civil commitment proceedings would also be required to quarantine a person infected with a contagious disease. See also, Gostin, "Traditional Public Health Strategies," in AIDS and the Law (H. Dalton and S. Burris, ed. 1987); and W. Parmet, AIDS and Quarantine: The Revival of An Archaic Doctrine, 14 Hofstra L. Rev. 553 (1985). Because the Act has itself failed to require such protections, it is all the more necessary for the proposed rule to provide them.

In order for any implementation of this section of the statute to even be arguably constitutional, certain key principles establishing due process protections must be followed. We recommend that the Department draft and publish for public comment a set of procedures based on these guidelines:

> **1. Any order issued pursuant to Sec. 16-3C-2(f)(4) shall state in writing the medical or epidemiological information which supports a finding that the person is**

[3]We reserve comment on whether a regulation can cure the unconstitutionality of the underlying statute. Regardless of the answer to that legal question, though, the Department has the responsibility to undertake the effort.

HIV infected and the factual information which supports a finding that the person poses a significant danger to the public health.

2. In enforcing Sec. 16-3C-2(f)(4), the Director shall utilize the least restrictive and least coercive option necessary under the circumstances to protect or preserve the public health. In every individual case, the Department must document that each less restrictive and less coercive alternative has been exhausted before a more restrictive or coercive option is invoked. Thus, any person identified in an order issued pursuant to this section shall first be required to report for counseling as to prevention of HIV transmission unless said counseling has already been attempted and is documented to have been unsuccessful; in such a case, the person may be required to be examined and tested for HIV infection if it is reasonably believed that testing will help bring about necessary behavior change, unless said testing is documented to have already been done and the danger to public health has not abated. Both of these options must be employed before the Director seeks a cease and desist order or an order imposing restrictions.

3. If the Director issues an order to require a person to be tested, the order should have a grace period of approximately seven (7) days during which the person can seek court review of the order.

4. If the Director determines that a cease and desist order is necessary, he or she should state in writing the medical basis for the cease and desist order, the specific conduct from which the person must desist, and the evidentiary basis for the belief that such person is currently engaging in said conduct.

5. Prior to issuing a cease and desist order, the Director should seek a judicial hearing, with notice having been given to the person named, as to the validity of the cease and desist order.

6. If the Director determines that imposition of restrictions pursuant to Sec. 16-3C-2(g) is necessary, he or she should petition the court having jurisdiction of the subject's cease and desist order to impose such restrictions. The person named shall be given notice of the medical basis for the restrictions being sought and the evidentiary basis for the belief that such restrictions are necessary to prevent conduct posing a significant danger to the health of others, as well as of the specific terms and conditions of the restrictions.

Sec. 16-3C-2(K)

This section of the statute, which presently has no corresponding proposed regulation, requires that each person giving consent to testing, whether orally or in writing, have been counseled in compliance with the statute's criteria for counseling. Whenever possible, however, the consent should be in writing, to protect both the test subject and the provider conducting the test in the event that there is later a claim that the testing was nonconsensual. We recommend that the Department add a new section to the proposed rule which would specify that:

Consent to an HIV test shall always be in writing unless the subject is unable to give written consent.

Indeed, we would encourage that Department to draft a model informed consent form which incorporates the relevant provisions of the law (Sec. 16-3C-2(b), (c), and (d)) and the language of the rule suggested above.

§64-64-5. Review of Marriage Licence

No comment.

§64-64-6. Charting Information

No comment.

§64-64-7. Confidentiality

We have no comment on the language contained in the proposed rule on confidentiality but we do believe that additional language is needed as to two sections of the statute which now have no corresponding regulatory provisions.

Sec. 16-3C-3(a)(3) provides that funeral directors or their authorized agents or employees may be given access to confidential information if they have a "need to know" that information, but neither the statute nor the proposed rule defines the critical phrase "need to know." We recommend an additional provision to remedy that gap:

> **7.3. A person described in Sec. 16-3C-3(a)(3) shall be deemed to have a need to know HIV test results only if standard infection control procedures (such as gloving) are inadequate to protect that person from a significant risk of transmission of HIV in the particular case for which the protected information is sought.**

Secondly, Sec. 16-3C-c(a)(4) provides that certain health care personnel can also be given access to the information if knowledge of test results is "necessary or useful to provide appropriate care or treatment, in an appropriate manner." This language, too, needs explanation. We recommend a regulatory provision which provides that as follows:

> **7.4. Test results may not be disclosed to a health care provider pursuant to Sec. 16-3C-3(a)(4) unless such disclosure is necessary for determining the best course of treatment for the patient. Risk or perceived risk to the health care provider may not be a basis for disclosure pursuant to this section.**

§64-64-8. Contact Notification

Section 8 of the proposed rule, which apparently implements §16-3C-3(d) and (e), should make clear that neither the Department nor any health care provider may require an HIV-infected person to reveal his contacts. The belief that a health care provider or the Department might be able to compel disclosure of sexual or intravenous drug contacts would obviously deter people from being tested for HIV and thus undermine the overall purpose of the proposed rule. Further, we believe that the guarantee of confidentiality for the index patient should be elaborated and the principle that notification should only be undertaken of contacts who are believed to be unknowingly at risk should be made explicit.

These principles have been reaffirmed as the basic components of a sound partner notification process by the recent Guide to Public Health Practice: HIV Partner Notification Strategies (September 1988) published by the Association of State and Territorial Health Officials. (Copy of relevant excerpts attached as Exhibit 1.) This Guide establishes the professional standard in the field. We recommend that the following language be substituted for the second sentence of section 8 of the proposed rule:

> **Contact notification shall be initiated by the Director when the Director has evidence to believe that contacts may be unknowingly at risk for HIV infection. The same confidentiality rules that apply to the names of HIV infected persons shall apply to the names of their contacts. Further, nothing in these rules shall be construed to require an HIV infected person to reveal his sexual or IV drug contacts.**

An additional and greater concern is that private health care

providers are provided with virtually no guidance in the proposed rule as to the professional and ethical criteria for doing contact notification. Although such providers may elect to notify the Department rather than undertake partner notification themselves, they are not bound to follow that course by the statute. Thus the greatest potential for abuse lies in the vagaries with which hundreds of private providers might seek to do notification. See ASTHO Guide, Exhibit 1 at 14-15.

We therefore urge the Department to add another section to the rule which would provide guidance to these providers:

> **8.2. In contact notification situations, the Department recommends that private health care providers refer cases to the Department rather than attempt notification themselves. The Department has expertise in handling this often delicate situation and has an established program for notifying partners of persons with infectious conditions. Private providers should notify partners only if the provider feels qualified to counsel the partners appropriately and to maintain the index patient's confidentiality.**

§64-64-9. Substituted Consent

No comment.

§64-64-10. School Exclusion

No comment.

§64-64-11 and -12. Reporting Requirements

The reporting requirements set out in the proposed rule are not authorized by any provision of the statute. While we recognize the importance for epidemiological and statistical purposes of

gathering information about HIV, we believe the Department has no justification in requiring the reporting of names. Moreover, the collection by the Department of the identities of persons being tested is likely to deter West Virginians from using testing programs which do not conduct anonymous testing. The ultimate result of collecting names is likely to be that less data, rather than more, is available to the Department.

We therefore recommend that the proposed rule require health care providers (section 11) and laboratories (section 12) to report positive HIV antibody test results without any identifying names and addresses linked to the testing data.

§64-64-13 Quality Control

Although laboratories are required to comply with the confidentiality and other provisions of the statute and of the rule, proposed rule Sec. 13.1.2(a), the section of the rule discussing revocation for noncompliance, Sec. 13.6.3(b), requires compliance only with the rule. To ensure that laboratories comply with the confidentiality, and other, sections of the law, we recommend that the phrase "or the applicable requirements of Article 3C, Chapter 16 of the West Virginia Code" be added to proposed rule 13.6.3(b).

§64-64-14 Banking Blood

No comment.

§64-64-15 Administrative Due Process

No comment.

§64-64-16 Severability

No comment.

CONCLUSION

While we have suggested some changes that could be made to the proposed rule to clarify it and strengthen its chances for being an effective measure in the effort to prevent the spread of HIV infection, we hope that in reviewing the proposed rule, the Department will try to shift its emphasis.

As it stands now, the proposed rule has diluted the consent testing provisions of the Act, and left the non-consensual testing provisions of the Act largely unclarified. It is our view that consensual informed testing is always preferable to non-consensual testing, and the rule should embody this principle as much as is consistent with the health of the people of West Virginia.

Moreover, we believe that the drastic and invasive power of the State to compel testing should be a last resort, and that it should be used only in conjunction with strict procedural safeguards.

Finally, we believe that the confidentiality provisions of the Act should be strengthened by the proposed rule whenever possible.

We believe that the suggestions made above promote these broad principles, and that the protection of the constitutional rights of West Virginians and sound public health policy require them.

GUIDE TO PUBLIC HEALTH PRACTICE:

HIV PARTNER NOTIFICATION STRATEGIES

Association of State and Territorial Health Officials

National Association of County Health Officials

U.S. Conference of Local Health Officers

September 1988

[redacted]

EXHIBIT 1

UNDERLYING PRINCIPLES

The Association of State and Territorial Health Officials (ASTHO), the National Association of County Health Officials (NACHO), and the U.S. Conference of Local Health Officers (USCLHO) believe that state and local health departments should establish programs to provide partner notification and referral services compatible with state and local laws, policies, and resources. At a minimum, the programs should include counseling protocols that encourage persons infected with HIV to notify their sex and needle-sharing partners they may have been exposed to the virus.

Program policies should emphasize that people infected with HIV have a responsibility to inform their partners and to refer them to counseling and testing sites or to health care providers for counseling and testing. Even after counseling, some HIV-infected persons may be reluctant to notify their partners, and assistance may be necessary. No matter what type of partner notification approach is used, the principles that follow should underlie all programs.

Voluntary Participation

Disclosing names of partners should always be voluntary. Counseling, testing, and referral services should be available to index patients regardless of whether or not they choose to disclose names of partners.

Confidentiality

All records must be confidential. Partner names must be used only for field investigation and notification. In no instance should the partner be told the name or identity of the index patient, the date or period of exposure, or that the index patient is infected. If confidentiality is not fully protected by law, all identifying partner information should be destroyed upon completion of the follow-up.

Accessibility

Partner notification services offered by health care providers should be made available and easily accessible to all persons with clinically validated HIV seropositive status, based on a repeated and confirmed test result.

Quality Assurance

Health departments should routinely evaluate the performance of counselors (also referred to as disease intervention specialists) and other program personnel to ensure that high quality services are being delivered. Health departments should establish quality assurance and training guidelines which all professionals engaged in the partner notification process must follow. A complete discussion of these guidelines is available in *Quality Assurance Guidelines for Managing the Performance of Disease Intervention Specialists in STD Control* (CDC, April, 1985).

Information Provided

Regardless of who notifies named partners that they may have been exposed to HIV, certain basic information should be communicated. The information should include a description of the modes of HIV transmission; the telephone numbers and addresses of HIV antibody testing sites; suggestions about how the partners should modify their behaviors whether or not they decide to be tested; information about the disease process itself; and

referral to support groups, mental health services, and medical facilities. Identified partners should also be cautioned about sharing the information about exposure or infection status with individuals who are not their sex or needle-sharing partners because of the possibility that this information could result in acts of discrimination.

Targeted Services

Health departments should tailor their partner notification programs, educational materials, and training procedures to specific populations. For example, gay men and nongay intravenous drug users are likely to require different programs. Intravenous drug users may be less willing to use health department assistance in notifying partners because their high-risk behavior is illegal and, if brought to the attention of law enforcement authorities, could result in legal action. The counseling session with an intravenous drug user should include discussions on safer sex practices and on how to effectively clean syringes and needles, and should include attempts to persuade the individual to enter a drug treatment program. This type of counseling requires different skills and, therefore, different training procedures, than would be necessary for counselors discussing safer sex practices with gay men. In addition, notifying intravenous drug users may be difficult or hazardous if, for instance, they can be found only in shooting galleries. However, there may be no other method of reaching such individuals because, ordinarily, they are not exposed to AIDS education messages.

ENSURING CONFIDENTIALITY

The public perceptions surrounding partner notification underscore the importance of accompanying these programs with strong confidentiality protections. Breaches of confidentiality during the process of partner notification could result in discrimination against index patients and their sex or needle-sharing partners. In addition, the perceived risk of weak confidentiality protections may discourage some individuals from seeking counseling and testing, or from participating in partner notification programs. These perceptions make it imperative that health departments and state legislatures implement strong measures to maintain confidentiality in partner notification programs, as well as in their counseling and testing programs.[4] The protection of confidentiality by public health agencies has been excellent, but the extent of breaches of confidentiality elsewhere is not known with any precision. It is important that health departments develop surveillance systems to document disclosures of confidential information.

Definition of Confidentiality

State and local health departments must protect the confidentiality of infected persons and their named partners. For purposes of this report, confidentiality is defined as:

> The protection from the release of information, without the consent of the named party, which links the individual's identity to facts about HIV seropositivity, behavioral risk factors, or application for related services. Disclosure of information without the documented consent of the individual is permitted only when the disclosure is necessary for the individual's medical care or is required by law.

Management of Confidential Records

Confidentiality principles should apply to all medical and public health information related to the identity of the index case or named partners, regardless of the manner in which the information is obtained or where the information is maintained. Subsequent disclosures of the information beyond that for which the individual has given consent must not be made without specific additional written permission.

Health care providers and agencies should develop policies and regulations, if they do not already have them, to ensure confidentiality of medical and public health information. Policies and regulations should cover record retention and destruction, secure physical storage of records, and access to those records by staff or other individuals, including legal authorities. Providers should also establish sanctions for breaches of confidentiality and all staff should know the consequences (e.g., disciplinary action) of violating these policies.

ASTHO, NACHO, and USCLHO believe that no written link should ever exist between the index patient and the partner unless there are strong confidentiality protections in place. With those protections, some health departments may choose to link these records so that, under the provider referral model, if a partner cannot be located, the index patient can be asked about additional locating information or asked to attempt to contact the partner. If confidentiality is not fully protected by law, written records on index patients and their partners should be destroyed after partners have been notified.

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[4] For a detailed discussion of AIDS confidentiality issues, see *Guide to Public Health Practice: AIDS Confidentiality and Anti-Discrimination Principles*. Association of State and Territorial Health Officials, March 1988.

Statutory Protection

ASTHO, NACHO, and USCLHO believe that states should establish statutory protection, if it does not already exist, prohibiting the release, under subpoena or court order, of name-linked information and public health records pertaining both to index patients and named partners. Until such protection is available, the following procedures should be followed:

- Public health agencies should not release HIV-related information upon subpoena but should respond with appropriate motion for protective order or to quash the subpoena.
- Public health agencies should advocate that court orders for disclosure of name-linked HIV-related information should not be issued except when compelling reasons for disclosure are demonstrated.
- Court proceedings concerning the disclosure of HIV-related information should be held in private. Records of the proceedings should not be open for public inspection and should be sealed following the proceedings.

In states where protective statutes regarding confidentiality of medical and public health records are in place, extending the existing provisions to include HIV-related conditions may be an effective way to further ensure confidentiality. States should also enact legislation to provide for civil and criminal sanctions against individuals who willfully or negligently violate these confidentiality provisions.

Notifying Partners in Person

ASTHO, NACHO, and USCLHO believe that, in almost all cases, partners should be notified in person of their possible exposure to HIV. Partners should not be notified by telephone or through the mail. This procedure will ensure that information about exposure is not inadvertently conveyed to the wrong person. In the few instances where face-to-face partner notification is not possible, procedures for providing notification other than in person may be developed and should be followed carefully.

PRIVILEGE TO DISCLOSE INFORMATION

Partner notification relies on the concept of infected persons either notifying their partners that they may have been exposed to HIV or disclosing the names of partners to health care providers who, in turn, contact the partners. On occasion, the health care provider may know the identity of at-risk partners of the index patient and may have knowledge that an index patient will not take appropriate action to notify those partners.

Because of these unusual situations, it is necessary to address the health care provider's "privilege to disclose" information that is otherwise protected in the patient-provider relationship. Privilege to disclose refers to the decision of the public or private health care provider to notify partners who are at risk of exposure when the index patient will not notify known partners, and will not agree to allow the provider to notify the partner.

Provider-Patient Privilege

The purpose of the provider-patient privilege is to encourage the free exchange of personal information. The privilege serves to protect the provider-patient relationship when an expectation or legal right to confidentiality is present. While the provider has a duty to protect the confidentiality of information, the index patient has a duty to prevent transmission of the infecting agent. The privilege to disclose exists only when the index patient fails to uphold his or her duty to protect others. The privilege between the provider and index patient evolves into a privilege of the provider to protect an unsuspecting third party pursuant to the provider's legal and ethical responsibilities. This is in contrast to the "duty to warn," which refers to the affirmative duty of the health care provider to disclose privileged information. Under the duty to warn concept, providers may face sanctions for failing to carry out their affirmative duty.

The major difference between partner notification and the privilege to disclose is that, in the latter, the health care provider knows of a named partner in tandem with the index patient's refusal to participate in the partner notification process. In most partner notification situations, especially when health department personnel test and counsel the index patient, a privilege to disclose situation does not arise because, in the absence of disclosure by the index patient, the identity of sexual or needle-sharing partners usually is not known.

Responsibilities of the Health Care Provider

The privilege to disclose may be invoked when all four of the following criteria have been met and documented:

- The provider knows of an identifiable third party at risk;
- The provider believes there is a significant risk of harm to the third party;
- The provider believes that the third party does not suspect that he or she is at risk; and
- The index patient has been urged to notify the at-risk partner and has refused or is considered to be unreliable in his/her willingness to notify the partner.

In general, the provider must rely on the index patient's interpretation of the facts as to whether the partner is at risk and whether the partner has been or will be notified. For example, an index patient may tell the provider that he or she will notify the identifiable third party or that there has been no past exposure to the third party and will be none in the future. In these instances, the provider must accept that interpretation unless he or she knows, from

contact with the partner of the index patient or from other compelling evidence, that the index patient's statements are unreliable.

ASTHO, NACHO, and USCLHO believe that in cases in which all of the above criteria are met, the need to prevent the unintentional spread of HIV by unsuspecting partners outweighs the need to abide by the wishes of the index patient. The health care provider has a responsibility to ensure that known partners are informed of their possible exposure to HIV. This obligation is discharged when the provider either notifies the partner directly or refers the index patient's name and the partner's name to the health department for partner notification. This does not mean the index patient's confidentiality should be breached, however. The partner should be notified in the same way as if the index patient had asked for assistance in notifying the partner; that is, the identity of the index patient is not revealed to the partner.

Strategies for Handling Difficult Situations

Serious ethical and legal concerns arise when the health care provider has reasonable grounds to suspect that the partner will remain at risk of repeated exposure to HIV by participating in ongoing sex or needle-sharing activities with the index patient. To address these concerns, state and local health departments should ensure that their pretest and posttest counseling protocols include, in addition to the standard recommendations about adopting risk reduction behaviors, emphatic admonitions that, before considering any future activities involving a risk of HIV transmission, individuals should discuss AIDS, risk reduction and avoidance, and serologic status with each and every sex and needle-sharing partner.

Providers, particularly health departments, should have contingency plans for those rare instances where evidence suggests that the admonitions will not be heeded, that the partner refuses to conceive of the index patient as a potential source of infection, and that continuing exposure is reasonably possible. Private providers should seek advice from the local health department on further disclosure or on whether other public health actions should be directed to the index patient or partner.

Invoking Privilege to Disclose

Privilege to disclose should be viewed by health care providers as a last resort. They should always attempt first to persuade index patients to either notify partners themselves or agree to have a qualified health care provider notify partners of their possible exposure to HIV. Only when these attempts have failed should a provider inform the partner without the consent of the index patient.

Privilege to disclose does not imply that providers should, against the wishes of the index patient, actively seek out the identities of the index patient's partners. In fact, the perception that this occurs may discourage persons from seeking counseling and testing. A privilege to disclose situation occurs only when the provider learns of at-risk partners through the provider's ordinary activities. For example, a private physician may know that a long-time patient who tests positive for the HIV antibody is married. In fact, privilege to disclose situations might occur more frequently among private providers because they are more likely to have continuing provider-patient relationships.

As with standard partner notification procedures, ASTHO, NACHO, and USCLHO recommend that, in privilege to disclose situations, the notification be performed by health departments because these agencies have the expertise, and usually the resources, to notify partners. In addition, since health departments have partner notification programs in place, they are better able to maintain the confidentiality of index patients and their partners.

Private providers should notify partners only if the provider feels qualified to counsel the partners appropriately and to maintain the index patient's confidentiality.

When private providers ask health departments to notify known partners of possible exposure to HIV, they should give the health department the name of the known partner and the name of the index patient. The private provider should certify, using a method specified by the health department, that the index patient is HIV seropositive. Depending upon the completeness of the information provided, the health department may proceed to notify the partner without interviewing the index patient. Any written link between the index patient and partner should be protected fully under confidentiality statutes.

On rare occasions, the index patient may not pose a threat to identifiable partners but, based on stated intended acts, may be dangerous to the general population. In these cases, the health care provider should disclose the index patient's identity to the health department so necessary action can be taken to protect the public.

In order to invoke the privilege to disclose effectively, it should be accompanied by certain statutory protections. Legislation should carefully outline the situations in which the privilege to disclose may be used. The legislation should be accompanied by immunity from liability for health care providers, for notifying partners without permission of the index patient, and also for deciding not to notify the partner. In either situation, it is important that the privilege to disclose be viewed as just that, a privilege, based on the reasoned judgment of the health professional. Action is neither affirmatively required nor restricted.

From W. Va. Nurses Association DRAFT

COMMENTS ON PROPOSED WEST VIRGINIA DEPARTMENT OF HEALTH LEGISLATIVE RULE ON AIDS-RELATED TESTING AND CONFIDENTIALITY

The West Virginia Department of Health has proposed a legislative rule concerning AIDS-related Medical Testing and Confidentiality as a "supplement" to West Virginia's AIDS-Related Medical Testing and Records Confidentiality Act, W. Va. Code Section 16-3C-1 et seq. (the "Act"). The stated purpose of the Rule is to provide "specific standards and procedures concerning" those subjects covered by the Act.

The West Virginia Civil Liberties Union believes that several sections of the proposed Rule fall short of the avowed purpose of establishing such specific standards and procedures, and that the Rule in fact omits discussion of several important procedures established by the Act itself. Furthermore, the Rule provides for no procedural protections for the most constitutionally offensive section of the Act, namely section 16-3C-2(f) & (g), dealing with "mandated testing" and enforcement of health department "cease and desist" orders.

In particular, section 4 of the Rule perpetuates and magnifies the Act's ambiguity concerning "HIV-related testing" by not clearly stating that the request by a "physician, dentist, or the Director" for an HIV-test is a request <u>of the patient or person in question</u>, and not a request to have the test performed without regard to the person's consent. Indeed, the Act itself, though not particularly clear on the meaning of "request,"

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nevertheless seems to establish that the "request" is a request for consent of the patient. The Rule is far less specific than the Act on standards for testing. Secondly, section 4.1(a) fails to define the phrase "cause to believe the test could be positive," and thus suggests that a health care provider might request a person to take an HIV-test based on non-medical criteria.

Perhaps more importantly, the proposed Rule does not provide any further clarification of the most troubling sections of the statute, and the West Virginia Civil LIberties Union believes that this omission enhances the unworkability of the Act and thus defeats the purpose of the adoption of the Rule. In specific, the Rule does not provide any standards concerning the Act's provisions for non-consensual testing of blood donors and recipients and in cases of "documented bona fide medical emergencies" (Act, section 13-C02(e)(1), nor are any specific procedures outlined for the carrying out of testing mandated by the Act (subsection (e)(2)).

Further, the West Virginia Civil Liberties Union notes that the proposed Rule provides no procedures for the most constitutionally doubtful sections of the Act, namely 16-3C-2(f)(4) & (g). These sections, pertaining to the power of the Department of Health to require testing absent a criminal conviction and to issue and enforce orders that interfere sharply with the federal and state constitutional rights of the people of West Virginia. Yet the proposed Rule does not even create any

procedural rights for those people whom the Act subjects to this highly intrusive power of the Department of Health.

The contact notification section of the proposed Rule does not provide any guidance to health care providers about procedures to be followed in eliciting sexual or intravenous drug use contact information and does not provide for keeping the names of contacts confidential. Confidentiality is further threatened by the proposed Rule's requirement that names and addresses of HIV-positive individuals be reported to the department of health.

The Proposed Rule's Testing Provisions

1. Non-Mandatory Testing

The language of the proposed Rule regarding HIV-testing is confusing and provides fewer specific guidelines than the Act itself (cf. proposed Rule section 4 with section 16-3C-2(a), (b), (c) and (d)). It is impossible to understand why a Rule aimed at providing more specific guidance in the implementation of a statute would omit reference to requirements of the statute on a subject like testing that is obviously a pivotal part of any government policy on HIV health care.

Part 4.1 of the proposed Rule parallels section 16-3C-2)a of the Act. Nevertheless, the proposed Rule does nothing to clarify any of the ambiguous language of the statute. Both the Rule and the Act provide three alternatives under which HIV-testing "may be requested by a physician, dentist or the

director" (substantially identical language in the Act and the proposed Rule). Neither the Act nor the proposed Rule, however, states anywhere that the "request" is a request of the person being tested. this leaves open the interpretation that the "request" is a request of some third party, presumably the Department of Health, to conduct an HIV test on a person. Taken together with the remainder of the subsection, the Act and the proposed Rule both suggest that such a third party could be requested to perform an HIV-related test on a person without that person's knowledge or consent. But whereas the Act's section 16-3C-2(b) quite specifically rules out this interpretation, the proposed Rule leaves it intact. Subsection (b) of 16-3C-2 states quite unambiguously that the patient shall be provided:

> (3) An explanation that the test is voluntary and may be obtained anonymously; and
>
> (4) An explanation that the consent for the test may be withdrawn at any time prior to drawing the sample for the test.

Although some ambiguity remains in the Act on the question of consent, th3e Act nevertheless establishes that "voluntary consent" must be given for testing performed under subsection (a). As it stands, however, the proposed Rule fails to make the crucial statement that no testing under (a) can be performed without the voluntary (informed) consent of the patient. We therefore suggest that proposed Rule be changed to include subsections 16-3C-2(b,c,d) of the Act verbatim. Without this change, the proposed Rule seems to permit the testing of a persons' blood without that person's knowledge or consent. Such

testing is repugnant to the Fourth Amendment to the United States Constitution and to Article III, section 6 of the West Virginia Constitution, which guarantee each person the right "to be secure" in her "person" against "unreasonable searches." A state-authorized non-consensual "search" for HIV antibodies or antigen is surely an unreasonable search. See, e.g., Schmerber v. California, 384 U.S. 757 (1966) (permitting a warrantless non-consensual blood alcohol test where the purpose of the test was to uncover, based on probable cause, evidence of a crime where that evidence might disappear).

There is a second problem with section 4 of the proposed Rule. The proposed Rule "defines" "cause to believe that the [HIV] test could be positive" by outlining the bases for that belief:

> high-risk behavior, or risk-exposure with an HIV-infected individual or exposure to blood products that were reported to be from an individual with a positive HIV-related test.

However, the proposed Rule fails to require medical evidence for these "causes to believe," thus allowing for the possibility of requests for HIV tests being made of patients simply because a health-care provider suspects, based on some personal criteria, that a patient is engaged in high-risk behavior or has been "risk-exposed" to someone who has engaged in such behavior. We therefore suggest that subsection 4.1 be rewritten and merged to read:

> A physician, dentist, or the director may request that a person consent to an HIV-related test when there is medical evidence providing reasonable cause to believe

that the person may have a positive HIV-related test and such condition would affect the decision on the type of patient care recommended.

This paragraph would then be followed by sections (b), (c) and (d) of the Act verbatim, as discussed above. In this way, the ambiguity in the Act and the confused language of the proposed Rule would be replaced by language that clearly describes of whom the test is "requested," and that all testing that is not "mandated" may only be done with the informed consent of the patient.

We believe there is no circumstance under which it would be ethical for a physician, dentist, or the Director to request a patient to permit an HIV-related test if that test is unrelated to the health care provided to the person. As they are written, the Act and the proposed Rule both suggest that there may be reasons other than the health of the patient to request HIV-testing. This implication concerns us deeply, for we believe that neither a health care provider nor the Department of Health should be able to request a person to consent to HIV-related testing simply out of curiosity or, viewed in the worst light, out of a desire to impose the unconstitutional provisions of the Act, section 16-3C-2(f)(4) & (g), on that person. Indeed, because we believe that some health care providers may request a patient to be tested for HIV in order that they may screen out patients who are infected with HIV, we strongly urge the Department to add the following to the Rule as a new section:

Nothing in this Rule or the Act which it supplements 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.

2. Mandatory Testing

The proposed Rule contains absolutely no clarification of the non-consensual or "mandated" testing provided for in the Act. Yet it is these sections of the Act which are obviously most intrusive to the lives of the people of West Virginia and most likely violative of their state and federal constitutional rights. We therefore suggest below language that could be added to the proposed Rule to mitigate the intrusiveness of these sections of the Act.

Section 16-3C-2(e) contains three provisions for non-consensual testing. We have no objections to subsection (3), which permits non-consensual HIV-testing for research purposes when the identity of the test subject remains anonymous. However, section (1) could be clarified in the proposed rule to make it clear that only the "human body part (including tissue and blood or blood products) donated" should be tested. It is common knowledge that transmission of HIV (or indeed any infectious disease) cannot magically occur from the recipient of a "human body part" to its donor; indeed, only the "human body part" itself can be the route of disease transmission, and we therefore believe that the Act does not mean to suggest the irrational need to test either recipients or donors. This

section of the Act could be clarified as follows by a new section in the proposed Rule:

> No consent for testing is required for a health care provider or a health facility to perform an HIV-related test on a human body part (including tissue and blood or blood products) when the health care provider or health facility procures, processes, distributes or uses a human body part donated for a purpose specified under the uniform anatomical gift act, or for transplant recipients, or semen provided for the purpose of artificial insemination.

Subsection (e)(2) perplexes us. We do not understand how a true medical emergency that is so urgent that the substituted consent provisions of 16-3C-4 are of no avail could await the results of HIV-related testing. Indeed, the Act itself seems to recognize this problem by stating quite rightly that "Necessary treatment may not e withheld pending HIV test results." We believe that this section of the Act is irrational, but that the proposed Rule might include the following as a new section to ameliorate the Act's illogic:

> In documented bona fide medical emergencies when the patient is unable to grant or withhold consent to an HIV-related test, but HIV-test results are medically necessary to provide appropriate emergency care or treatment, the provisions of section 9 of this Rule (Substituted consent) shall be used to avoid delay or denial of necessary medical treatment.

Section 16-3C-2(f) of the Act mandates testing of certain persons regardless of their ability to consent. These highly intrusive provisions are not elucidated at all by the proposed Rule. The Act's provisions fall into three categories: (1) the mandatory testing of persons convicted of certain crimes (prostitution, sexual abuse, sexual assault, incest or molestation); (2) the

discretionary non-consensual testing of persons "causing [HIV] exposure" to "a person who was possibly exposed to HIV infected blood or other bodily fluids as a result of receiving or rendering emergency medical aid or who possibly received such exposure as a funeral director;" and (3) the discretionary non-consensual testing of persons who the department believes may be infected with HIV and "is or may be" a danger to the public health, and the associated provisions to require such a person to seek counseling and to "cease and desist" from certain conduct. We address possible useful additions to the proposed Rule concerning each of these three categories in turn.

The mandatory testing of the classes of convicted criminals described in the Act is not discussed at all in the proposed Rule. We suggest that the proposed Rule should set up procedures that would allow the Department to test these groups of people after conviction.

Section 16-3C-2(f)(3) is confusing as written, and the proposed Rule could clarify the language of the Act substantially. The wording of the Act establishes no standards for what is meant by "protection of a person who was possibly exposed to HIV infected blood or bodily fluids." We suggest that the following be added to the proposed Rule to clarify and define when the "protection" of such a person justifies a non-consensual HIV-related test:

> The director may request a person to provide written informed consent to an HIV-related test if the director has medical evidence to support the belief that the person is infected with HIV and if the blood or other

> bodily fluids of that person may have exposed another person receiving or rendering emergency medical aid or a funeral director to HIV; provided that if the person believed by the director to be infected refuses to provide written informed consent or if substituted consent is refused in the case of a person unable to grant or withhold consent, the director may require an HIV test if information from such a 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. In no case, however, shall the identity of the person so tested be disclosed.

While this language still permits non-consensual testing of persons who may have exposed emergency workers of funeral directors to HIV, it provides a preferred consensual mechanism for testing, and preserves the anonymity of persons who are involuntarily tested.

Sections 16-3C-2(f)(4) and (g) of the Act are, we believe, unconstitutional on their face. It is obvious that (f)(4) permits great invasions of the procedural and substantive rights of the people of West Virginia. First, (f)(4) allows the director to force a person to do a variety of things based only the director's "knowledge" or "reason to believe" that a person is infected with HIV poses (or "may" pose) a danger to the public health. There is no provision for any type of fair hearing on these issues whatsoever. The proposed Rule should at least include a provision for some semblance of procedural due process when such gross infringements of personal freedom are at stake. Under the Act, a person could be compelled to submit to a medical examination and to undergo counselling against his will; and, in an even greater restriction of personal freedom, the director may effectively quarantine a person by "directing him to "cease and

desist from specified conduct which endangers health of others." Without any hearing on the questions of HIV infection or danger to the public health, a person might be deprived of freedoms basic to the notion of liberty under our Constitution. Yet the proposed Rule does not even attempt to provide procedural protections, although such protections are undoubtedly required in the enforcement of public health measures such as this Act. See Greene v. Edward, 263 S.E.2d 661 (W.Va. 1980) (finding that West Virginia quarantine statute lacked required procedural protections). In Greene, the Supreme Court of West Virginia decided that the procedural protections required in civil commitment proceedings would also be required to quarantine a person. Obviously, the Act has itself failed to require such protections, but there is no reason the proposed Rule should not set out some procedure to be followed before the director may deprive people of their right to refuse medical treatment or their right to engage in otherwise legal conduct. We note in passing that the Act leaves the specification of conduct that "endangers the public health" entirely to the discretion of the director, and that the proposed Rule could also warn the people of West Virginia of the extent to which the Department of Health may interfere with their conduct. Thus, for example, a section might be added to the proposed Rule that would confine the "cease and desist" orders to prohibition of conduct that poses a risk of HIV transmission.

Even if procedural protections were established by the proposed Rule, the invasion of the substantive rights of the people of West Virginia by the action of the department of health is itself probably unconstitutional. Nevertheless, the proposed Rule should be amended to limit the unbridled discretion of the director to curtail the constitutional rights of the people of West Virginia.

Contact Notification

Section 8 of the proposed Rule should be amended to require that the names of contacts given by HIV-infected persons are kept confidential. Absent the assurance that contact names are required by law to be kept confidential, many HIV-infected persons will likely resist providing names of contacts, thus impeding the purpose of contact notification. Further, we believe that it should be made clear that neither the department nor any health care provider may require an HIV-infected person to reveal his contacts. The belief that a health care provider or the department might be able to compel disclosure of sexual or intravenous drug contacts would obviously deter people from being tested for HIV, and thus undermine the overall purpose of the proposed Rule. Finally, we believe that the discretion of the director in determining whether to notify contacts of possible exposure should be limited. We suggest that the following language be substituted/added to section 8 of the proposed Rule:

> Contact notification shall be initiated by the Director when the Director has evidence to believe that contacts

may be at risk for HIV infection. The same confidentiality rules that apply to the names of HIV infected persons shall apply to the names of their contacts. Further, nothing in these rules shall be construed to require an HIV infected person to reveal his sexual or IV drug contacts.

Reporting Requirements

The reporting requirements set out in the proposed Rule are not based directly on any section of the Act. While we recognize the importance for epidemiological and statistical purposes of gathering information concerning HIV, we believe that there is no sound epidemiological basis for requiring health care providers (section 11) and laboratories (section 12) to report to the department the names or addresses of individuals tested whose tests are positive. Since the Act requires no such reporting of names and addresses, we see no reason for the proposed Rule to invent this additional potential deterrent to people seeking HIV counseling or testing.

Conclusion

While we have suggested some changes that could be made to the proposed Rule to clarify it and strengthen its chances for being an effective measure in the effort to prevent the spread of HIV infection, we hope that in reviewing the proposed Rule, the department will try to shift the emphasis of the Rule. As it stands now, the proposed Rule has diluted the consent testing provisions of the Act, and left the non-consensual testing provisions of the Act largely unclarified. It is our view that

consensual informed testing is always preferable to non-consensual testing, and the Rule should embody this principle as much as is consistent with the health of the people of West Virginia. Moreover, we believe that the drastic and invasive power of the State to compel testing should be a last resort, and that it should be used only in conjunction with strict procedural safeguards. Finally, we believe that the confidentiality provisions of the Act should be strengthened by the proposed Rule whenever possible. We believe that the suggestions made above promote these broad principles, and that the protection of the constitutional rights of West Virginians and sound public health policy require them.

West Virginia NURSES Association, Inc.

Carol S. Fulks
Executive Director

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Doc.: WVRULES.005
Draft: 11/08/88 5:56 pm

Received 11/17/88 Leg. Bond.

PRIMARY HEALTH CARE ASSOCIATES
23rd STREET AND GRAND CENTRAL AVENUE
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TELEPHONE 304/295-3356

MARY ANNE TOTTEN, M.D.
INTERNAL MEDICINE/ENDOCRINOLOGY

JOANNE T. KOWALSKI, R.N., ED.D.
ADULT NURSE PRACTITIONER

November 12, 1988

Gentlepersons

I would like to make several comments on the AIDS-Related Medical Testing and Confidentiality rule being considered for adoption by the State of West Virginia.

Section 64-64-4 a.

What would constitute "documented evidence" that an individual could be positive? and how is this information to be obtained?

Section 64-64-4 b

What is meant by those who have a positive HIV test may be subject to receiving a type of patient care that is different? and, who is to be involved in defining different types of medical/health care. This statement is not clear and definite enough to allow for implementation of this rule.

Section 64-64-6

Charting on any patients' record that they have an HIV-related illness poses serious compromise to all aspects of their daily living, including physical, emotional, social, and spiritual issues. A general statement printed on the test result

is not sufficient to protect the privacy of individuals

Section 64-64-7 7.2

What methods are available to the State to follow-up on "unauthorized disclosures" It would seem to me that implementing these aspects would have serious consequences on the financial aspects of the HIV health problem.

Section 64-64 9.1 c

Since the majority of AIDS victims are seen in the gay community, consideration must be given to those who are significant persons in the lives of those affected with the view in obtaining substituted consents. It is important that these significant persons be included in the decision making process

Section 64-64-10

There is no clear definition of "unacceptable risk" furthermore, since the modes of transmission of the HIV virus do not seem to apply to the school setting, decisions regarding exclusion may need to be addressed in another way.

In conclusion, I feel that there are a number of issues in this rule that need further clarification and others that need to be addressed in a more comprehensive manner to provide adequate protection of the HIV-infected individual and the community

Sincerely,
JoAnne T. Kowalski RN, CAE.

West Virginia STATE MEDICAL ASSOCIATION

MERWYN G SCHOLTEN
Executive Director

4307 MacCORKLE AVENUE, SE, CHARLESTON, WEST VIRGINIA
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WILLIAM C MORGAN, JR., M D.
Treasurer
Charleston

November 14, 1988

State of West Virginia
Department of Health
1800 Washington Street, East
Charleston, WV 25305

ATTENTION: David K. Heydinger, MD, Director

Re: Comments on Proposed Rules and Regulations for AIDS Legislation, for Submission at November 15, 1988 Public Hearing

Dear Dr. Heydinger:

On behalf of the West Virginia State Medical Association, hereinafter referred to as the Association, I am submitting this letter as commentary on the proposed legislative rules relating to AIDS-Related Medical Testing And Confidentiality, 64 CSR 64, which are the subject of a public hearing on Tuesday, November 15, 1988, at 9 AM.

The Association has grave concerns about proposed §4.1 of §64-64-4 relating to testing. We had previously expressed these concerns to you, and thought we had reached an agreement on the section. The current version of the section does not fully address our concerns, however, so we are compelled to make these comments again.

Subparagraph 4.1 (a). As a matter of semantics, we believe this section should begin with the word "When," not the word "Where," to be consistent with the Code and with the other sections of the regulation. More importantly, however, we believe all of the language in this proposed regulation section which goes beyond the language in West Virginia Code §16-3C-2 (a) (1) is superfluous, unnecessarily restrictive, and ill-advised, and should be stricken.

This paragraph of the regulation attempts to categorize and define the situations in which "cause to believe" that an HIV test could be positive would exist. This is a medical determination, which is subject to continuing change as research in this area progresses, and therefore is completely inappropriate for regulation. The Code, by merely stating that a test can be requested when there is "cause to believe that the test could be positive, " leaves the determination of "cause to believe" up to the medical profession, where it rightfully belongs. The effort in the regulations to further define this is an improper restriction upon the language in the Code. The situations discussed in the proposed regulation do not even fully encompass all of the circumstances currently known to medicine which

WEST VIRGINIA STATE MEDICAL ASSOCIATION
Box 4106, Charleston, West Virginia 25364
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might give cause to believe that a test could be positive; therefore, it is an improper limitation upon the language in the statute.

Moreover, by including the language in the regulation which is in addition to the language in the statue, the Department would in effect require physicians to categorize patients as being high risk individuals or individuals who participate in high risk behavior. Not only do our members feel that it is inappropriate for them, as physicians, to so categorize individuals, but requiring them to make such categorizations would simply open them up to multitudinous litigation for categorizations considered possibly defamatory.

Subparagraph 4.1 (b). The Association also takes strong objection to the language in this subparagraph, and believes that the regulations should state nothing more nor less than what is stated in West Virginia Code §16-3C-2 (a) (2). The Code indicates that a physician can request an HIV-related test "when there is cause to believe that the test could provide information important in the care of a patient." The regulation improperly expands upon this by attempting to require documented evidence giving a reason to believe that a person may have a positive HIV-related test result. Requiring "documented evidence" goes far beyond the scope of the statute, and improperly intrudes into medical decisionmaking; it also carries the same risks of litigations for physicians discussed above, and could subject them to charges of defamation.

Moreover, the thrust of West Virginia Code §16-3C-2 (a) (2) is not whether the patient may test positive for AIDS; that is the thrust of subparagraph (1) of that Code section (and of §4.1 (a) of the proposed rules). The thrust of subparagraph (2) of the Code is to when the test result, positive or negative, could provide information important in the care of the patient. In other words, the thrust of this Code section is to permit a physician to request an HIV-related test whenever the results of such test could provide important information in caring for the patient. For purposes of patient care, a negative test result could be just as important to a physician as a positive test result; for example, it might be important for diagnostic purposes for a physician to rule out the existence of the AIDS virus, or it might be important to have a negative test result in the file of a patient who later tests positive, to help pinpoint the timing of the patient's contracting of the virus, and therefore help pinpoint the determinative cause. These types of reasons for requesting the test are within the scope of West Virginia Code §16-3C-2 (a) (2); they would be outside the scope of §4.1 (b) of the proposed rules, however, and we therefore submit that the proposed rule improperly goes beyond the scope of the statute.

The proviso added to §4.1 (b) of the proposed rule is gratuitous and irrelevant; unless the provisions of West Virginia Code §16-3C-2 (e) or (f) apply, consents for HIV-related testing must be obtained in any event.

WEST VIRGINIA STATE MEDICAL ASSOCIATION

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In summary, the Association believes that §4.1 of the proposed emergency rules and regulations should be rewritten so that it reads, word for word, the same as West Virginia Code §16-3C-2 (a); to go beyond the language in the statute, particularly in the manner suggested in the proposed version of this rule, is to improperly restrict the scope of the statute, which intentionally leaves the determination of "cause to believe" that the test could either be positive or could provide information important in the care of a patient, to the physicians, dentists or director of the department, where that decision, as a medical decision, rightfully belongs.

Sincerely,

Bill M. Atkinson, MD /jes MS

Bill M. Atkinson, MD
President

November 15, 1988

West Virginia State Health Dept.
Regulatory Development
1800 Washington Street East
Charleston, WV 25305

Dear Sir:

I would like to comment on proposed legislative rule "AIDS Related Medical Testing and Confidentiality," 64CSR64. I would like to see a change in 64-64-6, Charting Information of the rule to read as follows: 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 with permission of the patient and the following statement printed on the test result: "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."

Thank you for the opportunity to respond.

Sincerely,

C. L. Baldwin, Jr.

WEST VIRGINIA HOSPITAL ASSOCIATION

November 14, 1988

David K. Heydinger, M.D.
Director, Department of Health
State of West Virginia
1800 Washington Street, East
Charleston, West Virginia 25305

Re: Comments on Proposed Legislative Rule:
AIDS-Related Medical Testing and Confidentiality,
Proposed 64 Consolidated State Regulations 64.

Dear Doctor Heydinger:

The West Virginia Hospital Association is pleased to respond to your invitation to comment on the proposed legislative rules captioned above.

Charting Medical Information

§64-64-6 of the proposed rules pertains to charting of medical information. The regulation apparently contemplates protection of confidentiality of HIV test results by use of a required disclosure statement. If this is the sole intent of the disclosure statement, no further comment is necessary. If the larger purpose of the disclosure statement is to protect patient confidentiality, however, the attainment of that goal may be unworkable, for many reasons. A positive HIV test result may appear in many places within the medical record, including the progress notes of a physician, nurse's notes, narrative summary or pre-operative profiles. Clinically unconfirmed evidence of an HIV positive and or conversion to AIDS can also be generated from a variety of sources. One example: Prior medical history during the initial physical examination based initially utterances from the patient himself. Thus, the disclosure statement may serve a limited purpose if it is attached to the results of an HIV lab test, but will not ensure confidentiality of the medical status of a patient.

Even if the first assumption of narrow protection is true, the proposed rules do not make clear if the statement may be required on laboratory tests which are being sent to referral laboratories outside of the health facility. Additionally, the language contained in §64-64-7.1:

> "Any laboratory performing an HIV related test shall have the following statement . . . returned to the health care provider"

should be changed to include "return to the health care provider or health care facility."

3422 Pennsylvania Avenue Charleston, West Virginia 25302 (304) 345-9842

Responsibility to Provide Pre and Post Test Counseling

The Committee Substitute for H.B. 303 clearly indicates that the provision of information which forms the basis for informed consent as well as pre and post test counseling is the responsibility of health care provider and not the health care facility:

§ 16-3C-2(b) states in part:

> "The requesting physician, dentist or the director of the department shall provide the patient with information . . . which contains the following:
>
> (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; [et seq.].

The proposed rules do not make clear that the responsibility for implementing the statutory duties normally rests with the health care provider and not the health care facility. Indeed, responsibility for obtaining informed consent in West Virginia rests with the physician; See: Cross v. Trapp.

Additionally, responsibility for post test counseling does not appear in the regulations. This obligation is also that of the health care provider.

Individual banking of blood by health care providers.

The proposed regulation at § 64-64-14 is narrowly drawn:

> "A blood bank shall store. . . a person's blood and the health care provider shall use such blood . . . to the extent such blood is available."

Certain identifiable problems can exist in the blood banking area. Assume an individual is HIV positive or has AIDS, does not know it and is a candidate for elective surgery. The blood banking facility agrees to store blood. Elective surgery proceeds. Sometime subsequent to the surgery and transfusion, the individual is diagnosed as HIV positive or AIDS positive. This places individual blood banks in a precarious legal position. The transfused individual now becomes a plaintiff against the blood banking facility. The proposed rules should allow these facilities adequate protection. This is especially true since no single test results can reveal with reasonable medical certainty that an individual is not HIV positive.

It is recommended that this portion of the rule contain an additional statement:

> In storing and banking any person's blood for subsequent use, nothing in this section shall be construed to hold the blood banking facility as a warrantor or guarantor of the condition of stored blood. Additionally, nothing in this section shall be construed to categorize blood as a "product" within the meaning of the Restatement of Torts 2d, § 402-A.

Reporting of Positive Serologic and Other Tests for the HIV Virus

§ 64-64-11 et seq. provides for a reporting scheme of positive and/or other tests indicative of the HIV infection to the Director of the Department of Health. It is recommended that health care providers and facilities be required to place the confidentiality warning contained in § 6-3C-(c) as a protection to these same providers.

Thank you for this opportunity to comment upon these proposed rules.

Respectfully,

Gil DeLaura, Esquire
Vice President/General Counsel

GD/dsm

COMMENTS CONCERNING
(PROPOSED)
TITLE 64
WEST VIRGINIA LEGISLATIVE RULES
DEPARTMENT OF HEALTH
SERIES 64
AIDS-RELATED MEDICAL TESTING AND CONFIDENTIALITY

SUBMITTED BY
THE MOUNTAIN STATE AIDS NETWORK
MORGANTOWN, WV
NOV. 15, 1988

On behalf of the many members and friends of the Mountain, I would like to take this opportunity to express our gratitude to the West Virginia Department of Health for allowing the Network the opportunity to express its comments concerning the proposed regulations for HB 303. The Mountain State AIDS Network is a non-profit tax-exempt community based AIDS education and support organization which serves Northern West Virginia. Through our work, the Network has discovered critical needs which are not being met in West Virginia in the the area of AIDS education and support.

H.B. 303 and its proposed regulations represent some of the first attempts at AIDS policy in West Virginia. It is unfortunate that many people who were involved in this law's development have the attitude "it's not the best law we could get but its all we could hope for." This law, its proposed regulations, and their development have pointed out the great need for further action in the area of AIDS prevention in West Virginia. The actions which are so critically needed in our state are in the area of AIDS education and support services. This law does not address either of these critical issues. It shows, rather, the tremendous fear and hysteria which not only exists within our own citizens concerning this disease, but also exists within the very legislature and current administration of our state. How many people must be infected before we take our heads out of the sand? How many of our fellow citizens must die before adequate attempts are made to help those who are affected by the disease?

A recent poll of West Virginians showed the tremendous lack of knowledge people have about AIDS. Much more needs to be done to educate ALL West Virginians about what AIDS is and is not. Communities, hospital workers, paramedics, housewives, blue and white collar workers, children, adolescents, as well as those at high risk are in desperate need of education. Thousands of infected individuals are in a desperate need of support services including medical, financial, housing, assistance. The infected people along with those who alrady have the disease need protection from the rampant discrimination which exists in this state.

passage of this law. Several publicized cases of hysteria driven AIDS related discrimination cases in West Virginia have been reported by the national media. However, many more cases are known be the Network. These cases range from abandonement of PWA's by families to violence perpetrated by law officers. Such cases of unfounded barbarism must cease. They must cease through the use of education and support services which have been shown nationwide to work.

West Virginia has no consistent state wide AIDS education program. West Virginia has no state wide AIDS case management program. Yet, we work on the assumption of fear and misinformation and pass weak legislation which does not meet the needs of our citizens. While we ignore the problem of AIDS in our state, the CDC is releasing figures which suugest as many as 1 in 300 college aged young persons are infected with HIV. Our children are truly at risk. What will we as health providers do to meet the challenge?

What is needed in this state is a committment to PROPERLY FUNDED Community based education and support programs. Federal money for these programs is available, yet those responsible for seeking these funds do nothing while the problem of AIDS increases. There are currently several groups including the Mountain State AIDS Network which struggle to meet the needs of AIDS education and support. We do this with a meager state committment of only 250 per month. We must do better. We need more than oppressive, hysteria driven laws to combat AIDS. We need a committement to our community based service agencies which are fighting on the forefront of AIDS prevention and support in West Virginia. We need an division of the West Virginia Department of Health which is responsible for the advocacy for persons affected by the disease. This division would provide a central person responsible only for the provision of needed AIDS support services including referral and guidance to government assistance, proper medical referral, updated treatment information, and most importantly case management.

This law is inadequate. But we must accept it. Therefore the Network would offer these comments.

1. Provisions be included which prohibits discrimination by all those affected by this law of those who have AIDS, ARC, or are infected by HIV or perceived to be at risk for exposure.

2. Clarification of procedure when a person refuses a "requested" HIV antibody test under section 64-64-4 part 4.1 page 3 of the proposed regulations.

3. Provisions protecting the confidentiality of students who are affected by section 64-64-10 page 5.

4. Elimination of sections 64-64-11 and 64-64-12 due to the reactive nature of West Virginia state government.

5. Provisions for the revocation of cerification of approval for HIV antibody test performance for breach of confidentiality by or as a result of actions of a testing entity in section 64-64-13 part 13.6.3 page 8.

These suggestions attempt to create some positivity from a negative situation. It is hoped that the good of the state is considered above our own personal fear in adopting thes suggestions. We owe our state more in the area of AIDS prevention than tactics rooted in misinformation. Let us begin to combat AIDS through education and support of those affected. Thank you.

Respectfully Submitted,

Roger D. Banks

Roger D. Banks
Executive Director
Mountain State AIDS Network

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November 15, 1988

HAND-DELIVERED

Regulatory Development
Department of Health
State of West Virginia
1800 Washington Street, East
Charleston, WV 25305

RE: AIDS-Related Medical Testing and Confidentiality, Title 64 ("Proposed Regulation")

Gentlemen:

I am writing on behalf of the American Council of Life Insurance ("ACLI"). The ACLI has 646 member life insurance companies which account for approximately 94% of the life insurance in force in the United States. ACLI is particularly interested in the Proposed Regulation.

Our comments with respect to the Proposed Regulation are based on what we believe to be an oversight by the Department of Health. In particular, West Virginia Code § 16-3c-2(j) provides as follows:

> Nothing in this section is applicable to any insurer regulated under Chapter 33 of this Code; provided, that the Commissioner of Insurance shall develop standards regarding consent for use by insurers which test for the presence of the HIV antibody.

We believe it is clear, based on the foregoing, that any insurer regulated under Chapter 33 of the West Virginia Code is exempt from certain requirements contained in this Proposed Regulation. Accordingly, we believe that this exemption should be included in the Proposed Regulation to avoid any possible confusion with respect to insurers. Said exemption might appear either through including a new section which specifically exempts insurers from these provisions or by including said exemption in Section 2.1 entitled "Application."

We appreciate this opportunity to comment on these regulations and are available for any questions you might have or assistance you might need in preparing an amendment to address same.

Sincerely yours,

T Randolph Cox, Jr

T. RANDOLPH COX, JR.
AMERICAN COUNCIL OF LIFE INSURANCE

TRC/lb

cc: Mr. Douglas Breitenbach

CHARLESTON AIDS NETWORK
P.O. Box 1024
Charleston, WV 25324

November 15, 1988

Regulatory Development Section
State Health Department
1800 Washington Street, East
Charleston, WV 25305

RE: Proposed regulations for H.B. 303

Dear Madam or Sir:

I am writing on behalf of the Charleston AIDS Network to express our comments on the proposed regulations for H.B. 303. While the regulations on balance are a positive step, we do have a few concerns with them as they currently stand.

First, we are very concerned with the requirement in Sections 11.1(d) and 12.1(d) of the regulations that individuals' names and addresses be reported after a positive test result. The reporting of this information, particularly if it is disseminated anywhere outside the State Health Department, such as to the various county departments, creates a serious risk for a breach of confidentiality. In our view, it would be much better to require reporting only of zip codes or counties of residence, as opposed to names and addresses.

As the provisos to Sections 11.5 and 12.6 indicate, a legitimate use of positive test information is to develop epidemiological data concerning the incidence of the HIV in West Virginia. From our standpoint, the reporting of the names and addresses of individuals testing positive opens the door to a breach of confidentiality, with all the resulting discrimination that may ensue. If such reporting nevertheless is required, the Department should take stringent steps to ensure that the information is not distributed outside the State Health Department, and that individuals' confidentiality will be protected.

Our second suggestion relates to Section 4.1(b), and more particularly, the phrase "if at all feasible." As presently worded, the regulation might be interpreted to mean that the testing in question could proceed in the absence of any consent because getting it is not "feasible." Such an interpretation clearly conflicts with the requirement of Section 16-3C-2 of the

statute that such testing proceed only on a permissive, as opposed to mandatory, basis. We assume that this is not the interpretation intended by the Department, and that the feasibility language actually refers to the provisions for substituted consent in the statute. If so, the regulation should be clarified.

Our final concern relates to an omission in Sections 4.1(a) & (b) of the regulations. Specifically, these regulations do not mention or discuss the requirements for informed consent in testing. As Section 16-3C-2 of the statute plainly requires informed consent, coupled with education and counseling, we feel that the regulation should require no less. A brief reference to the statutory requirements would suffice to cure this omission.

Thank you for your consideration of these comments. We appreciate the opportunity to share our views with the Department.

Sincerely yours,

William D. Turner

William D. Turner
Charleston AIDS Network

cc: Terrie Lee

Wheeling – Ohio County Health Department

City – County Building Wheeling, WV 26003 • Phone 234-3682

THOMAS L. THOMAS, M.D.
Director

November 10, 1988

Aids Prevention Program
Aids Project HE/RR Coordinator
Thomas Cobbs

Dear Mr. Cobbs:

Through my short experience with counseling and testing for the HTLV-III virus at the Wheeling - Ohio Health Dept., I can see a great need for this service. All clients have been truly concerned, not only with their own health, but the health and safety of their loved one. They are genuinely open with their personal reasons for wanting the test, which I feel would not be there if not for the confidentiality aspect of our service.

Sincerely,
Elizabeth Friedl, RN

American Red Cross

Blood Services/Tri-State Region
1111 Veterans Memorial Boulevard
P.O. Box 605
Huntington, West Virginia 25710
(304) 522-0328

DATE: November 9, 1988

TO: Regulatory Development, Health Department
1800 Washington Street, East
Charleston, W. Va. 25305

FROM: Mabel M. Stevenson, M.D., Director
Tri-State Red Cross Blood Services MMS

SUBJECT: Proposal for an Alteration in the Regulations 64; §16-3C-8

I wish to make the following proposal to be considered at the public hearing on November 15, 1988 on the above regulation pertaining to legislation titled "AIDS-Related Medical Testing and Records Confidentiality Act", West Virginia Code §16-3C-1:

I recommend the following change in wording in proposed rule §64-64-11, 11,2(3).

"These reports shall include.....

a.:....
b.....
c.....
d. The name or identification code of the individual to be tested and, if available, his or her sex, age and community location instead of address."

REASON:

Identification of the community in which an HIV infected person lives would be sufficient for compiling statistics for epidemiological purposes. If the complete address of such a person was required for follow-up by the Department of Health, this could be provided when and if the Director works with the individual's health care provider for that follow-up as specified in 11.4.

I would be grateful if that change could be made.

MMS/sjn

cc: Gary Gilbert, M.D.

WEST VIRGINIA DENTAL ASSOCIATION

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Editor
West Virginia Dental Journal
712 Stockton Street
Charleston, W. Va. 25312

November 15, 1988

David K. Heydinger, M.D.
Director, WV Dept. of Health
1800 Washington Street, East
Charleston, WV 25305

Dear Doctor Heydinger:

This Association submits the following comments regarding proposed rules for AIDS-Related Medical Testing and Confidentiality:

The language on Page 3, 64-64-4.1, sub-paragraphs a), b), and c) should be substituted with language contained in SB 303, 16-3C-2. Testing, sub-paragraphs (1), (2), and (3) under (a). The substituted language in the proposed rule would then read as follows:

> "4.1 HIV-related testing may be requested by a physician, dentist, or the Director for any of the following:
> a) When there is cause to believe that the test could be positive; or
> b) When there is cause to believe that the test could provide information important in the care of the patient; or
> c) When any person voluntarily consents to the test."

The language of the proposed rule extends beyond the intent of the legislation passed by the 1988 WV Legislature, thus restricting and limiting dentists' professional judgements in requesting patients to be HIV-tested.

These comments are submitted in response to the Health Department's Notice of Public Hearing, Title 64. Your consideration in adopting the language contained in the law as Rule 4.1. a), b) and c) is respectfully requested.

Very truly yours,

Richard D. Stevens
Executive Director