

**WEST VIRGINIA
SECRETARY OF STATE
JOE MANCHIN, III
ADMINISTRATIVE LAW DIVISION**

Form #2

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FILED

2002 MAY 29 P 2:29

OFFICE WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: Insurance Commissioner TITLE NUMBER: 114
RULE TYPE: Legislative CITE AUTHORITY: W. Va. Code §§ 33-2-10 and 16-3C-2(j)
AMENDMENT TO AN EXISTING RULE: YES NO
IF YES, SERIES NUMBER OF RULE BEING AMENDED: 27
TITLE OF RULE BEING AMENDED: AIDS Regulations

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: _____

TITLE OF RULE BEING PROPOSED: _____


IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON July 1, 2002 AT 4:30 p.m. ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

Mary Jane Pickens, Associate Counsel

West Virginia Insurance
Commission
P.O. Box 50540

Charleston, WV 25305-0540

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



Authorized Signature

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

SCANNED

**Department of Tax and Revenue
Agency Questionnaire**

Re: Legislative Rule to be Filed

AIDS REGULATIONS

TITLE 114, SERIES 27

Question 1: Are regulations required?

No.

Question 2: Is the rule you are proposing controversial? If yes, what are the pros and the cons?

The amendments to the rule are not expected to be controversial. This is an amendment that was attempted during the 2001 legislative session, but due to a final drafting error in the bill, language was reinserted in the rule that was intended to be deleted. This amendment will allow FDA-approved urine HIV tests to be used in this state. West Virginia is currently the only state in the United States that does not allow insurers to test for HIV using urine tests rather than blood tests. Urine-based tests are less invasive and are inexpensive and accurate.

Question 3: Is the rule you are proposing a copy of another state's rule? A model rule? Custom-drafted?

The rule and amendment thereto are custom drafted.

Question 4: What are the really important things you think the Secretary of Tax and Revenue should know about this rule and the issues that surround it?

This rule has been in place since August, 1991, and was modified in May 1999 and in 2001. It sets out guidelines which insurers must follow in underwriting for HIV in regard to life and accident and sickness insurance policies. Among other things, it prohibits questions relating to sexual preference or life-style, and limits HIV testing as to group insurance policies.

The amendments currently proposed permit the use of urine test specimens in testing for HIV. The urine tests have been approved by the Food and Drug Administration, are highly accurate, are administered only by professionals, and are less intrusive than oral or blood tests. The testing protocols are the same as for oral fluid or blood.

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AIDS REGULATIONS

TITLE 114, SERIES 27

BRIEF SUMMARY OF RULE

The AIDS rule has been in place since August, 1991, and was modified in May 1999 and in 2001. It sets out guidelines which insurers must follow in underwriting for HIV in regard to life and accident and sickness insurance policies. Among other things, it prohibits questions relating to sexual preference or life-style, and limits HIV testing as to group insurance policies.

The amendments currently proposed would permit the use of urine test specimens in testing for HIV. The urine tests have been approved by the Food and Drug Administration, are highly accurate, are administered only by professionals, and are less intrusive than oral or blood tests. The testing protocols are the same as for oral fluid or blood.

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STATEMENT OF CIRCUMSTANCES

Medical technology has advanced in recent years with regard to HIV testing. It is no longer necessary to draw blood to perform an accurate test for the presence of HIV. The U.S. Food and Drug Administration has approved the use of urine specimens for HIV testing. This is a less intrusive method of obtaining a test specimen, as opposed to a blood draw, and the test is inexpensive and accurate. The current AIDS rule allows the use of urine testing for screening only, to be followed by other more intrusive tests. These amendments would allow FDA-approved urine tests to be performed to determine the presence of HIV, and would bring West Virginia in line with the other 49 states that allow the use of urine tests rather than only blood or oral fluid tests.

The urine test's manufacturer requested that Series 27 be amended to accommodate this new testing method, in amendments that were before the legislature in 2001. However, due to inadvertent error in the bill drafting process, the amendments were not accomplished. The amendments currently proposed will allow urine tests for HIV, which was the intended amendment in 2001.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: AIDS Regulations
Title 114, Series 27

Type of Rule: X Legislative Interpretive Procedural

Agency: Insurance Commissioner

Address: Post Office Box 50540
1124 Smith Street, Greenbrooke Building
Charleston, West Virginia 25305-0540

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1. Effect of Proposed Rule

	ANNUAL FISCAL YEAR				
	Increase	Decrease	Current	Next	Thereafter
ESTIMATED TOTAL COST	None	None	None	None	None
PERSONAL SERVICES	None	None	None	None	None
CURRENT EXPENSE	None	None	None	None	None
REPAIRS AND ALTERATIONS	None	None	None	None	None
EQUIPMENT	None	None	None	None	None
OTHER	None	None	None	None	None

2. Explanation of above estimates:

The amendments to this rule will have no fiscal impact upon the Insurance Commissioner or State Government.

3. Objectives of these rules:

The amendments to this rule broaden the types of HIV testing available for life and health insurance underwriting. It allows the use of newer tests approved by the United States Food and Drug Administration.

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4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

None

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

None

C. Economic Impact on Citizens/Public at Large.

None

Date: May 29, 2002

Signature of Agency Head or Authorized Representative


MARY JANE DICKENS, ASSOCIATE COUNSEL

114CSR27
WEST VIRGINIA LEGISLATIVE RULE
INSURANCE COMMISSIONER

SERIES 27
AIDS REGULATIONS

Section

- 114-27-1. General.
- 114-27-2. Applicability.
- 114-27-3. Definitions.
- 114-27-4. Medical/Lifestyle Applications Questions and Underwriting Guidelines.
- 114-27-5. Testing.
- 114-27-6. Notice and Consent Form.

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SERIES 27
AIDS REGULATIONS

OFFICE WEST VIRGINIA
SECRETARY OF STATE

§114-27-1. General.

1.1. Scope. -- This legislative rule establishes standards for AIDS-related underwriting questions and AIDS testing in connection with applications for life or health insurance policies.

1.2. Authority. -- W. Va. Code §§33-2-10 and 16-3C-2(j).

1.3. Filing Date. -- ~~May 30, 2001.~~

1.4. Effective Date. -- ~~May 30, 2001.~~

§114-27-2. Applicability.

2.1. Insurers - All insurers who deliver or issue for delivery in this state any policies for life or accident and sickness insurance are subject to this regulation.

2.2. Service Corporations - All health service corporations who deliver or issue for delivery in this state any subscriber's contracts for health insurance are subject to this regulation.

2.3. Health Care Corporations - All health care corporations who issue to enrollees in this state evidence of health insurance coverage are subject to this regulation.

2.4. Fraternal Benefit Societies:

a. All fraternal benefit societies who deliver or issue for delivery life insurance benefit certificates in this state are subject to this regulation.

b. All domestic, foreign, or alien societies who issue any certificate or other evidence of any contract of accident or sickness insurance in this state are subject to this regulation.

2.5. Health Maintenance Organizations - All health maintenance organizations who deliver or offer for delivery in this state any evidence of coverage are subject to this regulation.

§114-27-3. Definitions.

3.1. Code - means the West Virginia Code.

3.2. Commissioner - means the Insurance Commissioner of the state of West Virginia.

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3.3. Acquired Immunodeficiency Syndrome (AIDS) - means the acquired immunodeficiency syndrome as may be from time to time defined by the Centers for Disease Control of the United States Public Health Service.

3.4. AIDS Related Complex (ARC) - means a syndrome in which the individual displays many of the same symptoms of AIDS, including the presence of the HIV antibody.

3.5. Human Immunodeficiency Virus (HIV) - means the virus responsible for the potential development of the Acquired Immunodeficiency Syndrome (AIDS).

3.6. Oral mucosal transudate or OMT - means a serous fluid that comes from transudation at the gingival crevice and across oral mucosal surfaces, as distinguished from whole saliva, and which is collected by a method approved by the FDA for OMT testing for HIV.

3.7. Enzyme Linked Immunosorbent Assay (ELISA) - means a test which has been licensed by the FDA and is used to determine the existence of the HIV antibody.

3.8. Insurer - includes all entities providing life or accident and sickness coverage.

3.9. Western Blot - means a test which has been licensed by the FDA and is used to determine the existence of the HIV antibody.

3.10. Health Care Professional or Health Care Provider - means any physician, nurse, physician's assistant, or any other person providing medical, dental, nursing or other health care services of any kind.

3.11. FDA - means the United States Food and Drug Administration.

§114-27-4. Medical/Lifestyle Applications Questions and Underwriting Guidelines.

4.1. General Propositions:

a. No inquiry in an application for health accident and sickness or life insurance coverage, or in an investigation conducted by an insurer or an insurance support organization on its behalf in connection with an application for such coverage shall be directed toward determining the proposed insured's sexual orientation.

b. Sexual orientation may not be used in the underwriting process or in the determination of insurability.

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c. Insurance support organizations shall be directed by insurers not to investigate, directly or indirectly, the sexual orientation of a proposed insured or beneficiary.

4.2. Medical/Lifestyle Applications Questions and Underwriting Standards.

a. No question shall be used which is designed to establish the sexual orientation of the proposed insured.

b. Questions relating to the proposed insured having or having been diagnosed as having AIDS or ARC are permissible if they are factual and designed to establish the existence of the condition.

For Example: Insurers should not ask "do you believe you may have . . .?", but rather "do you know or have reasons to know . . .?"

c. Questions inquiring as to whether the proposed insured has ever tested positive for the presence of the HIV virus or HIV virus antibodies are permissible; however, questions inquiring as to whether the proposed insured has ever been tested for the presence of the HIV virus or HIV antibodies are prohibited.

d. Questions relating to medical and other factual matters intending to reveal the possible existence of a medical condition are permissible if they are not used as a proxy to establish the sexual orientation of the proposed insured, and the proposed insured has been given an opportunity to provide an explanation for any affirmative answers given in the application.

For Example: "Have you had chronic cough, significant weight loss, chronic fatigue, diarrhea, enlarged glands, . . .?" would be permissible. These questions must relate to a definite time period immediately preceding the application and must be specific. The proposed insured shall be given the opportunity to explain the described symptoms.

e. Questions relating to the proposed insured's having or having been advised to seek treatment by a medical doctor, health nurse or other medical professional for a sexually transmitted disease are permissible.

f. Neither the marital status, the "living arrangements," the occupation, the gender, the medical history, the beneficiary designation, nor the zip code or other territorial classification of a proposed insured may be used to establish, or aid in establishing, the proposed insured's sexual orientation.

g. For purposes of rating a proposed insured for health and life insurance, an

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insurer may impose territorial rates, but only if the rates are based on sound actuarial principles and are related to actual or reasonably anticipated experience.

For Example: If a particular territory demonstrates a general propensity for high risk, an insurer may impose a rate higher for that territory than for similar risks located in other territories.

h. No questions shall seek to determine if the proposed insured has demonstrated AIDS-related concerns or has sought AIDS-related counseling.

i. No adverse underwriting decision shall be made because medical records or a report from an insurance support organization show(s) that the proposed insured has demonstrated AIDS-related concerns or has sought counseling. This subsection does not apply to a proposed insured seeking treatment and/or diagnosis.

§114-27-5. Testing.

5.1. AIDS-related testing in connection with the application for group life or accident and sickness insurance is prohibited; provided that an insurer may conduct such testing in relation to the application for group life and accident and sickness insurance when the insurance applied for is individually underwritten and evidence of insurability is required by the insurer because the proposed insured is either a late entrant, is applying for supplemental group life coverage, or is applying for small group insurance where the group consists of less than twenty-five members.

5.2. Whenever a proposed insured is requested to take an AIDS-related test in connection with an application for insurance, the use of such a test must be revealed to the proposed insured and his or her written, informed consent obtained.

5.3. The proposed insured should demonstrate an understanding that the test is being performed, of the nature of the test, of the persons to whom the results of that test may be disclosed, of the purpose for which test results may be used, of any limitations on the accuracy and meaning of the test results, and of any foreseeable risks and benefits resulting from the test.

5.4. The person requesting the test, and not the individual or individual's health care provider, must underwrite the cost of the test.

5.5. The individual undergoing the test has a choice to receive the test result directly or to designate in writing, prior to the administration of the test, any other person, such as a health care professional or clergyman, who may receive the results.

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5.6. The testing must be performed by an individual who is properly trained in the administration of the test; holds an appropriate medical license, if state or federal law requires licensure in order to perform the testing procedure; and is properly supervised in accordance with state and federal law and FDA approval requirements.

5.7. The insurer and its agents shall not release or disclose either that a HIV test has been conducted or the test results to any other party except under the following limited circumstances:

a. Negative test results only may be disclosed to a reinsurer where either:

1. The reinsurer is to reinsure a portion of the risk on a facultative basis;

or

2. The reinsurer is to reinsure a portion of a block of business on a treaty basis and where the release of HIV test information is disclosed by the ceding insurer only to the extent that the reinsurer is permitted to perform limited underwriting audits of the ceding insurer's underwriting files to verify that proper HIV underwriting has occurred.

b. Positive test results only may be disclosed to the Medical Information Bureau (MIB) provided that such information release is limited to a coded report identified only as a nonspecific abnormal blood, urine or oral fluid test code.

c. To the extent necessary to allow them to properly perform the functions for which their services were contracted by the insurer, an insurer may disclose HIV test information to certain contractors of the insurer such as audit firms, third party underwriters and claims adjusting firms. No person receiving HIV test information shall transmit information further, and each person shall maintain strict confidentiality.

d. To the extent that they are otherwise entitled to access to the insurer's files, government agencies may be permitted access to files containing HIV test information: Provided that confidentiality is maintained and the HIV test information is not shared with other persons.

5.8. Upon written request by the individual undergoing the test the insurer must provide within 30 days, a written list of all persons or entities to whom test information has been released or caused to be released by the insurer.

5.9. The testing is required to be administered on a nondiscriminatory basis for all individuals in the same underwriting class. No proposed insured may be denied coverage or rated a substandard risk on the basis of HIV testing unless acceptable testing protocol is followed. ~~The insurer may at its option use a urine HIV test as an initial screening device;~~

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~~provided that if the urine test yields a negative result for the purpose of HIV antibodies then HIV blood or OMT testing may be required by the insurer. The proposed insured may not be denied insurance coverage or rated a substandard risk on the basis of a positive urine HIV test alone, including the use of FDA-licensed tests. The following is the acceptable HIV testing protocol for use in this state An applicant may not be denied coverage on the basis of AIDS related testing unless:~~

a. An initial enzyme linked immunosorbent assay (ELISA) test is administered to the proposed insured, and it indicates the presence of HIV antibodies; and

b. A second ELISA test is administered and it indicates the presence of HIV antibodies ~~The initially reactive specimen is retested by ELISA in duplicate and at least one of the repeat tests is reactive. The specimen considered repeatedly reactive, is examined in a Western blot test to confirm the ELISA test results; and~~

c. A Western Blot test is ~~positive~~; conducted and it confirms the results of the two ELISA tests.

5.10. ~~If any of the tests in the ELISA-ELISA-Western Blot series produce a negative result, an initial ELISA test is negative, or both repeat-duplicate tests are negative, the testing ceases and the proposed insured cannot be denied coverage based on AIDS-related testing. If the initial and at least one of the repeat-duplicate ELISA tests is positive but the Western blot test is negative, for purposes of insurability, the results are negative.~~

For Example: If the initial ELISA test yields a negative result, the testing ceases. If the initial ELISA test yields a positive result and the subsequent ELISA test yields a negative result, the testing ceases. If both ELISA tests yield a positive result and the Western Blot test yields a negative result, for purposes of insurability, the results are negative.

5.11. News of a positive test result could result in serious emotional trauma to the proposed insured. For this reason, it is recommended that the insurer recommend to the proposed insured that positive results be communicated to the proposed insured face to face by a qualified health care professional who could provide AIDS counseling.

§114-27-6. Notice and Consent Form.

6.1. A notice and consent form must be executed by each proposed insured before AIDS-related testing is performed as to such proposed insured on behalf of any insurer.

6.2. The notice and consent form required by subsection 6.1 shall be as is set out in

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Appendix A attached hereto unless an alternative form is approved by the commissioner in writing.

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APPENDIX A

Examiner	_____	Insured	_____
Address	_____	Address	_____
	_____		_____

**NOTICE AND CONSENT FOR BLOOD, URINE, OR ORAL FLUID TESTING
WHICH MAY INCLUDE AIDS VIRUS (HIV) ANTIBODY/ANTIGEN TESTING**

To determine your insurability, the insurer named above (the Insurer) has requested that you provide a sample of your blood, urine, or oral fluids for testing and analysis. All tests will be performed by a licensed laboratory.

Tests may be performed to determine the presence of antibodies or antigens to the Human Immunodeficiency Virus (HIV), also known as the AIDS Virus. The HIV antibody test that we perform is actually a series of tests done by a medically accepted procedure. The HIV antigen test directly identifies AIDS viral particles. This series of tests is extremely reliable. Other tests which may be performed include determinations of blood cholesterol and related lipids (fats) and screening for liver or kidney disorders, diabetes, and immune disorders.

All test results will be treated confidentially. They will be reported by the laboratory to the Insurer. When necessary for business reasons in connection with insurance you have or have applied for with the Insurer, the Insurer may disclose test results to others such as its reinsurers, employees, or contractors. If the Insurer is a member of the Medical Information Bureau (MIB, Inc.), and if the test results for HIV antibodies/antigens are other than normal, the Insurer will report to the MIB, Inc. a generic code which signifies only a non-specific test abnormality. If your HIV test is normal, no report will be made about it to the MIB, Inc. Other test results may be reported to the MIB, Inc. in a more specific manner. The organizations described in this paragraph may maintain the test results in a file or data bank. There will be no other disclosure of test results or even that the tests have been done except as may be required or permitted by law or as authorized by you. If you desire, you have the right to request a complete list of the parties to whom the insurer has released test information.

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You should also be aware that the person who performs the blood, urine or oral fluid testing is subject to W. Va. Code §§16-3C-3 and 16-3C-4 which authorize that they may disclose test results to certain limited individuals under certain limited circumstances [these relate primarily to (1) persons you authorize to see the test results, (2) health care providers who may come into contact with you or specimens obtained from you, (3) the United States centers for disease control, (4) a court order to release the results, and (5) identified sex partners and persons sharing needles.] These persons are required by W. Va. Code §§16-3C-3 and 16-3C-4 to keep test information confidential.

You may direct that test results be disclosed directly to you or if you prefer to your personal physician or other health care professional. It is strongly suggested that you designate a physician or health care professional to receive your test results so that they may properly explain the results to you.

If your HIV test results are normal, no routine notification will be sent to you. If the HIV test results are other than normal, the Insurer will contact you. The Insurer may also contact you if there are other abnormal test results which, in the Insurer's opinion, are significant. If you have not already indicated one, the Insurer may ask you at that time for the name of a physician or other health care provider to whom you may authorize disclosure and with whom you may wish to discuss the results.

Positive HIV antibody/antigen test results do not mean that you have AIDS, but that you are at significantly increased risk of developing AIDS or AIDS-related conditions. Federal authorities say that persons who are HIV antibody/antigen positive should be considered infected with the AIDS virus and capable of infecting others.

Positive HIV antibody or antigen test results or other significant blood abnormalities will adversely affect your application for insurance. This means that your application may be declined, that an increased premium may be charged, or that other policy changes may be necessary.

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I wish my test results to be released to:

(Check Please)

_____ Myself only.

_____ My physician, health care provider, or other person indicated below.

_____ Both myself and my physician, health care provider or other person indicated below.

Physician, Health Care Provider, or other person.

Name: _____

Address: _____

I have read and I understand this Notice and Consent For Blood, Urine or Oral Fluid Testing Which May Include AIDS Virus HIV Antibody/Antigen Testing. I voluntarily consent to give a urine or oral fluid specimen and/or to the withdrawal of blood from me, the testing of that urine and/or blood or oral fluid, and the disclosure of the test results as described.

I understand that I have the right to request and receive a copy of this authorization. A photocopy of this form will be as valid as the original.

Proposed Insured

Date of Birth

Signature of Proposed Insured
or Parent/Guardian

Date

State of Residence

THIS AUTHORIZATION EXPIRES AFTER 60 DAYS