

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

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OFFICE WEST VIRGINIA  
SECRETARY OF STATE

Form #2

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: Insurance Commissioner TITLE NUMBER: 114  
RULE TYPE: Interpretive CITE AUTHORITY: West Virginia Code Sections 33-2-10 and 16-3C-2(j)  
AMENDMENT TO AN EXISTING RULE: YES  NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: \_\_\_\_\_

TITLE OF RULE BEING AMENDED: \_\_\_\_\_

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 27A

TITLE OF RULE BEING PROPOSED: AIDS Regulations

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 18, 2002 AT 4:30 PM 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



STATE OF WEST VIRGINIA

Offices of the Insurance Commissioner

Legal Division

**BOB WISE**  
Governor

**JANE L. CLINE**  
Insurance Commissioner

June 18, 2002

HAND DELIVERED

Ms. Judy Cooper, Director  
Administrative Law Division  
Office of Secretary of State  
State Capitol  
Charleston, West Virginia 25305

Dear Ms. Cooper:

Enclosed please find for filing one (1) copy of the following:

- 1) Notice Of A Comment Period On A Proposed Rule and consent of Tax and Revenue Cabinet Secretary;
- 2) Brief Summary of Rule;
- 3) Statement of Circumstances;
- 4) Fiscal Note; and
- 5) The proposed Interpretive Rule entitled "AIDS Regulations" (Series 27A).

Please contact me if further information is required.

Sincerely,

A handwritten signature in cursive script, appearing to read "Jane L. Cline".

Jane L. Cline  
Insurance Commissioner

JLC/jz  
Enclosures

Department of Tax and Revenue  
Agency Questionnaire

Re: Interpretive Rule to be Filed

AIDS REGULATIONS

TITLE 114, SERIES 27A

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 interpretive rule is not expected to be controversial. West Virginia is the last state in the United States to continue to disallow the use of FDA-approved urine tests for HIV rather than blood tests. Urine-based tests are less invasive and are inexpensive and accurate. This interpretive rule reflects amendments that were attempted during the 2001 legislative session, but due to a final drafting error in the bill, language was reinserted in the rule that was meant to be deleted. The interpretive rule will clarify the policy of the insurance commissioner that FDA-approved urine HIV tests may be used for underwriting in this state as an alternative to the protocol currently contained in 114CSR27, Section 5. The rule is also being amended by legislative rule, and the interpretive rule will sunset on the effective date of the amended legislative rule, following authorization by the legislature.

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

The interpretive rule is custom drafted.

**AIDS REGULATIONS  
TITLE 114, SERIES 27A**

**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?**

The AIDS rule, 114CSR27, 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 interpretive rule would permit the use of urine test specimens in testing for HIV as an alternative to the testing protocol set forth in current 114CSR27, Section 5. 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.

This interpretive rule will clarify the insurance commissioner's policy to allow urine testing for HIV. The AIDS rule, 114CSR27, is also being amended by legislative rule to reflect the same testing protocol as set forth in this interpretive rule.

Insurance Commissioner  
Interpretive Rule  
Title 114, Series 27A

**AIDS REGULATIONS**

**TITLE 114, SERIES 27A**

**BRIEF SUMMARY OF RULE**

Urine tests for HIV 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. This interpretive rule clarifies the insurance commissioner's policy regarding the use of FDA-approved urine HIV tests for insurance underwriting. The interpretive rule authorizes the use of urine HIV tests for underwriting, where testing is otherwise authorized under 114CSR27. The interpretive rule clarifies that if an insurer elects to use urine HIV testing as an alternative to the testing protocol set forth in 114CSR27, Section 5, the insurer will not be considered to be in violation of 114CSR27, Section 5. The interpretive rule will sunset on the effective date of amendments to 114CSR27.

Insurance Commissioner  
Interpretive Rule  
Title 114, Series 27

## **AIDS REGULATIONS**

### **TITLE 114, SERIES 27**

#### **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.

In 2001, the legislature considered amendments to the AIDS rule, 114CSR27, that would have allowed insurers to use FDA-approved urine tests for HIV, rather than using the urine test as a screening device only. The amendment was sought because urine tests have been approved by the Food and Drug Administration, are highly accurate, and are administered only by professionals. However, due to a drafting error in the bill authorizing the amendment, language that was meant to be deleted from the rule was reinserted, and the intended amendment to allow urine HIV testing did not occur. This interpretive rule reflects the language of the proposed amendments to the AIDS rule considered by the 2001 legislature, and clarifies the insurance commissioner's policy regarding the use of FDA-approved urine HIV tests for insurance underwriting. The insurance commissioner has also proposed amendments to the legislative rule, 114CSR27, consistent with this interpretive rule, to allow urine HIV tests.

**APPENDIX B**

**FISCAL NOTE FOR PROPOSED RULES**

**Rule Title:** AIDS Regulations  
Title 114, Series 27A

**Type of Rule:**  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 |
| <b>ESTIMATED TOTAL COST</b>    | None     | None     | None        | None | None       |
| <b>PERSONAL SERVICES</b>       | None     | None     | None        | None | None       |
| <b>CURRENT EXPENSE</b>         | None     | None     | None        | None | None       |
| <b>REPAIRS AND ALTERATIONS</b> | None     | None     | None        | None | None       |
| <b>EQUIPMENT</b>               | None     | None     | None        | None | None       |
| <b>OTHER</b>                   | None     | None     | None        | None | None       |

**2. Explanation of above estimates:**

This interpretive rule will have no fiscal impact upon the Insurance Commissioner or State Government.

**3. Objectives of these rules:**

This interpretive rule reflects policy of the insurance commissioner as they relate to the use of FDA-approved urine HIV tests. The interpretive rule clarifies that the use of urine tests for HIV may now be used for life and health insurance underwriting, and not just as an initial screening device. The interpretive rule contains a testing protocol that may be used as an alternative to that set forth in 114CSR27, Section 5.

Rule Title: AIDS Regulations  
Interpretive Rule  
Title 114, Series 27A

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.

There could be a cost savings for insurers as a result of allowing a less expensive urine test for HIV rather than a blood draw or oral fluids test.

C. Economic Impact on Citizens/Public at Large.

None

Date: June 18, 2002

Signature of Agency Head or Authorized Representative



JANE L. CLINE, INSURANCE COMMISSIONER

**114CSR27A  
INTERPRETIVE RULE  
INSURANCE COMMISSIONER**

**SERIES 27A  
AIDS REGULATIONS**

**Section**

- 114-27A-1. General.
- 114-27A-2. Interpretive Note.
- 114-27A-3. Allowance of FDA Approved Urine HIV Tests.
- 114-27A-4. Compliance with Protocol Established in Interpretive Rule.
- 114-27A-5. Sunset Date.

**114CSR27A  
INTERPRETIVE RULE  
INSURANCE COMMISSIONER**

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**SERIES 27A  
AIDS REGULATIONS**

OFFICE WEST VIRGINIA  
SECRETARY OF STATE

**§114-27A -1. General.**

1.1. Scope. -- Series 27 of the Insurance Commissioner's rules, 114CSR27, establishes the standards for AIDS related underwriting health and lifestyle questions and AIDS testing in connection with applications for life or health insurance policies. This interpretive rule sets forth an additional protocol which the underwriter and the proposed insured may agree to use in lieu of the protocol established in 114CSR27, §5. This additional protocol allows the use of urine specimens as the exclusive method for HIV testing in connection with applications for life or health insurance policies, as an alternative to the use of blood or oral specimens.

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

1.3. Filing Date. --

1.4. Effective Date. --

**§114-27A-2. Interpretive Note.**

2.1. Technology has advanced in recent years with regard to HIV testing, and since promulgation of the AIDS Regulation, 114CSR27 §1, et seq., the U.S. Food and Drug Administration has approved the use of urine specimens to determine the presence of HIV. This interpretive rule shall be read in *pari materia* with the AIDS Regulations (114CSR27, §1, et seq.) previously promulgated by the Insurance Commissioner pursuant to authority granted by the Legislature in W.Va. Code §§33-2-35 and 16-3C-2(j). The definitions, applicability provisions and all other provisions provided in 114CSR27, §1, et seq. are equally applicable to this interpretive rule, with the exception of the provisions in 114CSR27, subsections 5.9 and 5.10, to the extent they are inconsistent with this interpretive rule.

**§114-27A-3. Allowance of FDA Approved Urine HIV Tests.**

3.1. Any HIV Testing that is authorized by section 5 of the AIDS Regulations, 114CSR27, §5, or this rule, 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 an acceptable testing protocol is followed, including the use of FDA-licensed tests. In lieu of the HIV protocol established in 114CSR27, §5, the Insurance Commissioner will allow underwriters and a proposed insured to agree to use the following protocol:

**Insurance Commissioner  
Legislative Rule  
Title 114, Series 27A**

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

3.2. If any of the tests in the ELISA-ELISA-Western Blot series produce a negative result, the testing ceases and the proposed insured cannot be denied coverage based on AIDS-related testing.

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.

**§114-27A-4. Compliance with Protocol established in Interpretive Rule.**

An underwriter who follows the protocol established in section 3 of this interpretive rule will not be found by the Insurance Commissioner to be in violation of legislative rule 114CSR27, §5 for not following the protocol established in section 5 of that rule.

**§114-27A-5. Sunset Date.**

The Insurance Commissioner has proposed an amendment to legislative rule 114CSR27, §5 that replaces the existing HIV protocol with the protocol in section 3 of this interpretive rule. This interpretive rule shall terminate and be of no further effect on the day the Insurance Commissioner's proposed amended legislative rule, 114CRS27, takes effect following its authorization by the Legislature.