

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

Do Not Mark In This Box

FILED

JUL 30 12 16 PM '98

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

Form #3

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

AGENCY: Insurance Commission TITLE NUMBER: 114

CITE AUTHORITY: W. Va. Code §§ 33-2-10, 33-6-8, 33-25A-3(1), 33-25A-20 and 16-3C-2(j)

AMENDMENT TO AN EXISTING RULE: YES NO

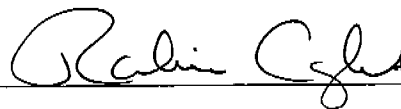
IF YES, SERIES NUMBER OF RULE BEING AMENDED: Series 27

TITLE OF RULE BEING AMENDED: Aids Regulations

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: _____

TITLE OF RULE BEING PROPOSED: _____

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



Robin C. Capehart, Cabinet Secretary
July 29, 1998

Date

\$7.60



STATE OF WEST VIRGINIA
Offices of the Insurance Commissioner

Legal Division

CECIL H. UNDERWOOD
Governor

HANLEY C. CLARK
Insurance Commissioner

July 30, 1998

HAND DELIVERED

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

FILED
JUL 30 12 15 PM '98
OFFICE OF SECRETARY OF STATE
WEST VIRGINIA

Dear Ms. Cooper:

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

- 1) Notice of Agency Approval of a Proposed Rule and filing with the Legislative Rule-Making Review Committee;
- 2) Consent of Tax and Revenue Cabinet Secretary to Proposed Rule;
- 3) Brief Summary of the Rule;
- 4) Statement of Circumstances;
- 5) Fiscal Note;
- 6) Legislative Rule-Making Review Committee Questionnaire; and
- 7) The Agency Approved Proposed Rule Entitled "AIDS Regulations" (Series 27).

Please contact me if further information is required.

Sincerely,

B. Keith Huffman
General Counsel

BKH/ksb

Enclosures



**STATE OF WEST VIRGINIA
DEPARTMENT OF TAX AND REVENUE**

CECIL H. UNDERWOOD
GOVERNOR

Charleston, West Virginia
P. O. Box 963
Charleston, WV 25324-0963
Ph. (304) 558-0211 - Fax (304) 558-2324

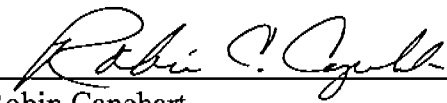
ROBIN C. CAPEHART
SECRETARY

CONSENT TO PROPOSAL OF RULE

To Whom It May Concern:

Pursuant to West Virginia Code §5F-2-2(a)(12), the undersigned hereby grants consent to the proposal of the following rule proposed by the Insurance Commissioner of the State of West Virginia: Title 114, Series 27, Aids Regulations relating to testing for Aids in life and health insurance underwriting.

Dated this 26th day of June, 1997.



Robin Capehart
Secretary of Tax and Revenue

"An equal opportunity/affirmative action employer"

Insurance Commissioner
Legislative Rule
Title 114, Series 27

AIDS REGULATIONS

TITLE 114, SERIES 27

BRIEF SUMMARY OF RULE

The Insurance Commissioner regulates Life and Accident Insurance policies. There is much concern as to what information insurers may request and when and how insurers may require HIV testing of insurance applicants.

The existing rule which has been in place since August, 1991, sets out guidelines which insurers must follow in underwriting for HIV in regard to Life and Accident and Sickness Insurance policies. Inter alia, it prohibits questions relating to sexual preference or life-style and limits HIV testing as to group insurance policies.

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

This is one of the rules which has been through the entire rulemaking process, but which was not ratified by the Legislature during the 1997-98 session due to the failure to pass House Bill 4177.

Insurance Commissioner
Legislative Rule
Title 114, Series 27

AIDS REGULATIONS

TITLE 114, SERIES 27

STATEMENT OF CIRCUMSTANCES

Medical technology has advanced since the promulgation of Series 27 in August, 1991. 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 oral specimens for use in HIV testing. This is obviously a less intrusive method of obtaining a test specimen, as opposed to a blood draw.

The insurance industry has requested that Series 27 be amended to accommodate this new testing method. A number of other states have either already done so, or are in the process of permitting oral testing.

This is one of the rules which has been through the entire rulemaking process, but which was not ratified by the Legislature during the 1997-98 session due to the failure to pass House Bill 4177.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: AIDS Regulations
 Title 114, Series 27

Type of Rule: Legislative Interpretive Procedural

Agency: Insurance Commissioner

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

=====

1. Effect of Proposed Rule

	ANNUAL FISCAL YEAR				
	Increase	Decrease	Current	Next	Thereafter
ESTIMATED TOTAL COST	\$		NONE		
PERSONAL SERVICES			NONE		
CURRENT EXPENSE			NONE		
REPAIRS AND ALTERNATIONS			NONE		
EQUIPMENT			NONE		
OTHER			NONE		

2. Explanation of above estimates:

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

Rule Title: AIDS Regulations
Title 114, Series 27

3. Objectives of these rules:

The objectives of these Rules are to: (1) eliminate the use of unfairly discriminatory underwriting and testing practices with regard to AIDS by health and life insurers; (2) establish guidelines as to when an insurer can ask AIDS-related questions, what type questions maybe asked, and when AIDS testing may be required, (3) establish a reasonable AIDS testing protocol, (4) insure the confidentiality of AIDS-related information released to the insurer by the applicant, and (5) allow insurers reasonable access to AIDS-related data so as to be able to perform proper underwriting of risks before coverage is bound on applicants.

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.

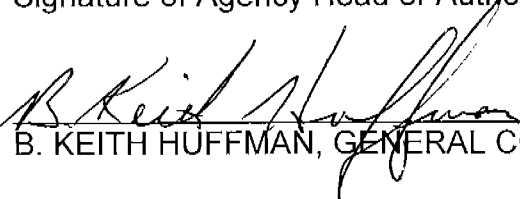
None

C. Economic Impact on Citizens/Public at Large.

None

Date: 7/23/98

Signature of Agency Head or Authorized Representative


B. KEITH HUFFMAN, GENERAL COUNSEL

DATE: JULY 23, 1998

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: OFFICE OF THE INSURANCE COMMISSIONER

LEGISLATIVE RULE TITLE: AIDS REGULATION, SERIES 27

1. Authorizing statute(s) citation:

West Virginia Code §§ 33-2-10, 33-6-8, 33-6-9, 3-25A-3(1), 33-25A-20 and 16-3C-2(j)

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

June 3, 1998

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

None

c. Date of hearing(s): The public comment period ended on July 6, 1998

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached: Yes No comments received: _____

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

July 30, 1998

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

B. Keith Huffman
General Counsel
(304) 588-0401

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.

Not applicable

b. Date of hearing: Not applicable

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

Not applicable

d. Attach findings and determinations and reasons:

Attached: Not applicable

ATTACHMENT TO QUESTION 2(d):

The West Virginia Insurance Commissioner received two comments to the proposed amendments to the rule. One was from Mr. Harvey Pogoriler, Assistant General Counsel for Northwestern Mutual Life Insurance Company. The other comment was from Sharon K. Roberson, Associate General Counsel for American General Life and Accident Insurance Company. (Copies attached)

Both sets of comments sought to have the new proposed language at § 5.6 of the proposed amendments to the rule changed so as to permit the use of non-medical personnel to administer the oral HIV test. The U.S. Food and Drug Administration (FDA) has authorized administration of the test by non-medical persons who have been properly trained and who administer the test under the supervision of a medical doctor. Based upon the comments and the FDA approval § 5.6 of the proposed amendments was re-worded as follows:

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.

Existing sections 5.6 through 5.10 were re-numbered as sections 5.7 through 5.11 due to the insertion of a new section at 5.6.

Also, the first sentence of the second page of Appendix A to the rule was amended to say "person" instead of "health care professional".

American General Life and Accident Insurance Company

American General Center • Nashville, Tennessee 37250-0001

A Subsidiary of
American General Corporation

Law Department

Jeffrey L. Baker
Marcus B. Bergh, Jr.
L. Overton Campbell
D. Randall Foster
Theron A. Guthrie, Jr.
Mary F. Kampa
Carolyn V. Moore
Shannon D. Nunnelee
Kenneth M. Palombo
Sharon K. Roberson
Rex H. Roberts
Jeanette R. Roch

July 2, 1998

Offices of the Insurance Commissioner
ATTN: Legal Division
P.O. Box 50540
Charleston, WV 25305-0540

Dear Sir or Madam:

Re: HIV/AIDS Regulation

The Department has solicited comments regarding the proposed amendments to Legislative Rule, Title 114, Series 27. These amendments permit the use of oral test specimens in testing for HIV. This document and its attachments represent the comments of American General Life and Accident Insurance Company, "AGLA."

AGLA would like to suggest that the Department consider revising the requirement in the proposal that testing be performed by medical professionals and allow testing by non-medical individuals whose training complies with Food and Drug Administration requirements. The language the company would like to see revised is found in section 5.6 of the proposal. We believe that we can demonstrate that the method used by our company is safe, effective, more economical and can be properly administered by trained non-medical individuals.

Our company uses a test called OraSure. The Food and Drug Administration has approved this test for use by trained individuals. Our test uses a toothbrush shaped probe, sold under the brand name EpiScreen, that the proposed insured inserts into their mouth to collect the specimen. The company we contract with that handles the device and procedure is Epitope. Epitope, as a requirement of the FDA approval, must restrict the administration of the device to individuals who have been trained in the use of this device according to approved labeling. Epitope requires a "Letter of Agreement for Physician" to be on file in order to distribute the product to a company. This "Letter of Agreement" was signed by Richard D. Lane, our medical director, who by signing the agreement assures that the test is made available only to individuals who have been trained to use the device according to the device labeling and training materials. I have enclosed a copy of the Epitope agreement form.



At AGLA agents are individually trained in the proper use of the test. As part of the approval process for the device, the information used in training our agents was submitted in a generic form to the FDA. This training material received approval.

Training classes consist of watching a training video, (the video is shown twice in the training session), reading a reference guide and watching a live demonstration by a trainer, of the use of a sample EpiScreen kit. The trainee must also conduct a test on a partner during the training session. Following the demonstration a quiz is given to the agent. A representative from the laboratory we use or Epitepe is present to answer any questions from the trainees.

I have enclosed, for your review, copies of information concerning the EpiScreen Device and the Epitepe test. I have also enclosed an article from Osborn Laboratories that discusses the approval by the FDA of the OraSure collection device and how this device may be used by insurance companies and their field forces.

We use the EpiScreen OraSure test in all jurisdictions that we operate in except West Virginia where it had been prohibited. Our experience in the use of the test has been extremely positive for the agents and applicants. Also, when tests are secured by an AGLA agent the cost of the test is \$19.71 as compared with \$55.11 when secured by a paramedical company. This results in substantial savings that can be passed to West Virginia policyholders.

Should you need further assistance regarding this issue please do not hesitate to contact me at (615) 749-1526.

Respectfully,



Sharon K. Roberson
Associate General Counsel

Enclosures

cc: Elaine McReynolds
John Coleman
Marcus Bergh
Donald Preston, ACLI



CLINICAL REFERENCE LABORATORY

July 2, 1998

Ronald Summers
Dir. of New Business MC-350S
American General Life & Accident Ins.
American General Center
Nashville, TN 37250

Dear Ron:

I enjoyed speaking with you today.

As we discussed, I have enclosed a copy of Epitepe's Letter of Agreement for Physician. This also confirms that Clinical Reference Laboratory has a signed copy of this form on file from Richard D. Lane, MD.

If you have any questions or need additional information, please feel free to contact me at 800-445-6917. Thank you for working with CRL.

Sincerely,



Bruce A. Dahlquist
Account Executive

EPITOPE, INC.

Letter of Agreement for Physician Ordered Purchase of OraSure® HIV-1 Oral Specimen Collection Device

Code #:

As a licensed physician, I am writing to advise you that I am aware of the following requirements for purchase and use of this device:

1. I am responsible to insure that the device is made available only to individuals who have been trained to use the device in accordance with the device labeling and training material provided.
2. I am responsible to insure that test results obtained on OraSure HIV-1 specimens will be reported to me or someone under my supervision.
3. I am responsible to insure that before his or her OraSure HIV-1 specimen is taken, each subject is counseled that if the result of the test on the OraSure HIV-1 specimen is positive for antibodies to HIV-1, he or she will be advised to have a blood specimen tested.
4. I am responsible to insure that OraSure HIV-1 specimen collection and testing are done in accordance with applicable laws and regulations concerning informed consent and confidentiality.

Sincerely,

Name: _____, M.D. Date: _____
Printed

Name: _____
Signature

Address: _____

Medical License No:	State:
---------------------	--------

Please fax this completed and signed form to Epitope at 503-520-6255 or 503-643-2781, ATTN: Customer Service.

Want to see an applicant smile?
Put away the needle.

■ **DRAWING SMILES
INSTEAD OF BLOOD.**

EpiScreen™ has taken the pain out of applicant screening. With EpiScreen™, the oral specimen collection device, you can **test for HIV-1, Cocaine and Cotinine without drawing blood.**

It's reliable. It's reassuring. So simple and convenient to use that agents or parameds can **collect samples anywhere, anytime—quickly and efficiently.**

EpiScreen™ not only streamlines the application process, it makes applicants feel good about your company.

It's a painless solution for the proposed insured and a cost effective solution for your company.

■ Oral
Specimen
Collection
Device



EpiScreen™ HIV-1
Oral Specimen Vial
See Oral Fluid Vials for
Cocaine, Marijuana, and
Cotinine Testing



A News Service Provided by Osborn Laboratories.

To: U.S. Client Insurance Companies

Date: December 28, 1994

Oral Fluid Collection is Approved by FDA

Last Friday, December 23, 1994, Epitope Inc. received approval from the FDA to market its OraSure oral fluid collection device. This marks the first time the FDA has approved an HIV test system for a bodily fluid other than blood. Epitope had been seeking FDA approval for the past three years.

Osborn Laboratories, an approved distributor of the OraSure collection device, has been working closely with Epitope to develop the best saliva products and services to meet the needs expressed by some life and health insurance companies. A specific training program has been developed which will enable non-medical personnel to collect and ship specimens to Osborn's centralized laboratory. As a result, insurance companies will be able to utilize this noninvasive method of collection with their field force.

The OraSure collection device is a small cotton pad that is affixed to the end of an applicator. It is positioned in the mouth between the cheek and gum for

approximately two minutes. The pad is then placed in a collection tube containing preservative

solution and shipped to Osborn Laboratories for testing.

Osborn Laboratories anticipates being able to supply collection kits and begin testing within the next 60 days. Currently, the product is only approved by the FDA for HIV testing; however, for the past three years, OraSure has been used for the testing of cotinine to determine an applicant's smoking status. Other tests such as cocaine are pending FDA approval. We will be providing all clients with additional information on this new, noninvasive, cost effective method of testing in the coming weeks.

We have been consulting with several companies to tailor our training program around their field requirements. If you or your company are interested in receiving more information or a consultation to determine your appropriate testing requirements, please feel free to call the Osborn AIDS Service Bureau at 913-764-5555, extension 266.

USA
(913) 764-5555

Canada
(800) 677-6726

This is one of 1 pages.

If you do not receive this number of pages, please call 913-764-5555, ext. 109.



OSBORN LABORATORIES®

The EpiScreen™ device is designed to collect:

- a) oral fluid.
- b) urine.
- c) blood.

When the Collection Pad is removed from the pouch:

- a) it should be grasped by the plastic handle.
- b) it should be grasped by the pad.
- c) the plastic handle should be immediately snapped off.

The Collection Pad should be placed:

- a) in the mouth, between the upper cheek and gum.
- b) under the tongue.
- c) in the mouth, between the lower cheek and gum.

The Collection Pad should be left in the subject's mouth for:

- a) at least five minutes, but no more than eight minutes.
- b) at least three minutes, but no more than ten minutes.
- c) at least two minutes, but no more than five minutes.

After specimen collection, the Collection Pad is placed pad first:

- a) onto the table top.
- b) into the Specimen Vial by the proposed insured.
- c) into the refrigerator.

After the pad is placed in the vial, the nylon stick is broken by:

- a) no one, it remains intact.
- b) a bending action until the stick snaps.
- c) a pair of forceps.

The Specimen Vial should:

- a) have the tamper proof tape and/or the proposed insured's identification information recorded on it.
- b) be protected from having its tip broken.
- c) both of the above.

EpiScreen™ specimens collected in a non-medical setting:

- a) require a trained collector.
- b) should be protected from temperatures over 98°F.
- c) both of the above.

ANSWERS: 1a, 2a, 3c, 4c, 5b, 6b, 7c, 8c

Frequently Asked Questions

Q.A. What is on the pad? (Why is it so salty?)

The pad is treated with a salt solution to enhance collection.

Q.A. Is the pad safe to put in my mouth?

Yes, all ingredients on the pad are on the FDA Generally Recognized As Safe (GRAS) list.

Q.A. I have a cold, the flu, dentures, false teeth, no teeth, etc. Can I still use this device?

Yes, studies show that a cold or the flu have no effect on the ability of the EpiScreen™ device to collect a proper sample. Also, no teeth or false teeth will not affect the function of the device.

Q.A. I just had (coffee, water, gum, candy, a cigarette). Will that be a problem?

Wait for a period of 5 minutes after drinking, eating or smoking before collection. Do not have anything in your mouth during collection.

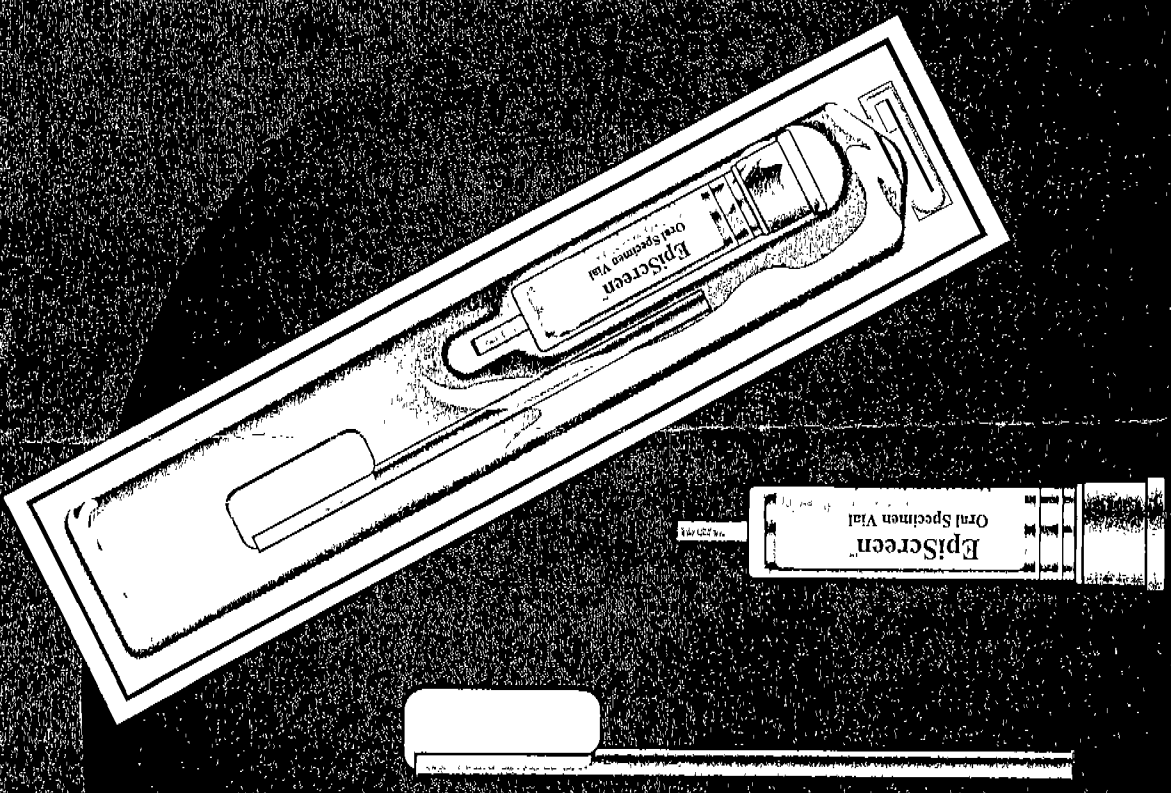
Q.A. What is the blue liquid in the vial?

The blue liquid is a non-toxic preservative that keeps the oral fluid sample from deteriorating.

Q.A. Will recent oral surgery (root canals, extraction's, etc.) or sutures make a difference?

Neither will affect the collection. However, if sutures are located between the lower cheek and gum, it is better to wait until they are removed so you do not disturb the healing process, or have the proposed insured collect on the other side of the mouth.

EpiScreen™ Training & Reference Guide



EPI TOPE

EpiScreen™ is a registered trademark of EpiTope, Inc.
EpiTope, Inc. 8505 S.W. Creekside Place, Beaverton, OR 97008, USA

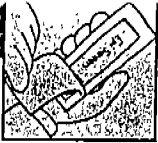
Part #203-0116-0

Introduction

The Episcreen™ Oral Specimen Collection Device is a non-invasive way to collect oral fluid specimens. This Training & Reference Guide is designed to teach you how to use the Episcreen™ device to properly collect oral fluid specimens from your proposed insured.

Episcreen™ Contents

- Collection Pad
- Specimen Vial containing a blue liquid (which preserves the specimen for up to 21 days from the time of collection)



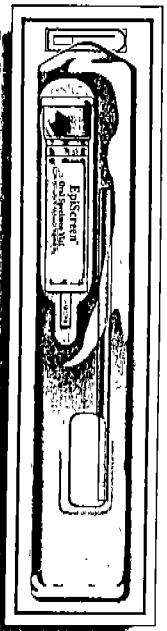
Additional Materials That May Be Provided

- Authorization Form including Notice & Consent
- Tamper-Evident Tape/ Security Identification Seal/ Tamper-Evident Bag
- Pre-addressed/Pre-paid Envelope

A wrist watch or similar timing device is also required.

Documentation Procedure

1. Carefully explain each step of the procedure to the proposed insured prior to collecting the specimen.
2. Complete the Authorization Form as required.
3. Have the proposed insured read, sign and date the Notice & Consent section of the Authorization Form.
4. When collecting specimens for HIV testing provide the proposed insured with the pamphlet entitled "Testing for HIV Antibodies with Episcreen™".



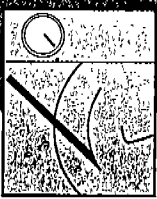
Collection Procedure



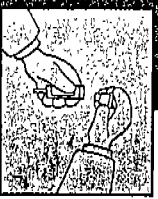
1. Open the outer package of Episcreen™ to access the package containing the Collection Pad. Carefully open the individually pouched Collection Pad. Be sure to peel open the packaging far enough to sufficiently expose the pad to allow for easy removal.



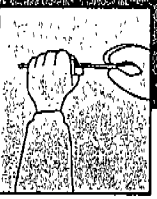
2. Offer the Collection Pad, stick end first, to the proposed insured and instruct the proposed insured to remove the Collection Pad from the pouch by grasping the stick.



3. Instruct the proposed insured to place the pad portion between the lower cheek and gum, and to gently rub back and forth until the pad is moist.



4. Instruct the proposed insured to leave the pad in the mouth. Keep track of the time the pad is in the mouth. The pad must stay in the mouth for at least two minutes and no longer than five minutes.



5. While timing the two minutes, remove the Specimen Vial from the outer pouch package; write the date on the specimen vial and if required write the proposed insured's name, identification or driver's license number.



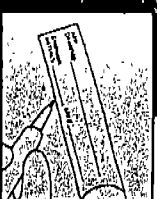
6. Holding the vial upright, with the tip pointed down, carefully remove the cap from the vial using a rocking motion.



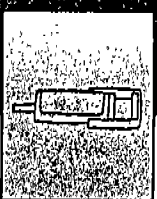
7. After two minutes, ask the proposed insured to remove the Collection Pad from his or her mouth; insert the Collection Pad into the vial while holding the stick; and push the Collection Pad all the way to the bottom of the vial.

8. Ask the proposed insured to bend the handle of the stick against the inner lip of the vial until the upper half of the stick breaks off.
9. Replace the cap, making sure you hear a "snap" that means the cap is properly seated in the vial. Be sure to handle the vial with care. Do not break the tip on the bottom of the vial. The tip is meant to be broken at the laboratory.

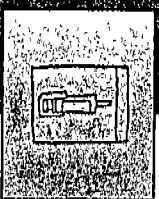
Final Procedure



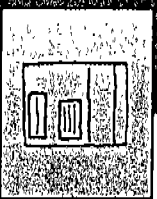
1. Have the proposed insured initial and date the Tamper-Evident Tape/Security Identification Seal or Tamper-Evident Bag as provided. You should also initial the above mentioned.



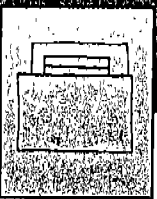
2. Carefully place the Tamper-Evident Tape/ Security Identification Seal over the vial cap and avoid covering the identification section of the Specimen Vial or, as provided, place the Specimen Vial in the Tamper-Evident Specimen Bag.



3. Place the Specimen Vial in the return envelope that has been provided.



4. Have the proposed insured read, sign and date the Chain-of-Custody section. You should also sign and date the Chain-of-Custody section. The Authorization Form consists of several copies. Please be certain to distribute as noted at the bottom of each copy.



5. Place the Laboratory copy of the Authorization Form into the provided return envelope and ship as instructed.

114CSR27
WEST VIRGINIA LEGISLATIVE RULE
INSURANCE COMMISSIONER

~~CHAPTER 33~~
SERIES 27

AIDS REGULATIONS

~~Section 1.~~114-27-1. Scope

~~Section 2.~~114-27-2. Applicability

~~Section 3.~~114-27-3. Definitions

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

~~Section 5.~~114-27-5. Testing

~~Section 6.~~114-27-6. Notice and Consent Form

~~Section 7.~~114-27-7. Separability

114CSR27
WEST VIRGINIA LEGISLATIVE RULE
INSURANCE COMMISSIONER

FILED

JUL 30 12 17 PM '98

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

Chapter 33
Series 27

AIDS REGULATIONS

Section 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 - West Virginia Code §§ ~~33-2-10, 33-6-8, 33-6-9, 33-25A-3(1), 33-25A-20,~~ and 16-3C-2(j).

1.3. Filing Date - ~~May 31, 1991.~~

1.4. Effective Date - ~~August 1, 1991.~~

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

~~(B)~~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.

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.

Section 3. Definitions

3.1. Code - means the West Virginia Code.

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

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.

3.67. Enzyme Linked Immunosorbent Assay (ELISA) - means a test used to determine the existence of the HIV antibody in the blood or in OMT.

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

3.89. Western Blot - means a test used to determine the existence of the HIV antibody in the blood or in OMT.

3.910. Health Care Professional or Health Care Provider - means any physician, nurse, physicians 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.

Section 4. Medical/Lifestyle Applications Questions and Underwriting Guidelines

4.1. General Propositions:

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

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

4.2. Medical/Lifestyle Applications Questions and Underwriting Standards.

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

~~(B)~~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)~~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)~~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)~~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)~~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)~~g. For purposes of rating a proposed insured for health and life insurance, an 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)~~h. No questions shall seek to determine if the proposed insured has demonstrated AIDS-related concerns or has sought AIDS-related counseling.

~~(I)~~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.

Section 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.

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.

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

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

~~(2)~~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 insurers underwriting files to verify that proper HIV underwriting has occurred.

~~(B)~~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 or oral fluid test code.

~~(C)~~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. ~~All such~~ No persons receiving HIV test information shall ~~not~~ transmit information further and shall maintain strict confidentiality.

~~(D)~~d. To the extent that they are otherwise entitled to access to the insurers 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.

5.78. Upon written request by the individual undergoing the test the insurer must provide within 30 days, a written list ~~within 30 days~~ of all persons or entities to whom test information has been released or caused to be released by the insurer pursuant to section 5.6 above or otherwise.

5.89. The testing is required to be administered on a nondiscriminatory basis for all individuals in the same underwriting class, ~~and no~~ No proposed insured may be denied coverage or rated a substandard risk on the basis of ~~such~~ HIV testing unless acceptable testing protocol is followed. The insurer may at its option use a urine HIV test as an initial screening device; provided that if such urine test yields a negative result no further HIV testing may be required of the proposed insured. If the urine test yields a positive result for the presence 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. The following is the acceptable blood or OMT HIV testing protocol for use in this state and an insured may not be denied coverage on the basis of AIDS related testing unless:

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

~~(B)~~b. A second ELISA blood or OMT test is administered and it indicates the presence of HIV antibodies in the blood or OMT; and

~~(C)~~c. A Western Blot blood or OMT test is conducted and it confirms the results of the two ELISA tests.

5.910. If any of the test results 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.

5.1011. 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.

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

Section 7. Separability

7.1. If any provision of this regulation or the application thereof to any person or circumstance is for any reason held to be invalid, the remainder of the regulation and the application thereof to other persons or circumstances shall not be affected thereby.

APPENDIX A

Examiner	_____	Insured	_____
Address	_____	Address	_____
	_____		_____

NOTICE AND CONSENT FOR BLOOD, ~~OR 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, ~~or 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 blood, or oral fluid 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.

APPENDIX A

You should also be aware that the ~~health care professional person~~ who performs the blood, urine or oral fluid testing is subject to West Virginia Code §§ 16-3C-3 and 16-3C-4 which authorizes 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 West Virginia 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.

