

Clearinghouse Rule 97-137



State of Wisconsin / OFFICE OF THE COMMISSIONER OF INSURANCE

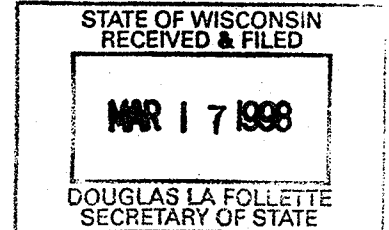


Tommy G. Thompson  
Governor

Randy Blumer  
Commissioner (Acting)

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(608) 266-3585

[http://badger.state.wi.us/agencies/oci/oci\\_home.htm](http://badger.state.wi.us/agencies/oci/oci_home.htm)



STATE OF WISCONSIN

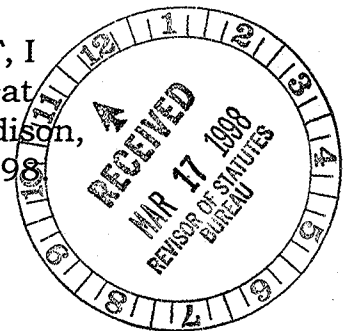
OFFICE OF THE COMMISSIONER OF INSURANCE

SS

I, Randy Blumer, Commissioner of Insurance and custodian of the official records, certify that the annexed rule affecting Section Ins 3.53, Wis. Adm. Code, relating to HIV testing procedures, is duly approved and adopted by this Office on March 17, 1998.

I further certify that I have compared this copy with the original on file in this Office and that it is a true copy of the original, and the whole of the original.

IN TESTIMONY WHEREOF, I have hereunto set my hand at 121 East Wilson Street, Madison, Wisconsin, on March 17, 1998



*Randy Blumer*

Randy Blumer  
Commissioner of Insurance

97-137  
6-1-98

**ORDER OF THE OFFICE OF THE COMMISSIONER OF INSURANCE AMENDING A RULE**

To amend Ins 3.53, Wis. Adm. Code, relating to HIV testing procedures.

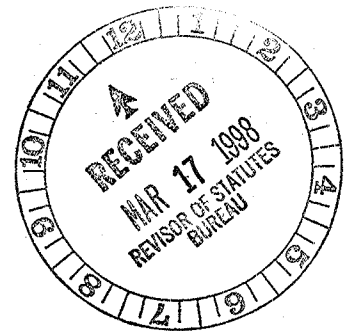
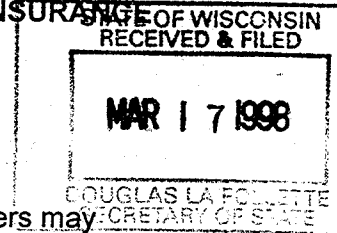
**ANALYSIS PREPARED BY THE OFFICE OF THE COMMISSIONER OF INSURANCE**

Statutory authority: ss., 601.41(3), 631.90 (3) (a), Stats.

Statutes interpreted: s 631.90 (3) (a) Stats.

This proposed rule amendment adheres to the legislative mandate that insurers may employ tests for HIV that have been designated by the state epidemiologist as reliable. The current rule is based upon a report from the state epidemiologist dated August 1990 which limited use to FDA licensed blood tests. This amended rule recognizes the January 1997 report by the state epidemiologist which expands the endorsed tests to include specimen samples in addition to blood.

Some additional changes have been made to this rule in response to comments received during the rule-making process. These changes clarify and update the rule.



**SECTION 1. INS. 3.53 IS AMENDED TO READ:**

**Ins 3.53 HIV testing. (1) FINDINGS.** The tests listed in sub. (4) (e) ~~1 to 3~~ have been specified by the state epidemiologist in ~~part C~~ part B (4) of a report entitled "Validated positive, ~~tests and~~ medically significant and sufficiently reliable tests to detect the presence of human immunodeficiency virus (HIV), antigen or nonantigenic products of HIV or an antibody to HIV," dated ~~August 31, 1990~~ January 24, 1997. The commissioner of insurance, therefore, finds that these tests are sufficiently reliable for use in underwriting individual life, accident and health insurance policies.

(2) **PURPOSES.** The purposes of this section are:

- (a) To implement s. 631.90 (3) (a), Stats.
- (b) To establish procedures for insurers to use in obtaining informed consent for HIV testing and informing individuals of the results of a positive HIV test.
- (c) To ensure the confidentiality of HIV test results.
- (d) To restrict the use of certain information on HIV testing in underwriting group life, accident and health insurance policies.

(3) **DEFINITIONS.** In this section:

- (a) "AIDS" means acquired immunodeficiency syndrome.
- (b) "AIDS service organization" means a ~~community-based~~ state designated organization in this state that provides AIDS prevention and education services to the general public and offers direct care and support services to persons with HIV ~~infection and AIDS~~ at no cost
- ~~(c) "ELISA" means enzyme-linked immunosorbent assay.~~
- ~~(d) "FDA-licensed test" means a test of a single whole blood, serum or plasma specimen which has been approved by the federal food and drug administration.~~
- ~~(e)~~ (c) "Health care provider" has the meaning given under s. 146.81 (1) Stats.
- ~~(f)~~ (d) "HIV" has the meaning given under s. 631.90 (1), Stats.
- ~~(g)~~ (e) "Medical information bureau, inc." means the nonprofit Delaware incorporated trade association, the members of which are life insurance companies, that operates an information exchange on behalf of its members.
- ~~(h)~~ (f) "State epidemiologist" has the meaning given under s. ~~146.025 (1) (f)~~ 252.01 (6), Stats.

(4) (g) "Wisconsin AIDSline" means the state designated statewide AIDS information and medical referral service.

- (4) TESTING: USE; PROHIBITIONS. (a) For use in underwriting an individual life accident or health insurance policy, an insurer may require that the person to be insured be tested, at the insurer's expense, for the presence of HIV, antigen or nonantigenic products of HIV or an antibody to HIV.
- (b) An insurer that requires a test under par. (a) shall, prior to testing, obtain a signed consent form, in substantially the format specified in Appendix A, either from the person to be tested or from one of the following if the specified condition exists:
1. The person's parent or guardian, if the person is under 14 years of age.
  2. The person's guardian, if the person is adjudged incompetent under ch. 880, Stats.
  3. The person's health care agent, as defined in s. 155.01 (4), Stats., if the person has been found to be incapacitated under s. 155.05 (2), Stats.
- (c) The insurer shall provide a copy of the consent form to the person who signed it and shall maintain a copy of each consent form for at least one year.
- (d) The insurer shall provide with the consent form a copy of the document "resources for persons with a positive HIV test / the implications of testing positive for HIV." Each insurer shall either obtain copies of the document from the office of the commissioner of insurance or reproduce the document itself. If the document is revised, the insurer shall begin using the revised version no later than 30 days after receiving notice of the revision from the office of the commissioner of insurance.

Note: The document referred to in this paragraph is form number OCI 17-001. It may be obtained from the Office of the Commissioner of Insurance, P.O. Box 7873, Madison, Wisconsin 53707-7873.

~~(e) The only tests an insurer may use under par. (a) are the following:~~

- ~~1. An FDA licensed test that is positive for the presence of an HIV antigen.~~
- ~~2. An FDA licensed ELISA test that is reactive for the presence of an antibody to HIV at least twice, followed by a reactive western blot test.~~
- ~~3. An FDA licensed latex agglutination test that is positive for the presence of an antibody to HIV at least once, followed by a reactive western blot test.~~

(e) Tests may be used under par. (a) only if the tests meet the following criteria:

1. A single specimen which is repeatedly reactive using any food and drug administration "FDA" licensed enzyme immunoassay "EIA" HIV antibody test and confirmed positive using an FDA licensed HIV antibody confirmatory test.
2. A single specimen which is repeatedly reactive using any FDA licensed HIV antigen test and an FDA licensed EIA HIV antibody test. A specimen which is repeatedly reactive to an FDA licensed HIV antigen test shall be confirmed through a neutralization assay. A specimen which is repeatedly reactive to an FDA licensed EIA HIV antibody test shall be tested with an FDA licensed HIV antibody confirmatory test.
3. A single specimen which is tested for the presence of HIV using a molecular amplification method for the detection of HIV nucleic acids consistent with national committee for clinical laboratory standards.
4. A single specimen which is tested for the presence of HIV using viral culture methods.

~~(f) For purposes of par. (e) 2. and 3., a western blot test is reactive when any 2 of the following protein or glycoprotein bands are present:~~

- ~~1. p24.~~
- ~~2. gp41.~~
- ~~3. gp120 or gp160.~~

~~Note: Because of the difficulty of distinguishing the gp120 band from the gp160 band the state epidemiologist has determined that the 2 glycoprotein bands may be considered as one reactant for the purpose of interpreting a western blot test.~~

~~(g) (f) A test under par. (e) shall be performed by a laboratory that participates in and satisfies the standards of a generally recognized HIV proficiency testing program, including a program conducted by the federal centers for disease control, the American association of bioanalysts, the college of American pathologists or a similar program with specifications that meet the standards of those programs which meets the requirements of the federal health care financing administration under the clinical laboratory improvement amendments act of 1988.~~

~~Note: An insurer may use any of the tests described in pars. (e) to (g), in underwriting individual life, accident and health insurance applications on and after May 1, 1994.~~

(h) (g) 1. An insurer that uses an application asking whether the person to be insured has been tested for the presence of HIV, antigen or nonantigenic products of HIV or an antibody to HIV may ask only whether the person has been tested using one or more of the tests specified in par. (e).

2. Notwithstanding subd. 1. the insurer may not require or request the disclosure of any information as to whether the person to be insured has been tested at an anonymous counseling and testing site designated by the state epidemiologist or at a similar facility in another jurisdiction or through the use of an anonymous home test kit, or to reveal the results of such a test.

(5) POSITIVE TEST RESULT; INSURER'S OBLIGATION. (a) If a test under sub. (4) (e) is positive and, in the normal course of underwriting, affects the issuance or terms of the policy, the insurer shall provide written notice to the person who signed the consent form that the person tested does not meet the insurer's usual underwriting criteria because of a test result. The insurer shall request that the person provide informed consent for disclosure of the test result to a health care provider with whom the person wants to discuss the test result.

(b) If informed consent for disclosure is obtained, the insurer shall provide the designated health care provider with the test result. If the person refuses to give informed consent for disclosure, the insurer shall, upon the person's request, provide the person who signed the consent form with the test result. The insurer shall include with the report of the test result all of the following:

1. A statement that the person should contact a private health care provider, a public health clinic, an AIDS service organization or the Wisconsin AIDSline ~~for information on the medical implications of a positive test, the desirability of further independent testing and the availability of anonymous testing~~ additional medical evaluation or referral for such services.

2. The toll-free telephone number of the Wisconsin AIDSline.

3. Copies of the document specified in sub. (4) (d).

(6) CONFIDENTIALITY OF TEST RESULTS. An insurer that requires a person to be tested under sub. (4) (a) may disclose the test result only as described in the consent form obtained under sub. (4) (b) or with written consent for disclosure signed by the person tested or a person specified in sub. (4) (b) 1. to 3.

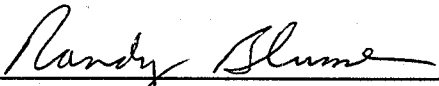
(7) GROUP POLICIES; ADDITIONAL PROHIBITION. In underwriting group life, accident or health insurance on an individual basis, in addition to the restrictions specified in s. 631.90 (2), Stats., an insurer may not use or obtain from any source, including the medical information bureau, inc., any of the following:

(a) The results of a person's test for the presence of HIV, antigen or nonantigenic products of HIV or an antibody to HIV.

(b) Any other information on whether the person has been tested for the presence of HIV, antigen or nonantigenic products of HIV or an antibody to HIV.

SECTION 2. This rule shall take effect on the first day of the month following publication in the Wisconsin administrative register as provided in s. 227.22 (2) (intro). Stats.

Dated this 17<sup>th</sup> day of March, 1998

  
\_\_\_\_\_  
Randy Blumer, Commissioner of Insurance

Ins 3.53 APPENDIX A

[Insurer name and address]

WISCONSIN NOTICE AND CONSENT FOR ~~AIDS-RELATED BLOOD HUMAN~~  
~~IMMUNODEFICIENCY TESTING~~  
~~REQUEST FOR CONSENT FOR TESTING~~

To evaluate your insurability, ( insurer name ) (Insurer) requests that you ~~provide a sample of your blood for testing and analysis, be tested~~ to determine the presence of human immunodeficiency virus (HIV) antibody or antigens. By signing and dating this form, you agree that this test may be done and that underwriting decisions may be based on the test results. A licensed laboratory will perform one or more tests approved by the Wisconsin Commissioner of Insurance.

PRETESTING CONSIDERATION

Many public health organizations recommend that, if you have any reason to believe you may have been exposed to HIV, you become informed about the implications of the test before being tested. You may obtain information about HIV and counseling from a private health care provider, a public health clinic, or one of the AIDS service organizations on the attached list. You may also wish to obtain an HIV test from an anonymous ~~HIV~~ counseling and testing site before signing this consent form. The Insurer is prohibited from asking you whether you have been tested at an anonymous ~~HIV~~ counseling and testing site and from obtaining the results of such a test. For further information on these options, contact the Wisconsin AIDSline at 1-800-334-2437.

MEANING OF POSITIVE TEST RESULTS

~~Any test administered~~ This is not a test for AIDS. It is a test for ~~antibodies to or antigens of HIV, the causative agent for AIDS,~~ HIV and shows whether you have been infected by the virus. A positive test result may have an effect on your ability to obtain insurance. A positive test result does not mean that you have AIDS, but it does mean that you are at a seriously increased risk of developing problems with your immune system. HIV tests are very sensitive and specific. Errors are rare but they can occur. If your test result is positive, you may wish to consider further independent testing from your physician, a public health clinic, or an anonymous HIV counseling and testing site. HIV testing may be arranged by calling the Wisconsin AIDSline at 1-800-334-2437.



## NOTIFICATION OF TEST RESULTS

If your HIV test result is negative, no routine notification will be sent to you. If your HIV test result is other than normal, the Insurer will contact you and ask 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 test results.

## DISCLOSURE OF TEST RESULTS

All test results will be treated confidentially. The laboratory that does the testing will report the result to the Insurer. If necessary to process your application, the Insurer may disclose your test result to another entity such as a contractor, affiliate, or reinsurer. If your HIV test is positive, the Insurer may report it to the Medical Information Bureau (MIB, Inc.), as described in the notice given to you at the time of application. If your HIV test is negative, no report about it will be made to the MIB, Inc. The organizations described in this paragraph may maintain the test results in a file or data bank. These organizations may not disclose the fact that the test has been done or the result of the test except as permitted by law or authorized in writing by you.

## CONSENT

I have read and I understand this notice and consent for ~~AIDS related blood~~ HIV testing. I voluntarily consent to ~~the withdrawal of my blood, the testing of that blood,~~ this testing and the disclosure of the test result as described above. A photocopy or facsimile of this form will be as valid as the original.

\_\_\_\_\_  
Signature of Proposed Insured  
or Parent, Guardian, or Health Care Agent/Date

\_\_\_\_\_  
Name of Proposed Insured (Print)

\_\_\_\_\_  
Date of Birth

\_\_\_\_\_  
Address

\_\_\_\_\_  
City, State, and Zip Code