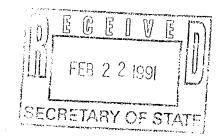
CR 90-219



STATE OF WISCONSIN)) OFFICE OF THE COMMISSIONER OF INSURANCE)

FEB 2 2 1991

Bureau

EIVED

I, Robert D. Haase, Commissioner of Insurance and custodian of the official records of this Office, certify that the attached rule-making order affecting ss. 3.53 and 7.02, Wis. Adm. Code, relating to medically significant and sufficiently reliable HIV testing for use in underwriting individual life, accident and health insurance policies, consent for HIV testing, the confidentiality and disclosure of test results, and restrictions on the use of information in underwriting group policies, was issued by this Office on $\underline{feh} \mathcal{Ad}, \underline{/9.9/}$.

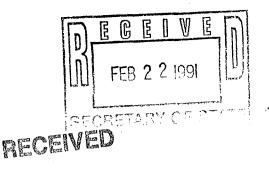
I further certify that I have compared this copy with the original on file in this Office and that it is a true copy of the whole of the original.

Dated at Madison, Wisconsin, this 22d day of

Robert D. Haase Commissioner of Insurance

1382M2

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FEB 2 2 1991

Revisor of Statutes Bureau

ORDER OF THE COMMISSIONER OF INSURANCE AMENDING AND REPEALING AND RECREATING A RULE

To amend Ins 7.02 (2); and to repeal and recreate Ins 3.53, relating to medically significant and sufficiently reliable HIV testing for use in underwriting individual life, accident and health insurance policies, consent for HIV testing, the confidentiality and disclosure of test results, and restrictions on the use of information in underwriting group policies.

ANALYSIS PREPARED BY THE OFFICE OF THE COMMISSIONER OF INSURANCE Statutory authority: ss. 601.41 (3) and 631.90 (3) (a), Stats. Statute interpreted: s. 631.90, Stats.

The commissioner of insurance is required by statute to promulgate a rule designating the tests for the presence of HIV, antigen or nonantigenic products of HIV or an antibody to HIV which are medically significant and sufficiently reliable for use by insurers in underwriting individual life, accident and health insurance policies. HIV is human immunodeficiency virus, which causes acquired immunodeficiency syndrome (AIDS).

The commissioner may designate a test only if it has been specified by the state epidemiologist in the department of health and social services as sufficiently reliable for use by insurers. The state epidemiologist recently issued a new report on AIDS-related testing, based on recent changes in technology. This rule updates the commissioner's rule to incorporate certain tests for the presence of an HIV antigen or an antibody to HIV which are licensed by the federal food and drug administration and designated by the state epidemiologist for use by insurers. The state epidemiologist has not yet designated any sufficiently reliable tests for the presence of nonantigenic products of HIV, so none are included in this proposed rule. Any insurer that requires a person to be tested must have the test performed by a laboratory that participates in and satisfies the standards of a generally recognized HIV proficiency testing program.

The current rule requires an insurer to obtain informed consent for HIV testing from the person who will be tested. This rule also permits an insurer to obtain informed consent from the parent or guardian of a minor applicant under 14 years of age, from the guardian of an incompetent applicant or, if the applicant has executed a power of attorney for health care instrument and has been found to be incapacitated, from the applicant's health care agent. With the consent form, the insurer must include information on the Wisconsin AIDSline, AIDS service organizations and the implications of testing positive.

If the test result is positive and affects the issuance or terms of the policy, the insurer is required to notify the person who signed the consent form that the person tested does not meet the insurer's usual underwriting criteria because of the test result. The insurer must try to obtain consent for disclosure to a health care provider with whom the person may discuss the result. If the person refuses to consent to disclosure, the insurer must disclose the result to the person upon request. The insurer must again provide information about the implications of a positive test and sources for obtaining further information.

This rule makes it clear that if an insurer inquires about an applicant's previous HIV testing, it may only ask about those tests that have been designated by the commissioner. This conforms with current practice. The rule retains the provision of the existing rule that insurers may not require or request the disclosure of any information about testing obtained at an anonymous HIV counseling and testing site designated by the state epidemiologist, but broadens that prohibition to include information about anonymous testing obtained outside of Wisconsin.

A consent for testing form, which insurers are required to use in substantially the same format, is included as an appendix to the rule. Test results may not be disclosed except as described in that consent form or with the written consent of the test subject or a person authorized to consent on behalf of the test subject.

Insurers may use the additional designated tests as soon as the rule takes effect (the first day of the first month after publication), but will have an additional 6 months to bring their forms into compliance with the new notice and consent requirements.

SECTION 1. Ins 3.53 is repealed and recreated to read:

Ins 3.53 HIV TESTING. (1) FINDING. The tests listed in sub. (4) (e) 1 to 3 have been specified by the state epidemiologist in part C of a report entitled "Validated positive tests and medically significant and sufficiently reliable tests to detect the presence of HIV, antigen or nonantigenic products of HIV or an antibody to HIV," dated August 31, 1990. 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 organization in this state that provides AIDS prevention and education services to the general public and offers direct support services to persons with HIV infection 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) "Health care provider" has the meaning given under s. 146.81 (1), Stats.

(f) "HIV" has the meaning given under s. 631.90 (1), Stats.

(g) "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) "State epidemiologist" has the meaning given under s. 146.025 (1)(f), Stats.

(i) "Wisconsin AIDSline" means the 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: Ins 3.53 (4) (d). The document referred to in this paragraph is form number OCI 26-002. 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.

(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: Ins 3.53 (4) (f) 3. 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) 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.

(h) 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 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

605R7 02/21/91 Wisconsin AIDSline for information on the medical implications of a positive test, the desirability of further independent testing and the availability of. anonymous testing.

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. Ins 7.02 (2) is amended to insert a reference to the following form:

26-002 Resources for Persons with a Positive HIV Test/The Implications of Testing Positive for HIV

SECTION 3. <u>APPLICABILITY</u>. (1) An insurer may use any of the tests described in s. Ins 3.53 (4) (e) to (g), as created by this rule, in underwriting individual life, accident and health insurance applications on and after the effective date of this rule.

(2) Section Ins 3.53 (1) to (3), (4) (h) and (7), as created by this rule, and the amendment of s. Ins 7.02 (2) by this rule first apply on the effective date of this rule.

(3) Section Ins 3.53 (4) (a) to (d), (5) and (6), as created by this rule, first apply to applications taken on the first day of the 6th month beginning after the effective date of this rule.

(4) Section Ins 3.53 (6) (a), (b) and (e) and (7), as they exist on the day before the effective date of this rule, continue to apply to informed consent for testing and disclosure of test results until the first day of the 6th month beginning after the effective date of this rule.

SECTION 4. <u>EFFECTIVE DATE.</u> This rule takes effect the first day of the first month beginning after publication, as provided in s. 227.22 (2) (intro.), Stats.

Dated at Madison, Wisconsin, this 22d day of the 1991.

Robert D. Haase . Commissioner of Insurance

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FEB 2 2 1991

Revisor of Statutes Bureau

APPENDIX A

[Insurer name and address]

WISCONSIN NOTICE AND CONSENT FOR AIDS-RELATED BLOOD TEST

REQUEST FOR CONSENT FOR TESTING

To evaluate your insurability, <u>(insurer name)</u> (Insurer) requests that you provide a sample of your blood for testing and analysis, 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 is not a test for AIDS. It is a test for antibodies to or antigens of HIV, the causative agent for AIDS, 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 results 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 testing. I voluntarily consent to the withdrawal of my blood, the testing of that blood, 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