

CR 86-230

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STATE OF WISCONSIN
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DOUGLAS LA FOLLETTE
SECRETARY OF STATE

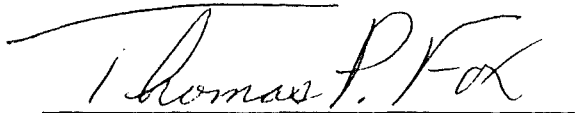
STATE OF WISCONSIN)
OFFICE OF THE COMMISSIONER OF INSURANCE)

TO ALL TO WHOM THESE PRESENTS SHALL COME, GREETINGS:

I, Thomas P. Fox, Commissioner of Insurance and custodian of the official records of said office, do hereby certify that the annexed order creating a rule relating to HTLV-III antibody testing was issued by this office on March 26, 1987.

I further certify that said copy has been compared by me with the original on file in this office and that the same is a true copy thereof, and of the whole of such original.

IN TESTIMONY WHEREOF, I have hereunto subscribed my name in the City of Madison, State of Wisconsin, this 26th day of March, 1987.



Thomas P. Fox
Commissioner of Insurance

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STATE OF WISCONSIN
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DOUGLAS LA FOLLETTE
SECRETARY OF STATE

ORDER OF THE COMMISSIONER OF INSURANCE

CREATING A RULE

To create Ins 3.53 relating to HTLV-III antibody testing.

ANALYSIS PREPARED BY THE COMMISSIONER OF INSURANCE

This rule interprets section 631.90 (3) (a), Stats.

The purpose of this rule is to designate a series of HTLV-III antibody tests which is sufficiently reliable for use in the underwriting of individual life, accident and health insurance policies.

Pursuant to the authority vested in the Office of the Commissioner of Insurance by section 601.41 (3), Stats., the Office of the Commissioner of Insurance hereby creates a rule interpreting s. 631.90 (3) (a), Stats., as follows:

SECTION 1. Ins 3.53 is created to read:

Ins 3.53. HTLV-III ANTIBODY TESTING. (1) FINDINGS. The commissioner of insurance finds and designates that the series of HTLV-III antibody tests found by the state epidemiologist in a report entitled "Serologic tests for the presence of antibody to human T-lymphotropic virus type III" and dated July 28, 1986, to be medically significant and sufficiently reliable for detecting the presence of the HTLV-III antibody is also sufficiently reliable for use in the underwriting of individual life, accident and health insurance. The state epidemiologist found that the combination of repeatedly reactive ELISA tests validated by a Western blot assay is highly predictive of a true infection with the HTLV-III virus, also known as the HIV or Human Immunodeficiency Virus. While this series of tests does not indicate that a person has AIDS, the use of this series for underwriting purposes is sufficiently reliable to indicate the presence of infection with the HTLV-III virus.

(2) PURPOSE. This section interprets s. 631.90 (3) (a), Stats., by designating which test or series of tests used to detect the HTLV-III antibody is sufficiently reliable for use in the underwriting of individual life, accident and health insurance policies.

(3) SCOPE. This section applies to any insurer writing individual life, accident and health insurance coverage in Wisconsin. Except as provided in sub. (6) (c), this section does not apply to any insurer writing group life, accident and health insurance coverage in Wisconsin, including group life, accident and health insurance coverage which is individually underwritten.

(4) DEFINITIONS. (a) "Alternate test site" means a human T-lymphotropic virus type III virus antibody counseling and testing facility designated by the state epidemiologist as an alternate test site.

(b) "ELISA" means an enzyme-linked immunosorbent assay serologic test which has been licensed by the federal food and drug administration.

(c) "Health care provider" has the meaning given under s. 146.81 (1), Stats.

(d) "Informed consent for testing or disclosure" has the meaning given under s. 146.025 (1) (d), Stats.

(e) "Informed consent for testing or disclosure form" has the meaning given under s. 146.025 (1) (e), Stats.

(f) "Medical Information Bureau, Inc." means the non-profit Delaware incorporated trade association whose members are life insurance companies and which operates an information exchange on behalf of its members.

(g) "Positive ELISA test" means an ELISA test licensed by the federal food and drug administration, performed in accordance with the manufacturer's specifications and resulting in a single serum or plasma specimen which is reactive, both on an initial testing and on at least one of two additional tests of the same specimen.

(h) "Reactive" as used in par. (g) means a single serum or plasma specimen which has an absorbency that is greater than the manufacturer's recommended cut-off.

(i) "Reactive Western blot assay" means a Western blot assay performed in accordance with standard accepted procedures and resulting in a demonstration of antibody to any of the following proteins:

1. p24 and gp41 in the presence or absence of other bands.
2. p24 and p55 in the presence or absence of other bands.
3. gp41 in the presence or absence of other bands.

(j) "Western blot" means an assay which uses reagents consisting of HTLV-III antigens separated by polyacrylamide-gel electrophoresis which are then transferred to nitro-cellulose paper.

(5) HTLV-III ANTIBODY TESTING. A series of tests consisting of a positive ELISA test and a reactive Western blot assay is sufficiently reliable for use in the underwriting of individual life, accident and health insurance policies.

(6) HTLV-III ANTIBODY TEST RESULTS. (a) Except as provided in par. (b), an insurer may only disclose the results of a test for the presence of an antibody to HTLV-III to one or more of the following persons:

1. The applicant or insured who is tested.
2. The applicant's or insured's health care provider if the applicant or insured provides the insurer with informed consent for testing or disclosure to the health care provider.
3. Such other person as the applicant or insured authorizes through an informed consent for testing or disclosure.

(b) An insurer may disclose the results of a test for the presence of an antibody to HTLV-III to the Medical Information Bureau, Inc. only for a series of tests which result in a positive ELISA test and a reactive Western blot assay and only after receiving the informed consent for disclosure from the applicant or insured who undergoes the test. The informed consent for testing or disclosure form shall disclose that the test results may be sent to the Medical Information Bureau, Inc.

(c) An insurer may not use or obtain from any source including the Medical Information Bureau, Inc., the results of a test for the presence of an antibody to HTLV-III taken by any individual or information on whether a test for the presence of any antibody to HTLV-III has been obtained by any individual who is a member of a group for which the insurer is underwriting group life, accident and health insurance on an individual basis.

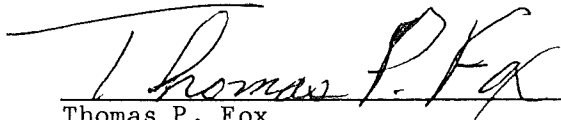
(d) An insurer may not require or request any individual to reveal whether the individual has undergone a test for the presence of an antibody to HTLV-III at an alternate test site or the results of such a test.

(e) An insurer which requires any individual to undergo a test for the presence of an antibody to HTLV-III shall provide the individual with an informed consent for testing or disclosure form prior to the time at which the individual undergoes the test. The insurer shall maintain a record of this consent.

(7) HTLV-III ANTIBODY TEST COSTS. An insurer may not require an applicant or insured to undergo a series of HTLV-III antibody tests unless the cost of such tests is borne by the insurer.

EFFECTIVE DATE. Pursuant to section 227.22 (2), Stats., this rule shall first apply on the first day of the month commencing after the date of publication.

Dated at Madison, Wisconsin, this 26th day of MARCH, 1987.


Thomas P. Fox
Commissioner of Insurance

The State of Wisconsin
Office of the Commissioner of Insurance



Thomas P. Fox
Commissioner
(608) 266-3585

RECEIVED

DATE: March 30, 1987
TO: Gary Poulson
FROM: Mary Grossman, Director
Office of Policy Analysis
SUBJECT: Ins 3.53, Clearinghouse Number 86-230

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Bureau

Enclosed are two copies of an Order of the Commissioner of Insurance creating Ins 3.53 relating to HTLV-III antibody testing.

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Enclosure
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