The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Health Regulation Committee

BILL:	CS/SB 1648
INTRODUCER:	Health Regulation Committee and Senator Saunders
SUBJECT:	HIV Testing
DATE:	April 2, 2008
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HR	**Fav/CS**
2.			HP	
3.				
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	x	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

The bill modifies three of the exceptions to the requirement that informed consent be obtained from a person before an HIV test is performed on the person. The three exceptions that are modified in the bill relate to cases in which a significant exposure to the HIV has occurred involving medical and nonmedical personnel providing treatment, assistance, or care. The bill authorizes HIV testing without consent, if consent cannot be timely obtained or if the individual who is the source of the significant exposure is incapable of providing consent. The bill requires the HIV testing to be conducted only after appropriate medical personnel under the supervision of a licensed physician documents in the medical record of the exposed personnel that a significant exposure has occurred and the testing is done in accordance with written protocols based on the Centers for Disease Control and Prevention guidelines on HIV postexposure prophylaxis and in the physician's medical judgment, the information is medically necessary to determine the course of treatment.

This bill amends section 381.004, Florida Statutes.

II. Present Situation:

HIV/AIDS

AIDS is the acronym for acquired immune deficiency syndrome. It is a fatal disease caused by a virus, a tiny organism similar to the organisms that cause colds and flu. The virus that causes AIDS is the human immunodeficiency virus, or HIV. HIV infection causes people to get AIDS by damaging their immune systems. The immune system is what defends the body against the many different organisms that can enter the body and cause sickness. Without the ability to resist disease, people with AIDS fall ill easily, get sick often, and have great difficulty recovering. People do not die from HIV infection directly. Rather, they die from the "opportunistic" infections and diseases they get because their immune system is not working properly.

There are two broad categories of HIV tests: screening tests and confirmatory tests. *Screening tests* are used for initial testing because they are easier to perform than confirmatory tests, are well suited to testing large numbers of people, and are less costly. They are highly sensitive and result in few false negatives (i.e., most infected people test positive). However, screening tests are not as specific as confirmatory tests, so in a small percentage of cases the test result will be positive even if the person is not infected. The most common screening tests are enzyme-linked immunosorbent assay (ELISA) tests. These tests measure antibodies to HIV. Different types of ELISA tests are available. Most require serum specimens, though there are urine and oral tests as well which have become available as technology evolves. A rapid HIV test is a test that usually produces results in up to 20 to 107 minutes depending on the technology used. Rapid testing technologies, under Florida law, are considered preliminary and may be released in accordance with the manufacturer's instructions as approved by the federal Food and Drug Administration.

In comparison, results from the commonly used HIV-antibody screening test, the ELISA, are not available for one to two weeks. The availability of these tests may differ from one place to another. The rapid HIV blood tests are considered to be just as accurate as the ELISA. As is true for all screening tests, a positive test result must be confirmed with an additional specific test before a diagnosis of infection can be given.

A *confirmatory test* is done when the results of a screening test are positive. The confirmatory test is expensive and labor intensive and requires subjective interpretation, but it is very specific (in other words, false-positive results are extremely rare). The Western blot test is considered by most to be the "gold standard" for confirmation of positive screening test results. This test also measures antibodies to HIV, but it is more specific than screening tests and false positives are minimal. The Western blot assay is a method in which individual proteins of an HIV-1 lysate are separated according to size by polyacrylamide gel electrophoresis. Serum is added and any existing HIV antibodies will bind to the HIV antigens. Finally, a chemical is added that changes color when it comes into contact with the protein-antibody-enzyme layers. This multi-layer process is similar to that of the ELISA test. However, the final result is a unique series of shaded bands. Positive and negative control serum specimens are run simultaneously to allow identification of viral proteins. Positive results from ELISA or rapid tests are commonly confirmed using a Western blot.

Florida law prohibits the release of positive preliminary HIV test results for the routine identification of HIV-infected individuals, or when HIV testing is incidental to the preliminary diagnosis or care of the patient.[1] Florida law requires, with few exceptions, medical consent of the test subject before HIV testing.

The United States Occupational Safety and Health Administration (OSHA) estimates that 5.6 million workers in the health care industry are at risk of occupational exposure to bloodborne pathogens.[2] Exposure that might place health care personnel at risk for HIV infection could occur through an injury by needlestick, instruments, or sharps; or contact of mucous membranes or nonintact skin such as exposed skin that is chapped, abraded, or afflicted with dermatitis with blood or body fluids. Risks vary with the type and severity of exposure. The average risk for HIV transmission after exposure to HIV-infected blood via a sharp object has been estimated to be approximately 0.3 percent and after a mucous membrane exposure, approximately 0.09 percent. Although episodes of HIV transmission after nonintact skin exposure have been documented, the average risk for transmission by this route has not been precisely quantified, but is estimated to be less than the risk for mucous membrane exposures.[3]

Post-Exposure Prophylaxis

In 2004, the federal FDA approved a rapid HIV test that provides screening results with over 99 percent accuracy in as little as 20 minutes. Once exposure to HIV is confirmed, a person may begin post-exposure prophylaxis (PEP) to preserve health and prevent the spread of disease. The PEP means taking antiretroviral medications as soon as possible after exposure to the HIV, so that the exposure will not result in HIV infection. Antiretroviral agents from five classes of drugs are currently available to treat HIV infection. The Centers for Disease Control and Prevention (CDC) recommends two or more drug PEP regimens on the basis of the level of risk for HIV transmission represented by the exposure.[4]

In September 2005, the CDC stated, "rapid HIV testing of source patients can facilitate making timely decisions regarding use of HIV PEP after occupational exposures to sources of unknown HIV status."[5] The CDC also advises that the PEP should be initiated as soon as possible, preferably within hours rather than days of exposure.[6] A person receiving the PEP should complete a full 4-week regimen, unless the source patient is later determined to be HIV-negative, in which case the PEP should be discontinued. However, as a result of the frequency, severity, and duration of side effects, many people do not complete a full 4-week course of therapy. A typical dosage for four weeks can cost $600 to $1,000 including the medicine, blood tests, and clinic visits.[7]

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[1] See s. 381.004(3)(d), F.S.
[2] U.S. Occupational Safety and Health Administration, <http://www.osha.gov/SLTC/bloodbornepathogens/recognition.html> (Last visited on March 31, 2008).
[3] Panlilio, Adelisa, "Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis," National Center for Infectious Diseases, September 30, 2005, <http://www.cdc.gov/mmwR/preview/mmwrhtml/rr5409a1.htm> (Last visited on March 31, 2008).
[4] *Id.*
[5] *Id.*
[6] *Id.*
[7] University of San Francisco AIDS Research Institute, "What is Post-Exposure Prevention?," <http://www.caps.ucsf.edu/pubs/FS/pdf/PEPFS.pdf> (Last visited on March 31, 2008).

Informed Consent

Section 381.004(3), F.S., specifies that an HIV test may not be ordered without first obtaining the informed consent of the person upon whom the test if being performed. However, s. 381.004(3)(h), F.S., outlines the exceptions to this requirement when a blood sample may be tested for HIV without the informed consent of the test subject upon whom the test is being performed.

According to s. 381.004(3)(h)10.-12., F.S., medical and nonmedical personnel exposed to HIV during the course of their employment or emergency treatment can have an individual's blood tested for HIV without consent when:

- The source *will not willingly consent or cannot be located*, but the physician determines there has been a significant exposure to HIV; or
- The source dies.

To test an individual's blood for HIV without his or her consent, the blood sample must have been previously obtained for other purposes or obtained during the medical emergency. The individual must be informed of the HIV test and offered counseling. If there is no previously obtained blood sample available and the source patient refuses to voluntarily submit to an HIV test, the medical personnel or the employer acting on behalf of the medical personnel may seek a court order directing the source of the exposure to submit to HIV testing.[8]

The term "medical personnel" includes a licensed or certified health care professional, an employee of a health care professional or health care facility, employees of a laboratory, personnel of a blood bank or plasma center, a medical student or other student who is receiving training as a health care professional at a health care facility, and a paramedic or emergency medical technician certified to perform life support procedures.[9]

The following information must be documented only in the medical personnel's file by a licensed physician when an individual's blood is tested for HIV without their consent:

- All information concerning the performance of an HIV test;
- Any HIV test results; and
- Documentation by the licensed physician that, in his or her medical judgment, the HIV test was medically necessary due to a significant exposure to HIV.

This information may only be entered into the tested individual's medical file if the person provides written consent.

Section 384.287, F.S., specifies that a law enforcement or correctional officer; support personnel employed by the Florida Department of Law Enforcement; firefighter; or ambulance driver, paramedic, or emergency medical technician who comes into contact with a person in such a way

[8] See sections 381.004(3)(h)10.f. and 381.004(3)(h)11.f., F.S.
[9] Section 381.004(3)(h)10., F.S.

that a significant exposure has occurred may request that the source person be screened for a sexually transmissible disease that can be transmitted through a significant exposure. If the source person will not voluntarily submit to screening, the employee may seek a court order directing the source person to submit to screening. The employee must also be screened for the same sexually transmissible disease.

III. Effect of Proposed Changes:

The bill amends s. 381.004, F.S., to authorizes an HIV test to be ordered on the available blood sample of a source patient, without the patient's consent, in the event of a significant exposure of medical personnel to HIV in a regular health care setting, if consent cannot be obtained from the patient within the time period necessary to perform the HIV test and begin prophylactic treatment of the exposed medical personnel. The bill authorizes the performance of an HIV test on the blood sample, without the patient's consent, if the source patient cannot be found or is incapable of providing consent. The HIV testing must be conducted only after appropriate medical personnel under the supervision of a licensed physician documents in the medical record of the medical personnel who was the subject of the significant exposure that a significant exposure has occurred and the testing is done in accordance with written protocols based on CDC's guidelines on HIV postexposure prophylaxis and in the physician's medical judgment the information is medically necessary to determine the course of treatment of the medical personnel subject to the significant exposure.

The exception to informed consent of a source patient who comes into contact with nonmedical personnel in a medical emergency in such a way that a significant exposure has occurred is modified to clarify that the provisions of s. 384.287, F.S., relating to significant exposure of certain persons to sexually transmitted diseases, do not apply. The effect is that nonmendical personnel would not have to obtain a court order to have the HIV test performed. An individual who is capable of providing consent shall be requested to consent to an HIV test prior to the testing. If consent cannot be obtained within the time necessary to perform the test and begin prophylactic treatment of the exposed medical personnel, the test may be performed. The HIV testing must be conducted only after appropriate medical personnel under the supervision of a licensed physician documents in the medical record of the medical personnel or nonmedical personnel who was the subject of the significant exposure that a significant exposure has occurred and the testing is done in accordance with written protocols based on the CDC's guidelines on HIV postexposure prophylaxis and in the physician's medical judgment the information is necessary to determine the course of treatment of the medical personnel or nonmedical personnel subject to the significant exposure.

The bill also requires HIV testing requested by a medical examiner or attending physician upon an individual who expired or could not be resuscitated while receiving emergency medical assistance or care and who was the source of a significant exposure to medical or nonmedical personnel to be conducted only after appropriate medical personnel under the supervision of a physician documents in the medical record of the medical or nonmedical personnel that a significant exposure has occurred and that the testing is in accordance with written protocols based on the CDC's guidelines on HIV postexposure prophylaxis.

The effective date of the bill is July 1, 2008.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Those medical personnel who suffer a significant exposure to HIV would potentially be able to have the source patient's blood or other specimen tested without informed consent and start HIV post-exposure prophylactic treatment earlier.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The provisions authorizing the HIV testing of persons without medical consent do not specify a timeframe for medical staff who is subject to HIV-exposure to first seek medical consent and to conduct the test and begin prophylactic treatment.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Regulation on April 1, 2008:

The committee substitute clarifies that the written protocols for HIV post-exposure prophylaxis in the bill should follow the CDC's HIV post-exposure prophylaxis guidelines. In instances where a significant exposure to HIV has occurred, an available blood specimen from the individual who is the source of a significant exposure to HIV may be tested for HIV, if the individual is incapable of providing consent to the performance of the test rather than being "unavailable."

B. Amendments:

None.