

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 Committee on Fiscal Policy

BILL: CS/CS/SB 512

INTRODUCER: Fiscal Policy Committee; Health Policy Committee; and Senators Thompson and Soto

SUBJECT: HIV Testing

DATE: April 17, 2015

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Harper</u>	<u>Stovall</u>	<u>HP</u>	Fav/CS
2.	<u>Brown</u>	<u>Pigott</u>	<u>AHS</u>	Recommend: Favorable
3.	<u>Jones</u>	<u>Hrdlicka</u>	<u>FP</u>	Fav/CS

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 512 defines “health care setting” and “nonhealth care setting” for the purposes of human immunodeficiency virus (HIV) testing, and differentiates between the notification and informed consent procedures for performing an HIV test in such settings.

Regardless of the setting, the person tested must be informed that a positive HIV test result will be reported to the county health department with sufficient information to identify him or her and of the availability and location of sites that perform anonymous testing.

The bill repeals the requirement that hospitals licensed under ch. 395, F.S., must have written informed consent for the HIV test to be able to release HIV test results contained in hospital medical records.

The bill amends the significant exposure exceptions to informed consent to repeal the consent requirements and delineate the exceptions into a medical personnel exception and a nonmedical personnel exception.

The bill updates the definition of “preliminary HIV test” to reflect current advances in HIV testing.

The bill has no fiscal impact.

II. Present Situation:

Human Immunodeficiency Virus

HIV is an immune system virus that can lead to acquired immunodeficiency syndrome, or AIDS. HIV affects specific cells of the immune system and, over time, the virus can destroy so many of these cells that the body cannot fight off infections and disease. However, with proper medical care, HIV can be controlled for most patients.¹

In the United States, HIV is spread mainly by having unprotected sex with someone who has HIV or by sharing needles, syringes, or other equipment used to prepare injection drugs with someone who has HIV.² The Centers for Disease Control and Prevention (CDC) estimates that more than 1.2 million persons 13 years of age and older in the U.S. are living with HIV, including 168,300 (14 percent) who are unaware of their infection. Approximately 50,000 people get infected with HIV each year.³

HIV in Florida

The Florida Department of Health (DOH) estimates that approximately 130,000 individuals are living with HIV in Florida.⁴ In 2013, Florida ranked first nationally in the number of new HIV infection cases diagnosed, with over 5,300 new cases. In 2014, there were more than 6,000 newly reported HIV infections in Florida.⁵

HIV Testing

The CDC supports HIV testing that occurs during an individual's routine healthcare visit.⁶ The most common types of HIV tests, test for the antibodies the human body makes against HIV. These tests are performed using blood or oral fluid and are considered "preliminary." If the result is positive, follow-up diagnostic testing is required to confirm the presence of HIV. Other HIV tests can detect both antibodies and antigen (part of the virus itself). These antibody-antigen tests can find recent HIV infection earlier than tests that detect only antibodies, but antibody-antigen combination tests are only available for testing blood, not oral fluid.⁷

¹ Centers for Disease Control and Prevention, *About HIV/AIDS*, (updated January 16, 2015), available at <http://www.cdc.gov/hiv/basics/whatishiv.html> (last visited April 9, 2015).

² Centers for Disease Control and Prevention, *HIV Transmission*, (updated January 16, 2015), available at <http://www.cdc.gov/hiv/basics/transmission.html> (last visited April 9, 2015).

³ Centers for Disease Control and Prevention, *HIV in the United States: At A Glance* (updated March 12, 2014), available at <http://www.cdc.gov/hiv/statistics/basics/ata glance.html> (last visited April 9, 2015).

⁴ Florida Health, *HIV AIDS*, available at <http://www.floridahealth.gov/diseases-and-conditions/aids/>, (last visited April 9, 2015).

⁵ Florida Health, *HIV Disease: United States vs. Florida*, available at <http://www.floridahealth.gov/diseases-and-conditions/aids/surveillance/documents/fact-sheet/2014/2014-us-vs-fl-fact-sheet.pdf> (last visited April 9, 2015).

⁶ Centers for Disease Control and Prevention, *State HIV Testing Laws: Consent and Counseling Requirements* (updated July 11, 2013), available at <http://www.cdc.gov/hiv/policies/law/states/testing.html> (last visited April 9, 2015).

⁷ Centers for Disease Control and Prevention, *Testing*, (updated March 24, 2015), available at <http://www.cdc.gov/hiv/basics/testing.html> (last visited April 9, 2015).

HIV Testing in Florida

Section 381.004, F.S., governs HIV testing in Florida and was enacted to create an environment in Florida in which people will agree to or seek HIV testing because they are sufficiently informed about HIV infection and assured about the privacy of a decision to be tested.⁸

A “HIV test” is a test ordered to determine the presence of the antibody or antigen to human immunodeficiency virus or the presence of human immunodeficiency virus infection.⁹ In Florida, county health departments (CHDs) are the primary sources for state-sponsored HIV programs. County health departments and any other person conducting a testing program for AIDS or HIV must register with the DOH and meet the necessary requirements.¹⁰

In 2013, CHD programs administered more than 428,000 HIV tests which resulted in 4,200 positive test results.¹¹

Informed Consent

Every person tested for HIV in Florida must first give his or her informed consent before a test is administered, except as specified in s. 381.004(2)(h), F.S. Informed consent for HIV testing requires:

- An explanation that the information identifying the person to be tested and the results of the test are confidential and protected against further disclosure to the extent permitted by law;
- Notice that persons who test positive will be reported to the local CHD; and
- Notice that anonymous testing is available and the locations of the anonymous sites.¹²

Informed consent must be in writing when it is:

- From the potential donor or donor’s legal representative prior to first donation of blood, blood components, organs, skin, semen, or other human tissue or body part;
- For insurance purposes; and
- For contract purposes in a health maintenance organization.¹³

Currently, test results contained in medical records of hospitals licensed under ch. 395, F.S., can be released under s. 395.3025, F.S., if the hospital has obtained written informed consent for the HIV test.

Informed consent is not required in numerous situations including when a significant exposure has occurred.¹⁴

⁸ Florida Health, *Florida’s Omnibus AIDS Act: A Brief Legal Guide for Health Care Professionals*, Jack P. Hartog, Esq., (August 2013), available at http://www.floridahealth.gov/diseases-and-conditions/aids/operations_management/documents/Omnibus-booklet-update-2013.pdf (last visited April 9, 2015).

⁹ Section 381.004(1)(a), F.S.

¹⁰ Section 381.004(1), F.S.

¹¹ *Supra* note 5.

¹² Rule 64D-2.004, F.A.C.

¹³ *Id.*

¹⁴ *See* s. 381.004(2)(h), F.S.

Significant exposure exceptions

Significant exposure is the exposure:

- To blood or body fluids through needlestick, instruments, or sharps;
- Of mucous membranes to visible blood or body fluids, to which universal precautions of the CDC apply; and
- Of skin to visible blood or body fluids, especially when the exposed skin is chapped, abraded, or afflicted with dermatitis or the contact is prolonged or involving an extensive area.¹⁵

If significant exposure occurs to **medical personnel** in the course of employment or within the scope of practice and the source of the exposure has voluntarily had blood taken for another purpose, it can be tested for HIV without informed consent from the source of the exposure.

Before the HIV test is performed:

- The source of the exposure must be requested to consent to the HIV test. If consent cannot be obtained, all information concerning the HIV test must be documented in only in the medical personnel's medical record.
- Reasonable attempts to locate the source of the exposure and to obtain consent must be made, and documented.
- It must be documented in the medical record of the medical personnel that there has been a significant exposure and that, in the physician's medical judgment, the test is medically necessary to determine the course of treatment for the medical personnel.¹⁶

If significant exposure has occurs to **medical personnel** in course of employment or within the scope of practice or to a **nonmedical personnel** while providing emergency medical assistance during a medical emergency and, consent for an HIV test must be requested. Before the HIV test is performed:

- The source of the exposure must be requested to consent to the HIV test, if capable of providing consent. If consent cannot be obtained all of the information about the performance of the test, and its results must be documented in the medical or nonmedical personnel's record.
- It must be documented in the medical record of the medical personnel or nonmedical personnel that a significant exposure has occurred and in the physician's medical judgment test is medically necessary to determine the course of treatment for the medical or nonmedical personnel.

The result of the HIV test is only entered into the source of the exposure's medical record if written consent is provided.¹⁷

In both of these exceptions, if the source of the exposure will not voluntarily submit to HIV testing, a court order may be sought directing the source of the exposure to submit to HIV testing. A sworn statement from a physician that a significant exposure has occurred and testing is medically necessary to determine the course of treatment constitutes probable cause for the

¹⁵ Section 381.004(1)(c), F.S.

¹⁶ Section 381.004(1)(h)10., F.S.

¹⁷ Section 381.004(1)(h)11., F.S.

issuance of the court order. The results of the test must be released to the source of the exposure and to the person who was exposed.¹⁸

III. Effect of Proposed Changes:

Section 1 amends s. 381.004, F.S., by adding definitions of “health care setting” and “nonhealth care setting,” differentiating between notification and informed consent requirements for the two settings, and making technical and conforming changes.

“Health care setting” is defined as a setting devoted to the diagnosis and care of persons or the provision of medical services to persons, such as:

- County health department clinics;
- Hospitals;
- Urgent care clinics;
- Substance abuse treatment clinics;
- Primary care settings;
- Community clinics;
- Blood banks;
- Mobile medical clinics; and
- Correctional health care facilities.

“Nonhealth care setting” is defined as a site that conducts HIV testing for the sole purpose of identifying HIV infection but does not provide medical treatment. A nonhealth care setting includes:

- Community-based organizations;
- Outreach settings;
- County health department HIV testing programs; and
- Mobile clinics.

The bill excludes hospitals licensed under ch. 395, F.S., from registering with the DOH as an entity that conducts HIV testing or meeting the DOH’s requirements to conduct HIV testing if the:

- Testing program is part of routine medical care; or
- Facility or person does not conspicuously advertise to significant numbers of the general public as conducting testing programs for HIV or specializing in HIV testing.

The bill updates the definition of a “preliminary HIV test” to reflect advances in HIV testing and deletes obsolete language.

Notification and Informed Consent

Before performing an HIV test in a health care setting, the person to be tested must be **notified** orally or in writing that the HIV test is planned and that he or she has the right to decline the test. If the person to be tested declines the HIV test, the decision must be documented in the person’s medical record. A person who has signed a general consent form for medical care is not required

¹⁸ Sections 381.004(1)(h)10.f. and 381.004(1)(h)11.f., F.S.

to sign or otherwise provide a separate consent form an HIV test during the period in which the general consent form is in effect.

Before performing a HIV test in a nonhealth care setting, a provider must obtain the **informed consent** of the person to be tested. Informed consent must be preceded by an explanation of the right to confidential treatment of information that identifies the subject of the test and the HIV test results, as provided by law.

The person being tested, in the health or nonhealth care setting, must also be informed that:

- Persons who test positive will be reported to the local CHD with sufficient information to identify him or her; and
- Anonymous testing is available and the locations of the anonymous sites.¹⁹

The bill repeals the requirement that hospitals licensed under ch. 395, F.S., must have written informed consent for the HIV test to be able to release HIV test results contained in hospital medical records. Hospitals can now release HIV test results in accordance with standard patient record provisions.

The bill makes conforming changes to the situations when informed consent, now notification or informed consent, does not apply.

Significant exposure exceptions

The bill amends the exceptions related to personnel acting in the course of employment and in emergency medical situations, to instead provide for exceptions related to medical personnel and nonmedical personnel.

An individual can be tested if he or she significantly exposes medical personnel acting within the course of employment and in emergency medical situations. The bill repeals the requirement that a blood sample be available for testing that was voluntarily taken for another purpose from the source of the exposure. The occurrence of the exposure must be recorded only in the personal record of the medical personnel. The bill repeals the related consent requirements and requirements related to recording information related to the performance and results of the test in the medical personnel's record and in the individual's record upon consent and to requiring a physician to first document the need for the test. The bill also repeals requirements to provide the source of the exposure with counseling if the test is performed without consent. To obtain a court order for testing, the individual must not be available and not voluntarily come to a health facility for testing; under current law, the court order may be obtained if the source of the exposure will not voluntarily submit to testing.

An individual can be tested if he or she significantly exposes nonmedical personnel acting in emergency medical situations. The bill makes similar changes to this exception as described above, and repeals all references to medical personnel in this section.

Section 2 amends s. 456.032(2), F.S., to conform a cross-reference.

¹⁹ Rule 64D-2.004, F.A.C.

Section 3 provides an effective date of July 1, 2015.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

Section 1 of the bill contains a stand-alone flush-left paragraph that contains language inconsistent with the preceding paragraph. The bill amends s. 381.004(2)(a), F.S., to provide the condition of “*Before* performing an HIV test” (emphasis added); however, the stand-alone paragraph after s. 381.004(2)(a)2, F.S., refers to “the test subject.” Test subject, as currently defined in s. 381.004(e), F.S., means the person upon whom an HIV test is performed. Technically, a person would not be considered a test subject until during or *after* the HIV test is performed. Therefore, the proposed bill language under this section is inconsistent as to when and to whom information should be given regarding reporting a positive HIV test result to a county health department. The bill language in the stand-alone paragraph may be revised to refer to “the person to be tested” instead of “test subject,” or the phrase “After performing an HIV test” may be substituted for “Before performing an HIV test” if the condition continues to apply to a test subject.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 381.004 and 456.032.

IX. Additional Information:**A. Committee Substitute – Statement of Substantial Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS/CS by Fiscal Policy on April 15, 2015:

The CS excludes hospitals licensed under ch. 395, F.S., from registering with the DOH as an entity that conducts HIV testing or meeting the DOH's requirements to conduct HIV testing if the:

- Testing program is part of routine medical care; or
- Facility or person does not conspicuously advertise to significant numbers of the general public as conducting testing programs for HIV or specializing in HIV testing.

The CS requires *all programs* to meet the informed consent provisions.

CS by Health Policy on March 17, 2015:

The CS revises the definitions of “health care setting” and “nonhealth care setting” for the purposes of HIV testing, and further clarifies the notification and informed consent procedures for performing an HIV test in such settings. The CS revises and clarifies provisions to address the occurrence of a significant exposure to medical personnel and nonmedical personnel. The CS provides that a county health department and any other person in Florida offering HIV tests in a nonhealth care setting may not conduct testing without first registering with the DOH.

B. Amendments:

None.