

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 Health Policy

BILL: CS/SB 512

INTRODUCER: Health Policy Committee and Senators Thompson and Soto

SUBJECT: HIV Testing

DATE: March 17, 2015

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Harper	Stovall	HP	Fav/CS
2.			AHS	
3.			FP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

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. In a health care setting, the person to be tested must be notified of the planned HIV test and of the right to decline the test. In a nonhealth care setting, a provider must obtain the patient’s informed consent to perform the HIV test after an explanation of the confidentiality protections of the test results.

Regardless of the setting, the test subject must be informed that a positive HIV test result will be reported to the county health department with sufficient information to identify the test subject. The test subject shall also be informed of the availability and location of sites that perform anonymous testing.

The bill authorizes hospitals to release HIV test results contained in hospital medical records, in accordance with standard patient record protections. The bill removes the need for hospitals to obtain informed consent before releasing these records.

The bill revises and clarifies provisions to address the occurrence of a significant exposure to medical personnel and nonmedical personnel.

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

II. Present Situation:

Human Immunodeficiency Virus

Human immunodeficiency virus (HIV) is an immune system virus that can lead to the fatal acquired immunodeficiency syndrome (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 U.S. Centers for Disease Control and Prevention (CDC) estimates that more than 1.2 million persons 13 years of age and older in the United States were living with HIV infection, including 168,300 (14 percent) who are unaware of their infection.³ Approximately 50,000 people get infected with HIV each year.⁴

HIV in Florida

The Florida Department of Health (DOH) estimates that approximately 130,000 individuals are living with HIV in Florida.⁵ In 2013, Florida ranked first nationally in the number of new HIV infection cases diagnosed, with over 5,300 new cases.⁶ Additionally, in 2013 all six of Florida's large metropolitan statistical areas reported more cases individually than many states as a whole.⁷ In 2014, there were more than 6,000 people newly reported with HIV infections in Florida.⁸

HIV Testing

In 2006, the CDC revised its recommendations for HIV testing after a comprehensive review of literature, a consensus of medical opinions, input of community organizations, and the opinion of persons living with HIV.⁹ The CDC's updated recommendations include the following:¹⁰

¹ U.S. Centers for Disease Control and Prevention, *About HIV/AIDS* (updated January 16, 2015), available at <http://www.cdc.gov/hiv/basics/whatishiv.html#panel0>, (last visited Mar. 11, 2015).

² U.S. Centers for Disease Control and Prevention, *HIV Transmission* (updated January 16, 2015), available at <http://www.cdc.gov/hiv/basics/transmission.html>, (last visited Mar. 11, 2015).

³ U.S. Centers for Disease Control and Prevention, *HIV in the United States: At a Glance* (updated November 25, 2014), available at <http://www.cdc.gov/hiv/statistics/basics/ataglance.html>, (last visited Mar. 11, 2015).

⁴ *Id.*

⁵ Florida Department of Health, *HIV AIDS*, available at <http://www.floridahealth.gov/diseases-and-conditions/aids/>, (last visited Mar. 11, 2015).

⁶ Florida Department of 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 Mar. 11, 2015).

⁷ *Id.* For example, Miami reported more cases than all but four other states in the U.S. Miami-Ft. Lauderdale-West Palm Beach, Tampa-St. Petersburg-Clearwater, Orlando-Kissimmee-Sanford, and Jacksonville ranked among the top 30 states for new HIV cases in 2013.

⁸ *Id.*

⁹ See *Revised CDC Recommendations: HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings* (September 12, 2006), accessible at: U.S. Centers for Disease Control and Prevention, *HIV Screening & Testing* (updated December 16, 2014), <http://www.cdc.gov/hiv/guidelines/testing.html> (last visited Mar. 11, 2015).

¹⁰ U.S. Centers for Disease Control and Prevention, *Revised CDC Recommendations: HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings, Annotated Guide* (September 2006), available at

- Opt-out HIV screening¹¹ in all health-care settings;¹²
- Tests for all high risk patients at least annually;
- No requirement for separate written consent for testing;
- No prevention counseling required in conjunction with HIV screening; and
- Inclusion in all routine prenatal screening, with repeat screening in the third trimester for high risk women.

The most common type of HIV test is the antibody screening test (immunoassay), which tests for the antibodies the human body makes against HIV. A “rapid test” is an immunoassay used for screening that produces quick results (in 30 minutes or less). Rapid tests use blood or oral fluid to look for antibodies to HIV. Antibody tests are considered “preliminary”; if the result is positive, follow-up diagnostic testing is required to confirm the presence of HIV. Other HIV tests being used 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.¹³

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 out HIV testing because they are sufficiently informed about HIV infection and assured about the privacy of a decision to be tested.¹⁴ Under s. 381.004, F.S., “HIV test” means a test ordered after July 6, 1988, to determine the presence of the antibody or antigen to human immunodeficiency virus or the presence of human immunodeficiency virus infection.¹⁵ “Test subject” means the person upon whom an HIV test is performed, or the person who has legal authority to make health care decisions for the test subject.¹⁶

In Florida, county health departments (CHDs) are the primary sources for state-sponsored HIV programs. In 2013, CHD programs administered more than 428,000 HIV tests which resulted in 4,200 positive test results.¹⁷ No other person in Florida shall conduct HIV testing services without first registering with the DOH and complying with the statutory requirements listed in s. 381.004(4), F.S., such as providing opportunities for pre-test and post-test counseling by

http://www.cdc.gov/hiv/testing/HIVStandardCare/resources/brochures/MMWR-Annotated%20508C_Full.pdf (last visited Mar. 11, 2015).

¹¹ Opt-out screening means the patient must be notified that the screening will be done; the patient may decline the test.

¹² U.S. Centers for Disease Control and Prevention, *Assessment of 2010 CDC-funded Health Department HIV Testing Spending and Outcomes* (February 2013), available at

http://www.cdc.gov/hiv/pdf/evaluation_HIVTesting_BudgetAllocation.pdf (last visited Mar. 11, 2015). The CDC refers to “health care settings” as a place where both medical diagnostic and treatment services are provided. A nonhealth care setting does not provide these services. Examples of nonhealth care settings include community-based organization and outreach venues.

¹³ U.S. Center for Disease Control and Prevention, *Testing*, available at <http://www.cdc.gov/hiv/basics/testing.html> (last visited Mar. 12, 2015).

¹⁴ Jack P. Hartog, Esq., *Florida’s Omnibus AIDS Act: A Brief Legal Guide for Health Care Professionals* (August 2013), Florida Department of Health, available at http://www.floridahealth.gov/diseases-and-conditions/aids/operations_management/documents/Omnibus-booklet-update-2013.pdf (last visited Mar. 12, 2015).

¹⁵ Section 381.004(1)(a), F.S.

¹⁶ Section 381.004(1)(e), F.S.

¹⁷ *Supra* note 6.

counselors specifically trained to address the needs of persons who may receive positive test results.

Informed Consent

Currently, in Florida, every person who is tested for HIV 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 is defined under department rule and requires:¹⁸

- An explanation that the information identifying the test subject 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;
- Notice that anonymous testing is available and the locations of the anonymous sites;
- Written informed consent only for the following:
 - 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 contracts purposes in a health maintenance organization, pursuant to s. 641.3007, F.S.

Exceptions to informed consent include:¹⁹

- When testing for sexually transmitted diseases is required by state or federal law or rule;
- Transfer of human tissue pursuant to s. 381.0041, F.S.;
- Performance of an HIV-related test by licensed medical personnel in bona fide medical emergencies if the patient is unable to consent or for the medical diagnosis of acute illness if the attending physician believes obtaining informed consent would be detrimental to the patient;
- When the HIV testing is performed as part of an autopsy for which consent was obtained;
- The testing of a defendant for any type of sexual battery crime, pursuant to the victim's request, if the blood sample is taken from the defendant voluntarily;
- When mandated by court order;
- For research purposes, if the identity of the test subject is not known and may not be retrieved by the researcher;
- When human tissue is collected lawfully without consent of the donor for corneal removal or enucleation of the eyes;
- Performance of an HIV test upon an individual who comes into contact with medical personnel in such a way that a significant exposure has occurred to the medical personnel during the course of employment or within the scope of practice and where a blood sample is available that was taken from the individual voluntarily by medical personnel for other purposes;
- Performance of an HIV test upon an individual who comes into contact with medical personnel or nonmedical personnel in such a way that a significant exposure has occurred to the individual during emergency medical treatment or assistance during a medical emergency;

¹⁸ Rule 64D-2.004, F.A.C.

¹⁹ Section 381.004(2)(h), F.S.

- Performance of an HIV test by a medical examiner or attending physician upon an individual who died while receiving emergency medical assistance or care and who was the source of significant exposure to medical or nonmedical personnel providing assistance or care;
- Performance of an HIV-related test medically indicated by licensed medical personnel for medical diagnosis of a hospitalized infant when, after a reasonable attempt, a parent cannot be contacted to provide consent;
- Testing conducted to monitor the clinical progress of a patient previously diagnosed to be HIV positive; and
- Performance of repeated HIV testing conducted to monitor possible conversion from a significant exposure.

Another exception to informed consent for HIV testing in Florida relates to pregnancy. Prior to testing, a health care practitioner must inform a pregnant woman that the HIV test will be conducted and of her right to refuse the test. If declined, the refusal will be noted in the medical record.²⁰

Minors meeting certain requirements, such as being married, pregnant, or able to demonstrate maturity to make an informed judgment, can be tested for HIV without parental consent if the minor provides informed consent.²¹

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 by the bill to mean, for the purposes of HIV testing, 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 by the bill to mean, for the purposes of HIV testing, a site that conducts HIV testing for the sole purpose of identifying HIV infection. A nonhealth care setting does not provide medical treatment. A nonhealth care setting may include:

- Community-based organizations;
- Outreach settings;

²⁰ Sections 381.004(2)(h) and 384.31, F.S.

²¹ Section 384.30, F.S. and Rule 64D-2.004(4), F.A.C.

- County health department HIV testing programs; and
- Mobile vans.

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

The bill specifies that 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 HIV test. If the person to be tested declines the HIV test in a health care setting, the decision will be documented in the person’s medical record. A person who has signed a general consent form for medical care is not required to sign or otherwise provide a separate consent for an HIV test during the period in which the general consent form is in effect.

The bill specifies that before performing an HIV test in a nonhealth care setting, a provider shall obtain the informed consent of the person upon whom the test is being performed. Informed consent shall be preceded by an explanation of the right to confidential treatment of information that identifies the test subject and the test result as provided by law.

The bill provides that, regardless of setting, the test subject of an HIV test must also be informed that a positive HIV test result will be reported to the county health department with sufficient information to identify the test subject. The test subject must also be provided with the availability and location of sites that perform anonymous testing.

The bill authorizes hospitals licensed under ch. 395, F.S., to release HIV test results contained in hospital medical records in accordance with standard patient record provisions. The bill removes the requirement that a hospital obtain written informed consent for the HIV test before releasing these records.

The bill provides that notification in a health care setting or informed consent in a nonhealth care setting is not required before performing an HIV test for the following reasons:

- When testing for sexually transmitted diseases is required by state or federal law or by rule, including HIV testing of inmates before their release from prison;
- Transfer of human tissue pursuant to s. 381.0041, F.S.;
- Performance of an HIV-related test by licensed medical personnel in bona fide medical emergencies if the patient is unable to consent or for the medical diagnosis of acute illness if the attending physician believes obtaining notification would be detrimental to the patient;
- If HIV testing is performed as part of an autopsy for which consent was obtained;
- The testing of a defendant for any type of sexual battery crime, pursuant to the victim’s request, if the blood sample is taken from the defendant voluntarily;
- If an HIV test is mandated by court order;
- For research purposes, if the identity of the test subject is not known and may not be retrieved by the researcher;
- If human tissue is collected lawfully without consent of the donor for corneal removal or enucleation of the eyes;
- Performance of an HIV test upon an individual who comes into contact with medical personnel in such a way that a significant exposure has occurred to the medical personnel

during the course of employment, within the scope of practice, or during the course of providing emergency medical assistance to the individual;

- Performance of an HIV test upon an individual who comes into contact with nonmedical personnel in such a way that a significant exposure has occurred to the nonmedical personnel while the nonmedical personnel provides emergency medical assistance during a medical emergency;
- Performance of an HIV test by a medical examiner or attending physician upon an individual who died while receiving emergency medical assistance or care and who was the source of significant exposure to medical or nonmedical personnel providing assistance or care;
- Performance an HIV-related test medically indicated by licensed medical personnel for medical diagnosis of a hospitalized infant when, after a reasonable attempt, a parent cannot be contacted to provide consent;
- Testing conducted to monitor the clinical progress of a patient previously diagnosed to be HIV positive; and
- Performance of repeated HIV testing conducted to monitor possible conversion from a significant exposure.

The bill clarifies procedures for testing when a significant exposure to medical personnel occurs. Specifically, the bill requires that the occurrence of a significant exposure to medical personnel must be documented by medical personnel under the supervision of a licensed physician and recorded only in the personal record of the medical personnel. Costs of an HIV test shall be covered by the medical personnel or the employer of the medical personnel. To fall under this provision of the bill, the medical personnel must be tested for HIV or provide the results of an HIV test taken within 6 months before the significant exposure if such test results are negative. The results of the HIV test shall be released to the source of the exposure and to the person who experienced the exposure.

The bill directs that, if the source of the exposure is not available and will not voluntarily present to a health facility for testing, the medical personnel or the employer of the medical personnel may seek a court order directing the source of the exposure to submit to HIV testing. The bill provides that a sworn statement by a physician licensed under chs. 458 or 459, F.S., that a significant exposure has occurred and that testing is medically necessary constitutes probable cause for the issuance of an order by the court.

The bill provides substantially similar procedures for nonmedical personnel when a significant exposure has occurred while the nonmedical personnel provides emergency medical assistance during a medical emergency.

The bill provides that a county health department and any other person in Florida offering HIV tests in a nonhealth care setting may not conduct or hold themselves out to the public as conducting a testing program for HIV or AIDS without first registering with the DOH. The bill provides that a program in a nonhealth care setting shall meet the informed consent criteria as contained in the bill.

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

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 proposed paragraph of s. 381.004(2)(a), F.S., states “*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*, or *after performing an HIV test* may need to be added if referring to the test subject.

VII. Related Issues:

The proposed stand-alone paragraph in section 1 of the bill makes vague reference to “the county health department.” The bill does not provide specificity as to which county health department a positive HIV test result will be reported. For example, the language used in Florida Administrative Code Rule 64D-2.004, more specifically refers to the “local county health department.” A revision may be needed for this bill to further clarify that a positive HIV test

result will be reported to the *local* county health department or to the county health department *in the county in which the HIV test was performed*.

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 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 DOH.

- B. **Amendments:**

None.