

**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.)

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Prepared By: The Professional Staff of the Committee on Health Policy

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BILL: CS/SB 1470

INTRODUCER: Health Policy Committee and Senator Thompson

SUBJECT: HIV Testing

DATE: April 1, 2014

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	Fav/CS
2.			JU	
3.			CA	

**Please see Section IX. for Additional Information:**

COMMITTEE SUBSTITUTE - Technical Changes

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**I. Summary:**

CS/SB 1470 defines “health care setting” and “nonhealth care setting” and distinguishes the two locations for the purposes of Human Immunodeficiency Virus (HIV) testing. In a health care setting, the patient will be notified of the planned test and be offered the opportunity to refuse the test, or opt out, instead of affirmatively providing informed consent. The health care provider must explain the confidentiality protections of the patient’s test results. In a nonhealth care setting, the bill requires the provider to obtain the patient’s informed consent after an explanation of the confidentiality protections of the test results.

In either setting, the bill requires the patient to be informed that positive HIV test results will be reported to the county health department (CHD) with sufficient information to identify the patient.

The bill requires all HIV testing programs in a health care setting to meet the notification criteria. All nonhealth care setting HIV testing programs must meet the informed consent criteria.

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

## II. Present Situation:

### Human Immunodeficiency Virus

Human immunodeficiency virus 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. There is no cure for HIV, yet with proper medical care, HIV can be controlled.<sup>1</sup>

Human immunodeficiency virus is typically spread by having unprotected sex with someone who has HIV, sharing needles, syringes, or other equipment used to prepare injection drugs with someone who has HIV. As of 2010, about 1.1 million people in the United States were living with HIV and approximately 50,000 people get infected with HIV each year.<sup>2</sup> In Florida, the estimated number of adults and children with an AIDS diagnosis was 117,612 through December 2008, making Florida the third highest state in cumulative reported AIDS cases.<sup>3</sup>

### HIV Testing

Of the 1.1 million Americans living with AIDS, it is also estimated that one fifth of those are unaware of their infection.<sup>4</sup> The Centers for Disease Control and Prevention (CDC) in 2006, 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.<sup>5</sup> The revised guidelines seek to achieve four objectives:<sup>6</sup>

- Increase HIV screening of patients;
- Foster earlier HIV detection;
- Link infected persons to counseling and treatment; and,
- Further reduce perinatal HIV transmission.

In 2006, the CDC's revised guidelines included additional recommendations to achieve these objectives. The updated recommendations include the following:<sup>7</sup>

- Opt-out HIV screening<sup>8</sup> in all health-care settings;<sup>9</sup>

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<sup>1</sup> Centers for Disease Control and Prevention, *About HIV/AIDS*, <http://www.cdc.gov/hiv/basics/whatishiv.html> (last visited Mar. 26, 2014).

<sup>2</sup> Centers for Disease Control and Prevention, *Basic Statistics*, <http://www.cdc.gov/hiv/basics/statistics.html> (last visited Mar. 26, 2014).

<sup>3</sup> Centers for Disease Control and Prevention, *Florida 2010 Profile*, [http://www.cdc.gov/nchhstp/stateprofiles/pdf/Florida\\_profile.pdf](http://www.cdc.gov/nchhstp/stateprofiles/pdf/Florida_profile.pdf) (last visited Mar. 26, 2014).

<sup>4</sup> *Id.*

<sup>5</sup> 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), [http://www.cdc.gov/hiv/testing/HIVStandardCare/resources/brochures/MMWR-Annotated%20508C\\_Full.pdf](http://www.cdc.gov/hiv/testing/HIVStandardCare/resources/brochures/MMWR-Annotated%20508C_Full.pdf) (last visited Mar. 26, 2014).

<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

<sup>8</sup> Opt-out screening means the patient must be notified that the screening will be done; the patient may decline the test.

<sup>9</sup> Centers for Disease Control and Prevention, *Assessment of 2010 CDC-funded Health Department HIV Testing Spending and Outcomes (February 2013)* [http://www.cdc.gov/hiv/pdf/evaluation\\_HIVTesting\\_BudgetAllocation.pdf](http://www.cdc.gov/hiv/pdf/evaluation_HIVTesting_BudgetAllocation.pdf) (last visited Mar. 28, 2014). The CDC refers to health care settings as a place where both medical diagnostic and treatment services are

- 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 checks for HIV antibodies in the body. Blood or oral fluid can be used to obtain results. Follow up diagnostic testing is performed if the first test is positive to confirm the result. An RNA test can detect the virus directly and identifies HIV at about 10 days after infection, before antibodies develop.<sup>10</sup>

### **Florida HIV Testing**

Currently, in Florida, every person who is tested for HIV must first give their informed consent before a test is administered, except as specified in s. 381.004(2)(h), F.S. Exceptions to informed consent include the testing of inmates from the state prison system prior to release, testing defendants in sexual battery crimes at the request of the victims; and when mandated by court order.

Informed consent for HIV testing is defined under the Florida Administrative Code and requires:<sup>11</sup>

- 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.

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.<sup>12</sup>

The other 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.<sup>13</sup>

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provided. A nonhealth care setting does not provide these services. Examples of nonhealth care settings include community-based organization and outreach venues.

<sup>10</sup> Center for Disease Control and Prevention, *Testing*, <http://www.cdc.gov/hiv/basics/testing.html> (last visited Mar. 26, 2014).

<sup>11</sup> Rule 64D-2.004, F.A.C.

<sup>12</sup> Section 384.30, F.S. and Rule 64D-2.004(4), F.A.C.

<sup>13</sup> Sections 381.004(2)(h)(2) and 384.31, F.S.

The Department of Health (DOH) has developed a comprehensive program for preventing the spread of HIV/AIDS with many testing options available throughout the state in a variety of settings. Over 30,000 people receive AIDS treatment and prevention services from the DOH through the CHD and different programs of the DOH.<sup>14</sup>

A nonhealth care setting that offers HIV testing services must first register with the DOH and comply with other statutory requirements listed in s. 381.004(4), F.S., such as providing opportunities for pre-test and post-test counseling by counselors specifically trained to address the needs of persons who may receive positive test results.

### III. Effect of Proposed Changes:

**Section 1** amends s. 381.004, F.S., and adds definitions for “health care setting” and “nonhealth care setting.”

A health care setting is defined as a setting devoted to both the diagnosis and care of persons, such as:

- County health department clinics;
- Hospital emergency departments;
- Urgent care clinics;
- Substance abuse treatment clinics;
- Primary care settings;
- Community clinics;
- Mobile medical clinics; and
- Correctional health care facilities.

CS/SB 1470 modifies the consent requirements for HIV tests specifically conducted in a health care setting to require the health provider to notify the patient the test is planned and advise the patient of his or her option to decline the planned test. This is changed from requiring informed consent and more closely implements the CDC guidelines for HIV testing. The provider must also inform the patient of his or her right to confidential treatment of identifying information under the law. If the patient opts out of the test, the provider must note the denial in the patient’s record.

A nonhealth care setting is defined as a site that conducts HIV testing for the sole purpose of identifying HIV infection. These locations do not provide medical treatment but may include sites such as:

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

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<sup>14</sup> Department of Health, *County Health Departments*, <http://www.floridahealth.gov/public-health-in-your-life/county-health-departments/index.html> (last visited: Mar. 26, 2014).

In a nonhealth care setting, the bill requires the provider to obtain the patient's informed consent for the HIV test after an explanation of the patient's right to confidential treatment of identifying information as provided under law, including test results.

In either setting, the patient must be informed that a positive HIV test will be reported to the local CHD with sufficient information to identify the patient. The patient must also be provided information about the availability of anonymous testing sites. Each CHD will be responsible for maintaining a list of available sites with locations, telephone numbers, and hours of operation.

The bill updates the definition for "preliminary HIV test" with current terminology and testing options.

The bill authorizes hospitals licensed under ch. 395, F.S., to release HIV test results, as is currently permitted, if the hospital notifies the patient of the confidentiality protections included in medical records. The bill conforms this requirement to the notification requirements in the bill related to HIV testing in a health care setting.

The bill makes conforming changes and corrects cross-references.

**Section 2** amends s. 456.032, F.S., to correct a cross-reference relating to hepatitis B or HIV carriers.

**Section 3** provides an effective date of July 1, 2014.

#### **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:

Private entities that provide HIV testing may need to modify their policies and procedures to meet any revised requirements for informed consent or notification, depending on their status as a health care setting or nonhealth care setting.

C. Government Sector Impact:

The DOH will need to revise Rule 64D-2.004, F.A.C., to conform to the changes in this bill.

VI. Technical Deficiencies:

None.

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 Changes:

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

**CS by Health Policy on April 1, 2014:.**

The CS re-inserts deleted language. The provision adds pregnant women to a list of populations for whom informed consent is not required for HIV testing.

B. Amendments:

None.