

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 321 HIV Testing
SPONSOR(S): Health Quality Subcommittee; Avila
TIED BILLS: **IDEN./SIM. BILLS:** SB 512

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	13 Y, 0 N, As CS	Castagna	O'Callaghan
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The bill relates to testing for Human Immunodeficiency Virus (HIV). HIV is an immune system debilitating virus that can lead to fatal acquired immunodeficiency syndrome (AIDS). Widespread testing prevents new HIV infections through awareness, and allows infected individuals to receive early treatment, which improves the lives of those living with HIV.

The bill defines a “health care setting” and a “nonhealth care setting” for the purpose of differentiating HIV testing requirements. The bill updates the definition of “preliminary HIV test” to reflect advances in HIV testing.

The bill revises the HIV testing requirement for health care settings to no longer require informed consent from the HIV test subject and establishes new notification requirements. The bill retains the requirement to obtain informed consent from a test subject when HIV testing is performed in nonhealth care settings.

The bill applies the same notification requirements for HIV testing in a health care setting to an HIV testing program in such setting. For an HIV testing program in a nonhealth care setting, the informed consent requirements apply.

The bill makes technical changes throughout s. 384.004, F.S., to clarify existing language and makes many conforming changes.

The bill appears to have no fiscal impact on state or local governments.

The bill provides an effective date of July 1, 2015.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Human Immunodeficiency Virus

Human Immunodeficiency Virus (HIV) is an immune system debilitating virus that can lead to 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. Untreated, HIV is almost always fatal.¹

HIV is typically spread by having unprotected sex with someone who has HIV or sharing needles, syringes, or other equipment used to prepare injection drugs with someone who has HIV.²

HIV Testing

In the United States, approximately 1.2 million people are living with HIV and 14 percent are unaware of their infection.³ HIV testing is essential for improving the health of people living with HIV and reducing new HIV infections. The Centers for Disease Control and Prevention recommend that testing occur as part of a routine healthcare visit.⁴ This is especially important for people who may not consider themselves at risk for HIV.⁵ HIV testing is recommended for people ages 15 to 65 and pregnant women, including those in labor who have not been tested and whose HIV status is unknown.⁶

The most common types of HIV tests check for HIV antibodies in the body. In these tests, blood, oral fluid, or urine can be used to obtain results. Antibody tests are considered preliminary; if the result is positive, follow-up diagnostic testing is required to confirm the presence of the virus. Antigen tests are another, less common, form of testing. Antigen tests can diagnose an HIV infection 1 to 3 weeks after a person is first infected with HIV and require a blood sample to obtain results.⁷

Over the past several decades there have been many advances in medical technology to increase access and utilization of HIV testing. Legal and programmatic advances have streamlined testing services to provide confidentiality, and, in some cases, anonymity to test subjects, to encourage widespread testing.

Most states require informed consent to test for HIV.⁸ Informed consent is a process of communication between a patient and a provider through which an informed patient can choose whether to undergo

¹ Centers for Disease Control and Prevention, *About HIV/AIDS*, accessible at: <http://www.cdc.gov/hiv/basics/whatishiv.html#panel0> (last accessed February 1, 2015).

² There are several less common ways HIV can be spread including: being born to an infected mother; being stuck with an HIV contaminated needle (which is a risk mainly for health care workers); and receiving blood transfusions, blood products, or organ/tissue transplants that are contaminated with HIV. Centers for Disease Control and Prevention, *HIV Transmission*, accessible at: <http://www.cdc.gov/hiv/basics/transmission.html> (last accessed February 1, 2015).

³ Centers for Disease Control and Prevention, *HIV in the United States: At a Glance*, accessible at: <http://www.cdc.gov/hiv/statistics/basics/ata glance.html#ref1> (last accessed February 1, 2015).

⁴ Centers for Disease Control and Prevention, *State HIV Testing Laws: Consent and Counseling Requirements*, July 11, 2013, accessible at <http://www.cdc.gov/hiv/policies/law/states/testing.html> (last accessed February 2, 2015).

⁵ In Florida, only 48.4% of adults under 65 reported having ever been tested for HIV. Florida Dep't of Health, Florida Charts, accessible at: <http://www.floridacharts.com/charts/Brfss/DataViewer.aspx?bid=29> (last accessed February 1, 2015).

⁶ U.S. Preventive Services Task Force, *Human Immunodeficiency Virus (HIV) Infection: Screening*, April 2013, accessible at: <http://www.uspreventiveservicestaskforce.org/uspstf/uspshivi.htm> (last accessed February 1, 2015).

⁷ U.S. Department of Health and Human Services, *Types of HIV Tests*, accessible at: <http://aids.gov/hiv-aids-basics/prevention/hiv-testing/hiv-test-types/index.html> (last accessed February 1, 2015).

⁸ Centers for Disease Control and Prevention, *State HIV Laws*, accessible at: <http://www.cdc.gov/hiv/policies/law/states/> (last accessed February 2, 2015).

HIV testing or decline to do so. During informed consent a patient is typically provided written or oral information on:

- The risks and benefits of testing;
- The implications of HIV test results; and
- How test results will be communicated.⁹

Florida HIV Testing

The Department of Health (Department) 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. The Department's county health departments (CHDs)¹⁰ are the primary sources for state-sponsored HIV programs and, in addition to testing services, CHDs provide prevention outreach and education free to the public. In 2013, CHD programs administered 428,002 HIV tests which resulted in 4,197 positive test results.¹¹

Section 381.004, F.S., which governs HIV testing in Florida and requires certain procedures to be followed when tests are given, 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.¹² To promote informed patient decision-making, s. 381.004, F.S., prohibits HIV testing without a person's knowledge and informed consent, except under certain defined circumstances,¹³ and gives the patient special rights to control who learns of the HIV test results.¹⁴ Informed consent for HIV testing is defined under the Florida Administrative Code and requires:¹⁵

- 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.¹⁶

⁹ Centers for Disease Control and Prevention, *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*, September 22, 2006, accessible at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm> (last accessed February 1, 2015).

¹⁰ County health departments are the local sector of the Florida Dep't of Health, providing public health services in all 67 Florida counties. Their core functions are infectious disease prevention and control, basic family health services, and environmental health services. Florida Dep't of Health, *County Health Departments*, accessible at: <http://www.floridahealth.gov/public-health-in-your-life/county-health-departments/index.html> (last accessed February 1, 2015).

¹¹ Florida Dep't of Health, *2013 Counseling and Testing Database*, Counseling and Testing Data Summary Report By Selected Variables, accessible at: <http://www.floridahealth.gov/diseases-and-conditions/aids/prevention/2013-testing-data.html> (last accessed February 2, 2015).

¹² "Florida's Omnibus AIDS Act," Jack P Hartog, Florida Dep't of Health, accessible at: www.floridahealth.gov/diseases.../Omnibus-booklet-update-2013.pdf (last accessed February 1, 2015).

¹³ Section 381.004(2)(h), F.S., lists the exceptions to the requirement to obtain informed consent, including: when a person is tested for sexually transmitted diseases; when blood, plasma, or other human fluids or tissues are donated; when a determination for appropriate emergency medical care or treatment is required; during an autopsy; when testing pregnant women; when a defendant is charged with sexual battery and is consented to by the defendant, pursuant to court order; or for certain research purposes.

¹⁴ *Supra* fn. 11.

¹⁵ Rule 64D-2.004, F.A.C.

¹⁶ Section 384.30, F.S. and Rule 64D-2.004(4), F.A.C.

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.¹⁷

Effect of Proposed Changes

The bill provides a definition for health care setting and nonhealth care setting to differentiate between the two for the purpose of HIV testing.

Health Care Setting

"Health care setting" is defined in the bill 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.

The bill changes the current requirement for informed consent for HIV testing performed in a health care setting by requiring a test subject to be notified that the test is planned and receive information on the HIV test. The test subject must also be informed that they have the right to decline the test. The bill retains the requirements in current law to explain the right to confidential treatment of information identifying the test subject and the results of the test.¹⁸ If a test is declined, it must be documented in the test subject's medical record.

Nonhealth Care Setting

"Nonhealth care setting" is defined in the bill as a site that conducts HIV testing solely for diagnosis purposes, not treatment. Such settings do not provide medical treatment but may include:

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

The bill clarifies that informed consent remains a requirement for testing performed in nonhealth care settings.

Programs in Health Care and Nonhealth Care Settings

Sometimes, an organization that offers HIV testing operates as both a health care and a nonhealth care setting. The bill requires that the same notification requirements for HIV testing in a health care setting be applied in a program in such setting. Informed consent requirements are applied to HIV testing programs in nonhealth care settings. For example, if a person is being seen at a CHD clinic, such as a family planning clinic, the provider must meet health care setting notification requirements. If a person is to be tested at a CHD with an HIV testing program, or a CHD sponsored outreach event, informed consent must be obtained.

¹⁷ Sections 381.004(2)(h)(2) and 384.31, F.S.

¹⁸ Section 381.004(2)(e), F.S.

Confidentiality

For both health care and nonhealth care settings, the test subject must be informed that a positive HIV test result will be reported to the local CHD with sufficient information to identify the test subject. The subject must also be informed of the availability of sites at which anonymous testing is performed and requires CHDs to maintain a list of those sites. The sites' locations, telephone numbers, and hours of operation must be kept on file with the CHD. All of these requirements exist in current law, but the bill ensures these requirements apply to both health care and nonhealth care settings.

Currently, a hospital licensed under ch. 395, F.S., may release HIV test results, but only if it has obtained written informed consent. The bill replaces the written informed consent requirement with the notification requirements related to health care setting HIV testing.

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

The bill also makes conforming changes and corrects a cross-reference.

The bill provides an effective date of July 1, 2015.

B. SECTION DIRECTORY:

Section 1. Amends s. 381.004, F.S., relating to HIV testing.

Section 2. Amends s. 456.032(2), F.S., relating to Hepatitis B or HIV carriers.

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

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill requires the Department of Health to revise rule 64D-2.004, F.A.C.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 11, 2015, the Health Quality Subcommittee adopted a technical amendment and reported the bill favorably as a committee substitute. The amendment corrected a cross-reference in s. 456.032(2), F.S. The analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.