

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 321 HIV Testing

SPONSOR(S): Health & Human Services Committee; 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 & Human Services Committee	18 Y, 0 N, As CS	Castagna	Calamas

SUMMARY ANALYSIS

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 "health care setting" and "nonhealth care setting" for the purpose of differentiating HIV testing requirements. The bill revises the HIV testing requirements for health care settings, and for programs within such settings, to eliminate the informed consent requirement and establish new notification requirements. The bill also provides that a person's signature on a general consent form suffices as consent to an HIV test.

The bill retains the requirement to obtain informed consent from the HIV test subject in nonhealth care settings, and programs within such settings.

The bill makes several changes to the current exemption to the informed consent requirement related to "significant exposure" of medical and nonmedical personnel in emergency and non-emergency situations.

The bill requires a significant exposure to be reported in a medical personnel's employee record and the nonmedical personnel's medical record. The bill removes certain record keeping requirements related to the reporting of the HIV test in the event of a significant exposure in only the medical or nonmedical personnel's record.

The bill also removes two public records exemptions for HIV test results recorded when medical and nonmedical personnel significant exposure incidents.

The bill also updates the definition of "preliminary HIV test" to reflect advances in HIV testing.

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

The bill has an insignificant negative fiscal impact on the Department of Health and no fiscal impact on 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 (CDC) 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 March 8, 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 March 8, 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 March 8, 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 March 8, 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 March 8, 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 March 8, 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 March 8, 2015).

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

HIV Testing in Florida

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:

- 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.¹⁵

Minors who meet 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 March 8, 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 March 8, 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 March 8, 2015).

¹² Hartog, Jack, *Florida's Omnibus AIDS Act*, Florida Dep't of Health, accessible at: http://www.floridahealth.gov/diseases-and-conditions/aids/operations_managment/documents/Omnibus-booklet-update-2013.pdf. (last accessed March 8, 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. 12.

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

Significant Exposure

Bloodborne viruses, such as HIV, may be transmissible in health care settings during medical procedures or emergency medical situations where blood and other bodily fluids may be exposed and come in contact with another person. “Significant exposure” is defined in s. 381.004(1)(c), F.S., and includes a person’s exposure:

- To blood or body fluids¹⁸ through needlestick, instruments, or sharps;
- Of mucous membranes to visible blood or body fluids, to which universal precautions apply according to the CDC; 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.

In the event that a significant exposure occurs, it is important to determine if the source is infected with HIV so that proper preventative medical treatment can immediately take place.

Post-exposure prophylaxis (PEP) can be prescribed for people who have potentially been exposed to HIV. This form of HIV treatment can prevent the virus from becoming established in the body of someone who has been recently exposed. PEP is an antiretroviral drug treatment that must be started within hours after a person is exposed to HIV to most effectively prevent HIV. PEP typically consists of a month long treatment of two or three different types of antiretroviral drugs.¹⁹

Significant Exposure HIV Testing

Currently, Florida law prohibits HIV testing without a person’s knowledge and informed consent, with the exception of certain defined situations.²⁰ In the event of a significant exposure, informed consent is not required if an available blood sample from a person whose medical care resulted in a significant exposure is available. If a blood sample is not available, reasonable attempts to obtain informed consent from the source person are required prior to their blood being drawn for an HIV test. This can cause problems in certain medical situations when a person is not physically able to consent to a test, such as when a person is incoherent from a medical condition or anesthesia. In situations where consent is not given but a test is performed, for timely PEP treatment for the medical personnel to begin, incidental information must only be documented in the medical personnel’s record unless the source gives consent to this information being entered into their medical record.

During emergency situations, nonmedical persons may also experience a significant exposure. The same process for HIV testing of the source is in place in these situations.

If the source of the exposure is not available or will not consent to an HIV test, and a blood sample is not available, the medical personnel, nonmedical personnel, or their employer may seek a court order legally directing the source to be tested for HIV. A licensed physician’s sworn statement that a significant exposure occurred and testing of the source is medically necessary constitutes probable cause for the issuance of a court order requiring the source to be tested.²¹

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

¹⁸ The following body fluids are included in the s. 381.004, F.S., definition: blood, semen, vaginal secretions, cerebro-spinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid.

¹⁹ Avert, *Post-exposure Prophylaxis: PEP*, available at <http://www.avert.org/post-exposure-prophylaxis-pep.htm> (last visited March 14, 2015).

²⁰ See fn. 13.

²¹ Section 381.004(2)(h)10.f., F.S.

The cost of an HIV test in a significant exposure occurrence must be paid by the medical personnel, nonmedical personnel, or their employer, not the test subject.²²

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 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.

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 orally or in writing that the test is planned and that he or she has the right to decline the test. If a test is declined, it must be documented in the test subject's medical record. The bill authorizes a patient's general consent for medical care to suffice as consent to HIV testing.

The bill removes the requirement that an HIV testing program in a health care setting register with the Department.

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. The bill also requires an HIV testing program in a nonhealth care setting to register with the Department.

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, health care setting notification requirements must be met. 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.

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. CHDs must 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 removes the requirement for the hospital to obtain written informed consent to release HIV test results under certain circumstances to conform to the bill's removal of the requirement to obtain informed consent for an HIV test.

The bill also removes two public records exemptions for HIV test results recorded in the event of medical and nonmedical personnel "significant exposure" incidents.

Significant Exposure

The bill makes several changes to the current exemption to the informed consent requirement related to a "significant exposure" of medical and nonmedical personnel in emergency and non-emergency situations in s. 381.004(2)(h)10., F.S., and s. 381.004(2)(h)11., F.S. The bill removes the requirement that:

- An available voluntarily obtained blood sample be used to test for HIV in an individual whose medical treatment results in a significant exposure;
- Attempts be made to obtain informed consent from the source patient for use of the available blood sample;
- Information pertaining to a significant exposure incident only be recorded in the medical personnel or nonmedical personnel's record unless the individual whose medical care resulted in a significant exposure consents to the information also being recorded in their medical record;
- Attempts be made and documented to obtain consent from an individual to obtain a blood sample for an HIV test to be performed; and
- If an individual does not consent, but a test must be performed anyway, counseling will be available to the individual.

The bill also provides two distinct sections for HIV testing procedures in the event of a significant exposure for medical personnel in emergency and non-emergency situations and nonmedical personnel in emergency situations. When a significant exposure occurs, the bill requires the incident to be reported in a medical personnel's employee record and the nonmedical personnel's medical record.

The bill updates the definition of "preliminary HIV test" 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:

The bill has an insignificant negative fiscal impact on the Department of Health associated with revenue loss. HIV testing programs in health care settings will no longer be required to register with the Department of Health (Department) and submit an initial \$100 registration fee.²³ There is no renewal fee for HIV testing programs in health care settings. It is difficult to determine the bill's specific fiscal impact on the Department because it is unknown how many new health care setting HIV testing programs would be initiated in the future.

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:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

²³ . Email correspondence with Department of Health staff on March 16, 2015 (on file with committee staff).

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.

On March 12, 2015, the Health and Human Services committee adopted a strike all amendment to the bill and reported the bill favorable as a committee substitute. The amendment:

- Amends the definition of “health care setting” to include hospitals and blood banks.
- Changes the HIV testing notification requirements for health care settings to incorporate consent to HIV testing into a patient’s general consent for medical care.
- Redrafts sections on “significant exposure” for medical and nonmedical personnel in emergencies and non-emergencies to clarify distinctions between them.
- Removes the requirement that an available voluntarily obtained blood sample be used to test for HIV in an individual whose medical treatment results in a significant exposure.
- Removes the requirement for information relating to HIV testing in the event of significant exposure to only be documented in the medical or nonmedical personnel’s record.
- Repeals two public records exemptions for HIV test results in the event of medical and nonmedical personnel significant exposure incidents.
- Requires only “nonhealth care setting” HIV testing programs to register with the Department of Health.

The analysis is drafted to the committee substitute as passed by the Health and Human Services Committee.