

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1225 HIV Testing
SPONSOR(S): Health Quality Subcommittee; Saunders and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1470

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	11 Y, 0 N, As CS	Castagna	O'Callaghan
2) Health & Human Services Committee		Castagna	Calamas

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 "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 provides that the Department of Health county health departments (CHDs) can operate as both a health care setting and a nonhealth care setting by recognizing testing programs within CHDs as nonhealth care settings.

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, 2014.

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

Data from 2009 indicates that of the estimated 1.1 million adults in the United States who are infected with the virus, 18% were unaware of their infection.³ HIV testing is essential for improving the health of people living with HIV and reducing new HIV infections. It is recommended that testing occur as part of a routine healthcare visit. This is especially important for people who may not consider themselves at risk for HIV.⁴ HIV testing is nationally 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.⁵

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 form of testing, which are not as readily available as antibody tests. Antigen tests can be used to diagnose HIV infection 1 to 3 weeks after a person is first infected with HIV and a blood sample is required to obtain results.⁶

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.

Florida HIV Testing

¹ "About HIV/AIDS," Centers for Disease Control and Prevention, accessible at: <http://www.cdc.gov/hiv/basics/whatishiv.html#panel0> (last accessed March 19, 2014).

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. "HIV Transmission," Centers for Disease Control and Prevention, accessible at: <http://www.cdc.gov/hiv/basics/transmission.html> (last accessed March 19, 2014).

³ "HIV in the United States: At a Glance," Centers for Disease Control and Prevention, accessible at: <http://www.cdc.gov/hiv/statistics/basics/ata glance.html> (last accessed March 20, 2014).

⁴ In Florida, only 48% of adults under 65 reported having ever been tested for HIV. Department of Health, Florida Charts, accessible at: <http://www.floridacharts.com/charts/Brfss/DataViewer.aspx?bid=29> (last accessed March 20, 2014).

⁵ "Screening for HIV, Current Recommendations," U.S. Preventive Services Task Force, April 2013, accessible at: <http://www.uspreventiveservicestaskforce.org/uspstf/uspshivi.htm> (last accessed March 20, 2014).

⁶ "Types of HIV Tests," U.S. Department of Health and Human Services, accessible at: <http://aids.gov/hiv-aids-basics/prevention/hiv-testing/hiv-test-types/index.html> (last accessed March 20, 2014).

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.⁷ To promote informed patient decision-making, s. 381.004, F.S., prohibits HIV testing without a person's knowledge and consent, except under certain defined circumstances,⁸ and gives the patient special rights to control who learns of the HIV test results.⁹

As stated in s. 381.004(2)(a), F.S., informed consent¹⁰ must be obtained by all persons receiving an HIV test. Consent must be in writing unless it is documented in the person's medical record that they have been educated about the test and given consent to be tested. The right to confidential treatment of information identifying the subject of the test and the results must then be explained to the test subject.¹¹ The subject of the test must be informed that a positive HIV test result will be reported to the local Department of Health county health department (CHD) with enough information to identify the test subject.¹² The test subject must also be informed about the location of local sites at which anonymous testing¹³ is available.¹⁴

The Department of Health 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. CHDs¹⁵ are the primary outlet for state-sponsored HIV programs and, in addition to testing services, CHDs provide prevention outreach and education free to the public.

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,

⁷ "Florida's Omnibus AIDS Act," Jack P Hartog, Department of Health, *accessible at*: www.floridahealth.gov/diseases.../Omnibus-booklet-update-2013.pdf (last accessed March 21, 2014).

⁸ 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.

⁹ *Supra* fn. 7.

¹⁰ Informed consent is a process of communication between patient and provider through which an informed patient can choose whether to undergo HIV testing or decline to do so. Elements of informed consent typically include providing oral or written information regarding HIV, the risks and benefits of testing, the implications of HIV test results, how test results will be communicated, and the opportunity to ask questions. Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings, Centers for Disease Control and Prevention, September 22, 2006, *accessible at*:

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm> (last accessed March 19, 2014).

¹¹ Under limited circumstances, test results may be released to certain persons, entities, or the Agency for Health Care Administration pursuant to s. 395.3025, F.S.

¹² HIV is a notifiable disease and positive test results must be reported to the Department of Health to effectively monitor disease trends, assess effectiveness of prevention and control measures, identify populations at a higher risk, and develop public health policies. National Notifiable Disease Surveillance System, Centers for Disease Control and Prevention, *accessible at*: <http://wwwn.cdc.gov/nndss/> (last accessed March 20, 2014).

¹³ Anonymous testing is available at some testing sites and does not require test subject to identify themselves. When a person takes an anonymous HIV test, they are given a unique identifier that allows only them to access their test results. Centers for Disease Control and Prevention, Testing, *accessible at*: <http://www.cdc.gov/actagainstaids/basics/testing.html> (last accessed March 20, 2014).

¹⁴ Section 381.004(2)(a), F.S.

¹⁵ County Health Departments are the local sector of the Department 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. County Health Departments, Department of Health, *accessible at*: <http://www.floridahealth.gov/public-health-in-your-life/county-health-departments/index.html> (last accessed March 20, 2014).

- 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 health care provider to instead notify the test subject that the test is planned, and provide information to the test subject on HIV, the risks of being tested, and implications of HIV test results. The provider must also inform the test subject that they have the right to decline the test. The explanation of the right to confidential treatment of information identifying the test subject and the results of the test as provided in current law¹⁶ is retained. The provider must document in the person's medical record if the test was declined.

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.

County Health Departments

For purposes of HIV testing, CHDs will operate as both health care and nonhealth care settings. If a person is to be tested at a CHD, or a CHD sponsored outreach event, for HIV testing only, the testing will be conducted following nonhealth care setting testing requirements. If a person is being seen at a CHD clinic, such as an STD or family planning clinic, the provider must meet health care setting notification requirements.

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.

The bill authorizes hospitals licensed under chapter 395, F.S., to release HIV test results, as is currently authorized, if the hospital notifies the patient of the confidentiality protections for HIV test results included in medical records. The bill conforms this requirement to the notification requirements in the bill 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.

B. SECTION DIRECTORY:

¹⁶ Section 381.004 (2)(e), F.S.
STORAGE NAME: h1225b.HHSC
DATE: 4/1/2014

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

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

Section 3. Provides an effective date of July 1, 2014.

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 to revise rule 64D-2.004, F.A.C.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 24, 2014, the Health Quality Subcommittee adopted an amendment and passed HB 1225 as a committee substitute (CS). The amendment reinstates current law which does not require informed consent when testing pregnant women for HIV.

The analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.