HOUSE OF REPRESENTATIVES
FINAL BILL ANALYSIS

BILL #:	CS/CS/HB 321	**FINAL HOUSE FLOOR ACTION:**	
SPONSOR(S):	Health & Human Services Committee; Health Quality Subcommittee; Avila; Edwards and others	119 **Y's**	0 **N's**
COMPANION BILLS:	CS/CS/SB 512	**GOVERNOR'S ACTION:**	Pending

SUMMARY ANALYSIS

CS/CS/HB 321 passed the House on April 22, 2015, and subsequently passed the Senate on April 27, 2015.

The bill defines "health care setting" and "nonhealth care setting" to differentiate HIV testing requirements. The bill revises the HIV testing requirements for health care 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.

The bill revises record keeping requirements in the event of a significant exposure in an emergency or non-emergency situation. When a medical personnel experiences a significant exposure, the bill requires the incident to be recorded in the medical personnel's employee record. When a nonmedical personnel experiences a significant exposure, the bill requires the incident to be recorded in the nonmedical personnel's medical record. The bill also requires either the nonmedical personnel or the employer to cover the cost of an HIV test in the event of a significant exposure and authorizes the employer of a nonmedical personnel to seek a court order under certain circumstances. The bill removes the requirement to:

- Obtain consent from the source of the significant exposure before conducting an HIV test;
- Record information pertaining to a significant exposure incident only 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;
- Have medical personnel, under the supervision of a licensed physician, document that a significant exposure has occurred and in the physician's medical judgment testing of the source is medically necessary, before HIV testing of the source occurs; and
- Make counseling available to an individual when an individual does not consent to an HIV test, but a test must be performed on their available blood sample.

The bill exempts a facility licensed under ch. 395, F.S., from the requirement to register with the Department of Health as an HIV testing program and other statutory HIV testing requirements if the HIV testing program is part of routine medical care or is not advertised to the general public.

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

The bill makes technical changes throughout s. 381.004, F.S., to clarify existing language, corrects a cross-reference, and makes many conforming changes.

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

Subject to the Governor's veto powers, the effective date of this bill is July 1, 2015.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF 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.

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[1] Centers for Disease Control and Prevention, *About HIV/AIDS*, accessible at: http://www.cdc.gov/hiv/basics/whatishiv.html#panel0 (last accessed May 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 May 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/ataglance.html#ref1 (last accessed May 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 May 1, 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 May 1, 2015).
[6] U.S. Preventive Services Task Force, *Human Immunodeficiency Virus (HIV) Infection: Screening*, Aril 2013, accessible at: http://www.uspreventiveservicestaskforce.org/uspstf/uspshivi.htm (last accessed May 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 May 1, 2015).

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 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]

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[8] Centers for Disease Control and Prevention, *State HIV Laws,* accessible at*:* http://www.cdc.gov/hiv/policies/law/states/ (last accessed May 1, 2015).
[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 May 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 May 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 May 1, 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 May 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. 12.
[15] Rule 64D-2.004, F.A.C.

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]

HIV Testing Program Registration Requirements

Section 381.004(4), F.S., requires that an HIV testing program that plans to advertise to the public must first register, and annually re-register, with the Department and must be in compliance with several statutory requirements, the program must:

- Be directed by a person with HIV/AIDS counseling experience, as established by Department rule;
- Have all medical care supervised by a physician licensed under chs. 458 or 459, F.S.;
- Have all laboratory procedures performed in a laboratory licensed under ch. 483, F.S.;
- Meet all the informed consent criteria contained in s. 381.004(2), F.S.;
- Provide the opportunity for pretest counseling on the implication of an HIV test, including medical indications for the test, the possibility of false positive or false negative results, the potential need for confirmatory testing, the potential social, medical, and economic consequences of a positive test result, and the need to eliminate high-risk behavior;
- Provide supplemental corroborative testing on all positive test results before the results of any positive test are provided to the patient;
- Provide the opportunity for face-to-face posttest counseling;
- Meet certain staffing requirements related to the completion of training on effective counseling of people who receive positive test results; and
- Provide a complete list of all charges for services to the patient and the Department.

Certain facilities and health care practitioners are exempt from registration and such requirements if the program or practitioner does not advertise to the public as conducting HIV testing programs or specializing in such testing.[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 fluids[18] 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

[16] Section 384.30, F.S. and Rule 64D-2.004(4), F.A.C.
[17] The facilities and health care practitioners exempted from registration and other HIV testing program requirements include clinical laboratories, multiphasic health testing centers, clinical laboratory personnel, and medical physicists (all regulated under ch. 483, F.S.), acupuncturists (ch. 457, F.S.), physicians (ch. 458, F.S.), osteopathic physicians (ch. 459, F.S.), chiropractors (ch. 460, F.S.), podiatrists (ch. 461, F.S.), dentists (ch. 466, F.S.), and midwives (ch. 467, F.S.). Section 381.004(4), 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.

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 to medical personnel[21] or nonmedical personnel, attempts must be made to obtain consent for an HIV test from a person whose medical care resulted in the significant exposure. An available, voluntarily obtained blood sample will be used for the HIV test. If a blood sample is not available, reasonable attempts to obtain consent are required prior to a source person's 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.[22]

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, the employer of the medical personnel, or the nonmedical personnel 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. The results of the test shall be released to the source of the exposure and to the person who experienced the exposure.[23]

The cost of an HIV test in a significant exposure occurrence must be paid by the medical personnel or the employer of the medical personnel or nonmedical personnel, not the test subject.[24]

[19] Avert, *Post-exposure Prophylaxis: PEP*, available at http://www.avert.org/post-exposure-prophylaxis-pep.htm (last visited May 1, 2015).
[20] *See* fn. 13.
[21] The term "medical personnel" includes a licensed or certified health care professional; an employee of a health care professional or health care facility; employees of a laboratory licensed under ch. 483, F.S.; personnel of a blood bank or plasma center; a medical student or other student who is receiving training as a health care professional at a health care facility; and a paramedic or emergency medical technician certified by the department to perform life-support procedures under s. 401.23, F.S.
[22] Section 381.004(2)(h)10., F.S. Before HIV testing of the source occurs, medical personnel under the supervision of a licensed physician must document that a significant exposure has occurred and in the physician's medical judgment testing of the source is medically necessary. For this testing process of the source to occur, the person who experienced the exposure must also be tested for HIV or provide negative HIV test results takin within 6 month prior.
[23] Section 381.004(2)(h)10.f., F.S. Results of an HIV test in the event of a significant exposure are required to remain confidential and are exempt from public records.
[24] Sections 381.004(2)(h)10.c., F.S., and 381.004(2)(h)11.c., F.S.

Effect of Proposed Changes

HIV Testing

The bill provides a definition for health care setting and nonhealth care setting to differentiate between the two for the purpose of HIV testing and makes other changes to s. 381.004, F.S., related to HIV testing in certain situations and registration requirements for HIV testing programs.

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.

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, health care setting notification requirements must be met. If a person is to be tested at a CHD HIV testing program, or a CHD sponsored outreach event, informed consent must be obtained.

HIV Testing Program Registration Requirements

The bill exempts a facility licensed under ch. 395, F.S.,[25] from the requirement to register with the Department as an HIV testing program and meet other statutory HIV testing program requirements under s. 381.004(4), F.S., if the HIV testing program is part of routine medical care or is not advertised to the general public. Specifically, exempt facilities will not be required to:

- Be directed by a person with HIV/AIDS counseling experience, as established by Department rule;
- Have all medical care supervised by a physician licensed under the provisions of chs. 458 or 459, F.S.;
- Have all laboratory procedures performed in a laboratory licensed under the provisions of ch. 483, F.S.;
- Meet all the informed consent criteria contained in s. 381.004(2), F.S.;
- Provide the opportunity for pretest counseling on the implication of an HIV test, including medical indications for the test, the possibility of false positive or false negative results, the potential need for confirmatory testing, the potential social, medical, and economic consequences of a positive test result, and the need to eliminate high-risk behavior;
- Provide supplemental corroborative testing on all positive test results before the results of any positive test are provided to the patient;
- Provide the opportunity for face-to-face posttest counseling;
- Meet certain staffing requirements related to the completion of training on effective counseling of people who receive positive test results; and
- Provide a complete list of all charges for services to the patient and the Department.

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.

Significant Exposure

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

- Obtain consent to test a blood sample for HIV that has been voluntarily obtained from an individual whose medical treatment resulted in a significant exposure;
- Record information pertaining to a significant exposure incident only 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;
- Have medical personnel, under the supervision of a licensed physician, document that a significant exposure has occurred and in the physician's medical judgment testing of the source is medically necessary, before HIV testing of the source occurs; and
- Make counseling available to an individual when an individual does not consent to an HIV test, but a test must be performed on their available blood sample.

[25] The facilities licensed under ch. 395, F.S., include hospitals, ambulatory surgical centers, and mobile surgical facilities.

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 the medical personnel's employee record and the nonmedical personnel's medical record.

Currently, in the event that a nonmedical personnel experiences a significant exposure, costs of an HIV test of the source must be paid by the employer of the nonmedical personnel. The bill requires either a nonmedical personnel or his or her employer to pay for the cost of the source's HIV test. The bill also authorizes an employer of a nonmedical personnel to seek a court order directing the source of the significant exposure to submit to HIV testing when the source of the significant exposure is not available or will not be tested for HIV, and their blood sample is not available. Currently, only a nonmedical personnel may seek a court order under such circumstances.

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.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.[26]

2. Expenditures:

   None.

A. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

B. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Health care settings may achieve an indeterminate amount of cost-savings associated with no longer having to obtain informed consent prior to testing a patient for HIV.

C. FISCAL COMMENTS:

[26] The Department of Health reports that, although facilities licensed under ch. 395, F.S., will be exempt from HIV testing program registration and the attendant registration fees, the bill does not have a negative fiscal impact on the Department. Email correspondence with Department of Health staff on May 4, 2015 (on file with committee staff).

None.