SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: Judiciary Committee

BILL:	CS/CS/SB 186
SPONSOR:	Judiciary Committee, Health Care Committee and Senator Lynn
SUBJECT:	Sexually Transmissible Disease Testing and Reporting
DATE:	March 31, 2005 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HE	**Fav/CS**
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3.			HA	
4.				
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6.				

I. Summary:

Committee Substitute for Committee Substitute for Senate Bill 186 revises the circumstances under which a positive preliminary human immunodeficiency virus (HIV) test result may be released, to allow the release of the results of rapid testing technologies in accordance with the test manufacturer's instructions as approved by the federal Food and Drug Administration. In addition, the committee substitute alters the requirement that a treating physician or midwife must *offer* HIV testing to pregnant women with the requirement that a treating physician or midwife *routinely test* for HIV, unless a pregnant woman specifically opts-out of the HIV test.

The committee substitute also revises the reporting requirements for healthcare professionals who diagnose and treat persons with sexually transmissible diseases, including HIV or acquired immune deficiency syndrome (AIDS), and for the laboratories that test for these diseases. In order for the state's reporting procedures to be current with reporting techniques, the committee substitute updates the current statute to allow for reporting infection of HIV and AIDS based upon "a system" developed by the Centers for Disease Control and Prevention or "an equivalent system."[1]

This committee substitute amends the following sections of the Florida Statutes: 381.004, 384.25, and 384.31.

[1] s. 384.25(2), F.S., currently requires the use of the "HIV/AIDS Reporting System (HARS)," which was developed by the Centers for Disease Control and Prevention (CDC), but it is outdated and has been updated several times. "A system" would more generally refer to whatever reporting system the CDC is currently using.

II. Present Situation:

General Background on HIV/AIDS and Testing

Acquired immune deficiency syndrome (AIDS) is a fatal disease caused by a virus, a tiny organism similar to the organisms that cause colds and flu. The virus that causes AIDS is the human immunodeficiency virus, or HIV. Human immunodeficiency virus (HIV) infection causes people to get AIDS by damaging their immune systems. The immune system is what defends the body against the many different organisms that can enter the body and cause illness. Without the ability to resist disease, people with AIDS fall ill easily, get sick often, and have great difficulty recovering. People do not die from HIV infection directly. Rather, they die from the "opportunistic" infections and diseases they get because their immune system is not working properly.

There are two broad categories of tests used to detect HIV: screening tests and confirmatory tests. *Screening tests* are used for initial testing because they are easier to perform than confirmatory tests, are well suited to testing large numbers of people, and are less costly. However, screening tests are not as specific as confirmatory tests, so in a small percentage of cases the test result will be positive even if the person is not infected. A *confirmatory test* is done when the results of a screening test are positive. The confirmatory test is expensive and labor intensive and requires subjective interpretation, but it is very specific (in other words, false-positive results are extremely rare).

HIV/AIDS Testing – Provisions for Release of Results

Section 381.004(3)(d), F.S., provides that no HIV test result shall be determined as positive, and no positive test result shall be revealed to any person, without corroborating or confirmatory tests being conducted. The statute provides exceptions that allow the release of preliminary test results to: 1) licensed physicians or the medical or nonmedical personnel subject to significant exposures or 2) health care providers and the person tested when decisions about medical care cannot await the results of confirmatory testing.[2] Justification for the release of preliminary test results must be documented in the medical record by the health care provider who ordered the test.

Current law prohibits the release of preliminary test results for routine identification of HIV infected individuals or when HIV testing is incidental to the preliminary diagnosis or care of a patient.[3] Corroborating or confirmatory testing must be conducted as followup to a positive preliminary test, and results must be communicated to the patient according to the statute regardless of the outcome. The person ordering the test or that person's designee shall ensure that all reasonable efforts are made to notify the test subject of his or her test result.

Notification of a person with a positive test result shall include information on the availability of appropriate medical and support services, on the importance of notifying partners who may have been exposed, and on preventing transmission of HIV. Notification of a person with a negative

[2] This section applies to all tested persons but also specifically addresses releasing preliminary positive test results to pregnant women in order to discuss treatment recommendations for her newborn.
[3] s. 381.004(3)(d)2., F.S.

test result shall include, as appropriate, information on preventing the transmission of HIV. When testing occurs in a hospital emergency department, detention facility, or other facility and the test subject has been released before being notified of positive test results, informing the county health department to notify the test subject fulfills this responsibility.

HIV/AIDS Testing – Consent

For an HIV test to be ordered, the testing subject must provide informed consent.[4] The informed consent need not be in writing if there is documentation in the medical record that the test has been explained and the consent has been obtained. For informed consent to be valid, before the test is administered the patient must be provided an explanation of the right to confidential treatment of information identifying the subject of the test and the results of the test subject to reporting requirements provided by law. The law requires that a positive HIV test result will be reported to the county health department with sufficient information to identify the test subject; however, the patient must also be informed of the availability and location of sites at which anonymous testing is performed.[5]

Section 381.004(3)(h), F.S., provides exceptions to the requirement of informed consent for HIV testing under the following circumstances:

- When testing for sexually transmissible diseases is required by state or federal law, or by rule, including HIV testing of persons convicted of prostitution or of procuring another to commit prostitution, HIV testing of inmates prior to their release from prison, and testing for HIV by a medical examiner;
- For those exceptions provided for blood, plasma, organs, skin, semen, or other human tissue in state law;
- For the performance of an HIV-related test by licensed medical personnel in bona fide medical emergencies when the test results are necessary for medical diagnostic purposes to provide appropriate emergency care or treatment to the person being tested and the patient is unable to consent;
- For the performance of an HIV-related test by licensed medical personnel for medical diagnosis of acute illness where, in the opinion of the attending physician, obtaining informed consent would be detrimental to the patient, as supported by documentation in the medical record, and the test results are necessary for medical diagnostic purposes to provide appropriate care or treatment to the person being tested;
- When HIV testing is performed as part of an autopsy for which consent was obtained;
- For the performance of an HIV test upon a defendant pursuant to the victim's request in a prosecution for any type of sexual battery where a blood sample is taken from the defendant voluntarily, pursuant to court order for any purpose, or pursuant to Florida law;[6]
- For epidemiological research, for research consistent with institutional review boards created by federal law, or for the performance of an HIV-related test for the purpose of

[4] s. 381.004(3)(a), F.S.
[5] Anonymous testing facilities must report a positive test result, but the anonymous facility does not report a patient's identifying information.
[6] The results of any HIV test performed shall be disclosed solely to the victim and the defendant.

research, if the testing is performed in a manner by which the identity of the test subject is not known and may not be retrieved by the researcher;

- When human tissue is collected lawfully without the consent of the donor for corneal removal or enucleation of the eyes;
- For the performance of an HIV test upon an individual who comes into contact with medical personnel in such a way that a significant exposure has occurred during the course of employment or within the scope of practice and where a blood sample is available that was taken from that individual voluntarily by medical personnel for other purposes;
- For the performance of an HIV test upon an individual who comes into contact with medical personnel in such a way that a significant exposure has occurred during the course of employment or within the scope of practice of the medical personnel while the medical personnel provides emergency medical treatment to the individual; or who comes into contact with nonmedical personnel in such a way that a significant exposure has occurred while the nonmedical personnel provides emergency medical assistance during a medical emergency;
- For the performance of an HIV test by the medical examiner or attending physician upon an individual who expired or could not be resuscitated while receiving emergency medical assistance or care and who was the source of a significant exposure to medical or nonmedical personnel providing such assistance or care;
- For the performance of an HIV-related test medically indicated by licensed medical personnel for medical diagnosis of a hospitalized infant as necessary to provide appropriate care and treatment of the infant when, after a reasonable attempt, a parent cannot be contacted to provide consent;
- For the performance of HIV testing conducted to monitor the clinical progress of a patient previously diagnosed to be HIV positive; or
- For the performance of repeated HIV testing conducted to monitor possible conversion from a significant exposure.

General Background on HIV/AIDS in Women and Infants

The number of women with HIV and AIDS is steadily rising,[7] and nationwide women infected with HIV or AIDS have given birth to more than 15,000 HIV-infected children since the epidemic began. The Centers for Disease Control (CDC) estimates that each year approximately 7,000 HIV-infected women give birth, and approximately 400 babies are born with HIV. Babies can get HIV from their mothers during the pregnancy, during labor, or through breastfeeding.

Perinatal transmission (mother-to-child) of AIDS accounts for 91 percent of pediatric AIDS cases reported nationally and 96 percent of pediatric AIDS cases in Florida. While the number of newly diagnosed AIDS cases in Florida children has declined 92 percent since 1992, the state had the second highest number pediatric AIDS cases in the nation in 2003.[8]

In 1994, a study conducted by the Pediatric AIDS Clinical Trials Group demonstrated that AZT (also known as zidovudine), given to HIV-infected women who had very little or no prior

[7] Women accounted for 19 percent of reported AIDS cases in 1992 and 27 percent of AIDS cases in 2003. Women now account for 36 percent of cumulative reported HIV cases in Florida.
[8] New York had the highest number of pediatric AIDS cases in 2003.

antiretroviral therapy, reduced the risk of mother to infant transmission from 25 percent to 8 percent. This study formed the basis for the treatment of HIV-infected pregnant women in the U.S. and has resulted in the dramatic decrease in the number of pediatric AIDS cases.

Since the release of the 1994 study, there have been multiple publications by public and private medical entities that report the need for testing pregnant women for HIV. Included among these reports are the following:

- The Institute of Medicine (IOM) recommended routine HIV testing of pregnant women to reduce the number of infants born with HIV;[9]
- Secretary Shalala of the U.S. Department of Health and Human Services stated that overall efforts to reduce perinatal transmission have been successful, and recommended that the best way to further reduce HIV transmission was to increase the number of women who access prenatal care;[10]
- The National Institutes of Health released data showing that when a woman delivers her baby by caesarean section, the rate of HIV transmission drops by 50 percent.

In 2001, the CDC published updated guidelines for testing pregnant women for HIV.[11] The guidelines were meant for public and private sector service providers who provide health care for pregnant women. The updated CDC guidelines were based on input from meetings, the IOM report, and public comment on draft guidelines published in the fall of 2000 in the *Federal Register*. The updated guidelines were also driven by scientific and programmatic advances in the prevention of perinatally acquired HIV and care of HIV-infected women. Major revisions from the 1995 guidelines included:

- Emphasizing HIV testing as a routine part of prenatal care and strengthening the recommendation that all pregnant women be tested for HIV;[12]
- Recommending simplification of the testing process so that pretest counseling is not a barrier to testing;
- Making the consent process more flexible to allow for various types of informed consent;
- Recommending that providers explore and address reasons for refusal of testing; and
- Emphasizing HIV testing and treatment at the time of labor and delivery for women who have not received prenatal testing and antiretroviral drugs.

The routine HIV testing of pregnant women is a key strategy in the new CDC initiative published in April 2003.[13] This initiative is aimed at reducing barriers to early diagnosis, increasing access to quality medical care, and providing ongoing prevention services. The initiative states that

[9] "Reducing the Odds: Preventing Perinatal Transmission of HIV in the United States," Institute of Medicine, National Research Council, 1999, Washington, D.C., National Academy Press.
[10] *Federal Register*, Vol. 65, No. 13, January 20, 2000, Notices.
[11] "U.S. Public Health Service Recommendations for Human Immunodeficiency Virus Counseling and Voluntary Testing for Pregnant Women," *Morbidity and Mortality Weekly Report ("MMWR")*, Recommendations and Reports, Centers for Disease Control, November 9, 2001, p. 63-85.
[12] These 2001 CDC guidelines also recommended voluntary HIV testing to preserve a woman's right to participate in decisions regarding testing, to ensure a provider-patient relationship conducive to optimal care for mothers and infants, and to support a woman's right to refuse testing if she does not think it is in her best interest.
[13] "Advancing HIV Prevention: New Strategies for a Changing Epidemic—U.S., 2003," *Morbidity and Mortality Weekly Report ("MMWR")*, Recommendations and Reports, Centers for Disease Control, April 18, 2003, p. 329-332.

routine testing of pregnant women is a proven public health approach in reducing the incidence and spread of disease.

HIV Testing in Pregnant Women and Infants

Section 384.31, F.S., and rules adopted thereunder, require health care providers attending pregnant women for conditions related to pregnancy to: test for sexually transmissible diseases as required by rule of the Florida Department of Health (DOH) at the initial visit and again at 28-32 weeks; and to counsel and offer HIV testing at the initial prenatal visit and again at 28-32 weeks gestation, regardless of risk behaviors.[14] Counseling must include a discussion of the availability of treatment if the pregnant woman tests HIV positive. If a pregnant woman objects to HIV testing, reasonable steps must be taken to obtain a written statement of objection. Any health care worker who offers HIV testing and obtains a written statement of objection signed by the patient shall be immune from liability arising out of or related to the contracting of HIV/AIDS by the child from the mother. Currently, there is no requirement to perform mandatory HIV testing of a newborn child in Florida.

Based on data collected through a survey conducted by the DOH, it is estimated that there are approximately 1,000 HIV-infected women who give birth each year in Florida. Without prenatal care and medical intervention, DOH reports that there is approximately a 30-percent chance the baby will be born infected with HIV. With appropriate treatment, that chance drops to about 2 percent. The vast majority of pregnant women are getting tested prenatally, although a few women do not receive prenatal care or refuse testing. The DOH does not currently have the authority to track newborns that test positive for HIV at birth since a positive test result is not a diagnosis of HIV in the infant.

III. Effect of Proposed Changes:

HIV/AIDS Test Results – Releasing and Reporting

The committee substitute amends s. 381.004, F.S., relating to human immunodeficiency virus (HIV) testing, to revise the circumstances under which a positive preliminary test result may be released, to include the results of rapid testing technologies. The results of rapid testing technologies must be considered preliminary (meaning that they must still be followed by a confirmatory test) but may be released in accordance with the manufacturer's instructions as approved by the federal Food and Drug Administration. The prohibition against the release of preliminary test results for the purpose of routine identification of HIV-infected individuals or when HIV testing is incidental to the preliminary diagnosis or care of a patient is eliminated.

The committee substitute clarifies s. 384.25, F.S., governing reporting requirements for healthcare professionals who diagnose and treat persons with sexually transmissible diseases, including HIV or acquired immune deficiency syndrome (AIDS), and for the laboratories that test for these diseases. When a test concludes with a positive report for a sexually transmissible disease or a result indicative of HIV or AIDS, healthcare professionals and laboratories must report such facts as may be required by the Florida Department of Health (DOH) by rule. The

[14] See Rules 64D-2.004 and 64D-3.019, Florida Administrative Code.

test results must be reported within the time period as specified by DOH rule which may not exceed 2 weeks. The department must adopt rules specifying the *maximum,* rather than a *minimum,* time period for reporting a sexually transmissible disease, *including but not limited to HIV/AIDS*. References to the HIV/AIDS Reporting System developed by the Centers for Disease Control and Prevention (CDC) of the U.S. Public Health Service are deleted to allow the use of "a system" for reporting of HIV/AIDS which is developed by the CDC or "an equivalent system." Under the current law, the CDC's reporting system is used to ensure the confidentiality of persons infected with HIV.

The DOH must adopt rules requiring each physician and laboratory to report any newborn or infant up to 18 months of age who has been exposed to HIV. The rules may include the method and time period for reporting, which may not exceed two weeks, information to be included in the report, requirements for enforcement, and followup activities by DOH.

The mandate for DOH to require reporting of physician-diagnosed cases of AIDS based upon diagnostic criteria from CDC is eliminated. Reports of HIV infection identified on or after the effective date of the DOH's administrative rule requiring reporting are eliminated, which in effect would no longer exempt reports of HIV infection identified before the effective date of such administrative rules. Certain university-based medical research protocols would no longer be exempt from HIV reporting.

The committee substitute eliminates the requirement for DOH to submit an annual report to the Legislature by February 1 of each year relating to all information obtained pursuant to its duties for HIV reporting.

HIV Testing in Pregnant Women and Infants

In addition, the committee substitute alters the requirement that a treating physician or midwife must *offer* HIV testing to pregnant women with the requirement that a treating physician or midwife *routinely test* for HIV unless a pregnant woman specifically opts-out of the HIV test.[15] The committee substitute also adds pregnant women to the current list of exceptions to the requirement of informed consent for HIV testing.[16] Under the new language, the requirement would be that a pregnant woman be informed of the HIV test (and other sexually transmitted disease tests) and her right to refuse the test; if the woman refuses the test, she must provide her objection in writing to be placed in her medical records.

Requirements for an HIV test to be done using a blood sample are removed, and corresponding provisions that require the health care provider to obtain a blood sample from the pregnant woman and to offer HIV testing and counseling are deleted. The committee substitute eliminates provisions that make a medical physician, osteopathic physician, or midwife who treats a pregnant woman who objects to HIV testing immune from liability arising out of or related to the

[15] s. 384.31(1), F.S., provides the current HIV testing practices.

[16] By removing the requirement of informed consent for HIV testing, the committee substitute would be following the recommendations of the Centers for Disease Control to make the consent process more flexible. See "U.S. Public Health Service Recommendations for Human Immunodeficiency Virus Counseling and Voluntary Testing for Pregnant Women," *supra* note 10.

contracting of HIV or AIDS by the child from the mother, to conform to the changes in the section that require routine testing of pregnant women for HIV.[17]

The committee substitute provides an effective date of upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this committee substitute have no impact on municipalities and the counties under the requirements of Article VII, s. 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this committee substitute have no impact on public records or open meetings issues under the requirements of Art. I, s. 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this committee substitute have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Additional costs may be borne by individuals for the required human immunodeficiency virus (HIV) testing of pregnant women under the proposed legislation. The Florida Department of Health (DOH) reports that there are approximately 200,000 live births each year and that 85 to 90 percent of these mothers currently accept offered HIV testing. If an additional 10 percent are tested, an additional 20,000 tests will be performed. DOH estimates that, at an average cost of $5.00 per test, the total cost would be about $100,000 per year.

C. Government Sector Impact:

The Department of Health indicates that the fiscal impact to the department would be minimal.

The Medicaid Program, which is administered by the Agency for Health Care Administration, may have a minimal fiscal impact.

[17] The bill requires routine HIV testing of pregnant women; however, the woman may object in writing and no HIV test will be administered.

VI. Technical Deficiencies:

None.

VII. Related Issues:

"Ryan White CARE Act Amendments" of 1996

Congress addressed the issue of HIV perinatal (mother-to-child) transmission when it passed the "Ryan White CARE Act Amendments" in 1996 (the "CARE Act"). The act authorized funding for states to carry out activities that reduce perinatal transmission of HIV. When the CARE Act was reauthorized in 1996, it designated $10 million in grant funds for states to engage in outreach and other activities that would assist in making HIV counseling and testing available to pregnant women. The legislation also gave priority to states with high HIV seroprevalence rates among childbearing women. However, the funds were never appropriated by Congress.

The CARE Act also required the Secretary of the U.S. Department of Health and Human Services to issue a determination by October 1998 as to whether it had become routine practice of health care in the United States to conduct mandatory HIV testing of all newborns whose mothers have not undergone prenatal HIV testing. If the secretary found that such testing was routine practice, in order to receive Ryan White Title II funding, states were required to demonstrate that they met one of three conditions: 1) mandatory newborn testing, 2) a 95 percent testing rate among pregnant women, or 3) a 50 percent reduction in new AIDS cases resulting from perinatal transmission. However, in January 2000, Secretary Shalala issued a determination that it had not become routine practice to require HIV testing in newborns.[18]

On more general terms, funds from the CARE Act continue to assist Florida in the state's efforts to treat HIV/AIDS patients. The state was recently awarded $116.8 million in federal funding to be used in the ongoing care of these patients. According to the Florida Department of Health, allowing for the use of the most current, accurate system for reporting infection of HIV and AIDS will avail the state of more federal funding for treatment because these funds are awarded based upon the number of reported cases in each state.

[18] See *Federal Register*, *supra* note 9.

VIII. Summary of Amendments:

None.