HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1399 Sexually Transmissible Disease Testing and Reporting
SPONSOR(S): Proctor
TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 186

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care General Committee	8 Y, 0 N	Schiefelbein	Brown-Barrios
2) Health Care Appropriations Committee	8 Y, 4 N	Money	Massengale
3) Health & Families Council		Schiefelbein	Moore
4)			
5)			

SUMMARY ANALYSIS

House Bill 1399 revises the circumstances under which a positive preliminary HIV test result may be released, in accordance with federal requirements. The prohibition on 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 bill authorizes the HIV testing of pregnant women pursuant to section 384.31, Florida Statutes, without meeting the requirements for HIV testing outlined in section 381.004(3)(a), Florida Statutes, which provides specific procedures for obtaining informed consent.

The bill specifies that each person who makes a diagnosis or treats a person with a sexually transmissible disease, and each laboratory that performs a test that concludes with a positive report for a sexually transmissible disease or a result indicative of HIV or AIDS, must report such facts to the Department of Health. 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.

This bill appears to have a minimal fiscal impact.

This bill provides for an effective date of upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

This bill does not appear to implicate any of the House Principles.

B. EFFECT OF PROPOSED CHANGES:

Centers for Disease Control Testing Guidelines

The Centers for Disease Control (CDC) published updated guidelines, *U.S. Public Health Service Recommendations for Human Immunodeficiency Virus Counseling and Voluntary Testing for Pregnant Women,* in 2001. The guidelines were meant for public and private sector service providers who provide health care for pregnant women. In 1999, the CDC convened consultation groups to discuss and comment on the Institute of Medicine (IOM) report published in 1998. The updated CDC guidelines were based on input from these meetings, the IOM report, and public comment on draft guidelines published in fall 2000 in the Federal Register. The updated guidelines were also driven by scientific and programmatic advances in the prevention of prenatal 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.
- 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.
- Emphasizing HIV testing and treatment at the time of labor and delivery for women who have not received prenatal testing and antiretroviral drugs.

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.

The routine HIV testing of pregnant women is a key strategy in the new CDC initiative, *Advancing HIV Prevention: New Strategies for a Changing Epidemic, April 17, 2003*. This initiative is aimed at reducing barriers to early diagnosis, increasing access to quality medical care, and providing ongoing prevention services. The routine testing of pregnant women is a proven public health approach in reducing the incidence and spread of disease.

HIV Testing of Pregnant Women and their Children in Florida

Section 384.31, Florida Statutes, and rules adopted within, require health care providers attending pregnant women for conditions related to pregnancy to test for sexually transmissible diseases as required by Department of Health (DOH) rule 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.[1] 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

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

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. There currently exists no requirement to perform mandatory HIV testing of a newborn child in Florida.

Section 381.004(3), Florida Statute, requires any person who orders an HIV test to obtain the informed consent of the person upon whom the test is being performed, with some exceptions. Under section 381.004(3)(h), Florida Statute, informed consent is not required:

- 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, and the results of any HIV test performed shall be disclosed solely to the victim and the defendant.
- When an HIV test is mandated by court order.
- 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 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 as authorized by law.
- 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.

- For the performance of repeated HIV testing conducted to monitor possible conversion from a significant exposure.

Informed consent for HIV testing must be preceded by an explanation of the right to confidential treatment of information identifying the subject of the test and the results of the test as provided by law. Information must also be provided on the fact that a positive HIV test result will be reported to the county health department with sufficient information to identify the test subject and on the availability and location of sites at which anonymous testing is performed. 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.

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 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 for that department to notify the test subject fulfills this responsibility.

Based on data collected through a survey conducted by 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 two percent. The majority of pregnant women are getting prenatal HIV/AIDS testing although a few women do not receive prenatal care or refuse testing. The Department of Health 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.

House Bill 1399

The bill authorizes the HIV testing of pregnant women pursuant to section 384.31, Florida Statutes, without meeting the requirements for HIV testing outlined in section 381.004(3)(a), Florida Statutes, which provides specific procedures for obtaining informed consent.

The bill amends section 384.25(1)(a), Florida Statutes, and deletes references to the HIV/AIDS Reporting System developed by the CDC of the U.S. Public Health Service to allow the use of a system for reporting of HIV/AIDS, which is developed by the CDC or an equivalent system. Under current law, the CDC's reporting system is used to ensure the confidentiality of persons infected with HIV.

The bill requires DOH to 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. Such rules may include the method and time period for reporting (not to exceed 2 weeks), information to be included in the report, enforcement requirements, and follow-up activities by the department. These changes should allow for early identification of children born to HIV-infected women who may require further evaluation and monitoring. The bill deletes the requirement for DOH to submit a report to the Legislature of physician-diagnosed cases of AIDS based on diagnostic criteria from CDC. DOH confirms that this report is available online.

C. SECTION DIRECTORY:

Section 1. Amends s. 381.004, F.S., relating to HIV testing; revising the circumstances under which a positive preliminary test result may be released to include the results of rapid testing technologies; providing an informed consent exemption.

Section 2. Amends s. 384.25, F.S., relating to reporting requirements of persons diagnosed or treated with a sexually transmissible disease.

Section 3. Amends s. 384.31, F.S., relating to the sexually transmissible disease testing of pregnant women; providing new language regarding the informed consent and right of refusal process.

Section 4. Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The Department of Health estimates the fiscal impact to the department would be minimal. The Agency for Health Care Administration estimates that the bill will not have a significant fiscal impact on HMOs or Medicaid. Medicaid fee-for-service reimbursement for prenatal visits currently includes voluntary counseling and testing of HIV services. Requiring mandatory testing will not impact the prenatal visit reimbursement rate, but may result in a slight overall increase in costs as a result of more pregnant women being tested.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Additional costs may be borne by individuals for the required HIV testing of pregnant women under the bill. DOH reports that there are approximately 200,000 live births each year and that 85 to 90 percent of these mothers currently accept 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 per test, the total cost would be about $100,000 per year.

Any fiscal impact on private insurance providers is not known, but it is expected to be minimal.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Department of Health has existing rulemaking authority.

C. DRAFTING ISSUES OR OTHER COMMENTS:

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.

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 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.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES