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: Health Care Committee

BILL:	CS/SB 186
SPONSOR:	Health Care Committee and Senator Lynn
SUBJECT:	HIV Testing and Reporting
DATE:	February 24, 2005 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HE	**Fav/CS**
2.			JU	
3.			HA	
4.				
5.				
6.				

I. Summary:

The bill revises the circumstances under which a positive preliminary HIV test result may be released, to include the results of rapid testing technologies. The results of rapid testing technologies must be considered preliminary and may be released in accordance with the manufacturer's instructions as approved by the federal Food and Drug Administration. 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 s. 384.31, F.S., without meeting the requirements for HIV testing outlined in s. 381.004(3)(a), F.S., which provides specific procedures for obtaining informed consent.

The bill clarifies that each person who makes a diagnosis of 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 as may be required by the Department of Health (DOH) by rule, within a time period as specified by rule of the department, but in no case to 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.

The Department of Health 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 required reporting of physician diagnosed cases of AIDS based upon diagnostic criteria from the Centers for Disease Control and Prevention is eliminated. Reports of HIV infection identified on or after the effective date of DOH's administrative rule which required 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 bill eliminates requirements 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.

The bill revises statutory requirements relating to serological testing of pregnant women, to require every medical physician, osteopathic physician, or midwife attending a pregnant woman to cause the woman to be tested for sexually transmissible diseases, including HIV, as required by rule of DOH. Requirements for the tests to be done with a blood sample are eliminated. The pregnant woman must be notified that the tests for sexually transmissible diseases, including HIV, will be conducted, and of her right to refuse testing. If a pregnant woman objects to testing, a written statement of objection, signed by the woman, must be placed in the woman's medical record and testing may not occur. 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 bill eliminates requirements that make a medical physician, osteopathic physician, or midwife who attends a pregnant woman who objects to HIV testing immune from liability arising out of or related to the contracting of HIV infection or AIDS by the child from the mother, to conform to the changes in the section that require all pregnant women to be tested for HIV.

This bill amends sections 381.004, 384.25, and 384.31, Florida Statutes.

II. Present Situation:

HIV/AIDS

AIDS is the acronym for acquired immune deficiency syndrome. It 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. 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 sickness. 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.

HIV Testing

There are two broad categories of HIV tests: 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. They are highly sensitive and result in few false negatives (i.e., most infected people test positive). 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. The most common screening tests are enzyme-linked immunosorbent assay (ELISA) tests. These tests measure antibodies to HIV. Different types of ELISA tests are available. Most require serum specimens, though there are urine and oral tests as well. A rapid HIV test is a test that usually produces results in up to 107 minutes. In comparison, results from the commonly used HIV-antibody screening test, the ELISA, are not available for one to two weeks. The availability of these tests may differ from one place to another. The rapid HIV blood tests are considered to be just as accurate as the ELISA. As is true for all screening tests, a positive test result must be confirmed with an additional specific test before a diagnosis of infection can be given.

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). The Western blot test is considered by most to be the "gold standard" for confirmation of positive screening test results. This test also measures antibodies to HIV, but it is more specific than screening tests and false positives are minimal. The Western blot assay is a method in which individual proteins of an HIV-1 lysate are separated according to size by polyacrylamide gel electrophoresis. Serum is added and any existing HIV antibodies will bind to the HIV antigens. Finally, a chemical is added that changes color when it comes into contact with the protein-antibody-enzyme layers. This multi-layer process is similar to that of the ELISA test. However, the final result is a unique series of shaded bands. Positive and negative control serum specimens are run simultaneously to allow identification of viral proteins. Positive results from ELISA or rapid tests are commonly confirmed using a Western blot test.

Florida law[1] provides that no 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 except preliminary test results may be released to: 1) licensed physicians or the medical or nonmedical personnel subject to significant exposures or 2) health care providers and to the person tested when decisions about medical care or treatment of, or recommendation to, the person tested and, in the case of a pregnant woman, when care, treatment, or recommendations regarding her newborn, cannot await the results of confirmatory testing. Justification for the use of preliminary test results must be documented in the medical record by the health care provider who ordered the test. 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 not authorized. Corroborating or confirmatory testing must be conducted as followup to a positive preliminary test. Results must be communicated to the patient according to the statute regardless of the outcome.

In Florida, the number of newly diagnosed AIDS cases rose last year by 24 percent for a total of 5,816 cases. The number of newly-infected HIV cases dropped by 3 percent in 2004. During 2004, AIDS cases rose higher in Broward County (1,010) and Miami-Dade County (1,349) relative to the other areas in the state. Officials at the Florida Department of Health note that the

[1] Section 381.004(3)(d), F.S.

increase in AIDS cases may be attributed in part to the large volume of publicly-funded HIV testing that has occurred over the past 3 years.

HIV and AIDS Prevalence in Women and Infants

The number of women with HIV and AIDS is steadily rising. Women accounted for 19 percent of reported AIDS cases in 1992 and 27 percent of AIDS cases in 2003. Most women with HIV/AIDS in the U.S. reside in the Northeast and the South. The highest numbers of cases were first observed in the Northeast, but the South has reported the greatest increases in recent years. African-American and Hispanic women are disproportionately affected by the epidemic and account for 80 percent of AIDS cases reported in the U.S. for women in 1999. HIV infection is now the third leading cause of death among women ages 25 to 44 and the leading cause of death among African-American women in this age group.

Women now account for 36 percent of cumulative reported HIV cases in Florida. Of the 21,618 female AIDS cases reported through 2003, 72 percent were among African-Americans, 17 percent were among Caucasians, 10 percent were among Hispanics and 1 percent other.

More than 15,000 HIV-infected children have been born to HIV-infected mothers in the U.S. since the epidemic began. The CDC estimates that approximately 7,000 HIV-infected women give birth and as many as 400 babies nationwide continue to be born with the HIV infection each year.

In Florida, the number of newly diagnosed AIDS cases in children has declined 92 percent since 1992. In 2003, Florida was in second place behind New York in the U.S. with the highest number of pediatric AIDS cases. Perinatal transmission (mother-to-child) accounts for 96 percent of pediatric AIDS cases reported in Florida. Babies can get HIV from their mothers during the pregnancy, during labor, or through breastfeeding. These transmissions have accounted for 91 percent of all AIDS cases reported among U.S. children.

Reducing Perinatal Transmission of HIV/AIDS

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 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 in the U.S.

Since the 1994 study, the availability of increasingly effective antiretroviral drugs for both the prevention of perinatal HIV transmission and maternal treatment has resulted in a greater emphasis on prenatal HIV testing and substantial increases in prenatal testing rates. In 2000, preliminary data indicated that 766 (93 percent) of 824 HIV-infected women in 25 states knew their HIV status before delivery (CDC, unpublished data, 2002). However, an estimated 280-370 perinatal HIV transmissions continue to occur in the U.S. each year.[2] The primary strategy to prevent perinatal HIV transmission is to maximize prenatal HIV testing of pregnant women.

[2] *Revised Recommendations for HIV Screening of Pregnant Women*. 2001. Centers for Disease Control and Prevention.

The results of the 1994 trial led the Public Health Service to develop guidelines for counseling and testing of pregnant women for HIV. The 1995 Public Health Service guidelines called for counseling of all pregnant women on the risk of AIDS and the benefits of HIV testing. Since then, most states have adopted policies or enacted legislation based on the Public Health Service guidelines.

Widespread implementation of the Public Health Service guidelines for universal counseling and testing and perinatal use of AZT has sharply reduced transmission risk and the number of perinatally acquired HIV infections.[3] A number of studies between 1995 and 2000 reported declining transmission rates due to drug therapies[4] and also in combination with cesarean sections.[5]

An analysis of U.S. perinatal AIDS surveillance data[6] reported through June 2000 showed a marked decline in the number of perinatal AIDS cases; this decline was temporally associated with increasing AZT use among pregnant women who knew their HIV status.[7] To more accurately monitor trends in perinatal HIV transmission and the implementation and influence of perinatal prevention programs (including HIV counseling and testing recommendations), the CDC, the Council of State and Territorial Epidemiologists, and the American Academy of Pediatrics recommended national reporting of perinatal HIV contact and HIV infection to help identify and target populations where opportunities for prevention are missed.[8]

Despite the declines, cases of perinatal HIV transmission continue to occur. It is believed that this is largely because of missed opportunities for prevention, particularly among women who lack prenatal care or who are not being offered voluntary HIV counseling and testing during pregnancy. The estimated 280-370 infants born with HIV infection each year represent populations in which prevention efforts are impeded by lack of timely HIV testing and treatment of pregnant women. For example, of 329 children with perinatally acquired AIDS born during 1995-1996, a total of 112 (34 percent) were born to mothers not tested for HIV before the child's birth and 67 (20 percent) to mothers for whom the time of testing was not known.[9]

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[3] Lindegren ML, Byers RH, Thomas P, et al. 1999. “Trends in perinatal transmission of HIV/AIDS in the United States.” *Journal of the American Medical Association* 282:531-8.

[4] Mofenson LM, Lambert JS, Stiehm ER, et al. 1999. “Risk factors for perinatal transmission of human immunodeficiency virus type 1 in women treated with zidovudine.” *New England Journal of Medicine.* 341:385-93.

Wade NA, Birkhead GS, Warren BL, et al. “Abbreviated regimens of zidovudine prophylaxis and perinatal transmission of the human immunodeficiency virus.” *New England Journal of Medicine*. 339:1409-14.

[5] The International Perinatal HIV Group. “The mode of delivery and the risk of vertical transmission of human immunodeficiency virus type 1.” *New England Journal of Medicine*. 340:977-87.

[6] Centers for Disease Control and Prevention. 2000. “U.S. HIV and AIDS cases reported through June 2000: midyear edition.” *HIVAIDS Surveillance Report.* 12(1):1-41.

[7] Lindegren ML, Byers RH, Thomas P, et al. 1999. “Trends in perinatal transmission of HIV/AIDS in the United States.” *Journal of the American Medical Association* 282:531-8.

[8] Centers for Disease Control and Prevention. 1999. “Prenatal discussion of HIV testing and maternal HIV testing--14 states, 1996-1997.” *Morbidity and Mortality Weekly Report*. 48:401-4.

Anonymous. 1998. “Surveillance of pediatric HIV infection. American Academy of Pediatrics.” *Pediatrics* 101:315-9.

[9] Lindegren ML, Byers RH, Thomas P, et al. 1999. “Trends in perinatal transmission of HIV/AIDS in the United States.” *Journal of the American Medical Association* 282:531-8.

Congress also addressed the issue of HIV perinatal transmission in the Ryan White CARE Act Amendments in 1996. The Ryan White CARE 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 in the provision of health care in the U.S. to conduct mandatory HIV testing of all newborns whose mothers have not undergone prenatal HIV testing. If the secretary did find 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. The secretary concluded that overall efforts to reduce perinatal transmission had been successful, and the best way to further reduce HIV transmission was to increase the number of women who access prenatal care (Federal Register/Vol. 65, No. 13/January 20, 2000/Notices).

The Institute of Medicine (IOM) extensively reviewed existing research and opinion on preventing mother-to-child transmission of HIV and recommended the routine HIV testing of pregnant women in its report to Congress in 1998.[10] The IOM reported that testing all pregnant women for the HIV virus could reduce the number of babies born with HIV. The report further recommended that HIV testing become part of routine prenatal care. However, according to the IOM, 15 percent of HIV-infected women do not receive prenatal care.

The National Institutes of Health released data in 2002 showing that when a woman delivers her baby by caesarean section, the rate of HIV transmission drops by 50 percent.

The 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 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 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;

[10] Institute of Medicine, National Research Council. 1999. Reducing the odds: preventing perinatal transmission of HIV in the United States. Washington, DC: National Academy Press.

- 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.

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

Section 381.004(3), F.S., 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 s. 381.004(3)(h), F.S., 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;

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

- 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; or
- 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 vast majority of pregnant women are getting tested prenatally, 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.

III. Effect of Proposed Changes:

Section 1. Amends s. 381.004, F.S., relating to 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 and may be released in accordance with the manufacturer’s instructions as approved by the federal Food and Drug Administration. A 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 bill authorizes the HIV testing of pregnant women pursuant to s. 384.31, F.S., without meeting the requirements for HIV testing outlined in s. 381.004(3)(a), F.S., which provides specific procedures for obtaining informed consent.

Section 2. Amends s. 384.25, F.S., to clarify that each person who makes a diagnosis of 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 as may be required by DOH by rule, within a time period as specified by rule of the department, but in no case to 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 Department of Health 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 2 weeks, information to be included in the report, requirements for enforcement, and followup activities by DOH.

The requirement 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 Department of Health's administrative rule which required 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 bill 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.

Section 3. Amends s. 384.31, F.S., relating to the serological testing of pregnant women, to require every medical physician, osteopathic physician, or midwife attending a pregnant woman to cause the woman to be tested for sexually transmissible diseases, including HIV, as required by rule of DOH. Requirements for the tests to be done with a blood sample are removed. The pregnant woman must be notified that the tests for sexually transmissible diseases, including HIV, will be conducted, and of her right to refuse testing. If a pregnant woman objects to testing, a written statement of objection, signed by the woman, must be placed in the woman's medical record and the testing may not occur. 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 bill eliminates requirements that make a medical physician, osteopathic physician, or midwife who attends a pregnant woman who objects to HIV testing immune from liability arising out of or related to the contracting of HIV infection or AIDS by the child from the mother, to conform to the changes in the section that require all pregnant women to be tested for HIV.

Section 4. Provides an effective date upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill 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 bill 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 bill 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 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 the offer of 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.

VI. Technical Deficiencies:

On page 13, line 5, the term “serological” in the catchline of s. 384.31, F.S., may be deleted because the bill amends s. 384.31, F.S., to eliminate requirements for the tests for sexually transmissible diseases of pregnant women to be done with a blood sample. Suchs test may include serological tests but is not limited to such tests. “Serological”or “serology” refers to laboratory tests of the blood used to determine the amount of a specific antibody, measure the effectiveness of medical treatment, and detect certain kinds of microorganisms and other infectious agents.[12]

VII. Related Issues:

None.

[12] *American Medical Association Complete Medical Encyclopedia* (2003).

VIII. Summary of Amendments:

None.