HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 725 HIV Infection Testing of Newborn Infants
SPONSOR(S): Cusack
TIED BILLS: None. **IDEN./SIM. BILLS:** CS/SB 144 (i)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Services (Sub)		Bench	Collins
2) Health Care			
3) Health Appropriations (Sub)			
4) Appropriations			
5)			

SUMMARY ANALYSIS

This bill requires all newborn infants to receive human immunodeficiency virus (HIV) testing, at the time of delivery, unless the parent or legal guardian makes a written objection based on religious beliefs. If the HIV test result is positive, the bill requires that all reasonable efforts be made to inform the mother of these results. It requires the mother's notification to include information on preventing HIV transmission and the availability of medical and support services for the newborn.

HIV may cause Acquired Immune Deficiency Syndrome (AIDS), and, if a person gets infected with HIV, her body will create antibodies in an attempt to fight off the virus. HIV Blood tests look for these antibodies. "The virus that causes AIDS, HIV, can be transmitted from an infected mother to her newborn child. Without treatment, about 20% of babies of infected mothers get infected." (AIDS.org: Pregnancy and HIV). 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. Over time, the newborns will both duplicate the mother's antibodies and acquire HIV themselves, or their mother's antibodies will slowly die off.

When newborns are tested, they test positive due to the presence of their mother's antibodies. The test will not determine whether the newborn itself has HIV. Therefore, HIV antibodies belonging to the newborns generally do not show up until 2 to 3 months after birth. (New Mexico AIDS InfoNet Dec. 27, 2003).

In Florida, the number of newly diagnosed AIDS cases in children has declined 92 percent since 1992. However, in 2002, Florida led 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.

This bill takes effect July 1, 2004.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

1. Reduce government?	Yes[]	No[]	N/A[X]
2. Lower taxes?	Yes[]	No[]	N/A[X]
3. Expand individual freedom?	Yes[]	No[]	N/A[X]
4. Increase personal responsibility?	Yes[]	No[X]	N/A[]
5. Empower families?	Yes[]	No[]	N/A[X]

For any principle that received a "no" above, please explain:

This bill places the burden of an infant's HIV testing on the medical personnel delivering the newborn.

B. EFFECT OF PROPOSED CHANGES:

HIV and 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.

The Centers for Disease Control and Prevention's (CDC) definition of AIDS has changed several times since the beginning of the AIDS epidemic. The changes have taken place as scientists learned more about the disease and thus were able to include more people with HIV who develop symptoms or immunodeficiency. The current AIDS definition includes the following conditions: 1) HIV positive and 2) CD4 (T-cell) count below 200 or presence of one or more opportunistic infections.

The HIV virus may be passed from one person to another when infected blood, semen, or vaginal secretions come in contact with an uninfected person's broken skin or mucous membranes. In addition, an infected pregnant woman can pass HIV to her baby during pregnancy or delivery, as well as through breast-feeding.

Two types of HIV are currently recognized: HIV-1 and HIV-2. Worldwide, the predominant virus is HIV-1. HIV-2 is only prevalent in Western Africa. Both types of virus are transmitted by sexual contact, through blood, and from mother to child, and they appear to cause clinically indistinguishable AIDS. Both HIV-1 and HIV-2 cause the body to produce antibodies within three to six months, although the period between initial infection and illness may be longer in the case of HIV-2.

Testing for HIV and AIDS

When HIV enters the body, it begins to attack certain white blood cells called T4 lymphocyte cells. The immune system then produces antibodies to fight off the infection. Although these antibodies are ineffective in wiping out HIV, their presence is used to confirm HIV infection. Therefore, the presence of antibodies to HIV result from HIV infection. HIV tests look for the presence of HIV antibodies; they do not test for the virus itself.[1]

[1] Centers for Disease Control and Prevention. 2003. National Testing Resources.

Voluntary testing can be obtained in medical care settings such as physician offices, hospitals, managed care organizations, and public health clinics, as well as through home-test kits. Although precise data on the total number of tests performed in the U.S. are unavailable, surveys have found that one third of adults have been tested for HIV, including those tested through blood donation. Approximately 24.6 million persons are tested in the U.S. during a 12-month period, primarily in private settings.[2]

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.

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 28 percent of AIDS cases in 2002. 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 38 percent of cumulative reported HIV cases in Florida. Of the 20,196 female AIDS cases reported through 2002, 72 percent were among African-Americans, 18 percent were among Caucasians and 10 percent were among Hispanics.

[2] Centers for Disease Control and Prevention. 2001. *HIV Counseling and Testing in Publicly Funded Sites Annual Report 1997 and 1998*. Atlanta (GA): Centers for Disease Control and Prevention.

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 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. However, in 2002, Florida led 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.[3] The primary strategy to prevent perinatal HIV transmission is to maximize prenatal HIV testing of pregnant women.

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.[4] A number of studies between 1995 and 2000 reported declining transmission rates due to drug therapies[5] and also in combination with cesarean sections.[6]

An analysis of U.S. perinatal AIDS surveillance data[7] 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.[8] 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

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

[4] 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.

[5] 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; and 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.

[6] 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.

[7] 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.

[8] 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.

HIV contact and HIV infection to help identify and target populations where opportunities for prevention are missed.[9]

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.[10]

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.[11] 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

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[9] 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.

[10] 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.

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

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;
- 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

Currently, Florida law requires that all pregnant women be offered HIV testing at their first prenatal visit and again at 28 to 32 weeks gestation. The health care provider attending the pregnant woman is required to counsel the woman to be tested for HIV, including providing information on 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, is immune from liability if the child contracts HIV/AIDS from the mother. There currently exists no requirement to perform mandatory HIV testing of a newborn child in Florida.

Based on data collected through a survey conducted by the Department of Health (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 proportion 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.

About 20 babies are born HIV-infected in Florida each year. Testing newborns whose mother's status is unknown could identify these infected newborns. However, antibody testing of newborns whose mother's HIV status is known provides no additional information on the status of the newborn. All newborns born to HIV infected mothers will test antibody positive to HIV since they all are carrying their mother's antibodies. These newborns would have to have a confirmatory test done at a later date and there is no guarantee that the mother will have the child tested.

Currently, no HIV testing exist that can conclusively determine whether or not the newborn has HIV at the time of delivery.

Mandatory HIV Testing

Proposals for mandatory HIV testing of specific populations have been met with strong resistance. To date, the only state legislatures that have enacted mandatory programs that impose HIV tests without consent have been New York and Connecticut. The state of New York has required mandatory HIV counseling and testing of newborns and voluntary testing of pregnant women since 1997. The measure was controversial, as many critics asserted that mandatory detection of passively acquired antibodies in the baby would essentially be mandatory HIV testing of pregnant women. New York and Connecticut do provide an exemption to the mandatory testing of the newborns on the basis of religious tenets and practices.

Florida Birth Statistics

Vital statistics from the Department of Health show that there were a total of 205,580 live births in Florida in 2002. The table below reports the births by place of delivery and attendant for 2002.

Hospital			Birthing Center			Other Named Place	Unknown
Physician	Midwife	Other	Physician	Midwife	Other		
179,304	22,849	734	3	785	20	1094	791

Source: *Florida Vital Statistics Annual Report,* 2002. Florida Department of Health.

C. SECTION DIRECTORY:

Section 1. Amends section 384.31, F.S., to require all newborns to be tested at the time of delivery for HIV infection. All reasonable efforts must then be made to notify the mother of her newborn's test result. For infants who test positive for HIV, information must be provided to the mother on the availability of appropriate medical and support services. Information must also be provided on ways to prevent the transmission of HIV.

This section provides an exemption to the HIV testing of newborns if the parent or legal guardian objects in writing to the testing on the basis of religious tenets and practices.

Section 2. Provides that the bill shall take effect July 1, 2004.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

This is a new screening requirement for hospitals, birth centers, and home birth providers to screen newborns at the time of delivery. Since most births occur in a hospital, the impact is mainly on hospital providers; it adds medical and administrative functions for the hospital provider.

The mandatory HIV testing of all newborns will have an unknown fiscal impact on private citizens or their insurance carriers depending on who will be required to pay for this additional test.

D. FISCAL COMMENTS:

Agency for Health Care Administration
This bill does not significantly affect the Agency except, there may be the potential for a small increase in the Medicaid per diem rate of hospital providers. HIV screening of newborns would be covered in the all-inclusive per diem rate paid by Medicaid to hospital providers. Hospital providers would include any additional costs for the HIV screening in their cost report. This could potentially increase the hospital's Medicaid per diem rate since per diem rates are based on providers' cost.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or to 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:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The language appears to conflict with s. 381.004(3)(b), F.S., which requires informed consent prior to HIV testing. Under this section, a legal guardian would have to give informed consent for the newborn to be tested for HIV infection.

The testing of infants whose mothers have no risk factors for HIV/AIDS, receive prenatal care and counseling, or have been tested and found not to be infected with HIV/AIDS seems unnecessary. Given the small number of newborns who test positive each year, (37 in 2002) compared to the total number of live births (205,580 in 2002), many children will be tested who are never at risk.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES