SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

Date:	April 7, 1998	Revised:		
Subject: Human Immunodeficiend		ncy Virus (HIV) Testing		
	Analyst	Staff Director	Reference	Action
1. Will 2.		Wilson	HC JU WM	Favorable/CS

I. Summary:

Committee Substitute for Senate Bill 2262 revises various provisions of statute relating to human immunodeficiency virus (HIV) infection and acquired immune deficiency syndrome (AIDS). The bill expands HIV/AIDS course requirements for employees and clients of specific health care facilities and for certain licensed health care professionals. The bill addresses: the streamlining of requirements relating to HIV testing, specifically relating to pre-and post-test counseling requirements; the sharing of preliminary test results under certain circumstances; disclosure of test results; informed consent for testing; confidentiality of test results; release of test results; significant exposure situations involving medical and non-medical personnel; registration of test sites with the Department of Health; and the department's model HIV testing protocol.

The bill amends sections 381.0035(1), 381.004(2)-(5) and (8), 384.25, and 455.604(1), Florida Statutes.

II. Present Situation:

Acquired Immune Deficiency Syndrome (AIDS) is a physical disorder that results in the loss of cell-mediated immunity in affected persons. It is caused by a retrovirus known as human immunodeficiency virus (HIV). The virus attacks the body's immune system, leaving an infected person vulnerable to a variety of life-threatening infections and tumors. Recent studies have shown an average incubation period of 10 years from HIV infection to development of clinical AIDS.

The first case of AIDS was diagnosed in the United States in 1981. As of June 30, 1997, 612,078 cases have been reported nationwide. Florida ranks third behind New York and California in the number of AIDS cases. In Florida, the cumulative number of reported cases of AIDS was 65,016

as of December 31, 1997. Of these total reported cases in Florida, 37,059, or 57 percent, have died.

Although 56 percent of the adult cases of AIDS in Florida have been reported from the southeastern counties of Dade, Broward, Palm Beach, and Monroe, all of Florida's 67 counties have reported cases of AIDS. State data show that the HIV/AIDS epidemic has disproportionately affected minorities. Although blacks and Hispanics compose only 26 percent of Florida's population, they represent 59 percent of all reported AIDS cases in the state. Florida's AIDS case mix differs in significant ways from the national case mix. Nine percent of the nationwide cases in adults have been heterosexually transmitted compared with 15 percent in Florida. In addition, women represent 20 percent of the total number of adult cases in Florida compared to 15 percent nationally.

The most widely used blood tests to detect HIV infection do not detect the virus particles themselves. Rather, the tests identify proteins called antibodies, which are produced by the body's immune system in response to infection with the virus. Those who test positive for HIV antibodies are considered to be infected with the virus and are capable of transmitting it to others. Possible modes of transmission of the virus include: sexual activity; by direct exposure to blood; and from an infected mother to her offspring during pregnancy, childbirth, or breast feeding. Public fear of contagion from casual contact is not supported by any scientific evidence.

To check a person for HIV antibodies, a screening blood test known as the ELISA is performed. If the ELISA test result is positive, supplemental testing must be performed before the test is confirmed as positive. Supplemental testing is not required to confirm a negative test result, however, because it can take from 2 weeks to 6 months from the time of infection for an infected person's body to build up sufficient antibodies to be detected by the ELISA. It is recommended that, in addition to baseline testing at the time of exposure, a person receive HIV testing six months after the date of the last possible exposure. More recently, tests known as Single-Use Diagnostic System (SUDS), have been developed which allow for more rapid HIV test results, but without confirmatory analysis of true positive test results.

Florida adopted comprehensive AIDS and HIV legislative measures in 1988, and these measures have been revisited several times since that time. Section 381.004, F.S., relating to HIV testing, provides legislative intent; definitions of relevant terms; testing, informed consent, test results, counseling, and confidentiality requirements; county health department network of voluntary test sites; other testing site requirements; penalties; exemptions; model protocol for HIV testing; fees; rules; and the prohibition regarding testing as a condition of treatment or admission. Other statutory provisions address education requirements for a variety of professions and for employees and residents in specific types of health care and residential facilities, as well as public education responsibilities for the Department of Health.

Since the adoption of the 1988 omnibus AIDS act, the level of public knowledge regarding HIV/ AIDS, including how the virus is transmitted and how transmission can be prevented, has greatly increased. In addition, new and improved treatments for HIV/AIDS are now available, resulting in a decrease in the number of HIV-related deaths for the first time since the beginning of the epidemic. HIV testing procedures continue to evolve and improve. These and other changes require that HIV/AIDS-related laws be revised to meet the changing challenges of the HIV/AIDS epidemic.

III. Effect of Proposed Changes:

Section 1. Amends s. 381.0035(1), F.S., relating to HIV and AIDS course requirements for employees and clients of certain health care facilities and residential treatment facilities, to add to the required elements of such education instruction regarding protocols and procedures applicable to HIV counseling and testing; reporting; the offering of HIV testing to pregnant women; and partner notification issues pursuant to ss. 381.004 and 384.25, F.S.

Section 2. Amends s. 381.004(2)-(5) and (8), F.S., relating to testing for HIV, to incorporate the following revisions:

Subsection (2), relating to definitions, is amended to add a definition for "preliminary HIV test," which means an antibody screening test, such as the enzyme-linked immunosorbent assays (ELISAs) or the Single-Use Diagnostic System (SUDS).

Subsection (3), relating to HIV testing, counseling, informed consent, test results, and confidentiality, is amended to:

Modify the information-sharing requirements that are part of the pre-test, informed consent requirements to specifically require informing the test subject that a positive test result will be reported to the county health department with sufficient information to identify the test subject and about the availability and location of sites where anonymous testing is performed. There is also a restatement of an existing requirement that county health departments maintain a list of all sites at which anonymous testing is performed, including the locations, phone numbers, and hours of operation of the sites.

Add to the existing exceptions to informed consent requirements a provision for a situation in which the person to be tested is incapacitated.

Delete specific requirements as to the information that must be shared with a person to be tested for HIV and the requirement that a follow-up visit is required for sharing HIV test results. Instead, the person ordering the test or that person's designee is required to ensure that all reasonable efforts are made to notify the test subject of test results. Notification of a person with a positive test result must include information regarding appropriate medical and support services, partner notification, and prevention of transmission. Notification of a person with a negative test result must include, as appropriate, information on prevention of transmission. When testing occurs at a hospital emergency department, detention facility, or other facility and the test subject is released before being notified of a positive test result, informing the county health department for the department to notify the test subject fulfills this responsibility.

Authorize the release of preliminary HIV test results to nonmedical personnel subject to a significant exposure.

Authorize the release of preliminary HIV test results to health care providers and to the person tested when decisions about medical care or treatment of the person tested cannot await the results of confirmatory testing. Positive preliminary HIV test results must not be characterized to the patient as diagnosis of HIV infection. Justification for the use of the preliminary test result must be documented in the medical record by the health care provider who ordered the test. Preliminary test results may not be released for the purpose of routine identification of HIV-infected individuals or when HIV testing is incidental to preliminary diagnosis or care of the patient. Corroborating or confirmatory testing must be conducted as follow-up to a positive preliminary test. Results must be communicated to the test subject according to the statute regarding the test outcome.

Delete the existing provision requiring face-to-face counseling for the purpose of sharing an HIV test result, and deleting existing provisions regarding the sharing of HIV test results by phone for home HIV test kits.

Modify the list of exceptions regarding the prohibition on the sharing of HIV test results to allow results to be shared as follows:

Authorizes the sharing of HIV test results with those employees of residential facilities or of community-based care programs which care for developmentally disabled persons pursuant to ch. 393, F.S., who are directly involved in the care, control, or custody of the test subject and who have a need to know such information;

A health care provider involved in the delivery of a child can note the mother's HIV test results in the child's medical records;

Results can be shared with nonmedical personnel who are the subject of a significant exposure; and

The medical examiner is required to disclose positive HIV test results to the department in accordance with rules for reporting the spread of disease.

Require reporting of positive test results to the department when testing is performed in a medical emergency as part of a medical work-up of a patient.

Require reporting of positive test results to the department when testing is performed as part of treatment of an acute illness, when such reporting would not be detrimental to the patient.

Provide a process whereby a court proceeding can take place in those situations when the source of a significant exposure refuses to allow a sample of blood to be taken for HIV testing purposes. A physician's documentation that a significant exposure has occurred and that a test result is necessary to determine an appropriate course of treatment shall serve as probable cause in such instances. The results of tests so ordered shall be released to the source patient and to the exposed person.

Provide an exception to the informed consent requirements for:

An HIV test by the medical examiner upon a deceased individual who is the source of a significant exposure that occurs during treatment for a medical emergency;

An HIV test conducted to monitor the clinical progress of a patient previously diagnosed to be HIV positive; and

Repeated HIV testing conducted to monitor possible conversion from a significant exposure.

Subsection (4), relating to the county health department network of voluntary HIV testing programs, to incorporate a technical revision.

Subsection (5), relating to HIV testing entities and their registration with the Department of Health, to: delete an out-dated reference to AIDS-related complex; require HIV testing entities to re-register with the department each year; require such entities to provide *the opportunity for* pre-test counseling; and authorize the department to deny, suspend, or revoke the registration of an entity that violates this section or rules adopted under this section, that constitutes an emergency affecting the immediate health, safety, or welfare of test subjects.

Subsection (8), relating to the department's model protocol for HIV counseling and testing, to require the department to develop the protocol by rule, and to specify the inclusion of criteria for evaluating a patient's risk for HIV infection and for offering HIV testing, on a voluntary basis, as a routine part of primary health care or admission to a health care facility. The department is to ensure that the protocols developed under this section are made available to health care providers.

Section 3. Amends s. 384.25, F.S., relating to sexually transmissible disease reporting requirements, to delete language relating to protocols for reporting, including pretest counseling content.

Section 4. Amends s. 455.604(1), F.S., relating to HIV and AIDS instruction requirements for specified health care professionals, to add course requirements relating to protocols and procedures applicable to HIV counseling and testing; reporting; the offering of HIV testing to pregnant women; and partner notification issues pursuant to ss. 381.004 and 384.25, F.S.

Section 5. Provides a July 1, 1998, effective date.

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, Section 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 Article I, Subsections 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:

Those private sector health care providers who order HIV tests will be able to do so with less-burdensome requirements relating to pre- and post-test counseling than those currently required. This may result in more providers being willing to order such tests for their patients.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill reduces the pre-test counseling requirements that are currently imposed in law. The change is proposed under the theory that the testing requirements will be less burdensome and will result in more medical providers offering HIV tests to their patients as a routine part of care. On its face, this seems like a well-intended modification. Recent reviews by the Centers for Disease Control and Prevention indicate that nearly one in three people who undergo the test for the virus that causes AIDS in voluntary test programs never collect their test results. The agency said 26 percent of those tested positive and 33 percent of those who tested negative never bothered to return for their test results. A major contributing factor for the lack of follow-up is the period of time before test results are available. This bill, by curtailing pre-test counseling requirements, could result in patients who seek testing missing a valuable, and perhaps their only, opportunity for the receipt of crucial HIV education information.

VIII. Amendments:

None.

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.