

STORAGE NAME: h3715.hcs

DATE: March 2, 1998

**HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH CARE SERVICES
BILL RESEARCH & ECONOMIC IMPACT STATEMENT**

BILL #: HB 3715

RELATING TO: Acquired Immune Deficiency Syndrome (AIDS)

SPONSOR(S): Representatives Frankel and Brooks

COMPANION BILL(S): SB 2262 (similar)

ORIGINATING COMMITTEE(S)/COMMITTEE(S) OF REFERENCE:

- (1) HEALTH CARE SERVICES
 - (2) GOVERNMENTAL RULES & REGULATIONS
 - (3) FINANCE & TAXATION
 - (4) HEALTH & HUMAN SERVICES APPROPRIATIONS
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I. SUMMARY:

Since the Omnibus AIDS Act was enacted in 1988, public knowledge regarding prevention and transmission of HIV/AIDS has greatly increased, and new treatments are now available. According to the Department of Health, these changes require that HIV/AIDS-related laws be revised to meet the changing needs of the HIV/AIDS epidemic. HB 3715 makes the following revisions to the current law related to HIV/AIDS:

- Expands HIV/AIDS education requirements for employees and clients of certain health care facilities, as well as funeral directors and embalmers;
- Provides for sterile needle and syringe exchange projects with emphasis on education and referrals for drug treatment to be included in the department's education program;
- Provides a definition of preliminary HIV tests and allows for the release of preliminary results in extreme situations;
- Creates additional exceptions in which HIV information can be released without the consent of the test subject. These exceptions include 1) employees of residential facilities and community-based programs who are directly involved in the care, control and custody of the developmentally disabled, 2) health care providers involved in the delivery of a child to note the mother's HIV test results in the child's medical record, 3) non-medical personnel who experience a significant exposure while providing care in a medical emergency. Medical examiners would also be allowed to report positive HIV test results to the county health department;
- Removes the requirements that pretest counseling be given at the time the HIV test is ordered and that the test subject who test positive be offered immediate opportunity for individual, face-to-face counseling;
- Requires that persons ordering an HIV test make all reasonable efforts to notify the test subject of a positive result. Notification must include information that is needed by the test subject to obtain appropriate medical services and prevent the spread of HIV;
- Authorizes testing without informed consent, in the event of a significant exposure to medical or non-medical personnel who provide emergency care to a victim who dies and to monitor a previously diagnosed HIV-possible patient's clinical progress;
- Requires the re-registration of HIV testing sites and gives DOH authority to inspect and set fees for re-registration;
- Adds requirements for DOH's model protocol for HIV testing and counseling; and
- Deletes language addressing the release of HIV information to school superintendents.

The fiscal impact of this legislation involves the fees associated with the re-registration of HIV testing sites. According to the Department of Health, the amount will be minimal.

II. SUBSTANTIVE RESEARCH:

A. PRESENT SITUATION:

HIV/AIDS in Florida

Over 62,000 AIDS cases have been reported statewide in Florida. Although Florida has seen a decrease in the the rate of reported AIDS cases and in mortality rates due to HIV infection, HIV/AIDS is still Florida's leading cause of death for white male, non-white males and nonwhite females ages 25-44. According to DOH the estimated number of Floridians living with HIV infection range from 65,000-100,000.

HIV/AIDS surveillance activities include coordination of HIV/AIDS casefinding and investigation, maintenance of the confidential HIV/AIDS case registry, and the design and conduct of special HIV/AIDS epidemiologic studies. These activities allow DOH to monitor and characterize AIDS trends and to clarify the distribution of HIV infection in special populations or selected groups in order to develop education, prevention and patient care programs.

DOH's HIV prevention strategies include education, counseling, outreach, prevention case management, referral, and peer interventions through programs in 32 county health departments and 28 community-based organizations. Sixty-five HIV prevention projects have been implemented statewide. Using state AIDS funds the department created the Florida AIDS Hotline for English, Spanish, and Haitian Creole speaking Floridians, which receives more the 38,000 calls per year. The department also distributes more than 12 million condoms a year, mostly in low-income neighborhoods where people are thought to be at risk of becoming HIV infected.

HIV/AIDS Education and Prevention

Because there is no cure for AIDS, educating the public and providing them with information on prevention remain the most effective way to halt the epidemic. Section 381.0038, F.S. requires the Department of Health to establish a program to educate the public about the threat of AIDS. This program must be designed to reach all segments of Florida's population with special components to reach individuals who engage in behaviors placing them at high risk. The program must also place emphasis on the design of educational materials to be used by businesses, schools, and health care providers.

Under s. 381.0035, F.S., the Department of Health must require all employees and clients licensed in areas including developmental disabilities, mental health, substance abuse, hospitals, nursing homes, assisted living facilities, home health agencies, and hospices to complete continuing educational courses every two years on the modes of transmission, infection control procedures, clinical management, and prevention of HIV and AIDS with emphasis on appropriate behavior and attitude changes.

Injection drug users play a major role in perpetuating the deadly AIDS epidemic. In Florida, injection drug users constitute the second largest sub-population of persons with AIDS (18%). According to the Center for AIDS Prevention Studies at the University

of California at San Francisco, one-third of all AIDS cases are linked to injection drug use. Individuals who inject drugs not only increase their chances of contracting HIV by sharing their contaminated needles, but they also endanger their sexual partners and offspring. For women, nearly 70% of all AIDS cases are due to injection drug use or sex with partners who inject drugs. According to the Center for Disease Control, intravenous drug use is the source of infection for more than half of all children born with HIV; however other studies state this number to be as high as 80%.

It is illegal in Florida to deliver, possess, or manufacture drug paraphernalia with knowledge, or under circumstances where one reasonably should know, that such paraphernalia will be used along with a controlled substances in violation of the law. (S. 893.147, F.S.) Most states have similar paraphernalia laws that make it a crime to possess or distribute drug paraphernalia not for legitimate medical purposes.

Around the world and in many locations in the United States, needle exchange programs have been established to distribute clean needles for injection drug users. Many programs also offer referrals to drug treatment and HIV counseling and testing. Needle exchange programs are illegal in many places due to drug paraphernalia laws, but in some places underground programs are tolerated or willfully overlooked. Other programs are permitted because they are done in conjunction with research projects or because they have been state approved and are under local control. Sponsors of needle-swap programs in states including New York, Illinois, Connecticut and California claim the programs have been effective and lead to a decrease in infection rate.

A survey done by the University of Illinois at Chicago found that the HIV infection rate dropped 50% in North Side Chicago neighborhoods after individuals in those neighborhoods began participating in the university's needle exchange program. Another study released by the British medical journal, *The Lancet*, which tracked 1,600 injection drug users in New York and Puerto Rico, claims that injection drug users who get clean needles from syringe-exchange programs are 70% less likely to get infected with HIV than those who do not.

Opponents of needle exchange programs are concerned that the programs are seen as approving and even encouraging drug use. Supporters argue that needle exchange programs do not make drug violations less illegal nor do they make drugs more available. They also believe that needle exchange programs can help to decrease drug abuse by offering participants support and referrals for drug treatment. The American Medical Association has formally recognized needle exchange programs as an effective strategy in reducing the spread of HIV among injection drug users.

HIV Testing Requirements

Section 381.004, F.S., establishes the procedures to be followed for HIV testing. All individuals who submit to an HIV test must receive counseling both before and after the test. In creating this section, the Legislature recognized that strong confidentiality provisions were necessary to encourage individuals to seek testing without fear of discrimination. As a result s. 381.004, F.S. provides that a person may generally neither be tested for HIV nor may the test result be disclosed without the person's informed consent. The Legislature, however, also recognized that it is sometimes vitally important to test or obtain the test results of individuals without obtaining consent. Therefore, s. 381.004, F.S., contains exceptions to the informed consent requirements designed

generally to protect individuals from being exposed to the virus, to perform emergency medical treatment, and to provide relief for victims of sex crimes.

In limited situations, HIV testing may be performed on an individual without consent in the event of a significant exposure to medical or nonmedical personnel who provide help to the individual. This exception applies to hospital settings and in emergency situations outside a hospital or health care facility. This exception, however, does not apply to situations in which an exposure occurs during emergency care and the individual dies. Studies indicate that the risk of HIV infection among health care workers who take zidovudine prophylactically after exposure to the HIV infection was reduced by about 81%. Data on the safety and tolerability of such treatment, however, remains limited. Therefore, knowledge of the source individual's HIV statute is important in determining long-term treatment.

Current statute also requires that, along with informed consent, an individual who is tested for HIV must also be given both pretest and posttest counseling. Pretest counseling includes providing individuals with HIV/AIDS prevention information and scheduling a return visit for the purpose of disclosing the test results, regardless of a positive or negative result. The release of HIV test results is prohibited without affording the person the immediate opportunity for individual, face-to-face counseling, which must include specific information outlined in s. 381.004(3)(e), F.S.

Preliminary HIV tests

Current statutory language prohibits the release of positive preliminary test results except for situations involving significant exposure of blood or tissue donation. There is no current exception allowing for release of preliminary results in situations when decision about care or treatment of the person tested cannot await the results of confirmatory testing. There is also no definition for preliminary HIV tests in the list of HIV/AIDS-related definitions.

HIV Testing Sites

Any county health department or persons who "conduct or hold themselves out" as an HIV testing program, must register with DOH. Each person or private organization that registers as an AIDS/HIV testing site pays a fee of \$100 according to agency rule. These testing sites receive certificates that remain effective for an indefinite time period. Many of these testing sites registered several years ago with the former Department of Health and Rehabilitative Services, and DOH has no way to ensure that these testing sites are up-to-date with appropriate testing procedures and standards and do not threaten the immediate health, safety, or welfare of persons receiving services.

Model Protocol

DOH is required by statute to develop a model protocol for counseling and testing individuals for HIV. The protocol is to be consistent with the provision of the Omnibus AIDS Act.

Reporting Requirements

All states require AIDS reporting by name. Under s. 384.25, F.S., all physicians must report diagnosed cases of AIDS. AIDS reporting throughout the United States is done according to HIV/AIDS Reporting System (HARS) developed by the Centers for Disease Control and Prevention.

In 1996 the Florida Legislature passed legislation permitting the Department to require HIV infection reporting by name. In response to this legislation, the Department promulgated rules requiring physician and laboratory reporting of HIV. According to the department these requirements facilitate partner notification, which plays a vital role with regards to outreach to persons most at risk for HIV infection, including those already infected who do not know their status. The department contends that the reporting requirements further the department's goal to strengthen prevention efforts while reducing morbidity and mortality, because it allows the department to offer all individuals contacted, whether positive or negative, information on the prevention of transmission and on the benefits of early treatment. Section 384.25, F.S., specifically notes that DOH may, with the consent of the test subject, notify school superintendents of students and school personnel who test positive for HIV. Test subjects, however, can give permission for their test results to be shared with anyone.

B. EFFECT OF PROPOSED CHANGES:

HIV/AIDS Education and Prevention

Additional instructions will be included in required educational courses on HIV and AIDS, and the program established by the Department of Health to educate the public about the threat of AIDS will include a needle exchange project designed to combat HIV/AIDS, educate the participants about substance abuse and HIV/AIDS transmission, and provide referrals for substance abuse.

HIV Testing Requirements

The specific requirements of pretest counseling will be eliminated, and the specific requirements of posttest counseling will be minimized. The test subject must be informed that a positive result will be reported to the department and that anonymous testing is available. Health care professionals will be required to ensure that a reasonable effort is made to notify positive individuals of their results, and notification will be left to the discretion of the health care professional but should be made with due regard for the information that is needed by the test subject to obtain appropriate medical care and information on preventing the spread of HIV.

Addition exceptions to confidentiality protections for HIV test results are created. The release of HIV test results to employees of facilities or of community-based care programs that care for the developmentally disabled persons pursuant to ch. 393, F.S., will be authorized to those who are directly involved in the care, control, or custody of the subject and who have a need to know. A health care provider involved in the delivery of a child will be given the authority to note the mother's HIV test result in the child's medical record. A medical examiner will be authorized to disclose positive test results to the county health department in accordance with rule on reporting and controlling the spread of disease.

Additional exceptions to the informed consent requirement will be created. Testing of the source of the exposure if the source dies during treatment for a medical emergency will be authorized, and exception to informed consent is granted when HIV testing is done repeatedly to monitor the progress of an already diagnosed HIV-positive individual.

Preliminary HIV Tests

Preliminary HIV test is defined for clarification and the release of preliminary positive test results will be authorized when decisions about care and treatment cannot await the results of confirmatory testing. The release of preliminary results for the routine identification of HIV-infected individuals or when HIV testing is incidental to primary diagnosis or the care of the patient will remain unauthorized.

HIV Testing Sites

HIV testing sites will be required to re-registered with DOH each year. Authority for a re-registration fee is also granted to DOH. DOH will also be given the authority to inspect and investigate the sites in response to complaints and to institute court proceeding when violations constitute and emergency affecting the immediate health, safety, and welfare of a person receiving services.

Model Protocol

DOH will be required to include in its model protocol for testing and counseling criteria for evaluating a patient's risk for HIV and offering HIV testing, on a voluntary basis, as a routine part of primary health care or admission to a health care facility.

Reporting Requirements

DOH will no longer have specific authority to notify school superintendents of students and school personnel whose HIV tests are positive.

C. APPLICATION OF PRINCIPLES:

1. Less Government:

a. Does the bill create, increase or reduce, either directly or indirectly:

(1) any authority to make rules or adjudicate disputes?

No.

(2) any new responsibilities, obligations or work for other governmental or private organizations or individuals?

Yes, the bill requires DOH to determine yearly fees for re-registration as a HIV testing site, and to establish needle exchange projects as part of the HIV/AIDS education program. DOH is also give them authority to institute court proceeding against a testing program for violations constituting an emergency.

- (3) any entitlement to a government service or benefit?

No.

- b. If an agency or program is eliminated or reduced:

- (1) what responsibilities, costs and powers are passed on to another program, agency, level of government, or private entity?

N/A

- (2) what is the cost of such responsibility at the new level/agency?

N/A

- (3) how is the new agency accountable to the people governed?

N/A

2. Lower Taxes:

- a. Does the bill increase anyone's taxes?

No.

- b. Does the bill require or authorize an increase in any fees?

Yes, the bill requires persons or private organizations registered as an HIV/AIDS testing site to pay a yearly re-registration fee to be set by DOH rule.

- c. Does the bill reduce total taxes, both rates and revenues?

No.

- d. Does the bill reduce total fees, both rates and revenues?

No.

- e. Does the bill authorize any fee or tax increase by any local government?

No.

3. Personal Responsibility:

- a. Does the bill reduce or eliminate an entitlement to government services or subsidy?

No.

- b. Do the beneficiaries of the legislation directly pay any portion of the cost of implementation and operation?

No.

4. Individual Freedom:

- a. Does the bill increase the allowable options of individuals or private organizations/associations to conduct their own affairs?

No.

- b. Does the bill prohibit, or create new government interference with, any presently lawful activity?

No.

5. Family Empowerment:

- a. If the bill purports to provide services to families or children:

- (1) Who evaluates the family's needs?

N/A

- (2) Who makes the decisions?

N/A

- (3) Are private alternatives permitted?

N/A

(4) Are families required to participate in a program?

N/A

(5) Are families penalized for not participating in a program?

N/A

b. Does the bill directly affect the legal rights and obligations between family members?

N/A

c. If the bill creates or changes a program providing services to families or children, in which of the following does the bill vest control of the program, either through direct participation or appointment authority:

(1) parents and guardians?

N/A

(2) service providers?

N/A

(3) government employees/agencies?

N/A

D. STATUTE(S) AFFECTED:

Sections 381.0035, 381.0038, 381.004, 384.25, 455.604, 775.0877, and 960.003, F.S.

E. SECTION-BY-SECTION RESEARCH:

Section 1. Amends s. 381.0035, F.S., relating to educational courses on HIV and AIDS for health care facilities clients and employees, to include in the educational course an emphasis on any protocols and procedures applicable to human immunodeficiency counseling and testing, reporting, and partner notification issues pursuant to ss. 381.004 and 384.25, F.S.

Section 2. Amends s. 381.0038, F.S., relating to the Department of Health program to educate the public about the threat of AIDS, to authorize and set requirements for the State Health Officer to establish and administer harm reduction sterile needle and syringe exchange projects to combat HIV/AIDS transmission.

Section 3. Amends s. 381.004, F.S., relating to testing for HIV, to: define "preliminary HIV test"; expand information to be provided prior to obtaining informed consent for an

HIV test; provide for informed consent of the legal guardian of an incapacitated person; revise provisions relating to notification of test results; authorize release of preliminary HIV test results under certain conditions; delete provisions relating to post-test counseling; provide additional persons to whom the identity of a test subject may be disclosed; provide additional exceptions to informed consent requirements; require annual registration of testing programs; provide for fees; delete obsolete terminology; authorize inspections and investigations by officers or employees of the Department of Health; direct the department to institute court proceeding under certain circumstances; and provide requirements with respect to the department's protocol for HIV testing and counseling.

Section 4. Amends 384.25, F.S., relating to reporting required, to remove language that addresses the release of HIV information to school superintendents and to delete provisions relating to protocols and to certain notifications in order to remove duplications and conform to the act.

Section 5. Amends s. 455.2226, F.S., relating to directors and embalmers instruction on HIV and AIDS, to require that educational courses on HIV and AIDS include an emphasis on any protocols and procedures applicable to human immunodeficiency counseling and testing, reporting, and partner notification issues pursuant to ss. 381.004 and 384.25, F.S.

Section 6. Amends s. 775.0877, F.S., relating to criminal transmission of HIV, to correct references.

Section 7. Amends s. 960.003, F.S., relating to testing for persons charged with or alleged by petition for delinquency to have committed certain offenses and disclosure of results of victims, to correct references.

Section 8. Provides an effective date of upon becoming a law.

III. FISCAL RESEARCH & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE AGENCIES/STATE FUNDS:

1. Non-recurring Effects:

None.

2. Recurring Effects:

The proposed legislation will require HIV testing sites to pay a re-registration fee to the department, which will result in generated revenue for the department. There are approximately 1500 testing sites currently registered in Florida.

3. Long Run Effects Other Than Normal Growth:

See Fiscal Comments.

4. Total Revenues and Expenditures:

The re-registration fee is not established in statute, but must be determined by rule. If there-registration fee is established at \$50.00, the revenue generated would be \$75,000. The increased administrative cost cannot be determined at this time.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS AS A WHOLE:

1. Non-recurring Effects:

N/A

2. Recurring Effects:

N/A

3. Long Run Effects Other Than Normal Growth:

N/A

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

1. Direct Private Sector Costs:

Private HIV testing sites that re-register with the department will be required to pay a fee. The fee amount will be determined by agency rule.

2. Direct Private Sector Benefits:

Providing individuals with information and services that decrease risk of transmission of HIV, may prevent the individual and his/her sexual partners and offspring from being faced with a lifetime of physical and mental problems and exorbitant medical expenses.

3. Effects on Competition, Private Enterprise and Employment Markets:

Indeterminate.

D. FISCAL COMMENTS:

Studies show that the lifetime cost of treating an HIV-infected individual can be as high as \$200,000. By helping to prevent the transmission of HIV, the programs and required procedures in this bill may decrease the number of HIV/AIDS infected individuals and save the citizens and the state from spending millions of dollars in health care treatment.

IV. CONSEQUENCES OF ARTICLE VII, SECTION 18 OF THE FLORIDA CONSTITUTION:

A. APPLICABILITY OF THE MANDATES PROVISION:

This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

This bill does not reduce the authority that municipalities or counties have to raise revenues.

C. REDUCTION OF STATE TAX SHARED WITH COUNTIES AND MUNICIPALITIES:

This bill does not reduce the percentage of a state tax shared with counties or municipalities.

V. COMMENTS:

None.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

A strike everything amendment to this bill has been written that does the following:

- Expands HIV/AIDS education requirements for employees and clients of certain health care facilities, as well as funeral directors and embalmers;
- Provides that the State Health Officer may authorize a one-county needle exchange project if the State Health Officer determines that the project is likely to be an effective component of an HIV prevention program in the community, and provides project criteria;
- Provides a definition of preliminary HIV test, allows for the release of preliminary results in extreme situations, and adds the word "medical" to describe the type of care that cannot await confirmatory results and necessitates release of preliminary test results;
- Creates additional exceptions in which HIV information can be released without the consent of the test subject. These exceptions include 1) employees of residential facilities and community-based programs who are directly involved in the care, control and custody of the developmentally disabled, 2) health care providers involved in the delivery of a child to note the mother's HIV test results in the child's medical record, 3) non-medical personnel who experience a significant exposure while providing care in a medical emergency. Medical examiners would also be required to report positive HIV test results to the county health department;
- Removes the requirements that pretest counseling be given at the time the HIV test is ordered and that the test subject who test positive be offered immediate opportunity for individual, face-to-face counseling;
- Requires that persons ordering an HIV test make all reasonable efforts to notify the test subject of a positive result. Notification must include information that is needed by the test subject to obtain appropriate medical services and prevent the spread of HIV;

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- Provides that during notification of results, specific information must be provided on available medical services, support services, and the importance of partner notification;
- Addresses the need to provide prevention information to high risk persons who test negative;
- Authorizes hospital emergency departments and detention facilities to enlist public health services in the notification of positive individuals who have been discharged prior to notification of positive results;
- Authorizes testing without informed consent, in the event of a significant exposure to medical or non-medical personnel who provide emergency care to a victim who dies, to monitor a previously diagnosed HIV-possible patient's clinical progress, and for the performance of repeated HIV testing conducted to monitor possible conversion from a significant exposure;
- Establishes probable cause for a court order if the source of a significant exposure refuses testing and no blood is available;
- Requires the re-registration of HIV testing sites and gives authority for inspection;
- Gives DOH the authority to deny, suspend or revoke the registration of a HIV testing site;
- Adds requirements for DOH's model protocol for HIV testing and counseling and provides that the model protocol be established by agency rule; and
- Creates requirements on protocols which address the HIV testing of pregnant women.

VII. SIGNATURES:

COMMITTEE ON HEALTH CARE SERVICES:

Prepared by:

Legislative Research Director:

Amy K. Guinan

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