

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.)

BILL: CS/SB 2216

SPONSOR: Health, Aging, and Long-Term Care Committee and Senator Jones

SUBJECT: Public Health Care

DATE: March 23, 2004 REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HC	Fav/CS
2.	_____	_____	AHS	_____
3.	_____	_____	AP	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

I. Summary:

The bill revises several provisions relating to public health. The bill expands the Department of Health’s (DOH) enforcement authority to permit the issuance of citations for certain environmental health violations. The Department of Health’s authority to adopt rules to enforce onsite sewage treatment and disposal system regulation is expanded to include requirements for implementation of the U.S. Environmental Protection Agency’s voluntary national guidelines for management of onsite and clustered or decentralized wastewater treatment systems.

The bill revises HIV/AIDS testing and reporting requirements to provide additional criteria for releasing positive HIV preliminary rapid test results. 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 clarifies that each person who makes a diagnosis of or treats a person with a sexually transmissible disease, *including but not limited to HIV and AIDS*, and each laboratory that performs a test for a sexually transmissible disease, *including but not limited to HIV*, which concludes with a positive report 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 information required in and a *maximum* rather than a *minimum* time period for reporting a sexually transmissible disease, *including but not limited to, HIV/AIDS*.

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 adds HIV to the list of sexually transmissible diseases for which health care providers must test, rather than offer to test, pregnant women along with tests for other sexually transmissible diseases. Pregnant women must be notified that the tests for sexually transmissible diseases, including HIV, will be conducted, and of their right to refuse testing. If a woman objects to testing, a written statement of objection, signed by the patient, must be placed in the patient's medical record and no testing shall occur.

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, information to be included in the report, requirements for enforcement, and followup activities by DOH.

The bill provides for employee health and wellness programs in state agencies and establishes requirements for such programs. The bill requires DOH to establish a Health Promotion and Health Education Statewide Initiative to provide funding to counties to improve individual and community health.

The Correctional Medical Authority (CMA or authority) is authorized to enter into an agreement or may contract with the Department of Children and Family Services, subject to available funding, to conduct surveys of medical services and to provide medical quality assurance and improvement assistance at secure confinement and treatment facilities for persons detained or committed as sexually violent predators under part V, chapter 394, F.S.

This bill amends sections 381.0012, 381.004, 381.0065, 381.0101, 384.25, 384.31, and 945.601, Florida Statutes.

This bill creates ss. 381.104, 385.104, and 945.6038, F.S.

II. Present Situation:

Environmental Health

The Department of Health is responsible for enforcing regulations for particular conditions affecting public health, such as nuisances or conditions that may be injurious to health, or sanitary nuisances. A nuisance injurious to health includes:

- Untreated or improperly treated human waste, garbage, offal, dead animals, or dangerous waste materials from manufacturing processes harmful to human or animal life and air pollutants, gases, and noisome odors which are harmful to human or animal life;
- Improperly built or maintained septic tanks, water closets, or privies;
- The keeping of diseased animals dangerous to human health;
- Unclean or filthy places where animals are slaughtered;
- The creation, maintenance, or causing of any condition capable of breeding flies, mosquitoes, or other arthropods capable of transmitting diseases, directly or indirectly to humans; or

- Any other condition determined to be a sanitary nuisance.

A sanitary nuisance is the commission of any act, by an individual, municipality, organization, or corporation, or the keeping, maintaining, propagation, existence, or permission of anything, by an individual, municipality, organization, or corporation, by which the health or life of an individual, or the health or lives of individuals, may be threatened or impaired, or by which or through which, directly or indirectly, disease may be caused.¹ The department has some administrative authority to abate such nuisances but does not have authority to issue a citation to impose administrative fines for violations which constitute a public health nuisance or a sanitary nuisance.

The Department of Health inspects group care facilities to ensure that basic sanitation and safety standards are maintained. The department conducts site evaluations and final inspections for onsite sewage treatment and disposal systems to determine compliance with standards and to determine setbacks to wells on adjoining property. The department supervises research on, demonstration of, and training on the performance, environmental impact, and public health impact of onsite sewage treatment and disposal systems in Florida. Such projects must be initially approved by the technical advisory panel and awarded through competitive negotiation. The environmental health professionals employed by the department who work in primary areas of environmental health such as onsite sewage treatment and disposal systems and food safety are statutorily required to be certified to do such work.

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.

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

¹ See s. 386.01, F.S.

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.

Florida law prohibits the release of positive preliminary HIV test results for the routine identification of HIV-infected individuals, or when HIV testing is incidental to the preliminary diagnosis or care of the patient.² Florida law is inconsistent with the recent U.S. Food and Drug Administration approval of rapid HIV testing technology.

Florida law authorized physician and laboratory reporting of HIV infection in 1996 and the law was implemented by administrative rule in July 1997. Florida law exempts reports of HIV infection identified before the effective date of the administrative rules and also exempts certain university-based medical research protocols from HIV reporting.³ Statutes also prohibit the reporting of newborns and infants up to 18 months of age who have been exposed to HIV perinatally or through breast-feeding.

In December 1999, the Centers for Disease Control (CDC) issued guidelines for national HIV case surveillance. These guidelines emphasize the importance of complete HIV reporting to effectively and accurately monitor the HIV/AIDS epidemic. The guidelines also set minimum requirements that states must achieve to receive support from CDC for HIV/AIDS surveillance activities. The guidelines state that the CDC will evaluate and award proposals for federal funding of state and local surveillance programs based on their capacity to meet these performance measures. Current Florida laws on HIV infection reporting are not in compliance with CDC guidelines.

Section 384.31, F.S., requires health care providers attending pregnant women for conditions related to pregnancy to: test for sexually transmissible diseases as required by rule of DOH (syphilis) 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.⁴ Counseling must include a discussion of the availability of treatment if the pregnant woman tests HIV

² See s. 381.004(3)(d), F.S.

³ See s. 384.25, F.S.

⁴ See Rules 64D-2.004 and 64D-3.019, Florida Administrative Code.

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.

Correctional Medical Authority

Pursuant to ss. 945.601-945.6035, F.S., CMA advises the Governor, Legislature and the Department of Corrections on issues relating to the delivery of primary, convalescent, dental and mental health care provided to inmates in Florida's correctional institutions. The authority conducts comprehensive surveys at each institution and monitors the quality of health care services provided to inmates to ensure that inmates have access to health care services that conform to the standard of care generally accepted in the professional health care community.

III. Effect of Proposed Changes:

Section 1. Amends s. 381.0012, F.S., relating to DOH's enforcement authority, to provide for citations. The department may issue a citation for any violation of sanitary nuisances under s. 386.01, F.S., or nuisances injurious to the public health under s. 386.041, F.S., or rules adopted for environmental health under chapter 381, F.S., if such violation is enforceable by administrative or civil remedy or is a second-degree misdemeanor. The department may issue a citation that contains an order of correction, an order to pay a fine, or both. Any citation issued by the department constitutes a notice of proposed agency action.

Citations must be in writing and must describe the particular nature of the violation and cite the specific statute or rule violated. The fines imposed by the department may not exceed \$500 for each violation, and each day is a separate violation for which a citation may be issued. The official providing the citation must inform the recipient of specified administrative remedies, including the right to an administrative hearing. The citation must include a conspicuous statement that failure to pay the fine within the allotted time or failure to appear to contest the citation after having requested a hearing constitutes a waiver of the right to contest the citation.

The department may reduce or waive the citation fine under certain circumstances. Any person who willfully refuses to sign and accept a citation issued by the department commits a second degree-misdemeanor punishable by jail time up to 6 months and the imposition of a fine up to \$500. The department must deposit all fines it collects under the authority of this subsection in the County Health Department Trust Fund for use in the environmental health program under which the fine was issued and must use such fines to improve the respective programs or to provide training to the regulated industry and department staff working in such programs.

The enforcement authority created in this section is an alternative means to enforce the environmental health requirements and does not prohibit the department from using other means of enforcement. The department is limited to the use of only one method of enforcement for a single violation. To ensure compliance with environmental health requirements, the department may use positive means of enforcement such as requiring attendance at training courses

applicable to violations committed and requiring the use of best management practices currently used or recognized by the appropriate industry or governmental agency.

Section 2. Amends s. 381.004, F.S., relating to HIV testing, to provide additional criteria for releasing positive HIV preliminary rapid test results. 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. Positive rapid tests are considered preliminary and may be released in accordance with the manufacturer's instructions as approved by the U.S. Food and Drug Administration. Positive rapid test results require confirmatory testing for diagnosis and reporting of HIV infection.

Section 3. Amends s. 381.0065, F.S., relating to onsite sewage treatment and disposal systems regulation, to expand DOH's authority to adopt rules to enforce such regulation to include requirements for implementation of the U.S. Environmental Protection Agency's voluntary national guidelines for management of onsite and clustered or decentralized wastewater treatment systems. A provision is eliminated that prohibits the award of research projects to firms or entities that employ or are associated with persons who serve on either the technical advisory panel or the research review and advisory committee.

The department's personnel are authorized to enter the premises of others when necessary to conduct site evaluations and inspections relating to the permitting of onsite sewage treatment and disposal systems. Such entry does not constitute trespass, and department personnel making such entry are not subject to arrest or to civil action by reason of such entry. An employee of the department is not authorized to destroy, injure, or damage, or move anything on the premises of another without written permission of the landowner. Such authority to enter the premises of others is comparable to that given to surveyors to enter adjoining property while conducting surveys.

Section 4. Amends s. 381.0101, F.S., relating to certification requirements for environmental health professionals, to define "accredited" to mean recognized by the American Council on Education as meeting acceptable levels of quality and performance. "Primary environmental health program" is redefined to allow DOH to establish such programs by rule and these programs include food protection program work and onsite sewage treatment and disposal systems program work.

A person may not conduct environmental health evaluations in a primary program area unless the person is certified in that program area or works under direct supervision of a certified environmental health professional during his or her initial probationary period for that position. Persons who begin employment in a primary environmental health program must be certified in that program within the initial probationary period (1 year) for that position rather than 6 months after employment, which the current law requires.

Obsolete terminology is updated in the section.

Section 5. Creates s. 381.104, F.S., to authorize each state agency to allocate, from existing resources, the necessary funding and facilities for the development and maintenance of an employee health and wellness program and to seek additional funding from other sources to

support the program for the benefit of the agency's employees. Each state agency may establish policies that allow employees no more than 30 minutes of work time three times each week, as individual work allows, to use for engaging in health and wellness activities, which may include physical activity, stress reduction, tobacco cessation, personal training, nutrition counseling, or weight reduction and control. The Department of Health must develop an employee health and wellness activity agreement form which each state agency must use to document employee participation in any health and wellness activity. The form must be completed by the employee and submitted it to the personnel office.

Each state agency may designate up to 1 hour each month for the purpose of providing inservice health and wellness training for its employees. Each state agency is authorized and encouraged to promote health or wellness education or activity programs by:

- Entering into agreements with other entities to collaborate or participate jointly in such programs;
- Implementing health education activities that focus on skill development and lifestyle behavior change which may be tailored to employees' interests and needs;
- Reviewing and offering recommendations to agency leadership on environmental and social support policies that relate to the improvement of employee health;
- Linking employee health and wellness programs to other programs which may help employees balance work and family; and
- Offering free, low-cost, or employee-fee-based programs on-site.

State agencies that develop and implement an employee health and wellness program must include and document an evaluation and improvement process in an annual report to help enhance the program's efficiency and effectiveness. The annual report must be submitted to DOH by July 1 annually. The Department of Health must provide employee health and wellness model program guidelines and ongoing technical assistance to other state agencies to assist in the development of each agency's employee health and wellness program.

Section 6. Amends s. 384.25, F.S., to revise HIV/AIDS reporting requirements, to clarify that each person who makes a diagnosis of or treats a person with a sexually transmissible disease, *including but not limited to HIV and AIDS*, and each laboratory that performs a test for a sexually transmissible disease, *including but not limited to HIV*, which conclude with a positive report 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 information required in and a *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. A requirement for the Department of Health 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 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, information to be included in the report, requirements for enforcement, and followup activities by DOH.

Section 7. Amends s. 384.31, F.S., relating to 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, but not limited to, HIV, as required by rule of the Department of Health at a time or times specified by the department, notwithstanding s. 381.004(3)(a), F.S., which provides for informed consent. Requirements for the tests to be done with a blood sample are removed. Pregnant women must be notified that the tests for sexually transmissible diseases, including HIV, will be conducted, and of their right to refuse testing. If a woman objects to testing, a written statement of objection, signed by the patient, must be placed in the patient's medical record and no testing shall 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 to conform to the changes in the section.

Section 8. Creates s. 385.104, F.S., to require DOH to establish the "Health Promotion and Health Education Statewide Initiative" to provide a comprehensive and community-based health promotion and education program. The program is designed to provide funding to counties in Florida to improve individual and community health, aimed specifically at reducing the impact of chronic diseases and promoting healthy lifestyles. Targeted diseases under the program include, but are not limited to, diabetes, heart disease, stroke, asthma, and cancer, with a focus on the preventable risk factors of tobacco use, physical inactivity, and poor nutrition.

The program must be coordinated with and linked to existing state plans and national priorities. Subject to availability of funds, DOH may award funding to county health departments for purposes of improving individual and community health by expanding and improving the health infrastructure through environmental and policy changes aimed specifically at preventing chronic diseases and reducing the impact of chronic disease and promoting healthy lifestyles. To be eligible to receive funding under the program, a county health department must submit an application with specified information which includes:

- A description of the proposed activities and how they promote tobacco cessation, healthy eating, or physical fitness and address the health and social consequences to residents of Florida that have chronic diseases.
- Information describing how health promotion and education activities are to be coordinated with other health activities.
- Information describing how local health promotion and education activities reflect state and national objectives.
- A description of the collaborative process that the county health department employed in the development of the health promotion and education program.
- A description of how the county health department will evaluate the effectiveness of its programs.

Subject to the availability of funds, a county health department receiving funds under this section must, pending successful implementation or evaluation, conduct the project for at least a period of 3 consecutive years. A county health department that receives funds under this section may use the funds to carry out one or more of the following activities:

- Collect, analyze, and disseminate data related to diabetes, heart disease, stroke, asthma, and cancer, with a focus on the preventable risk factors of tobacco use, physical inactivity, and poor nutrition.
- Develop and implement activities to create a comprehensive, coordinated nutrition and physical fitness awareness and chronic disease prevention program.
- Develop and implement programs in schools and worksites to increase physical fitness and to enhance the nutritional status of Floridians.
- Develop and implement policy and environmental changes related to the cessation of tobacco, healthful nutrition, and physical education.
- Collaborate with community-based organizations, volunteer organizations, state medical associations, and public health groups to develop and implement health education and promotion activities.
- Collaborate with public and private organizations that have a mission to increase public awareness of the importance of a balanced diet and lifestyle.

Section 9. Amends s. 945.601, F.S., relating to CMA, to change a statutory cross-reference to incorporate s. 945.6038, F.S., a provision, created in the bill that authorizes CMA to enter into agreements or contracts with other state agencies, subject to the availability of funding, to conduct surveys of medical services and to provide medical quality assurance and improvement assistance at facilities for persons detained or committed as sexually violent predators.

Section 10. Creates s. 945.6038, F.S., to authorize CMA to enter into an agreement or contract with the Department of Children and Family Services, subject to available funding, to conduct surveys of medical services and to provide medical quality assurance and improvement assistance at secure confinement and treatment facilities for persons detained or committed as sexually violent predators under part V, chapter 394, F.S. Subject to the availability of funds, CMA is authorized to enter into similar agreements with other state agencies. CMA is prohibited from entering into any such agreement if doing so would impair the authority's ability to fulfill its obligations with regard to the Department of Corrections as set forth in chapter 945, F.S.

Section 11. Provides that this act takes effect 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 Article 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:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.