Health Quality Subcommittee

Wednesday, March 04, 2015
9:00 AM - 11:00 AM
306 HOB

Steve Crisafulli
Speaker

Cary Pigman
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health Quality Subcommittee

Start Date and Time:	Wednesday, March 04, 2015 09:00 am
End Date and Time:	Wednesday, March 04, 2015 11:00 am
Location:	306 HOB
Duration:	2.00 hrs

Consideration of the following bill(s):

HB 475 Infectious Disease Elimination Pilot Program by Edwards
HB 673 Cosmetic Product Registration by Latvala
HB 697 Public Health by Gonzalez
HB 751 Emergency Treatment for Opioid Overdose by Gonzalez, Renuart
HB 4017 Pain-Management Clinics by Spano

Pursuant to rule 7.12, the deadline for amendments to bills on the agenda by non-appointed members is 6:00 p.m., Tuesday, March 3, 2015.

By request of the chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Tuesday, March 3, 2015.

NOTICE FINALIZED on 03/02/2015 15:16 by Iseminger.Bobbye

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 475 Infectious Disease Elimination Pilot Program
SPONSOR(S): Edwards and others
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Castagna MC	O'Callaghan MO
2) Government Operations Subcommittee			
3) Judiciary Committee			
4) Health & Human Services Committee			

SUMMARY ANALYSIS

The bill amends s. 381.0038, F.S., to create the Miami-Dade Infectious Disease Elimination Act (IDEA). The IDEA authorizes the University of Miami and its affiliates to establish a needle and syringe exchange pilot program (pilot program) in Miami-Dade County. The pilot program is to offer free, clean, and unused needles and hypodermic syringes as a means to prevent the transmission of HIV/AIDS and other blood-borne diseases among intravenous drug users, their sexual partners, and offspring. The pilot program may operate at a fixed location or through a mobile health unit.

The pilot program must:

- Provide maximum security of the exchange site and equipment;
- Account for the number, disposal, and storage of needles and syringes;
- Adopt any measure to control the use and dispersal of sterile needles and syringes;
- Operate a one sterile needle and syringe unit to one used unit exchange ratio; and
- Make available educational materials; HIV and viral hepatitis counseling and testing; referral services to provide education regarding HIV, AIDS, and viral hepatitis transmission; and drug-abuse prevention and treatment counseling and referral services.

The bill provides that the possession, distribution, or exchange of needles or syringes as part of the pilot program does not violate the Florida Comprehensive Drug Abuse Prevention and Control Act under ch. 893, F.S., or any other law. However, pilot program staff and participants are not immune from prosecution for the possession or redistribution of needles or syringes in any form if acting outside of the pilot program.

The bill requires the collection of data for annual and final reporting purposes, but prohibits the collection of any personal identifying information from a participant. The pilot program expires on July 1, 2020. Six months prior to expiration, the Office of Program Policy Analysis and Government Accountability is required to submit a report to the Legislature that includes data on the pilot program and a recommendation on whether the pilot program should continue.

The bill prohibits the use of state funds to operate the pilot program and requires the use of grants and donations from private sources to fund the program. The bill includes a severability clause.

The bill may have a positive fiscal impact on state government or local governments. *See* FISCAL COMMENTS.

The bill provides an effective date of July 1, 2015.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES

Current Situation

Needle and syringe exchange programs (NSEPs) provide sterile needles and syringes in exchange for used needles and syringes to reduce the transmission of human immunodeficiency virus (HIV) and other blood-borne infections associated with reuse of contaminated needles and syringes by injection-drug users (IDUs).

Federal Ban on Funding

In 2009, Congress passed the FY 2010 Consolidated Appropriations Act, which contained language that removed the ban on federal funding of NSEPs. In July 2010, the U.S. Department of Health and Human Services issued implementation guidelines for programs interested in using federal dollars for NSEPs.[1]

However, on December 23, 2011, President Obama signed the FY 2012 omnibus spending bill that, among other things, reinstated the ban on the use of federal funds for NSEPs; this step reversed the 111th Congress's 2009 decision to allow federal funds to be used for NSEPs.[2]

Safe Sharps Disposal

Improperly discarded sharps pose a serious risk for injury and infection to sanitation workers and the community. "Sharps" is a medical term for devices with sharp points or edges that can puncture or cut skin.[3]

Examples of sharps include:[4]

- Needles – hollow needles used to inject drugs (medication) under the skin.
- Syringes – devices used to inject medication into or withdraw fluid from the body.
- Lancets, also called "fingerstick" devices – instruments with a short, two-edged blade used to get drops of blood for testing. Lancets are commonly used in the treatment of diabetes.
- Auto Injectors, including epinephrine and insulin pens – syringes pre-filled with fluid medication designed to be self-injected into the body.
- Infusion sets – tubing systems with a needle used to deliver drugs to the body.
- Connection needles/sets – needles that connect to a tube used to transfer fluids in and out of the body. This is generally used for patients on home hemodialysis.

On November 8, 2011, the Federal Drug Administration (FDA) launched a new website[5] for patients and caregivers on the safe disposal of sharps that are used at home, at work, and while traveling.[6]

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[1] Matt Fisher, *A History of the Ban on Federal Funding for Syringe Exchange Programs*, SMARTGLOBALHEALTH.ORG (Feb. 6, 2012), available at http://www.smartglobalhealth.org/blog/entry/a-history-of-the-ban-on-federal-funding-for-syringe-exchange-programs/ (last visited January 30, 2015).
[2] *Id.*
[3] Food and Drug Administration, *Needles and Other Sharps (Safe Disposal Outside of Health Care Settings)*, available at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/Sharps/ucm20025647.htm (last visited January 29, 2015).
[4] *Id.*
[5] *Supra fn.* 3.
[6] *Supra fn.* 3.

According to the FDA, used needles and other sharps are dangerous to people and animals if not disposed of safely because they can injure people and spread infections that cause serious health conditions. The most common infections from such injuries are Hepatitis B (HBV), Hepatitis C (HCV), and Human Immunodeficiency Virus (HIV).[7] Moreover, injections of illicit drugs have been estimated to represent approximately one-third of the estimated 2 to 3 billion injections occurring outside of health-care settings in the U.S. each year, second only to insulin injections by persons with diabetes.[8]

For these reasons, communities are trying to manage the disposal of sharps within the illicit drug population. In San Francisco in 2000, approximately 2 million syringes were recovered at NSEPs, and an estimated 1.5 million syringes were collected through a pharmacy-based program that provided free-of-charge sharps containers and accepted filled containers for disposal. As a result, an estimated 3.5 million syringes were recovered from community syringe users and safely disposed of as infectious waste.[9] Other NSEPs offer methods for safe disposal of syringes after hours. For example, in Santa Cruz, California, the Santa Cruz Needle Exchange Program, in collaboration with the Santa Cruz Parks and Recreation Department, installed 12 steel sharps containers in public restrooms throughout the county.[10]

National Data & Survey Results

In the United States, the sharing of contaminated needles during injection drug use accounts for 7-14% of new HIV infections each year. According to the Centers for Disease Control and Prevention (CDC), NSEPs can help prevent blood-borne pathogen transmission by increasing access to sterile syringes among IDUs and enabling safe disposal of used needles and syringes.[11] Often, programs also provide other public health services, such as HIV testing, risk-reduction education, and referrals for substance-abuse treatment.[12]

In 2002, staff from the Beth Israel Medical Center in New York City and the North American Syringe Exchange Network mailed surveys asking the directors of 148 NSEPs about syringes exchanged and returned, services provided, budgets, and funding. The survey found for the first time in 8 years, the number of NSEPs, the number of localities with NSEPs, and public funding for NSEPs decreased nationwide; however, the number of syringes exchanged and total budgets across all programs continued to increase.[13]

In 2011, the Beth Israel Medical Center conducted another survey of NSEPs in the U.S.[14] The results revealed that the most frequent drug being used by participants was heroin, followed by cocaine, and that usually the problems NSEPs encountered had to do with the lack of resources and staff shortages.[15]

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[7] *Id.*

[8] Centers for Disease Control and Prevention, *Update: Syringe Exchange Programs --- United States, 2002*, MMWR WEEKLY, July 15, 2005, available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5427a1.htm (citing American Association of Diabetes Educators, American Diabetes Association, American Medical Association, American Pharmaceutical Association, Association of State and Territorial Health Officials, National Alliance of State and Territorial AIDS Directors, *Safe Community Disposal of Needles and Other Sharps, Houston, TX: Coalition for Safe Community Needle Disposal* (2002)) (last visited February 1, 2015).

[9] *Id.* (citing Brad Drda et al., *San Francisco Safe Needle Disposal Program, 1991—2001*, 42 J. AM PHARM ASSOC. S115—6 (2002), available at http://japha.org/article.aspx?articleid=1035735) (last visited February 1, 2015).

[10] Centers for Disease Control and Prevention, *Update: Syringe Exchange Programs --- United States, 2002*, *supra* note 8.

[11] *Id.*

[12] *Supra fn.* 8.

[13] *Supra fn.* 8.

[14] North American Syringe Exchange Network, *2011 Beth Israel Survey, Results Summary, (PowerPoint slide)* available at http://www.nasen.org/news/2012/nov/29/2011-beth-israel-survey-results-summary/ (last visited February 1, 2015).

[15] *Id.*

A separate 2013 report, examining the results of a needle exchange program in the District of Columbia shows an 81 percent decline between 2008 and 2012 in the number of HIV cases in which injection drug use was reported as transmission mode.[16]

A 2012 study compared improper public syringe disposal between Miami, a city without NESPs, and San Francisco, a city with NSEPs.[17] Using visual inspection walk-throughs of high drug-use public areas, the study found that Miami was eight times more likely to have syringes improperly disposed of in public areas.[18]

Heroin Use in Florida

An estimated 1.2 million people in the U.S. are living with HIV/AIDs[19], and it has been estimated that one-third of those cases are linked directly or indirectly to injection drug use, including the injection of heroin.[20] Recently the National Institute on Drug Abuse reported an epidemic of heroin use in South Florida and particularly in Miami-Dade County.[21] The number of heroin-related deaths in Miami-Dade County jumped to 40 in 2013 from 32 in 2012. Statewide, Florida has also seen an upswing in heroin deaths, which rose to 199 in 2013 from 108 in 2012, an increase of 84 percent.[22]

Florida Comprehensive Drug Abuse Prevention and Control Act

Section 893.147, F.S., regulates the use or possession of drug paraphernalia. Currently, it is unlawful for any person to use, or to possess with intent to use, drug paraphernalia:

- To plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, or conceal a controlled substance in violation of ch. 893, F.S.; or
- To inject, ingest, inhale, or otherwise introduce into the human body a controlled substance in violation of ch. 893, F.S.

Any person who violates the above provision is guilty of a misdemeanor of the first degree.[23]

Moreover, it is unlawful for any person to deliver, possess with intent to deliver, or manufacture with intent to deliver drug paraphernalia, knowing, or under circumstances where one reasonably should know, that it will be used:[24]

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[16] The District of Columbia Department of Health, *2013 Annual Epidemiology and Surveillance Report, Section 2: Newly Diagnosed HIV Cases* (2014), available at http://doh.dc.gov/page/2012-annual-epidemiology-and-surveillance-report (last visited February 3, 2015).

[17] Hansel E. Tookes, *et al.*, *A Comparison of Syringe Disposal Practices Among Injection Drug Users in a City with Versus a City Without Needle and Syringe Programs*, 123 DRUG & ALCOHOL DEPENDENCE 255 (2012), available at http://www.ncbi.nlm.nih.gov/pubmed/22209091 (last visited February 1, 2015).

[18] *Id.* at 255 (finding "44 syringes/1000 census blocks in San Francisco, and 371 syringes/1000 census blocks in Miami.").

[19] Centers for Disease Control and Prevention, *HIV in the United States: At a Glance,* accessible at: http://www.cdc.gov/hiv/statistics/basics/ataglance.html#ref1 (last visited February 1, 2015).

[20] Health Resources and Services Administration, *Innovative Programs for HIV Positive Substance Users,* available at http://www.drugabuse.gov/publications/topics-in-brief/linked-epidemics-drug-abuse-hivaids (last visited February 3, 2015).

[21] James N. Hall, *Drug Abuse Patterns and Trends in Miami-Dade and Broward Counties, Florida—Update: January 2014*, available at http://www.drugabuse.gov/about-nida/organization/workgroups-interest-groups-consortia/community-epidemiology-work-group-cewg/meeting-reports/highlights-summaries-january-2014/miami (last visited February 1, 2015).

[22] Florida Department of Law Enforcement, Medical Examiners Commission, *Drugs Identified in Deceased Persons by Florida Medical Examiners, 2013 Interim Report*, (May 2014), available at http://www.fdle.state.fl.us/Content/getdoc/0f1f79c0-d251-4904-97c0-2c6fd4cb3c9f/MEC-Publications-and-Forms.aspx (last visited February 2, 2015).

[23] A second degree misdemeanor is punishable by up to 60 days in county jail and a $500 fine. Sections 775.082 and 775.083, F.S.

[24] Section 893.147(2), F.S.

- To plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, or conceal a controlled substance in violation of ch. 893, F.S.; or
- To inject, ingest, inhale, or otherwise introduce into the human body a controlled substance in violation of ch. 893, F.S.

Any person who violates the above provision is guilty of a felony of the third degree.[25]

Federal Drug Paraphernalia Statute

Persons authorized by state law to possess or distribute drug paraphernalia are exempt from the federal drug paraphernalia statute.[26]

EFFECT OF PROPOSED CHANGES

The bill amends s. 381.0038, F.S., to allow the University of Miami and its affiliates to establish a 5-year needle and syringe exchange pilot program in Miami-Dade County. The pilot program is to offer free, clean, and unused needles and hypodermic syringes as a means to prevent the transmission of HIV/AIDS and other blood-borne diseases among intravenous drug users and their sexual partners and offspring. The University of Miami may operate the pilot program at a fixed location or by using a mobile health unit.

The exchange program must:

- Provide maximum security of the exchange site and equipment;
- Account for the number, disposal, and storage of needles and syringes;
- Adopt any measure to control the use and dispersal of sterile needles and syringes;
- Operate a 1 sterile to 1 used needle and syringe exchange ratio; and
- Make available educational materials; HIV and viral hepatitis counseling and testing; referral services to provide education regarding HIV, AIDS, and viral hepatitis transmission; and drug-abuse prevention and treatment counseling and referral services.

The bill provides that the possession, distribution, or exchange of needles or syringes as part of the pilot program does not violate the Florida Comprehensive Drug Abuse Prevention and Control Act under ch. 893, F.S., or any other law. However, pilot program staff and participants are not immune from prosecution for the possession or redistribution of needles or syringes in any form if acting outside of the pilot program.

The bill requires the collection of data for annual and final reporting purposes, but prohibits the collection of any personal identifying information from a participant. The data collected must include:

- The number of participants served;
- The number of needles and syringes exchanged and distributed;
- The demographic profiles of the participants served;
- The number of participants entering drug counseling and treatment;
- The number of participants receiving HIV, AIDS, or viral hepatitis testing;
- The rates of HIV, AIDS, viral hepatitis, or other blood borne disease before the pilot program began and every subsequent year thereafter; and
- Other data deemed necessary for the pilot program.

[25] A third degree felony is punishable by up to five years imprisonment and a $5,000 fine. Sections 775.082 and 775.083, F.S.
[26] 21 U.S.C. § 863(f)(1).

The pilot program expires on July 1, 2020. Six months prior to expiration, the Office of Program Policy Analysis and Government Accountability is required to submit a report to the President of the Senate and the Speaker of the House that includes the data listed above on the pilot program and a recommendation on whether the pilot program should continue.

The bill prohibits the use of state funds to operate the pilot program and requires the use of grants and donations from private sources to fund the program.

The bill includes a severability clause[27] and provides an effective date of July 1, 2015.

B. SECTION DIRECTORY:

Section 1. Names the act the "Miami-Dade Infectious Disease Elimination Act (IDEA)."
Section 2. Amends s. 381.0038, F.S., relating to education.
Section 3. Creates an unnumbered section to provide a severability clause.
Section 4. Provides an effective date of July 1, 2015.

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:

None.

D. FISCAL COMMENTS:

The pilot program required by the bill may significantly reduce state and local government expenditures for the treatment of blood borne diseases associated with intravenous drug use for individuals in Miami-Dade County.[28] The reduction in expenditures for such treatments depends on the extent to which the

[27] A "severability clause" is a provision of a contract or statute that keeps the remaining provisions in force if any portion of that contract or statute is judicially declared void or unconstitutional. Courts may hold a law constitutional in one part and unconstitutional in another. Under such circumstances, a court may sever the valid portion of the law from the remainder and continue to enforce the valid portion. *See Carter v. Carter Coal Co.*, 298 U.S. 238 (1936); *Florida Hosp. Waterman, Inc. v. Buster*, 984 So.2d 478 (Fla. 2008); *Ray v. Mortham*, 742 So.2d 1276 (Fla. 1999); and *Wright v. State*, 351 So.2d 708 (Fla. 1977).

[28] The State of Florida and county governments incur costs for HIV/AIDS treatment through a variety of programs, including Medicaid, the AIDS Drug Assistance Program, and the AIDS Insurance Continuation Program. The lifetime treatment cost of an HIV infection is estimated at $379,668 (in 2010 dollars). Centers for Disease Control and Prevention,

needle and syringe exchange pilot program reduces transmission of blood-borne diseases among intravenous drug users, their sexual partners, offspring, and others who might be at risk of transmission.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not Applicable. This bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

HIV Cost-effectiveness, (Apr. 16, 2013) available at http://www.cdc.gov/hiv/prevention/ongoing/costeffectiveness/ (last visited February 1, 2015). Miami-Dade County has 3,274 reported cases of individuals living with HIV/AIDS that have an IDU-associated risk. Florida Department of Health, *HIV Infection Among Those with an Injection Drug Use-Associated Risk, Florida, 2012* (PowerPoint slide) (Sept. 17, 2013), available at http://www.floridahealth.gov/diseases-and-conditions/aids/surveillance/_documents/HIV-AIDS-slide%20sets/IDU_2012.pdf (last visited February 1, 2015) (noting that HIV IDU infection risk includes IDU cases, men who have sex with men (MSM)/IDU, heterosexual sex with IDU, children of IDU mom). If 10 percent of those individuals with an IDU-associated risk had avoided infection, this would represent a savings in treatment costs of approximately $124 million.

A bill to be entitled

An act relating to an infectious disease elimination pilot program; creating the "Miami-Dade Infectious Disease Elimination Act (IDEA)"; amending s. 381.0038, F.S.; authorizing the University of Miami and its affiliates to establish a sterile needle and syringe exchange pilot program in Miami-Dade County; establishing pilot program criteria; providing that the distribution of needles and syringes under the pilot program is not a violation of the Florida Comprehensive Drug Abuse Prevention and Control Act or any other law; providing conditions under which a pilot program staff member or participant may be prosecuted; prohibiting the collection of participant identifying information; providing for the pilot program to be funded through private grants and donations; providing for expiration of the pilot program; requiring the Office of Program Policy Analysis and Government Accountability to submit a report and recommendations regarding the pilot program to the Legislature; providing for severability; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. This act may be cited as the "Miami-Dade

Infectious Disease Elimination Act (IDEA)."

Section 2. Section 381.0038, Florida Statutes, is amended to read:

381.0038 Education; sterile needle and syringe exchange pilot program.—The Department of Health shall establish a program to educate the public about the threat of acquired immune deficiency syndrome.

(1) The acquired immune deficiency syndrome education program shall:

(a) Be designed to reach all segments of Florida's population;

(b) Contain special components designed to reach non-English-speaking and other minority groups within the state;

(c) Impart knowledge to the public about methods of transmission of acquired immune deficiency syndrome and methods of prevention;

(d) Educate the public about transmission risks in social, employment, and educational situations;

(e) Educate health care workers and health facility employees about methods of transmission and prevention in their unique workplace environments;

(f) Contain special components designed to reach persons who may frequently engage in behaviors placing them at a high risk for acquiring acquired immune deficiency syndrome;

(g) Provide information and consultation to state agencies to educate all state employees; ~~and~~

(h) Provide information and consultation to state and local agencies to educate law enforcement and correctional personnel and inmates;~~.~~

(i) Provide information and consultation to local governments to educate local government employees;~~.~~

(j) Make information available to private employers and encourage them to distribute this information to their employees;~~.~~

(k) Contain special components which emphasize appropriate behavior and attitude change; and~~.~~

(l) Contain components that include information about domestic violence and the risk factors associated with domestic violence and AIDS.

(2) The education program designed by the Department of Health shall use ~~utilize~~ all forms of the media and shall place emphasis on the design of educational materials that can be used by businesses, schools, and health care providers in the regular course of their business.

(3) The department may contract with other persons in the design, development, and distribution of the components of the education program.

(4) The University of Miami and its affiliates may establish a single sterile needle and syringe exchange pilot program in Miami-Dade County. The pilot program may operate at a fixed location or through a mobile health unit. The pilot program shall offer the free exchange of clean, unused needles

and hypodermic syringes for used needles and hypodermic syringes as a means to prevent the transmission of HIV, AIDS, viral hepatitis, or other blood-borne diseases among intravenous drug users and their sexual partners and offspring.

(a) The pilot program shall:

1. Provide for maximum security of exchange sites and equipment, including an accounting of the number of needles and syringes in use, the number of needles and syringes in storage, safe disposal of returned needles, and any other measure that may be required to control the use and dispersal of sterile needles and syringes.

2. Operate a one-to-one exchange, whereby the participant shall receive one sterile needle and syringe unit in exchange for each used one.

3. Make available educational materials; HIV and viral hepatitis counseling and testing; referral services to provide education regarding HIV, AIDS, and viral hepatitis transmission; and drug-abuse prevention and treatment counseling and referral services.

(b) The possession, distribution, or exchange of needles or syringes as part of the pilot program established under this subsection is not a violation of any part of chapter 893 or any other law.

(c) A pilot program staff member, volunteer, or participant is not immune from criminal prosecution for:

1. The possession of needles or syringes that are not a part of the pilot program; or

2. Redistribution of needles or syringes in any form, if acting outside the pilot program.

(d) The pilot program shall collect data for annual and final reporting purposes, which shall include information on the number of participants served, the number of needles and syringes exchanged and distributed, the demographic profiles of the participants served, the number of participants entering drug counseling and treatment, the number of participants receiving HIV, AIDS, or viral hepatitis testing, and other data deemed necessary for the pilot program. However, personal identifying information may not be collected from a participant for any purpose.

(e) State funds may not be used to operate the pilot program. The pilot program shall be funded through grants and donations from private resources and funds.

(f) The pilot program shall expire July 1, 2020. Six months before the pilot program expires, the Office of Program Policy Analysis and Government Accountability shall submit a report to the President of the Senate and the Speaker of the House of Representatives that includes the data collection requirements established in this subsection; the rates of HIV, AIDS, viral hepatitis, or other blood-borne diseases before the pilot program began and every subsequent year thereafter; and a recommendation on whether to continue the pilot program.

Section 3. If any provision of this act or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the act that can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

Section 4. This act shall take effect July 1, 2015.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 673 Cosmetic Product Registration
SPONSOR(S): Latvala
TIED BILLS: **IDEN./SIM. BILLS:** SB 612

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Castagna	O'Callaghan
2) Government Operations Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The federal Food and Drug Administration (FDA) is responsible for regulating cosmetic products in the United States. The FDA prohibits adulterated or misbranded cosmetic products from being sold to consumers and enforces cosmetic product labeling requirements. Unlike drugs, cosmetic products are not subject to safety inspections and premarket approval. However, the FDA encourages cosmetic manufacturers to voluntarily submit information on facilities, products, and ingredients, which provides the FDA with post-market product information and assists in the assessment of product safety.

The Florida Department of Business and Professional Regulation's Division of Drugs, Devices, and Cosmetics (Division) regulates cosmetics that are manufactured and repackaged in Florida. Cosmetic manufacturers physically located in Florida are required to hold an active cosmetic manufacturer permit issued by the Division. In addition, each product produced or repackaged by such manufacturers is required to be registered with the Division.

HB 673 amends ch. 499, F.S., to remove the requirement that Florida cosmetic manufacturers register cosmetic products with the Division. The bill makes conforming changes by removing registration and renewal requirements for cosmetic products, including the requirements to submit registration applications, product labels, and registration and renewal fees.

The bill also removes the Division's authority to issue certificates of free sale for registered cosmetic products in s. 499.003(6), F.S.

The bill has a significant negative fiscal impact on the Department of Business and Professional Regulation and no fiscal impact on local governments.

The bill provides an effective date of July 1, 2015.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Federal Regulation of Cosmetics

In the United States more than 8 billion cosmetics are sold annually which results in over $60 billion in annual sales.[1] The federal Food and Drug Administration's (FDA) definition of cosmetics covers a broad range of products. For regulatory purposes, the term includes products for the eyes, face, nails, hair, skin, and mouth, which may be in the form of products such as makeup, polish, hair dyes, fragrances, deodorants, shave gel, oral care, lotions, bath products, and products for infants and children.[2]

The FDA regulates cosmetics under the authority of the federal Food Drug and Cosmetic Act (FDCA) and the Fair Packaging and Labeling Act (FPLA). The FDCA prohibits the adulteration and misbranding of cosmetics and the introduction, receipt, and delivery of adulterated or misbranded cosmetics into interstate commerce.[3] A cosmetic is considered to be adulterated if it contains a substance that may cause injury to users under the conditions of use prescribed on the product's labeling or if it contains a soiled or decomposed substance.[4] A cosmetic is considered to be misbranded if its labeling is false or misleading, if it does not bear the required labeling information, if the container is made or filled in a deceptive manner, or if it does not comply with child resistant packaging requirements.[5] The FDA is authorized to take action against a cosmetic on the market if a product is found to be adulterated or misbranded, as well as companies and individuals who market such products.[6]

Voluntary Regulations

The FDA's legal authority over cosmetics is less comprehensive than other products regulated such as drugs and medical devices with regard to mandatory product approval, regulation, and registration. The FDA does not impose registration requirements on cosmetic manufacturers but allows cosmetic manufactures to follow voluntary registration regulations. These voluntary regulations include facility registration, reporting of product's ingredients, and reporting of adverse reactions to products. The FDA does not have the authority to require a manufacturer to recall a cosmetic product from the marketplace, although the agency has general regulations on voluntary recalls.[7]

Voluntary cosmetic regulation compliance is managed electronically through the FDA's Voluntary Cosmetic Registration Program (VCRP). The VCRP is an electronic reporting system for manufacturers, packers, and distributors of cosmetic products that are distributed commercially in the United States.[8] Voluntary submission to the VCRP provides the FDA with information on cosmetic

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[1] Landa, Michael. "Examining the Current State of Cosmetics," testimony on March 27, 2012, before the Subcommittee on Health Committee on Energy and Commerce, U.S. House of Representatives, accessible at http://www.fda.gov/NewsEvents/Testimony/ucm297215.htm (last viewed February 25, 2015).
[2] 21 C.F.R. §720.4(c)(12) (1992).
[3] Corby-Edwards, Amalia, Congressional Research Service, FDA Regulation of Cosmetics and Personal Care Products, July 9, 2012, accessible at http://asbcouncil.org/sites/default/files/library/docs/crs_report_fda_regulation_of_cosmetics_and_personal_care_products.pdf (last viewed February 23, 2015).
[4] *Id.*
[5] *Supra fn.* 3.
[6] Food and Drug Administration, *FDA Authority over Cosmetics*, March 20, 2014, accessible at: http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm (last viewed February 23, 2015).
[7] *Supra fn.* 3.
[8] Federal Food and Drug Administration, *Voluntary Cosmetic Registration Program*, accessible at http://www.fda.gov/Cosmetics/RegistrationProgram/UCM2005171.htm (last viewed February 23, 2015).

businesses and products, which helps support product safety review processes.[9] As of February 2015, there are 2,446 active online accounts, 1,252 registered establishments, and 42,325 product formulations on file with the VCRP.[10]

The FDA does not require good manufacturing practices (GMP) for cosmetic products as it does with drugs and medical devices, unless the product is considered both a cosmetic and a drug.[11] GMPs provide standards for product development, monitoring, and control of processes and facilities, providing assurance that products meet FDA quality and safety standards. With the exception of color additives, the FDA does not require safety testing or premarket approval of the ingredients and chemicals used in cosmetic products.[12]

Labeling

The FPLA requires that packages and their labels provide consumers with accurate information about the quantity of contents to prevent consumer deception.[13] FDA regulations require cosmetic product labels to disclose:[14]

- Identification of the product;
- Net quantity of contents in terms of weight, measure, or numerical count;
- Material facts about product and its use, such as directions for safe use;
- Name and place of business of the product's manufacturer, packer, or distributor;
- Warning and caution statements for products that are required to bear such statements by the FDCA and FDA regulations; and
- A list of ingredients in descending order of predominance.

Product Ingredients

The FDA is not statutorily authorized to approve a premarket cosmetic product. Therefore, manufactures are responsible for verifying the safety of their products before they are sold to consumers. FDA regulations prohibit or restrict the use of 10 types of ingredients in cosmetic products including chloroform, bithioniol, methylene chloride, and mercury-containing compounds[15] and require warning statements on the labels of certain types of cosmetics. Manufacturers must remove dangerous products from the market once a safety concern emerges. The FDA can pursue enforcement actions against such products or against firms or individuals who violate the law.[16] In general, except for color additives and those ingredients that are prohibited or restricted by regulation, a manufacturer may use any ingredient in the formulation of a cosmetic, provided that the:[17]

- Ingredient and the finished cosmetic are safe under labeled or customary conditions of use;
- Product is properly labeled; and
- Use of the ingredient does not otherwise cause the cosmetic to be adulterated or misbranded under the laws that FDA enforces.

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[9] Information from the VCRP is used by the Cosmetic Ingredient Review, an industry funded organization, to assess ingredient safety and determine priorities for ingredient safety review. *Id.*

[10] Federal Food and Drug Administration, *Registration Reports*, accessible at http://www.fda.gov/Cosmetics/RegistrationProgram/RegistrationReports/default.htm (last viewed February 26, 2015).

[11] In some cases products that are used for two purposes are considered both a cosmetic and a drug. For example, a shampoo is a cosmetic because its intended use is to cleanse the hair. An antidandruff treatment is a drug because its intended use is to treat dandruff. Consequently, an antidandruff shampoo is both a cosmetic and a drug. Such products must comply with the requirements for both cosmetics and drugs. Food and Drug Administration, *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?),* http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm (last viewed February 25, 2015).

[12] *Supra fn.* 3.

[13] 15 U.S.C. 1451-1460 (2009).

[14] *Supra fn.* 1.

[15] Federal Food and Drug Administration, *Prohibited and Restricted Ingredients*, accessible at http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm127406.htm (last viewed February 26, 2015).

[16] *Supra fn.* 1.

[17] *Supra fn.* 6.

State's Cosmetic Laws

All 50 states have laws and regulations in place that conform to the FDCA, the FPLA, and FDA regulations for cosmetics.[18] Further cosmetic related laws and regulation vary state by state. Very few states, including Louisiana[19] and Florida, have mandatory registration requirements for both cosmetic products and manufacturers. New Jersey [20] and Pennsylvania [21] require only cosmetic facilities, not products, to be registered with their respective state agencies. Other states, such as Texas [22] and Illinois, [23] authorize their respective state agencies to issue certificates of free sale for the export of in-state produced products.

California and Washington require post-market product reporting. The California Safe Cosmetics Act requires cosmetic manufacturers to notify the state of any product ingredients that are on state or federal lists of chemicals that cause cancer or birth defects.[24] Washington only requires this notification for children's cosmetic products.[25]

Florida Cosmetic Regulation

The Department of Business and Professional Regulation's Division of Drugs, Devices, and Cosmetics (Division) serves to protect the health, safety, and welfare of Florida citizens from injury due to the use of adulterated, contaminated, and misbranded drugs, drug ingredients, and cosmetics[26] by administering the provisions of ch. 499, F.S., the Florida Drug and Cosmetic Act (Act).[27]

The Act conforms to FDA cosmetic laws and regulations and authorizes the Division to issue permits to Florida cosmetic manufacturers and register cosmetic products manufactured or repackaged in Florida.

Manufacturer Permit

Cosmetic manufacturers physically located in Florida must obtain a cosmetic manufacturer permit through the Division. Manufacture in this context means the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any cosmetic.[28] Cosmetic manufacturers also repackage products by changing the container, wrapper, or label of a product, which may include altering the quantity of a product into different containers. A person that only labels or changes the label of a cosmetic, but does not open the container sealed by the manufacturer of the product, is exempt from obtaining a permit.[29]

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[18] Federal Food and Drug Administration, *Subchapter 3.3- State Operational Authority,* accessible at http://www.fda.gov/ICECI/Inspections/IOM/ucm122520.htm (last viewed on February 26, 2015).
[19] Louisiana Dep't of Health and Human Services, *Cosmetics*, accessible at http://dhh.louisiana.gov/index.cfm/page/727 (last viewed on February 26, 2015).
[20] New Jersey Dep't of Health, *Wholesale Food and Cosmetic Project,* accessible at http://www.nj.gov/health/foodanddrugsafety/wfcp.shtml (last viewed February 26, 2015).
[21] Pennsylvania Dep't of Health, *Drug, Device, and Cosmetic Program*, accessible at http://www.health.pa.gov/facilities/Laws%20and%20Regulations/DDCR/Pages/DDC_Main.aspx#.VO9dB2xOncs (last viewed February 26, 2015).
[22] 25 Tex. Admin. Code §§ 229.301-229.306 (2010).
[23] Ill. Admin. Code Food Drug and Cosmetic 77 § 720 (2014).
[24] Campaign for Safe Cosmetics, *State Legislation,* accessible at http://www.safecosmetics.org/get-the-facts/regulations/legislation/ (last viewed February 26, 2015).
[25] *Id.*
[26] Florida law defines a cosmetic as an article, with the exception of soap, that is: (a) intended to be rubbed, poured, sprinkled, or sprayed on; introduced into; or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance; or (b) intended for use as a component of any such article. Section 499.003(12), F.S.
[27] Florida Dep't of Business and Professional Regulation, *Division of Drugs, Devices, and Cosmetics,* accessible at http://www.myfloridalicense.com/DBPR/ddc/index.html (last viewed February 23, 2015).
[28] Florida Dep't of Business and Professional Regulation, *Cosmetic Manufacturer,* accessible at http://www.myfloridalicense.com/dbpr/ddc/CosmeticManufacturer.html (last viewed February 25, 2015).
[29] Section 499.01(2)(o), F.S.

Cosmetic manufacturers must complete and submit an application, pass an onsite inspection,[30] and pay a fee. The application fee is $800 for a biennial permit, including renewal requirements, and a one-time pre-permit inspection fee of $150.[31] Currently, there are 125 establishments with Division issued permits.[32]

Division regulations provide guidelines for cosmetic manufacturers to ensure cosmetic product safety and quality and compliance with FDA laws and regulations. The regulations provide that: [33]

- Manufacturers must assure that personnel do not contribute to contamination or adulteration of the product;
- Any facility used for the manufacture, processing, packaging, or labeling of a cosmetic shall be of suitable size and construction to produce a product that is not adulterated or misbranded;
- Any facility and equipment used in the manufacture, processing, packaging, or labeling of a cosmetic shall be maintained in a clean and sanitary condition;
- Components, containers, and closures shall not be reactive, additive, or absorptive so as to alter the safety or purity of the cosmetic;
- Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the cosmetic product; and
- An appropriate identification or tracking system should be in place to facilitate a rapid and effective recall or market withdrawal.

Registration of Products

Cosmetics manufactured, packaged, repackaged, labeled or relabeled in Florida must be registered with the Division.[34] Products that are both a cosmetic and a drug must be registered as a drug.[35] Registration of cosmetic products requires a manufacturer to submit a detailed Division application, a copy of the product labels, and a fee for each product. The application includes the following information: [36]

- Manufacturer's contact and address information, type of ownership, and operating hours;
- Identification of cosmetic product, whether domestic or exported, from the following categories:
    - Baby products;
    - Bath preparations;
    - Eye makeup preparations;
    - Fragrance preparations;
    - Hair preparations (not color related);
    - Hair coloring preparations;
    - Makeup preparations (not eye area);
    - Manicuring preparations;
    - Oral hygiene preparations;
    - Personal cleanliness;
    - Shaving preparations;
    - Skin care preparations (creams, lotions, powder, and sprays); and
    - Suntan preparations.
- Name of product as shown on label;

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[30] If the applicant also holds a drug manufacturer permit at the same time an inspection is not required. *Supra fn.* 28.
[31] *Supra fn.* 28.
[32] Letter from the Director of the Division of Drugs, Devices, and Cosmetics to a representative of the Florida Cosmetic Manufacturers Coalition on November 26, 2014. (on file with committee staff).
[33] Rule 61N-1.010, F.A.C.
[34] Section 499.015(1)(a), F.S.
[35] Rule 61N-1.016(1)(a), F.A.C.
[36] Florida Dep't of Business and Professional Regulation, Application for Product Registration-Cosmetics Form No.: DBPR-DDC-228, accessible at http://www.myfloridalicense.com/DBPR/ddc/ProductRegistrationforCosmetics.html (last viewed February 26, 2015).

- Identification of the product if it is for professional use only;
- Manufacturer of the product including their name, city, and state; and
- Signed affidavit section.

New cosmetic products must be registered prior to sale. If a manufacturer has existing registered products, its registered product list must be updated through the formal application process to include any new products.[37] The registration and biennial renewal fee for cosmetic products is $30.

Manufacturers often produce similar products or slightly alter products from an outside manufacturer; for example, they may use a different brand name, container, or scent for an almost identical product. In these instances, for registration purposes, the product is not considered separate and distinct. The process for "identical products" requires submission of an application and a $15 fee and biennial renewal fee for each additional size, quantity, color, flavor, and scent of a registered cosmetic product.[38]

The Division reviews applicants' product labels to determine compliance with the requirements of the FDCA.[39] The Division reviews the ingredients of the cosmetic to determine if the ingredients are approved for use in cosmetics or otherwise safe for cosmetic products.[40] Division pharmacists or drug inspectors review products that may contain ingredients that are prohibited or may change the classification of the product to a drug.[41]

The majority of cosmetic product registration applicants are not voluntarily registered with the FDA and are in noncompliance with FDA warning and labeling requirements. Oftentimes to spare the applicant from an application denial, the Division assists the applicant in correcting their product labels to be in compliance and properly registered.[42] The cosmetic product renewal process does not include a product and label review as is required when the product is initially registered with the Division.[43]

Currently, there are 7,278 active cosmetic product registrations[44] and from 2013 to 2014, the Division approved 1,196 cosmetic product registrations.[45] The Division's average processing time for cosmetic product registration is approximately 60 days.[46]

Certificates of Free Sale

Manufacturers exporting products from the United States are often asked by foreign customers or foreign governments to supply a certificate of free sale (COFS) to ensure that products are in compliance with FDA laws and regulations. A COFS is a document issued by a regulatory agency containing information about a product's regulatory or marketing status.[47] The Division, when requested by a cosmetic manufacturer, issues a certificate of free sale for a registered cosmetic product that is to be exported to another country.[48]

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[37] Rule 61N-1.016(4)(b), F.A.C.
[38] Rule 61N-1.016(1)(b), F.A.C.
[39] Rule 61N-1.009, F.A.C.
[40] Florida Dep't of Business and Professional Regulation, 2015 Legislative Bill Analysis HB 673 (on file with committee staff).
[41] *Supra fn.* 32.
[42] *Supra fn.* 32.
[43] *Supra fn.* 32.
[44] *Supra fn.* 40.
[45] *Supra fn.* 32.
[46] *Supra fn.* 32.
[47] Food and Drug Administration, *FDA Export Certificate,* December 18, 2014, accessible at http://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm, (last viewed February 24, 2015).
[48] Rule 61N-1.017, F.A.C.

Effect of Proposed Changes

HB 673 amends ch. 499, F.S., to remove the requirement that Florida cosmetic manufacturers register cosmetic products with the Division. The bill makes conforming changes by removing registration and renewal requirements for cosmetic products, including the requirements to submit registration applications, product labels, and registration and renewal fees.

This bill also removes the Division's authority to issue certificates of free sale for registered cosmetic products in s. 499.003(6), F.S.

The bill provides an effective date of July 1, 2015.

B. SECTION DIRECTORY:

Section 1. Amends s. 499.015, F.S., relating to registration of drugs, devices, and cosmetics; issuance of certificates of free sale.
Section 2. Amends s. 499.003, F.S., relating to definitions.
Section 3. Amends s. 499.041, F.S., relating to schedule of fees for drug, device, and cosmetic applications and permits, product registration, and free-sale certificates.
Section 4. Provides an effective date of July 1, 2015.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The Division will experience a decrease in revenues associated with no longer receiving payment of fees for cosmetic product registration, product registration renewal, and certificates of free sale (COFS). There are 7,278 current, active registered cosmetic products. Product registrations are renewed biennially. The Division's biennial renewal fees from the 7,278 products are approximately $187,275.00 (or $93,637.50 annually). In Fiscal Year 2013-14, the Division received $52,470.00 in new product registration fees. In Fiscal Year 2013-14, the Division received $7,862.00 in COFS fees. [49]

If enacted, HB 673 will cause an estimated Fiscal Year 2015-16 revenue reduction of $176,115.50 [$93,637.50 (annual renewals) + $72,450.00 (initial product registrations) + $10,028.00 (COFS)]. This amount is estimated to increase annually.[50] The negative fiscal impact on the Division is significant.

The State General Revenue Fund will experience a decrease in revenues associated with the 8% surcharge on Division revenues collected. Approximately $14,089 will not be contributed to the State General Revenue Fund in fiscal year 2015-2016.[51]

2. Expenditures:

The Division will incur minimal costs associated with rulemaking which can be absorbed within existing resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

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[49] *Supra fn.*40.
[50] *Supra fn.*40.
[51] *Supra fn.*40.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill has a positive fiscal impact for cosmetic manufacturers associated with no further payment of product registration and renewal fees to the Division.

D. FISCAL COMMENTS:

Revenue reductions will accelerate the timeline for the Drugs, Devices and Cosmetics Trust Fund (DDCTF) to be in a deficit. With these reductions, the DDCTF is anticipated to be in a deficit by Fiscal Year 2016-17.[52]

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[52] *Supra fn.* 40.

A bill to be entitled

An act relating to cosmetic product registration; amending s. 499.015, F.S.; removing the requirement that a person who manufactures, packages, repackages, labels, or relabels a cosmetic in this state must register such cosmetic biennially with the Department of Business and Professional Regulation; amending ss. 499.003 and 499.041, F.S.; conforming provisions to changes made by this act; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 499.015, Florida Statutes, is amended to read:

499.015 Registration of drugs and~~,~~ devices~~, and cosmetics~~; issuance of certificates of free sale.—

(1)(a) Except for those persons exempted from the definition of manufacturer in s. 499.003, any person who manufactures, packages, repackages, labels, or relabels a drug or~~,~~ device~~, or cosmetic~~ in this state must register such drug or~~,~~ device~~, or cosmetic~~ biennially with the department; pay a fee in accordance with the fee schedule provided by s. 499.041; and comply with this section. The registrant must list each separate and distinct drug or~~,~~ device~~, or cosmetic~~ at the time of registration.

(b) The department may not register any product that does

not comply with the Federal Food, Drug, and Cosmetic Act, as amended, or Title 21 C.F.R. Registration of a product by the department does not mean that the product does in fact comply with all provisions of the Federal Food, Drug, and Cosmetic Act, as amended.

(2) The department may require the submission of a catalog and specimens of labels at the time of application for registration of drugs or ~~,~~ devices~~, and cosmetics~~ packaged and prepared in compliance with the federal act, which submission constitutes a satisfactory compliance for registration of the products. With respect to all other drugs and~~,~~ devices~~, and cosmetics~~, the department may require the submission of a catalog and specimens of labels at the time of application for registration, but the registration will not become effective until the department has examined and approved the label of the drug or~~,~~ device~~, or cosmetic product~~. This approval or denial must include written notification to the manufacturer.

(3) Except for those persons exempted from the definition of manufacturer in s. 499.003, a person may not sell any product that he or she has failed to register in conformity with this section. Such failure to register subjects such drug or~~,~~ device~~, or cosmetic product~~ to seizure and condemnation as provided in s. 499.062, and subjects such person to the penalties and remedies provided in this part.

(4) Unless a registration is renewed, it expires 2 years after the last day of the month in which it was issued. The

department may issue a stop-sale notice or order against a person that is subject to the requirements of this section and that fails to comply with this section within 31 days after the date the registration expires. The notice or order shall prohibit such person from selling or causing to be sold any drugs or~~,~~ devices~~, or cosmetics~~ covered by this part until he or she complies with the requirements of this section.

(5) A product regulated under this section which is not included in the biennial registration may not be sold until it is registered and complies with this section.

(6) The department may issue a certificate of free sale for any product that is required to be registered under this part.

(7) A product registration is valid only for the company named on the registration and located at the address on the registration. A person whose product is registered by the department under this section must notify the department before any change in the name or address of the establishment to which the product is registered. If a person whose product is registered ceases conducting business, the person must notify the department before closing the business.

(8) Notwithstanding any requirements set forth in this part, a manufacturer of medical devices that is registered with the federal Food and Drug Administration is exempt from this section and s. 499.041(6) if:

(a) The manufacturer's medical devices are approved for

marketing by, or listed with the federal Food and Drug Administration in accordance with federal law for commercial distribution; or

(b) The manufacturer subcontracts with a manufacturer of medical devices to manufacture components of such devices.

(9) However, the manufacturer must submit evidence of such registration, listing, or approval with its initial application for a permit to do business in this state, as required in s. 499.01 and any changes to such information previously submitted at the time of renewal of the permit. Evidence of approval, listing, and registration by the federal Food and Drug Administration must include:

(a) For Class II devices, a copy of the premarket notification letter (510K);

(b) For Class III devices, a federal Food and ~~Federal~~ Drug Administration premarket approval number;

(c) For a manufacturer who subcontracts with a manufacturer of medical devices to manufacture components of such devices, a federal Food and ~~Federal~~ Drug Administration registration number; or

(d) For a manufacturer of medical devices whose devices are exempt from premarket approval by the federal Food and ~~Federal~~ Drug Administration, a federal Food and ~~Federal~~ Drug Administration registration number.

Section 2. Subsection (6) of section 499.003, Florida Statutes, is amended to read:

499.003 Definitions of terms used in this part.—As used in this part, the term:

(6) "Certificate of free sale" means a document prepared by the department which certifies a drug or~~,~~ device~~, or cosmetic,~~ that is registered with the department~~,~~ as one that can be legally sold in the state.

Section 3. Subsection (6) of section 499.041, Florida Statutes, is amended to read:

499.041 Schedule of fees for drug, device, and cosmetic applications and permits, product registrations, and free-sale certificates.—

(6) A person that is required to register drugs or~~,~~ devices~~, or cosmetic products~~ under s. 499.015 shall pay an annual product registration fee of not less than $5 or more than $15 for each separate and distinct product in package form. The registration fee is in addition to the fee charged for a free-sale certificate.

Section 4. This act shall take effect July 1, 2015.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 697 Public Health
SPONSOR(S): Gonzalez
TIED BILLS: **IDEN./SIM. BILLS:** SB 950

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		O'Callaghan	O'Callaghan
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The State Health Officer is responsible for declaring public health emergencies and issuing public health advisories. A public health emergency exists when there is an occurrence, or threat of an occurrence, whether natural or manmade, which results or may result in substantial injury or harm to the public health from infectious disease, chemical agents, nuclear agents, biological toxins, or situations involving mass casualties or natural disasters. The State Health Officer is authorized to take certain actions that are necessary to protect the public health after declaring a public health emergency, including ordering an individual to be examined, tested, vaccinated, treated, or quarantined for communicable diseases that have significant morbidity or mortality and present a severe danger to public health.

HB 697 allows the State Health Officer to also isolate an individual who has a communicable disease that has a significant morbidity or mortality and presents a severe danger to the public health. The bill defines "quarantine" and "isolation" to distinguish the two terms.

The bill also authorizes law enforcement officers to immediately enforce orders by the Department of Health (Department), which relate to the isolation or quarantine of persons, animals, and premises when controlling communicable diseases or providing protection from unsafe conditions that pose a threat to public health. The bill provides that a violation of an order of isolation constitutes a misdemeanor of the second degree.

The bill authorizes the Department to adopt rules to specify the conditions and procedures for imposing and lifting an order for isolation; rules related to the Department's access to persons in isolation or quarantine or the premises housing such persons; rules related to the disinfection of isolated animals, persons, or premises; and rules related to the methods of isolation.

The bill states that rules related to isolation and the Department's enforcement actions supersede all other agency rules and ordinances, and regulations enacted by political subdivisions of the state.

The bill may have an indeterminate negative fiscal impact on state and local government associated with using resources to enforce isolation orders during a declared public health emergency.

The bill provides an effective date of July 1, 2015.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Isolation and quarantine help protect the public by preventing exposure to people who have or may have a communicable disease[1]. Specifically, "isolation" separates people infected with a communicable disease from people who are not infected, while "quarantine" separates and restricts the movement of people who were exposed to a communicable disease to determine whether they have been infected.[2]

Federal Authority

The federal government derives its authority to isolate and quarantine individuals from the Commerce Clause[3] of the U.S. Constitution. Under section 361 of the Public Health Service Act,[4] the U.S. Secretary of Health and Human Services is authorized to take measures to prevent the entry and spread of communicable diseases from foreign countries into the United States and between states. The authority for carrying out these functions has been delegated to the Centers for Disease Control and Prevention (CDC).[5]

The CDC is authorized to detain, medically examine, and release persons who arrive into the U.S. or travel between states, and who are suspected of carrying communicable diseases.[6] The CDC routinely monitors persons arriving at U.S. land border crossings and passengers and crew arriving at U.S. ports of entry for signs or symptoms of communicable diseases.[7] When alerted about an ill passenger or crew member by the pilot of a plane or captain of a ship, the CDC may detain passengers and crew as necessary to investigate whether the cause of the illness on board is a communicable disease.[8]

The CDC may quarantine or isolate individuals who may have been infected with, or have been infected with, certain communicable diseases that have been declared "quarantinable diseases" by Presidential Executive Order.[9] Currently, the following diseases have been declared quarantinable diseases:

- Cholera;
- Diphtheria;
- Infectious tuberculosis;
- Plague;
- Smallpox;
- Yellow fever;
- Viral hemorrhagic fevers (e.g. Ebola and Marburg viruses);

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[1] "Communicable disease" is an illness due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host, either directly from an infected person or animal or indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment. 42 C.F.R. § 70.1.

[2] Centers for Disease Control and Prevention, "Quarantine and Isolation: Fact Sheet-October 2014," available at: http://www.cdc.gov/quarantine/aboutlawsregulationsquarantineisolation.html (last visited on February 25, 2015).

[3] Art. I, Sect. 8, Clause 3, U.S. Const.

[4] 42 U.S.C. § 264.

[5] *Supra* fn. 2.

[6] 42 C.F.R. Parts 70, 71.

[7] There are 20 U.S. Quarantine Stations, located at ports of entry and land border crossings. A map of the location of each station is available at: http://www.cdc.gov/ncezid/dgmq/quarantine-fact-sheet.html (last visited on February 25, 2015).

[8] *Supra* fn. 2.

[9] Centers for Disease Control and Prevention, "Quarantine and Isolation: Questions and Answers on the Executive Order Adding Potentially Pandemic Influenza Viruses to the List of Quarantinable Diseases," available at: http://www.cdc.gov/quarantine/qa-executive-order-pandemic-list-quarantinable-diseases.html (last visited on February 25, 2015).

- Severe acute respiratory syndromes; and
- New types of flu (influenza) that could cause a pandemic.[10]

If the CDC issues a federal isolation or quarantine order, the U.S. Customs and Border Protection and U.S. Coast Guard officers are authorized to help enforce the federal order. State law enforcement may also assist in the enforcement of a CDC order. Breaking a federal isolation or quarantine order is punishable by fines and imprisonment.[11]

CDC isolation and quarantine orders are rare. A large-scale isolation and quarantine order has not been enforced since the influenza ("Spanish Flu") pandemic, which lasted from 1918 to 1919. In recent history, only a few public health events have prompted federal isolation or quarantine orders.[12]

State Authority

The 10th Amendment to the U.S. Constitution has been interpreted by the U.S. Supreme Court to give states "police power," which allows states to quarantine and isolate individuals to protect the health, safety, and welfare of persons within their borders.[13] To control the spread of disease within their borders, states enact laws to enforce the use of isolation and quarantine. These laws can vary from state to state and can be specific or broad. In some states, local health authorities implement state law. In most states, breaking a quarantine order is a criminal misdemeanor.[14]

Florida Quarantine Authority

The State Health Officer is responsible for declaring public health emergencies and issuing public health advisories.[15] A public health emergency exists when there is an occurrence, or threat of an occurrence, whether natural or manmade, which results or may result in substantial injury or harm to the public health from infectious disease, chemical agents, nuclear agents, biological toxins, or situations involving mass casualties or natural disasters.[16] The State Health Officer is authorized to take certain actions that are necessary to protect the public health after declaring a public health emergency, including ordering an individual to be examined, tested, vaccinated, treated, or quarantined for communicable diseases that have significant morbidity or mortality and present a severe danger to public health.[17]

The State Health Officer may subject an individual to quarantine if the individual poses a danger to the public health.[18] If there is no practical method to quarantine the individual, the State Health Officer may use any means necessary to vaccinate or treat the individual.[19]

Currently, the Department of Health (Department) has a duty and the authority to declare, enforce, modify, and abolish quarantines of persons, animals, and premises for controlling communicable diseases or providing protection from unsafe conditions that pose a threat to public health. However,

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[10] *Supra* fn. 2.
[11] A person violating quarantine laws is punishable by a fine of not more than $1,000 or by imprisonment for not more than one year, or both. 42 U.S.C. § 271.
[12] *Supra* fn. 2.
[13] *Jacobson v. Mass.,* 197 U.S. 11 (1905).
[14] Centers for Disease Control and Prevention, "Isolation and Quarantine: Legal Authorities for Isolation and Quarantine," available at: http://www.cdc.gov/quarantine/aboutLawsRegulationsQuarantineIsolation.html (last visited on February 25, 2015).
[15] Section 381.00315, F.S.
[16] Section 381.00315(1)(b), F.S.
[17] *Id.*
[18] Individuals, who are unable or unwilling to be examined, tested, vaccinated, or treated for reasons of health, religion, or conscience, may also be subjected to quarantine. Section 381.00315(1)(b), F.S.
[19] *Id.*

there are exceptions and limitations to the Department's duty and authority to quarantine individuals who are infected with sexually transmitted diseases[20] or tuberculosis[21].

A State Health Officer's order to quarantine an individual during a declared public health emergency is immediately enforceable by a law enforcement officer.[22] A person who violates a quarantine order commits a misdemeanor of the second degree.[23,24]

Individuals who assist the State Health Officer at his or her request on a volunteer basis during a public health emergency are entitled to the following benefits:

- Free temporary lodging;
- Transportation reimbursement or the utilization of state vehicles in the performance of department-related duties;
- State liability protection under s. 768.28, F.S.; and
- Workers' compensation coverage in accordance with ch. 440, F.S.[25]

The Department is required to adopt rules to specify the conditions and procedures for imposing and releasing a quarantine order.[26] The rules must include provisions related to:

- The closure of premises.
- The movement of persons or animals exposed to or infected with a communicable disease.
- The tests or treatment, including vaccination, for communicable disease required prior to employment or admission to the premises or to comply with a quarantine.
- Testing or destruction of animals with or suspected of having a disease transmissible to humans.
- Access by the Department to quarantined premises.
- The disinfection of quarantined animals, persons, or premises.
- Methods of quarantine.[27]

Rules adopted by the Department that relate to public health emergencies, including quarantine rules, supersede all rules enacted by other state departments or boards and commissions, and ordinances and regulations enacted by political subdivisions of the state.[28]

Effect of Proposed Changes

HB 697 allows the State Health Officer to isolate an individual who has a communicable disease that has a significant morbidity or mortality and presents a severe danger to the public health.

The bill defines "quarantine" and "isolation" to distinguish the two terms. "Quarantine" is defined as the separation of an individual reasonably believed to have been exposed to a communicable disease, but who is not yet showing symptoms, from others who have not been exposed to the disease to prevent the possible spread of the disease. "Isolation" is defined as the separation of an individual who is reasonably believed to be infected with a communicable disease from those who are not infected with the disease to prevent the spread of the disease.

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[20] Section 384.28, F.S.
[21] Sections 392.545-.60, F.S.
[22] Section 381.00315(1), F.S.
[23] A second-degree misdemeanor is punishable by a term of imprisonment not exceeding 60 days, or a fine up to $500. Sections 775.082 and 775.083, F.S.
[24] Section 381.00315(6), F.S.
[25] *See* s. 381.00315(2) and ss. 110.504(2), (3), (4), (5), F.S.
[26] Section 381.00315(5), F.S.
[27] *See* rules 64D-3.037 and 64D-3.038, F.A.C.
[28] *Id.*

The bill also authorizes law enforcement officers to immediately enforce orders by the Department, which relate to the isolation or quarantine of persons, animals, and premises when controlling communicable diseases or providing protection from unsafe conditions that pose a threat to public health. The bill makes a violation of an order of isolation a misdemeanor of the second degree.

The bill authorizes the Department to adopt rules to specify the conditions and procedures for imposing and lifting an order for isolation; rules related to the Department's access to persons in isolation or quarantine or the premises housing such persons; rules related to the disinfection of isolated animals, persons, or premises; and rules related to the methods of isolation.

The bill states that rules related to isolation and the Department's enforcement actions supersede all other agency rules and ordinances, and regulations enacted by political subdivisions of the state.

The bill has an effective date of July 1, 2015.

B. SECTION DIRECTORY:

Section 1: Amends s. 381.0012, F.S., relating to enforcement authority.
Section 2: Amends s. 381.00315, F.S., relating to public health advisories; public health emergencies; and isolation and quarantines.
Section 3: Provides an effective date of July 1, 2015.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The Department may incur indeterminate costs associated with enforcing isolation orders and for providing benefits pursuant to s. 381.00315(2), F.S., to those persons assisting with the enforcement of an isolation order. Additionally, the Department will incur costs associated with rulemaking.

   The bill creates a new misdemeanor of the second degree for violations of isolation orders. Therefore, it could have a negative jail bed impact and a positive fiscal impact associated with any fines that are assessed.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   Local governments may incur indeterminate costs associated with assisting the Department with the enforcement of isolation orders, including the transport, security, and monitoring of isolated individuals.[29]

[29] Florida Department of Health, 2015 Agency Legislative Analysis of HB 697, February 19, 2015, on file with the Health Quality Subcommittee.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Health care facilities may incur indeterminate costs associated with the care, monitoring, and security of isolated individuals.[30]

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

The county/municipality mandates provision of Art. VII, section 18, of the Florida Constitution may apply because this bill requires local law enforcement agencies to use their resources to enforce isolation orders. However, quarantines of individuals exposed to a communicable disease have historically been rare.[31] Because it is likely that even fewer individuals would be infected with a communicable disease and ordered to be isolated, it appears the costs to a county or municipality would be insignificant.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill authorizes the Department to adopt rules to specify the conditions and procedures for imposing and lifting an order for isolation; rules related to the Department's access to persons in isolation or quarantine or the premises housing such persons; rules related to the disinfection of isolated animals, persons, or premises; and rules related to the methods of isolation.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[30] *Id.*

[31] During the only two declared public health emergencies in the last 5 years, the State Health Officer and the Department of Health did not quarantine a single person. Department of Health e-mail to professional staff of the Health Quality Subcommittee, on file with the committee, received February 27, 2015.

A bill to be entitled

An act relating to public health; amending s. 381.0012, F.S.; providing additional enforcement authority relating to public health orders issued by the Department of Health; amending s. 381.00315, F.S.; defining terms; authorizing the department to declare, enforce, modify, and abolish isolation of persons, animals, and premises for controlling communicable diseases or providing protection from unsafe conditions that pose a threat to public health; requiring the department to establish rules for conditions and procedures for imposing and releasing an order for isolation; providing that rules established under this section supersede all rules enacted by other state agencies, boards, or political subdivisions; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (5) of section 381.0012, Florida Statutes, is amended to read:

381.0012 Enforcement authority.—

(5) It shall be the duty of every state and county attorney, sheriff, police officer, and other appropriate city and county officials upon request to assist the department or any of its agents in enforcing the state health laws, ~~and the~~

rules, and orders adopted under this chapter.

Section 2. Section 381.00315, Florida Statutes, is amended to read:

381.00315 Public health advisories; public health emergencies; isolation and quarantines.—The State Health Officer is responsible for declaring public health emergencies, issuing public health advisories, and ordering isolation or ~~and~~ quarantines ~~and issuing public health advisories~~.

(1) As used in this section, the term:

(a) "Isolation" means the separation of an individual who is reasonably believed to be infected with a communicable disease from individuals who are not infected, to prevent the possible spread of the disease.

(b) ~~(a)~~ "Public health advisory" means any warning or report giving information to the public about a potential public health threat. Before ~~Prior to~~ issuing any public health advisory, the State Health Officer must consult with any state or local agency regarding areas of responsibility which may be affected by such advisory. Upon determining that issuing a public health advisory is necessary to protect the public health and safety, and prior to issuing the advisory, the State Health Officer must notify each county health department within the area which is affected by the advisory of the State Health Officer's intent to issue the advisory. The State Health Officer is authorized to take any action appropriate to enforce any public health advisory.

(c) ~~(b)~~ "Public health emergency" means any occurrence, or threat thereof, whether natural or man made, which results or may result in substantial injury or harm to the public health from infectious disease, chemical agents, nuclear agents, biological toxins, or situations involving mass casualties or natural disasters. Before ~~Prior to~~ declaring a public health emergency, the State Health Officer shall, to the extent possible, consult with the Governor and shall notify the Chief of Domestic Security. The declaration of a public health emergency shall continue until the State Health Officer finds that the threat or danger has been dealt with to the extent that the emergency conditions no longer exist and he or she terminates the declaration. However, a declaration of a public health emergency may not continue for longer than 60 days unless the Governor concurs in the renewal of the declaration. The State Health Officer, upon declaration of a public health emergency, may take actions that are necessary to protect the public health. Such actions include, but are not limited to:

1. Directing manufacturers of prescription drugs or over-the-counter drugs who are permitted under chapter 499 and wholesalers of prescription drugs located in this state who are permitted under chapter 499 to give priority to the shipping of specified drugs to pharmacies and health care providers within geographic areas that have been identified by the State Health Officer. The State Health Officer must identify the drugs to be shipped. Manufacturers and wholesalers located in the state must

respond to the State Health Officer's priority shipping directive before shipping the specified drugs.

2. Notwithstanding chapters 465 and 499 and rules adopted thereunder, directing pharmacists employed by the department to compound bulk prescription drugs and provide these bulk prescription drugs to physicians and nurses of county health departments or any qualified person authorized by the State Health Officer for administration to persons as part of a prophylactic or treatment regimen.

3. Notwithstanding s. 456.036, temporarily reactivating the inactive license of the following health care practitioners, when such practitioners are needed to respond to the public health emergency: physicians licensed under chapter 458 or chapter 459; physician assistants licensed under chapter 458 or chapter 459; licensed practical nurses, registered nurses, and advanced registered nurse practitioners licensed under part I of chapter 464; respiratory therapists licensed under part V of chapter 468; and emergency medical technicians and paramedics certified under part III of chapter 401. Only those health care practitioners specified in this paragraph who possess an unencumbered inactive license and who request that such license be reactivated are eligible for reactivation. An inactive license that is reactivated under this paragraph shall return to inactive status when the public health emergency ends or before ~~prior to~~ the end of the public health emergency if the State Health Officer determines that the health care practitioner is

no longer needed to provide services during the public health emergency. Such licenses may only be reactivated for a period not to exceed 90 days without meeting the requirements of s. 456.036 or chapter 401, as applicable.

4. Ordering an individual to be examined, tested, vaccinated, treated, <u>isolated,</u> or quarantined for communicable diseases that have significant morbidity or mortality and present a severe danger to public health. Individuals who are unable or unwilling to be examined, tested, vaccinated, or treated for reasons of health, religion, or conscience may be subjected to <u>isolation or</u> quarantine.

a. Examination, testing, vaccination, or treatment may be performed by any qualified person authorized by the State Health Officer.

b. If the individual poses a danger to the public health, the State Health Officer may subject the individual to <u>isolation or</u> quarantine. If there is no practical method to <u>isolate or</u> quarantine the individual, the State Health Officer may use any means necessary to vaccinate or treat the individual.

Any order of the State Health Officer given to effectuate this paragraph shall be immediately enforceable by a law enforcement officer under s. 381.0012.

<u>(d) "Quarantine" means the separation of an individual reasonably believed to have been exposed to a communicable disease, but who is not yet ill, from individuals who have not</u>

been so exposed, to prevent the possible spread of the disease.

(2) Individuals who assist the State Health Officer at his or her request on a volunteer basis during a public health emergency are entitled to the benefits specified in s. 110.504(2), (3), (4), and (5).

(3) To facilitate effective emergency management, when the United States Department of Health and Human Services contracts for the manufacture and delivery of licensable products in response to a public health emergency and the terms of those contracts are made available to the states, the department shall accept funds provided by counties, municipalities, and other entities designated in the state emergency management plan required under s. 252.35(2)(a) for the purpose of participation in those contracts. The department shall deposit those funds in the Grants and Donations Trust Fund and expend those funds on behalf of the donor county, municipality, or other entity for the purchase of the licensable products made available under the contract.

(4) The department has the duty and the authority to declare, enforce, modify, and abolish the isolation and quarantine ~~quarantines~~ of persons, animals, and premises as the circumstances indicate for controlling communicable diseases or providing protection from unsafe conditions that pose a threat to public health, except as provided in ss. 384.28 and 392.545-392.60. Any order of the department issued pursuant to this subsection shall be immediately enforceable by a law enforcement

officer under s. 381.0012.

(5) The department shall adopt rules to specify the conditions and procedures for imposing and releasing an isolation or a quarantine. The rules must include provisions related to:

(a) The closure of premises.

(b) The movement of persons or animals exposed to or infected with a communicable disease.

(c) The tests or treatment, including vaccination, for communicable disease required before ~~prior to~~ employment or admission to the premises or to comply with an isolation or a quarantine.

(d) Testing or destruction of animals with or suspected of having a disease transmissible to humans.

(e) Access by the department to isolated or quarantined premises.

(f) The disinfection of isolated or quarantined animals, persons, or premises.

(g) Methods of isolation or quarantine.

(6) The rules adopted under this section and actions taken by the department pursuant to a declared public health emergency, isolation, or quarantine shall supersede all rules enacted by other state departments, boards or commissions, and ordinances and regulations enacted by political subdivisions of the state. Any person who violates any rule adopted under this section, any isolation or quarantine, or any requirement adopted

by the department pursuant to a declared public health emergency, commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

Section 3. This act shall take effect July 1, 2015.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 697 (2015)

Amendment No. 1

COMMITTEE/SUBCOMMITTEE ACTION	
ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Gonzalez offered the following:

Amendment (with title amendment)

T I T L E A M E N D M E N T

Remove line 2 and insert:

An act relating to public health emergencies; amending s.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 697 (2015)

Amendment No. 2

COMMITTEE/SUBCOMMITTEE ACTION	
ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Gonzalez offered the following:

Amendment (with title amendment)

Remove line 186 and insert:

Section 3. The Legislature finds that this act fulfills an important state interest.

Section 4. This act shall take effect July 1, 2015.

T I T L E A M E N D M E N T

Remove line 16 and insert:

subdivisions; providing a legislative finding of important state interest; providing an effective date.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 697 (2015)

Amendment No. 3

COMMITTEE/SUBCOMMITTEE ACTION	
ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Harrell offered the following:

Amendment (with title amendment)

Between lines 185 and 186, insert:

Section 3. Subsection (1) of section 817.50, Florida Statutes, is amended to read:

817.50 Fraudulently obtaining goods, services, etc., from a health care provider.—

(1) Whoever shall, willfully and with intent to defraud, obtain or attempt to obtain goods, products, merchandise, or services from any health care provider in this state, as defined in s. 641.19(14), including a person who willfully and with intent to defraud claims that he or she has contracted a communicable disease to obtain or attempt to obtain such goods, products, merchandise, or services or falsely reports such to a

law enforcement officer, as defined under s. 943.10, during a declared public health emergency under s. 381.00315, commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

T I T L E A M E N D M E N T

Remove line 16 and insert:

subdivisions; amending s. 817.50, F.S.; applying a current criminal penalty to a person intending to defraud a health care provider or law enforcement officer under certain circumstances; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 751 Emergency Treatment for Opioid Overdose
SPONSOR(S): Gonzalez and others
TIED BILLS: **IDEN./SIM. BILLS:** HB 155, SB 758

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		CR McElroy	O'Callaghan MO
2) Civil Justice Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Deaths from drug overdose have steadily increased over the past few decades and have become the leading cause of accidental deaths in the United States. The vast majority of these deaths involved an overdose related to opioid analgesics, which are narcotic pain relievers derived from the opium poppy, or its synthetic analogues. Although some of these deaths are unpreventable, opioid antagonists have proven successful in reversing opioid related drug overdoses when administered in a timely manner.

HB 751 creates the Emergency Treatment and Recovery Act, which authorizes health care practitioners to prescribe, and pharmacists to dispense, emergency opioid antagonists to patients and caregivers. Patients and caregivers are authorized to store and possess emergency opioid antagonists. In an emergency situation when a physician is not immediately available, patients and caregivers are authorized to administer an emergency opioid antagonist to a person believed in good faith to be experiencing an opioid overdose, regardless of whether that person has a prescription for an emergency opioid antagonist.

The bill provides for civil liability protections under the Good Samaritan Act for all individuals, and professional disciplinary exemptions for certain health care providers, who comply with the bill's requirements. The bill does not limit other existing immunities currently afforded to certain health care providers.

The bill defines the terms emergency opioid antagonist and caregiver.

The bill does not appear to have a fiscal impact on state or local government.

The bill takes effect upon becoming a law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Opioids

The drug overdose death rate has more than doubled from 1999 through 2013 and has now become the leading cause of accidental deaths in the United States.[1] In 2013, there were 43,982 drug overdose deaths in the United States of which 22,767 (51.8%) were related to pharmaceuticals.[2] The majority of the pharmaceutical related deaths, 16,235 (71.3%), involved opioid analgesic drugs (opioids).[3]

Opioids are psychoactive substances derived from the opium poppy, or their synthetic analogues.[4] They are commonly used as pain relievers to treat acute and chronic pain. An individual experiences pain as a result of a series of electrical and chemical exchanges among his or her peripheral nerves, spinal cord and brain.[5] Opioid receptors occur naturally and are distributed widely throughout the central nervous system and in peripheral sensory and autonomic nerves.[6] When an individual experiences pain the body releases hormones, such as endorphins, which bind with targeted opioid receptors.[7] This disrupts the transmission of pain signals through the central nervous system and reduces the perception of pain.[8] Opioids function in the same way by binding to specific opioid receptors in the brain, spinal cord and gastrointestinal tract, thereby reducing the perception of pain.[9] Opioids include[10]:

- Buprenorphine (Subutex, Suboxone)
- Codeine
- Fentanyl (Duragesic, Fentora)
- Heroin
- Hydrocodone (Vicodin, Lortab, Norco)
- Hydromorphone (Dilaudid, Exalgo)
- Meperidine
- Methadone
- Morphine
- Oxycodone (OxyContin, Percodan, Percocet)
- Oxymorphone

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[1] More deaths occur each year due to drug overdose than deaths caused by motor vehicle crashes. *Prescription Drug Overdose in the United States: Fact Sheet*, Centers for Disease Control and Prevention. http://www.cdc.gov/homeandrecreationalsafety/overdose/facts.html (last visited 2/27/15).

[2] *Prescription Drug Overdose in the United States: Fact Sheet*, Centers for Disease Control and Prevention. http://www.cdc.gov/homeandrecreationalsafety/overdose/facts.html (last visited 2/27/15).

[3] Id.

[4] *Information Sheet on Opioid Overdose*, World Health Organization, November 2014. http://www.who.int/substance_abuse/information-sheet/en/ (last visited 2/27/15).

[5] Mayo Clinic Health Library, http://www.riversideonline.com/health_reference/Nervous-System/PN00017.cfm (lasted visited).

[6] *Imaging of Opioid Receptors in the Central Nervous System,* Gjermund Henriksen, Frode Willoch; Brain (2008) 131 (5): 1171-1196.

[7] Id.

[8] Id.

[9] *SAMHSA Opioid Overdose Toolkit: Facts for Community Members*, Department of Health and Human Services- Substance Abuse and Mental Health Services Administration.

[10] *Drugs Identified in Deceased Persons by Florida Medical Examiners 2012 Report,* Florida Department of Law Enforcement, September 2013.

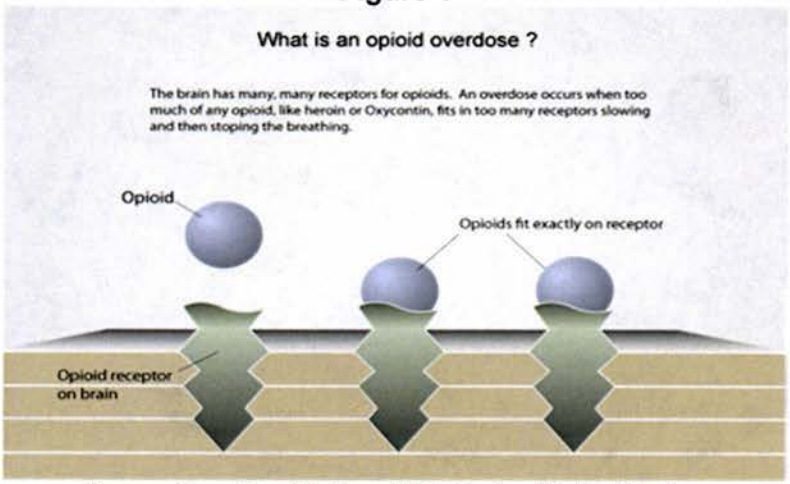
- Tramadol

Opioids are commonly abused with an estimated 15 million people worldwide suffering from opioid dependence.[11] Opioids can create a euphoric feeling because they affect the regions of the brain involved with pleasure and reward which can lead to abuse.[12] Continued use of these drugs can lead to the development of tolerance and psychological and physical dependence.[13] This dependence is characterized by a strong desire to take opioids, impaired control over opioid use, persistent opioid use despite harmful consequences, a higher priority given to opioid use than to other activities and obligations, and a physical withdrawal reaction when opioids are discontinued.[14]

An overabundance of opioids in the body can lead to a fatal overdose. In addition to their presence in major pain pathways, opioid receptors are also located in the respiratory control centers of the brain.[15] Opioids disrupt the transmission of signals for respiration in the identical manner that they disrupt the transmission of pain signals (figure 1). This leads to a reduction, and potentially cessation, of an individual's respiration. Oxygen starvation will eventually stop vital organs like the heart, then the brain, and can lead to unconsciousness, coma, and possibly death.[16] Within 3-5 minutes without oxygen, brain damage starts to occur, soon followed by death.[17] However, this does not occur instantaneously as people will commonly stop breathing slowly, minutes to hours after the drug or drugs were used.[18] An opioid overdose can be identified by a combination of three signs and symptoms referred to as the "opioid overdose triad":[19]

- Pinpoint pupils;
- Unconsciousness; and,
- Respiratory depression.

Figure 1



Source: Maya Doe-Simkins, MPH, Boston Medical Center.

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[11] *Information Sheet on Opioid Overdose*, World Health Organization, November 2014. http://www.who.int/substance_abuse/information-sheet/en/ (last visited 2/27/15).

[12] *How Do Opioids Affect the Brain and Body?*, National Institute on Drug Abuse. http://www.drugabuse.gov/publications/research-reports/prescription-drugs/opioids/how-do-opioids-affect-brain-body (last visited 2/27/15).

[13] *Imaging of Opioid Receptors in the Central Nervous System*, Gjermund Henriksen, Frode Willoch; Brain (2008) 131 (5): 1171-1196.

[14] *Information Sheet on Opioid Overdose*, World Health Organization, November 2014. http://www.who.int/substance_abuse/information-sheet/en/ (last visited 2/27/15).

[15] *Opioids and the Control of Respiration*, K.T.S. Pattinson, BJA, Volume 100, Issue 6, Pages 747-758. http://bja.oxfordjournals.org/content/100/6/747.full (last visited 2/27/15).

[16] *Guide to Developing and Managing Overdose Prevention and Take-Home Naloxone Projects*, Harm Reduction Coalition, Fall 2012. http://harmreduction.org/our-work/overdose-prevention/ (last visited 2/27/15).

[17] Id.

[18] Id.

[19] *Information Sheet on Opioid Overdose*, World Health Organization, November 2014. http://www.who.int/substance_abuse/information-sheet/en/ (last visited 2/27/15).

Opioid Antagonist

An opioid overdose can be reversed if an opioid antagonist is administered in a timely manner. Opioid antagonists are used in opioid overdoses to counteract life-threatening depression of the central nervous system and respiratory system, allowing an overdose victim to breathe normally.[20] This occurs because opioid antagonists create a stronger bond with opioid receptors than opioids. This forces the opioids from the opioid receptors and allows the transmission of signals for respiration to resume.[21] This effect lasts only for a short period of time[22] with the narcotic effect of the opioids returning if still present in large quantities in the body. In this scenario additional doses of an opioid antagonist would be required and it is why it is generally recommended that anyone who has experienced an overdose seek medical attention.

Community-based opioid antagonist prevention programs can be successful in increasing the number of opioid overdose reversals. Opioid antagonists were originally prescribed and distributed only to emergency personnel (EMTs, firefighters and law enforcement). In 1996, community-based programs began offering opioid antagonists and other opioid overdose prevention services, in states authorizing such activities, to persons who use drugs, their families and friends and service providers (health-care providers, homeless shelters and substance abuse treatment programs).[23] In October 2010, a national advocacy and capacity-building organization surveyed 50 programs known to distribute opioid antagonists in the United States, to collect data on various issues including overdose reversals.[24] Forty-eight programs responded to the survey and reported training and distributing opioid antagonists to 53,032 persons and receiving reports of 10,171[25] overdose reversals.[26] Based upon these findings, the report concluded that providing opioid overdose education and opioid antagonists to persons who use drugs and to persons who might be present at an opioid overdose can help reduce opioid overdose mortality.[27]

Multiple states have enacted statutes to allow for the prescription and lay-person use of opioid antagonists (figure 2). For example, as of November 2014:[28]

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[20] *Understanding Naloxone,* Harm Reduction Coalition. http://harmreduction.org/issues/overdose-prevention/overview/overdose-basics/understanding-naloxone/ (last visited 2/27/15).

[21] *Guide to Developing and Managing Overdose Prevention and Take-Home Naloxone Projects*, Harm Reduction Coalition, Fall 2012. http://harmreduction.org/our-work/overdose-prevention/ (last visited 2/27/15).

[22] The half-life for a common opioid antagonist in adults ranged from 30 to 81 minutes. Acute opiate withdrawal is a potential side-effect of naloxone; however, this would be time limited to the half-life of naloxone.

[23] *Community-Based Opioid Overdose Prevention Programs Providing Naloxone — United States, 2010*, Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report (MMWR), February 17, 2012 / 61(06);101-105. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6106a1.htm (last visited 2/27/15).

[24] Id.

[25] The findings in this report are subject to at least three limitations. First, other opioid antagonist distribution programs might exist that were unknown to the national advocacy group. Second, all data is based on unconfirmed self-reports from the 48 responding programs. Finally, the numbers of persons trained in opioid antagonist administration and the number of overdose reversals involving opioid antagonists likely were underreported because of incomplete data collection and unreported overdose reversals. However, because not all untreated opioid overdoses are fatal, some of the persons with reported overdose reversals likely would have survived without opioid antagonist administration. *Community-Based Opioid Overdose Prevention Programs Providing Naloxone — United States, 2010*, Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report (MMWR), February 17, 2012 / 61(06);101-105.

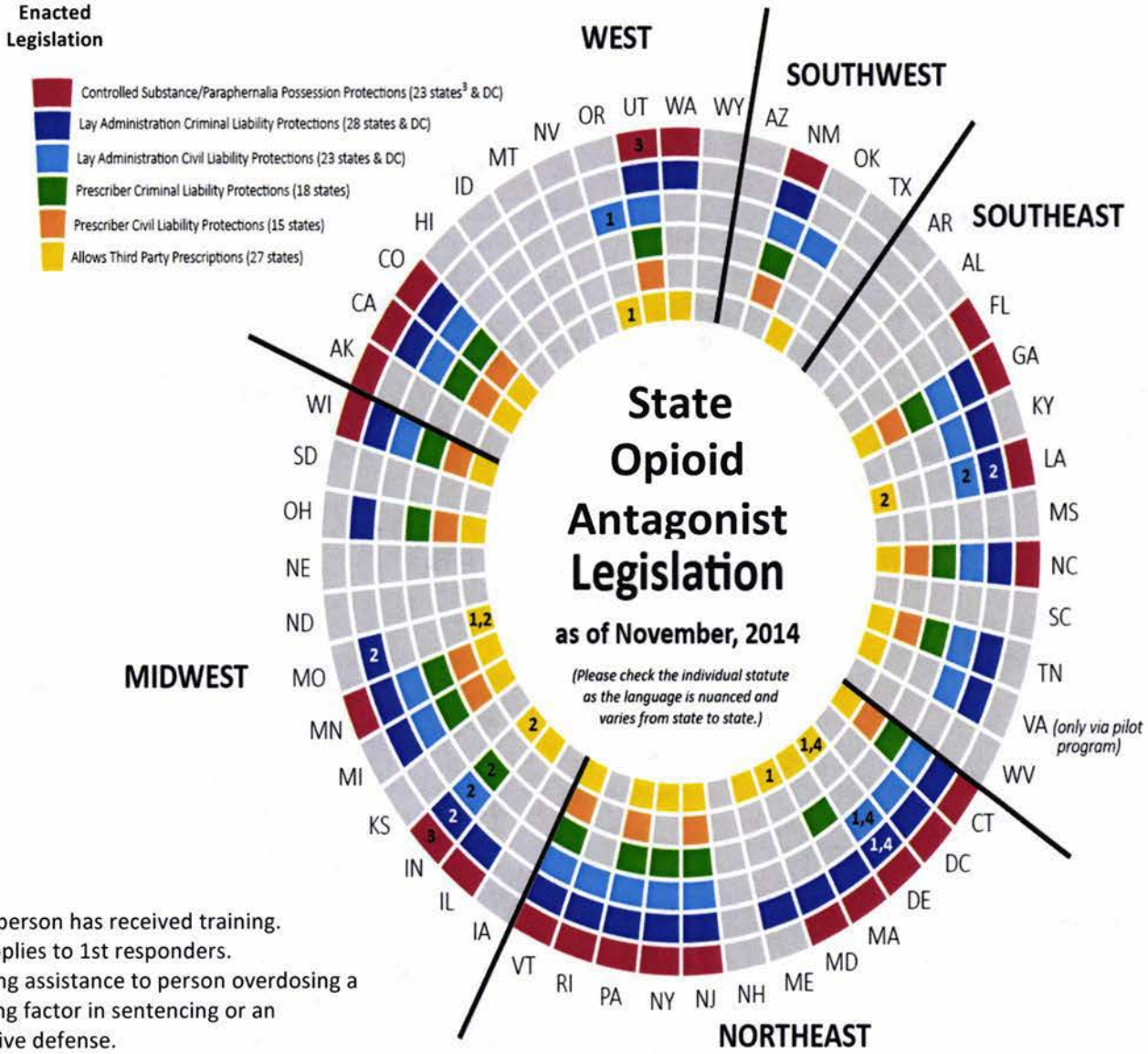
[26] *Community-Based Opioid Overdose Prevention Programs Providing Naloxone — United States, 2010*, Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report (MMWR), February 17, 2012 / 61(06);101-105. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6106a1.htm (last visited 2/27/15).

[27] Id.

[28] *Updated Infographic: Overdose Prevention, State by State*, Office of National Drug Control Policy. http://www.whitehouse.gov/blog/2014/12/17/updated-infographic-overdose-prevention-state-state (last visited 2/27/15).

- Twenty-seven states have statutes which allow for "third-party" prescriptions of opioid antagonists.
- Fifteen states have statutes which protect prescribers from civil liability actions.
- Eighteen states have statutes which protect prescribers from criminal liability actions.
- Twenty-three states and the District of Columbia have statutes which protect lay persons from civil liability for administering opioid antagonists to someone believed to be experiencing an opioid induced overdose.
- Twenty-eight states and the District of Columbia have statutes which protect lay persons from criminal liability for administering opioid antagonists to someone believed to be experiencing an opioid induced overdose.
- Twenty-three states and the District of Columbia have statutes which prevent charge or prosecution for possession of a controlled substance and/or paraphernalia for persons who seek medical/emergency assistance for someone that is experiencing an opioid induced overdose.

Figure 2



[1]Only if person has received training.
[2]Only applies to 1st responders.
[3]Providing assistance to person overdosing a mitigating factor in sentencing or an affirmative defense.
[4]Only applies to peace officers.

Source: Office of National Drug Control Policy

Florida Opioid –Related Data

Opioids also play a prominent role in drug overdose deaths in Florida. In 2012, there were 8,330 drug-related deaths in the state.[29] Opioids were listed as the cause of death in 2,577 cases and were present in an additional 3,029 cases.[30] The four most harmful drugs, found in more than 50 percent of the deaths in which these drugs were present, were all opioids:[31]

- Heroin (92.3 percent)
- Methadone (68.3 percent)
- Fentanyl (54.2 percent)
- Oxycodone (51.5 percent).

Florida's Good Samaritan Act

The Good Samaritan Act, found in s. 768.13, F.S., provides immunity from civil liability for those who render emergency care and treatment to individuals in need of assistance. The statute provides immunity from liability for civil damages to any person who:

- Gratuitously and in good faith renders emergency care or treatment either in direct response to emergency situation or at the scene of an emergency, without objection of the injured victim, if that person acts as an ordinary reasonably prudent person would have acted under the same or similar circumstances.[32]
- Participates in emergency response activities of a community emergency response team if that person acts prudently and within scope of his or her training.[33]
- Gratuitously and in good faith renders emergency care or treatment to an injured animal at the scene of an emergency if that person acts as an ordinary reasonably prudent person would have acted under the same or similar circumstances.[34]

Effect of Proposed Changes

HB 751 creates the Emergency Treatment and Recovery Act in s. 381.887, F.S., which authorizes health care practitioners to prescribe, and pharmacists to dispense, emergency opioid antagonists to patients and caregivers. Patients and caregivers are authorized to store and possess emergency opioid antagonists. In an emergency situation when a physician is not immediately available, patients and caregivers are authorized to administer the emergency opioid antagonist to a person believed in good faith to be experiencing an opioid overdose, regardless of whether that person has a prescription for an emergency opioid antagonist.

The bill authorizes emergency responders to possess, store, and administer approved emergency opioid antagonists. The bill does not limit any existing immunities for emergency responders or others provided under this chapter or any other applicable provision of law.

The bill provides civil liability immunity under s. 768.13, F.S., (Good Samaritan Act) for any person who possesses, administers, prescribes, dispenses, or stores an approved emergency opioid antagonist in compliance with the bill's requirements. The bill also provides that any authorized health care practitioner, dispensing health care practitioner, or pharmacist will not be subject to professional

[29] *Drugs Identified in Deceased Persons by Florida Medical Examiners 2012 Report,* Florida Department of Law Enforcement, September 2013.
[30] Id. It also important to note that a decedent may have more than one drug listed as the cause of death.
[31] Id.
[32] Section 768.13(2)(a), F.S.
[33] Section 768.13(2)(d), F.S.
[34] Section 768.13(3), F.S.

sanction or other disciplinary licensing action for acts or omissions if he or she is otherwise in compliance with the bill's requirements.

The bill defines emergency opioid antagonist as a drug that blocks the effects of exogenously administered opioids and is approved by the United States Food and Drug Administration for the treatment of opioid overdose.

The bill defines caregiver as a family member, friend, or person or entity in a position to have recurring contact with a person at risk of experiencing an opioid overdose.

The act will take effect upon becoming a law.

B. SECTION DIRECTORY:

Section 1: Provides citation for the Emergency Treatment and Recovery Act.
Section 2: Creates s. 381.887, F.S., relating to emergency treatment for suspected opioid overdose.
Section 3: Provides the act shall take effect upon becoming a law.

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:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to emergency treatment for opioid overdose; providing a short title; creating s. 381.887, F.S.; providing definitions; providing purpose; authorizing certain health care practitioners to prescribe an emergency opioid antagonist to a patient or caregiver under certain conditions; authorizing storage, possession, and administration of an emergency opioid antagonist by such patient or caregiver and certain emergency responders; providing immunity from liability; providing immunity from professional sanction or disciplinary action for certain health care practitioners; providing applicability; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. This act may be cited as the "Emergency Treatment and Recovery Act."

Section 2. Section 381.887, Florida Statutes, is created to read:

381.887 Emergency treatment for suspected opioid overdose.—

(1) As used in this section, the term:

(a) "Administer" or "administration" means to introduce an emergency opioid antagonist into the body of a person, using a

formulation approved by the United States Food and Drug Administration.

(b) "Authorized health care practitioner" means a licensed practitioner authorized by the laws of the state to prescribe drugs.

(c) "Caregiver" means a family member, friend, or person or entity in a position to have recurring contact with a person at risk of experiencing an opioid overdose.

(d) "Emergency opioid antagonist" means a drug that blocks the effects of exogenously administered opioids and is approved by the United States Food and Drug Administration for the treatment of opioid overdose.

(e) "Patient" means a person at risk of experiencing an opioid overdose.

(2) The purpose of this section is to provide for the prescription of an emergency opioid antagonist to patients and caregivers and to encourage the prescription of emergency opioid antagonists by health care practitioners in a formulation approved by the United States Food and Drug Administration for emergency treatment of known or suspected opioid overdoses when a physician is not immediately available.

(3) An authorized health care practitioner may prescribe an emergency opioid antagonist to a patient or caregiver for use in accordance with this section, and pharmacists may dispense an emergency opioid antagonist pursuant to a prescription issued in the name of the patient or caregiver, appropriately labeled with

instructions for use. Such patient or caregiver is authorized to store and possess approved emergency opioid antagonists and, in an emergency situation when a physician is not immediately available, administer the emergency opioid antagonist to a person believed in good faith to be experiencing an opioid overdose, regardless of whether that person has a prescription for an emergency opioid antagonist.

(4) Emergency responders, including, but not limited to, law enforcement officers, paramedics, and emergency medical technicians, are authorized to possess, store, and administer approved emergency opioid antagonists as clinically indicated.

(5) A person, including, but not limited to, an authorized health care practitioner, a dispensing health care practitioner, or a pharmacist, who possesses, administers, prescribes, dispenses, or stores an approved emergency opioid antagonist in compliance with this section and s. 768.13 is afforded the civil liability immunity protections provided under s. 768.13.

(6) An authorized health care practitioner, dispensing health care practitioner, or pharmacist is not subject to professional sanction or other disciplinary licensing action for acts or omissions if otherwise in compliance with this section.

(7) This section does not limit any existing immunities for emergency responders or others provided under this chapter or any other applicable provision of law.

Section 3. This act shall take effect upon becoming a law.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 4017 Pain-Management Clinics
SPONSOR(S): Spano
TIED BILLS: **IDEN./SIM. BILLS:** SB 450

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Nilson	O'Callaghan
2) Health & Human Services Committee			

SUMMARY ANALYSIS

Leading up to 2009, parts of Florida had become centers for prescription drug trafficking, particularly in opioids. This trafficking stemmed, in part, from unregulated pain-management clinics. The resulting increases in crime and mortality, and the resulting decrease in the quality of life experienced by Floridians, resulted in the Florida Legislature determining that pain-management clinics, as well as other entities in the drug supply chain, should be regulated to prevent these outcomes.

From 2009 to 2012, the Legislature enacted and refined a substantial set of regulations designed to combat the overprescribing and drug trafficking of prescription drugs. In 2011, the Legislature enacted pain-management clinic regulations that included "sunset provisions," effective January 1, 2016. Therefore, as the law stands, the two sections that regulate pain-management clinics will expire on January 1, 2016.

The law currently defines pain-management clinics as facilities that advertise in any medium for any type of pain-management services or where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol. The law currently requires pain-management clinic registration, inspection, reporting, and penalties for violations of several laws. The law also currently requires physicians practicing at the clinic to ensure that the clinic meets certain requirements. The law also currently authorizes the Department of Health to enact rules for these purposes.

HB 4017 repeals the sunset provisions for pain-management clinic regulations, requiring such clinics to continue to be subject to those regulations beyond January 1, 2016.

This bill does not appear to have a fiscal impact on state or local government.

This bill becomes effective upon becoming a law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Prescription Drug Trafficking

In early 2009, Florida was the largest of 12 states without a Prescription Drug Monitoring Program.[1] In part, the absence of such a program attracted drug traffickers, dealers, and users to Florida.[2] Florida pain-management clinics became a harbor for illegally trafficked drugs, including oxycodone, carisoprodol, and alpazolam.[3] Physicians could "plausibly deny" any illegal activity, as long as the drug traffickers would follow the same basic procedures a general patient would follow if that patient were truly in pain and in need of medication.[4] The cash-only pain-management clinic structure was especially effective for traffickers if the owners of the pain-management clinics were not physicians, as this specific type of clinic was unregulated by any state agency.[5] From 2007 to 2009, the number of pain-management clinics in Broward County alone increased from 4 to 115.[6] From late 2008 to early 2009, doctors in South Florida dispensed over 53% of the total oxycodone dispensed by the top 100 doctors in the United States.[7]

This increase correlated to higher mortality, higher crime, higher addiction rates, and lower quality of life in Florida.[8] From 2006 to 2008, the number of deaths per day with lethal dose reports of prescription drugs increased from 7 to 10.[9] Drug crime and its related costs to Florida increased substantially.[10] From 2004 to 2008, treatment admissions related to prescription drugs rose 150%.[11]

Past Pain-Management Clinic Legislation

The Legislature determined that unregulated pain-management clinics were the source of a substantial amount of drug trafficking in Florida, primarily in opioids like oxycodone, a Schedule II controlled substance.[12]

In 2009, the Florida Legislature addressed this problem by enacting a wide set of regulations that touched every point in the drug chain supply. The Legislature established a Prescription Drug Monitoring Program[13] and a regulatory structure for pain-management clinics.[14]

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[1] *The Proliferation of Pain Clinics in South Florida*, Interim Report of the Broward County Grand Jury 3 (17th Jud. Cir. Fla., Nov. 19, 2009).
[2] *Id.*
[3] *Id.*
[4] *Id.* at 4.
[5] *Id.* at 17.
[6] *Id.* at 6.
[7] *Id.* at 9.
[8] *Id.* at 9-11.
[9] *Id.* at 9.
[10] *Id.* at 10-11.
[11] *Id.* at 12.
[12] *See* ch. 893, F.S.
[13] *See* ch. 2009-197, Laws of Florida.
[14] Chapter 2009-198, ss. 3, 4, Laws of Florida. As of March 2014, 49 states have a Prescription Drug Monitoring Program. "The Role of a Prescription Drug Monitoring Program in Reducing Prescription Drug Diversion, Misuse, and Abuse," U.S. DEP'T OF HEALTH & HUMAN SERVICES (June 2014).

In 2010, the Legislature created s. 458.3265 and s. 459.0137, F.S., to consolidate, clarify, and expand the standards for pain-management clinics.[15]

In 2011, the Legislature modified the standards substantially, in part by codifying rules promulgated by the Department of Health (DOH).[16] In addition to the substantive modifications, the Legislature enacted sunset provisions requiring the pain-management clinic regulations in s. 458.3265 and s. 459.0137, F.S., to automatically expire on January 1, 2016.[17]

In 2012, the Legislature further modified these standards by adding exemptions for certain types of medical practice;[18] however, the Legislature left the sunset provisions intact.[19]

Current Law

Florida law defines a "pain-management clinic" as a publicly or privately owned facility that advertises in any medium for any type of pain-management services or where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol.[20]

Section 458.3265, F.S., within the medical practice act and s. 459.0137, F.S., within the osteopathic practice act regulate the registration, management, and inspections of pain-management clinics, and the allopathic and osteopathic physicians employed by such clinics.

DOH must adopt rules for the registration and inspection, and in particular must establish specific requirements, procedures, forms, and fees.[21] Each governing board must adopt rules establishing training requirements for all facility health care practitioners.[22]

Currently, s. 458.3265 and s. 459.0137, F.S., governing pain-management clinics, are set to expire on January 1, 2016.[23]

Registration

A pain-management clinic must register with DOH unless:

- The clinic is licensed under ch. 395, F.S.;
- The majority of the physicians who provide services in the clinic primarily provide surgical services;
- The clinic is publicly owned, with total assets exceeding $50 million in the most recent fiscal quarter;
- The clinic is affiliated with an accredited medical school;
- The clinic does not prescribe controlled substances for pain treatment;
- The clinic is owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3);
- The clinic is wholly owned and operated by one or more board eligible[24] or board-certified anesthesiologists, physiatrists, rheumatologists, or neurologists; or

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[15] Chapter 2010-211, ss. 4, 8, Laws of Florida.
[16] Chapter 2011-141, ss. 4, 7, Laws of Florida.
[17] *Id.*
[18] Chapter 2012-160, ss. 32, 33, Laws of Florida.
[19] *Id.*
[20] S. 458.3265(1)(a)(1.)(c.), F.S.; s. 459.0137(1)(a)(1.)(c.), F.S.
[21] S. 458.3265(4)(a), F.S.; s. 459.0137(4)(a), F.S.
[22] S. 458.3265(4)(b), F.S.; s. 459.0137(4)(b), F.S.
[23] S. 458.3265(6), F.S.; s. 459.0137(6), F.S.
[24] "Board eligible" means successful completion of an anesthesia, physical medicine and rehabilitation, rheumatology, or neurology residency program approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association

- The clinic is wholly owned and operated by a physician multispecialty practice where one or more board eligible[25] or board-certified medical specialists have both (1) completed certain fellowships in pain medicine or are board-certified in pain medicine by certain boards, and (2) perform interventional pain procedures of the type routinely billed using surgical codes.[26]

Each location must be registered separately, regardless of whether it is operated under the same name or management as another clinic.[27] Additionally, a change of ownership requires submission of a new registration application.[28]

DOH must deny a pain-management clinic's registration if:

- The clinic is neither fully owned by a physician or group of physicians licensed under ch. 458 or ch. 459, F.S.; nor health care clinic licensed under ch. 400, Part X.[29]
- The clinic is owned by, has a contractual relationship with, or employs a physician:
  - Whose Drug Enforcement Administration number has ever been revoked;
  - Whose application for a license to prescribe, dispense, or administer a controlled substance has been denied by any jurisdiction; or
  - Who has been convicted of or pleaded guilty or nolo contendere to a felony for receipt of illicit and diverted drugs, including any Schedule I-V substance, anywhere in the United States.[30]

DOH must revoke a pain-management clinic's registration if the same reasons for denial above apply to a registered clinic.[31] However, by rule, DOH may grant an exemption to such denial or revocation for felony convictions if more than 10 years have elapsed since adjudication.[32] DOH may also revoke a clinic's registration based on inspection.[33]

If a clinic's registration is revoked or suspended, the clinic must stop operating, and the clinic must remove all identification that the location is a pain-management clinic.[34] Additionally, the clinic must follow certain procedures to dispose of its medicinal drugs.[35] A required 5 year cooling-off period prohibits anyone whose registration has been revoked from applying for a permit to operate a pain-management clinic.[36] If a clinic's registration is suspended, that suspension may not exceed 1 year.[37]

Pain-Management Physicians

A physician may not practice medicine at a pain-management clinic unless the clinic is registered and the physician is qualified to practice in the clinic pursuant to the governing board's rules. If a physician practices medicine at the clinic in violation of these requirements, the physician is subject to board discipline under s. 456.072, F.S.[38]

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for a period of 6 years from successful completion of such residency program. S. 458.3265(1)(a)(1.)(a.), F.S.; s. 459.0137(1)(a)(1.)(a.), F.S.

[25] *See* note 21, *supra*.

[26] S. 458.3265(1)(a)(2.), F.S.; s. 459.0137(1)(a)(2.), F.S.

[27] S. 458.3265(1)(b), F.S.; s. 459.0137(1)(b), F.S.

[28] S. 458.3265(1)(m), F.S.; s. 459.0137(1)(m), F.S.

[29] S. 458.3265(1)(d), F.S.; s. 459.0137(1)(d), F.S.

[30] S. 458.3265(1)(e), F.S.; s. 459.0137(1)(e), F.S.

[31] S. 458.3265(1)(f), F.S.; s. 459.0137(1)(f), F.S.

[32] *Id.*

[33] S. 458.3265(1)(g), F.S.; s. 459.0137(1)(g), F.S.

[34] S. 458.3265(1)(h), (i), F.S.; s. 459.0137(1)(h), (i), F.S.

[35] S. 458.3265(1)(j), F.S.; s. 459.0137(1)(j), F.S.

[36] S. 458.3265(1)(k), F.S.; s. 459.0137(1)(k), F.S.

[37] S. 458.3265(1)(l), F.S.; s. 459.0137(1)(l), F.S.

[38] S. 458.3265(2)(a), F.S.; s. 459.0137(2)(a), F.S. Discipline may include suspension or revocation of a license, restriction of practice or license, reprimand, fines, or other actions available to the board. S. 465.072(2), F.S.

Only physicians licensed under ch. 458 or ch. 459, F.S., may dispense medication at pain-management clinics.[39] If a physician prescribes a controlled substance for a patient, the physician, or a physician assistant or advanced registered nurse practitioner, must perform a physical examination of the patient on the same day.[40] If that prescription[41] is for more than a 72-hour dose and for the treatment of chronic nonmalignant pain, the physician must document the reason for the quantity in the patient's record.[42]

Every physician practicing in a pain-management clinic must ensure compliance with a list of requirements, which relate to clinic access, clinic infrastructure, patient privacy, clinic security,[43] infection control,[44] clinic safety, and clinic personnel.[45] However, these requirements do not supersede the standard of care, skill, and treatment required of physicians recognized in general law related to health care licensure.[46]

Designated Physicians

Each clinic must designate a physician who is responsible for complying with the registration and other requirements in the section.[47] This designated, fully licensed physician must practice at the clinic, and if the clinic does not have this designated physician, the clinic is at risk for summary suspension.[48]

A designated physician at a registered clinic must notify the governing board within 10 days after the designated physician's termination of employment at the clinic.[49] Any physician at a registered clinic must notify the governing board within 10 days after beginning or ending the physician's practice at the clinic.[50]

The designated physician must ensure compliance with a list of quality and reporting requirements. The designated physician must implement a quality assurance program ("QAP") for each clinic to monitor and evaluate patient care, evaluate methods to improve the care, identify and correct facility deficiencies, alert the designated physician to identify and resolve recurring problems, and provide for opportunities to improve the facility's performance and enhance and improve the quality of care provided to the public. In addition, the QAP must:

- Identify, investigate, and analyze the frequency and causes of adverse incidents to patients;
- Identify trends or patterns of incidents;
- Develop measures to correct, reduce, minimize, or eliminate the risk of adverse incidents to patients; and
- Document these functions which must be periodically reviewed at least every quarter by the designated physician.[51]

The designated physician must report all adverse incidents to DOH pursuant to s. 458.351 or s. 459.026, F.S., as applicable, and must quarterly report to the governing board:

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[39] S. 458.3265(2)(b), F.S.; s. 459.0137(2)(b), F.S.
[40] S. 458.3265(2)(c), F.S.; s. 459.0137(2)(c), F.S.
[41] Physicians are responsible for their prescription blanks (and any other method used for prescription), must comply with the security requirements of s. 893.065, F.S., and must notify DOH of any stolen or missing prescription blanks (or breach of any other method used for prescription). S. 458.3265(2)(d), F.S.; s. 459.0137(2)(d), F.S.
[42] S. 458.3265(2)(c), F.S.; s. 459.0137(2)(c), F.S.
[43] S. 458.3265(2)(f)(1.), F.S.; s. 459.0137(2)(f)(1.), F.S.
[44] S. 458.3265(2)(g), F.S.; s. 459.0137(2)(g), F.S.
[45] S. 458.3265(2)(h), F.S.; s. 459.0137(2)(h), F.S.
[46] S. 458.3265(2)(f)(2.), F.S.; s. 459.0137(2)(f)(2.), F.S.
[47] S. 458.3265(1)(c), F.S.; s. 459.0137(1)(c), F.S.
[48] *Id.*
[49] S. 458.3265(2)(e), F.S.; s. 459.0137(2)(e), F.S.
[50] *Id.*
[51] S. 458.3265(2)(i), F.S.; s. 459.0137(2)(i), F.S.

- The number of new and repeat patients seen and treated at the clinic who are prescribed controlled substance medications for the treatment of chronic, nonmalignant pain;
- The number of patients discharged due to drug abuse;
- The number of patients discharged due to drug diversion; and
- The number of treated at the pain clinic who have their domicile outside of Florida.[52]

Inspections

DOH is required to inspect each pain-management clinic annually, unless the clinic is accredited by a board-approved agency.[53] During this inspection, DOH must make a reasonable attempt to discuss each violation with the owner or designated physician before issuing a formal written notification.[54] The owner or designated physician must document any action taken to correct a violation, and DOH must verify this action with followup visits.[55]

Penalties

DOH may impose a fine on a clinic of up to $5,000 per violation[56] of:

- DOH rules;
- S. 458.3265 or s. 459.0137, F.S., relating to pain-management clinics;
- The Florida Drug and Cosmetic Act;
- The Federal Food, Drug, and Cosmetic Act;
- The Florida Comprehensive Drug Abuse Prevention and Control Act; or
- The federal Comprehensive Drug Abuse Prevention and Control Act.[57]

Additionally, if the clinic's designated physician knowingly and intentionally misrepresents actions taken to correct a violation, DOH may impose a fine and, if the clinic is owner-operated, may revoke or deny registration.[58]

DOH must consider the following factors when determining the amount of the fine:

- The gravity of the violation, including the probability of death or serious harm to a patient from the clinic's or physician's action, the severity of the action or harm, and the extent of the violation;
- Actions the owner or designated physician took to correct the violation;
- Prior violations at the clinic; and
- The financial benefits that the clinic derived from the violation.[59]

An owner or designated physician who operates an unregistered clinic is subject to a $5,000 fine per day,[60] and an owner of a clinic who fails to apply to register the clinic upon a change of ownership and then operates the clinic under the new ownership is subject to a fine of $5,000.[61]

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[52] S. 458.3265(2)(j), F.S.; s. 459.0137(2)(j), F.S.
[53] S. 458.3265(3)(a), F.S.; s. 459.0137(3)(a), F.S.
[54] S. 458.3265(3)(b), F.S.; s. 459.0137(3)(b), F.S.
[55] S. 458.3265(3)(c), F.S.; s. 459.0137(3)(c), F.S.
[56] Each day a violation continues constitutes an additional violation. S. 458.3265(5)(b), F.S.; s. 459.0137(5)(b), F.S.
[57] S. 458.3265(5)(a), F.S.; s. 459.0137(5)(a), F.S.
[58] S. 458.3265(5)(c), F.S.; s. 459.0137(5)(c), F.S.
[59] S. 458.3265(5)(a), F.S.; s. 459.0137(5)(a), F.S.
[60] S. 458.3265(5)(d), F.S.; s. 459.0137(5)(d), F.S.
[61] S. 458.3265(5)(e), F.S.; s. 459.0137(5)(e), F.S.

Florida Prescription Drug Overdoses

Overall prescription drug overdose deaths dropped 7.3% during 2012-2013, while oxycodone overdose deaths dropped 27.3%.[62] Oxycodone deaths have decreased a total of 64.8% when comparing deaths in 2010 to 2013.[63]

Effect of the Bill

This bill repeals the sunset provisions in s. 458.3265 and s. 459.0137, F.S., which would otherwise cause those sections to expire on January 1, 2016.

B. SECTION DIRECTORY:

Section 1: Amends s. 458.3265, F.S., related to pain-management clinics.
Section 2: Amends s. 459.0137, F.S., related to pain-management clinics.
Section 3: Provides that the act takes effect upon becoming a law.

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:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not Applicable. This bill does not appear to affect county or municipal governments.

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[62] "Drugs Identified in Deceased Persons by Florida Medical Examiners," FLA. DEP'T OF LAW ENFORCEMENT 2013 ANNUAL REPORT i (Oct. 2014).
[63] *Id.*

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to pain-management clinics; amending ss. 458.3265 and 459.0137, F.S.; deleting the expiration of provisions related to the registration and regulation of pain-management clinics; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (6) of section 458.3265, Florida Statutes, is amended to read:

458.3265 Pain-management clinics.—

~~(6) EXPIRATION.—This section expires January 1, 2016.~~

Section 2. Subsection (6) of section 459.0137, Florida Statutes, is amended to read:

459.0137 Pain-management clinics.—

~~(6) EXPIRATION.—This section expires January 1, 2016.~~

Section 3. This act shall take effect upon becoming a law.