Health & Human Services Committee

Tuesday, February 27, 2018
1:30 PM – 2:30 PM
Morris Hall (17 HOB)

Richard Corcoran
Speaker

W. Travis Cummings
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health & Human Services Committee

Start Date and Time: Tuesday, February 27, 2018 01:30 pm

End Date and Time: Tuesday, February 27, 2018 02:30 pm

Location: Morris Hall (17 HOB)

Duration: 1.00 hrs

Consideration of the following bill(s):

CS/HB 579 Infectious Disease Elimination Pilot Programs by Health Quality Subcommittee, Jones, Plasencia

Consideration of the following proposed committee bill(s):

PCB HHS 18-03 -- Ratification of an Agency for Health Care Administration Rule

Pursuant to rule 7.11, the deadline for amendments to bills on the agenda by non-appointed members shall be 6:00 p.m., Monday, February 26, 2018.

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., Monday, February 26, 2018.

NOTICE FINALIZED on 02/26/2018 4:02PM by Iseminger.Bobbye

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 579 Infectious Disease Elimination Pilot Programs
SPONSOR(S): Health Quality Subcommittee; Jones and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 800

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	15 Y, 0 N, As CS	Siples	McElroy
2) Health & Human Services Committee		Siples	Calamas

SUMMARY ANALYSIS

In 2016, the Legislature authorized the University of Miami to operate a needle and syringe exchange pilot program in Miami-Dade County. The pilot program offers free, clean, unused needles and syringes to intravenous drug users as a means to prevent the transmission of blood-borne diseases, such as HIV, AIDS, and viral hepatitis. The pilot program must:

- Operate a one sterile needle and syringe unit to one used unit exchange ratio;
- Account for the number, disposal, and storage of needles and syringes;
- Adopt measures to control the use and dispersal of sterile needles and syringes;
- Provide maximum security of the exchange site and equipment;
- Make available educational materials and referrals to educational resources regarding the transmission of HIV, AIDS, viral hepatitis, and other blood-borne diseases;
- Provide HIV and viral hepatitis testing; and
- Provide or refer for drug abuse prevention and treatment.

The program began offering services on December 1, 2016, and has provided 44,497 clean, unused syringes in exchange for used 50,509 syringes. Staff and participants of the pilot program are exempt from prosecution under the Florida Comprehensive Drug Abuse Prevention and Control Act, or any other law for the possession, distribution, and exchange of needles or syringes. However, individuals acting outside the scope of the program are not immune from prosecution.

The pilot program is explicitly prohibited from using state, county, or municipal funds to operate, and may only use grants and donations to fund the program. The pilot program is scheduled to sunset on July 1, 2021.

CS/HB 579 extends the pilot program statewide and retains all of the existing requirements for operation. The bill authorizes an eligible entity to operate a sterile needle and syringe exchange at a fixed location or through a mobile unit. An eligible entity that establishes a pilot program must notify the Department of Health (DOH) and provide certain identification and contact information. Eligible entities include:

- Hospitals licensed under ch. 395, F.S.;
- Health care clinics licensed under ch. 400, F.S.;
- Accredited medical schools;
- Substance abuse treatment programs; and
- HIV/AIDS service organizations.

The bill extends the expiration date of the pilot programs from July 1, 2021, to July 1, 2023.

The bill may have an indeterminate, positive fiscal impact on state or local governments, resulting from lower transmission rates of blood-borne diseases. The bill may have an indeterminate negative impact on DOH for the administrative duties required under the bill's provisions.

The bill provides an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

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 first degree misdemeanor.[1]

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:[2]

- 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 third degree felony.[3]

Federal Drug Paraphernalia Statute

Under federal law, it is unlawful for any person to sell or offer for sale drug paraphernalia, use the mails or any other facility of interstate commerce to transport drug paraphernalia or to import or export drug paraphernalia.[4] The penalty for such crime is imprisonment for not more than three years and a fine.[5] Persons authorized by local, state, or federal law to possess or distribute drug paraphernalia are exempt from the federal drug paraphernalia statute.[6]

[1] A first-degree misdemeanor is punishable by a term of imprisonment not to exceed 1 year and a $1,000 fine. Sections 775.082 and 775.083, F.S.
[2] Section 893.147(2), F.S.
[3] 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.
[4] 21 U.S.C. § 863(a).
[5] 21 U.S.C. § 863(b).
[6] 21 U.S.C. § 863(f)(1).

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.[7] Examples of sharps include:[8]

- 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, generally used for patients on home hemodialysis.

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.[9] The most common infections from such injuries are hepatitis B, hepatitis C, and HIV.[10]

Needle and Syringe Exchange Programs

Syringe services programs (SSPs)[11] provide sterile needles, syringes, and other injection equipment and facilitate the disposal of 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).[12] Additionally, these programs may help to: [13]

- Increase the number of drug users who enter treatment for substance use disorder;
- Reduce needlestick injuries among first responders by providing proper disposal;
- Reduce overdose deaths by providing education on overdose prevention and safer injection practices;
- Provide referrals to medical, mental health, and social services; and
- Provide other tools, such as counseling, condoms, and vaccinations, to prevent HIV, hepatitis C, and sexually transmitted infections.

Approximately 2.6 percent of the U.S. population[14] has injected illicit drugs.[15] During the last decade, there has been increase in drug injection that has been attributed to the use of prescription opioids and heroin among individuals who started using opioids with oral analgesics and transitioned to injection.[16]

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[7] Food and Drug Administration, *Safely Using Sharps (Needles and Syringes) at Home, at Work, and on Travel*, (last rev. Mar. 3, 2016), available at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/Sharps/ucm20025647.htm (last visited December 15, 2017).

[8] Id.

[9] Id.

[10] Id.

[11] Also referred to as syringe exchange programs (SEPs), needle exchange programs (NEPs), or needle and syringe exchange programs (NSEPs).

[12] Centers for Disease Control and Prevention, *Syringe Services Programs – United States, 2008*, Morbidity and Mortality Weekly Report (MMWR) (Nov. 19, 2010), 59(45); 1488-1491, available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5945a4.htm/Syringe-Exchange-Programs-United-States-2008 (last visited on December 11, 2017).

[13] Centers for Disease Control and Prevention, *Reducing Harms from Injection Drug Use & Opioid Use Disorder with Syringe Services Programs*, available at https://www.cdc.gov/hiv/pdf/risk/cdchiv-fs-syringe-services.pdf (last visited December 11, 2017).

[14] This population represents persons aged 13 years or older in 2011.

[15] A. Lansky, T. Finlayson, C. Johnson, et. al.; *Estimating the Number of Persons Who Inject Drugs in the United States by Meta-Analysis to Calculate National Rates of HIV and Hepatitis C Virus Infections*; PLoS ONE, May 19, 2014; 9(5), available at http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0097596 (last visited on December 11, 2017).

The danger of used needles and other sharps, combined with the number of injections of illicit drugs, has prompted communities to try and manage the disposal of sharps within the illicit drug population. In San Francisco in 2000, approximately two million syringes were recovered at SSPs, 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.[17] Other SSPs 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.[18]

In 2015, five percent (2,392) of the 39,513 new HIV diagnoses and 10 percent (1,804) of the 18,303 AIDS diagnoses in the U.S. were attributed to injection drug use.[19] According to the Centers for Disease Control and Prevention (CDC), SSPs can help prevent blood-borne pathogen transmission by increasing access to sterile syringes among IDUs and enabling safe disposal of used needles and syringes.[20] There are approximately 350 SSP sites operating in the U.S.[21]

A 2012 study compared improper public syringe disposal between Miami, a city without an SSP at the time, and San Francisco, a city with SSPs.[22] 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.[23]

Federal Funding of NSEPs

In 2009, Congress passed the FY 2010 Consolidated Appropriations Act, which contained language that removed a ban on federal funding of NSEPs.[24] In July 2010, the U.S. Department of Health and Human Services issued implementation guidelines for programs interested in using federal dollars for NSEPs. [25] On December 23, 2011, President Obama signed the FY 2012 omnibus spending bill[26] that, among other things, reinstated the ban on the use of federal funds for NSEPs; reversing the 111th Congress' 2009 decision that permitted federal funds to be used for NSEPs.[27]

On December 18, 2015, President Obama signed into law the Consolidated Appropriations Act, which prohibits the use of federal funds for the purchase of sterile needles or syringes used to inject illegal

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[16] Centers for Disease Control and Prevention, *Syringe Service for Persons Who Inject Drugs in Urban, Suburban, and Rural Areas – United States, 2013*, Morbidity and Mortality Weekly Report (MMWR) (Dec. 11, 2015), 64(48); 1337-1341, available at https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6448a3.htm (last visited December 15, 2017).
[17] *Supra* note 15. (citing Brad Drda et al., San Francisco Safe Needle Disposal Program, 1991—2001, 42 J. Am Pharm Assoc. S115—6 (2002).
[18] *Centers for Disease Control and Prevention, Update: Syringe Exchange Programs --- United States, 2002,* Morbidity and Mortality Weekly Report (MMWR) (July 15, 2005), 54(27), 673-676, available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5427a1.htm (last visited March 4, 2016).
[19] Centers for Disease Control and Prevention, *HIV and Injection Drug Use* (Nov. 2016) available at https://www.cdc.gov/hiv/pdf/risk/cdc-hiv-idu-fact-sheet.pdf (last visited on December 11, 2017). An additional 3 percent (1,202) of the HIV diagnoses and 4% (761) of the AIDS diagnoses were attributable to male-to-male sexual contact and injection drug use.
[20] Id.
[21] North American Syringe Exchange Network, *Directory of Syringe Exchange Programs*, available at https://nasen.org/directory/ (last visited December 15, 2017). The directory provides a list of SSP sites in each state; an SSP may operate more than one site.
[22] 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 March 4, 2016).
[23] Id. at 255 (finding "44 syringes/1000 census blocks in San Francisco, and 371 syringes/1000 census blocks in Miami.").
[24] Pub. L. No. 111-117.
[25] Matt Fisher, *A History of the Ban on Federal Funding for Syringe Exchange Programs*, The Global Health Policy Center (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 December 15, 2017).
[26] Pub. L. No. 112-74.
[27] *Supra* note 25.

drugs.[28] However, the act allows funds to be used for other elements of the program if the state or local health department, in consultation with the CDC, determines that the state or local jurisdiction is, or at risk of, experiencing a significant increase in hepatitis or HIV infection due to intravenous drug use.

Miami-Dade Infectious Disease Elimination Act (IDEA)

In 2016, the Legislature passed the Miami-Dade Infectious Disease Elimination Act (IDEA), authorizing the University of Miami and its affiliates to establish a needle and syringe exchange pilot program (pilot program) in Miami-Dade County.[29] The pilot program offers free, clean, and unused needles and hypodermic syringes to IDUs to prevent the transmission of blood-borne diseases.

The University of Miami is authorized to operate the pilot program at a fixed location or through a mobile health unit. The pilot program is required to:[30]

- Operate a one sterile needle and syringe unit to one used unit exchange ratio;
- 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;
- Provide maximum security of the exchange site and equipment;
- Make available educational materials and referrals to education regarding the transmission of HIV, AIDS, viral hepatitis, and other blood-borne diseases;
- Provide HIV and viral hepatitis testing; and
- Provide or refer for drug abuse prevention and treatment.

The University of Miami must collect data for quarterly, annual, and final reporting purposes, but may not collect any personal identifying information from a participant.[31] The pilot program must issue an annual report to the Department of Health (DOH), as well as a final report on the performance and outcomes of the pilot program to DOH by August 1, 2021. The pilot program expires on July 1, 2021.[32]

The pilot program is expressly prohibited from using state, county, or municipal funds for its operation, and must use grants and donations from private sources to fund the program.[33]

The pilot program began operating on December 1, 2016, as the IDEA Exchange at a fixed location; and as of May 2017, the program began offering services through a mobile unit and provides backpacking services.[34] As of July 31, 2017, the program has enrolled 409 participants, had made 2,426 exchanges, and provided 44,497 unused syringes in exchange for 50,509 used syringes.[35] Additionally, the program achieved the following results:[36]

- Referred 43 individuals for substance use disorder treatment;
- Administered 266 anonymous HIV/hepatitis C tests;
- Referred 9 individuals for HIV treatment and 35 for hepatitis C treatment; and
- Provided 251 doses of naloxone[37] to participants and family members, resulting in 73 overdose reversals.

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[28] Pub. L. No. 114-113.
[29] Chapter 2016-68, Laws of Fla., codified at s. 381.0038(4), F.S.
[30] Section 381.0038(4)(a), F.S.
[31] Section 381.0038(4)(d), F.S.
[32] Section 381.0038(4)(f), F.S.
[33] Section 381.0038(4)(e), F.S.
[34] IDEA Exchange, Department of Medicine, University of Miami Miller School of Medicine, *IDEA Exchange Annual Report*, (Aug. 1, 2017), (on file with the Health Quality Subcommittee). Backpacking services are services provided on foot.
[35] Id. The program has recovered a surplus of 6,012 syringes through routine exchanges and neighborhood cleanup initiatives.
[36] Id.
[37] Naloxone is an opioid antagonist used to reverse the effects of an opioid overdose by counteracting the depression of the central nervous system and respiratory, allowing an overdose victim to breathe normally. *See* Harm Reduction Coalition, *Understanding Naloxone,* available at: http://harmreduction.org/issues/overdose-prevention/overview/overdose-basics/understanding-naloxone/ (last visited December 15, 2017).

Staff, volunteers, and participants of the pilot program are immune from prosecution for the possession, distribution, or exchange of needles or syringes under the Florida Comprehensive Drug Abuse Prevention and Control Act under ch. 893, F.S., or any other law.[38] Since the pilot program staff, volunteers, and participants are authorized to possess needles and syringes when acting under the authority of the pilot program, such possession would also be exempt from the federal drug paraphernalia statute.[39] However, pilot program staff, volunteers, and participants are not immune from prosecution under state and federal law for the possession or redistribution of needles or syringes in any form if acting outside of the pilot program.

Effect of Proposed

CS/HB 579 expands the existing Miami-Dade Infectious Disease Elimination pilot program by authorizing any eligible entity to operate a sterile needle and syringe exchange at a fixed location or through a mobile unit, regardless of its location within the state. The entity must provide DOH the name and address of the pilot program, the name of the eligible entity operating the program, and the name, address, and telephone number of a contact person. Eligible entities include:

- Hospitals licensed under ch. 395, F.S.;
- Health care clinics licensed under ch. 400, F.S.;
- Accredited medical schools;
- Substance abuse treatment programs; and
- HIV/AIDS service organizations;

The bill extends the expiration date of the pilot programs from July 1, 2021 to July 1, 2023. The bill retains all of the existing requirements of the Miami-Dade pilot program, including the reporting requirements, the prohibition against the use of state, county, or municipal funds, and the immunity from criminal prosecution for the possession or distribution of needles or syringes.

The bill includes a severability clause[40] and provides an effective date of July 1, 2018.

B. SECTION DIRECTORY:

Section 1: Creates an unnumbered section to title the act the "Florida Infectious Disease Elimination Act (IDEA).
Section 2: Amends s. 381.0038, F.S., relating to education; sterile needle and syringe exchange pilot program.
Section 3: Creates an unnumbered section to provide a severability clause.
Section 4: Provides an effective date of July 1, 2018.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

In those counties in which a pilot program is operated, the state may realize a cost savings related to the expenditures for the treatment of blood-borne diseases associated with intravenous drug

[38] Section 381.0038(4)(c), F.S.
[39] *Supra* note 6.
[40] 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).

use.[41] The reduction in expenditures for such treatments depends on the extent to which the needle and syringe exchange pilot program reduces the transmission of blood-borne diseases among IDUs, their sexual partners, offspring, and others who might be at risk of transmission.

2. Expenditures:

   The bill may have an insignificant, negative fiscal impact on DOH related to the receipt of notification of the establishment of pilot programs, and the receipt and processing of reports pilot programs are required to submit.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   A local government entity may realize a cost savings related to the expenditures for the treatment of blood-borne diseases associated with intravenous drug use, if there is a pilot program located in its jurisdiction.[42] The reduction in expenditures for such treatments depends on the extent to which the needle and syringe exchange pilot program reduces the transmission of blood-borne diseases among IDUs, their sexual partners, offspring, and others who might be at risk of transmission.

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.

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[41] 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. For a list of patient care programs available in the state, see Department of Health, *Florida HIV/AIDS Patient Care* Programs, available at http://www.floridahealth.gov/diseases-and-conditions/aids/patient-care/_documents/eligibility-information/Appendix.pdf (last visited December 15, 2017). The average lifetime treatment cost of an HIV infection is estimated at $379,668 (in 2010 dollars). Centers for Disease Control and Prevention, *HIV Cost-effectiveness*, (March 7, 2017), available at https://www.cdc.gov/hiv/programresources/guidance/costeffectiveness/index.html (last visited December 15, 2017).

[42] Id.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On January 24, 2018, the Health Quality Subcommittee adopted an amendment that eliminated the requirement that DOH administer the pilot programs and added accredited medical schools to the list of entities that are eligible to operate a pilot program.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.

A bill to be entitled

An act relating to infectious disease elimination pilot programs; providing a short title; amending s. 381.0038, F.S.; authorizing eligible entities to establish sterile needle and syringe exchange pilot programs, rather than a single program established in Miami-Dade County; specifying who may operate a pilot program; providing an expiration date for all pilot programs; 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 "Florida Infectious Disease Elimination Act (IDEA)."

Section 2. Subsection (4) of 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.

(4) The following eligible entities ~~The University of Miami and its affiliates~~ may establish a ~~single~~ sterile needle and syringe exchange pilot program: a hospital licensed under chapter 395, a health care clinic licensed under part X of

chapter 400, an accredited medical school, a substance abuse treatment program, or an HIV or AIDS service organization ~~in Miami-Dade County~~. A pilot program must notify the department when the pilot program is established and provide the name and address of the pilot program, the name of the eligible entity operating the program, and the name, address, and telephone number of a contact person. A ~~The~~ pilot program may be operated ~~operate~~ at a fixed location or through a mobile health unit by an eligible entity. A ~~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) A ~~The~~ pilot program must:

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 and referrals to

education regarding the transmission of HIV, viral hepatitis, and other blood-borne diseases; provide referrals for drug abuse prevention and treatment; and provide or refer for HIV and viral hepatitis screening.

(b) The possession, distribution, or exchange of needles or syringes as part of a ~~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. The redistribution of needles or syringes in any form, if acting outside the pilot program.

(d) A ~~The~~ pilot program must collect data for quarterly, annual, and final reporting purposes. The annual report must 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 testing for HIV, AIDS, viral hepatitis, or other blood-borne diseases; and other data necessary for the pilot program. However, personal identifying information may not be collected from a participant for any purpose. Quarterly reports must be submitted to the department

~~of Health in Miami-Dade County~~ by October 15, January 15, April 15, and July 15 of each year. An annual report must be submitted to the department ~~of Health~~ by August 1 every year until the program expires. A final report is due on August 1, 2023 ~~2021~~, to the department ~~of Health~~ and must describe the performance and outcomes of the pilot program and include a summary of the information in the annual reports for all pilot program years.

(e) State, county, or municipal funds may not be used to operate a ~~the~~ pilot program. A ~~The~~ pilot program must ~~shall~~ be funded through grants and donations from private resources and funds.

(f) All ~~The~~ pilot programs established under this subsection ~~program~~ shall expire July 1, 2023 ~~2021~~.

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 which 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, 2018.

Amendment No.

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 & Human Services Committee

Representative Jones offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Subsection (4) of 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.

(4) The University of Miami and its affiliates may establish a ~~single~~ sterile needle and syringe exchange pilot program in Miami-Dade County, Broward County, and Palm Beach 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 must:

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 and referrals to education regarding the transmission of HIV, viral hepatitis, and other blood-borne diseases; provide referrals for drug abuse prevention and treatment; and provide or refer for HIV and viral hepatitis screening.

(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. The redistribution of needles or syringes in any form, if acting outside the pilot program.

(d) The pilot program must collect data for quarterly, annual, and final reporting purposes. The annual report must 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 testing for HIV, AIDS, viral hepatitis, or other blood-borne diseases; and other data necessary for the pilot program. However, personal identifying information may not be collected from a participant for any purpose. Quarterly reports must be submitted to the Department of Health ~~in Miami-Dade County~~ by October 15, January 15, April 15, and July 15 of each year. An annual report must be submitted to the Department of Health by August 1 every year until the program expires. A final report is due on August 1, 2021, to the Department of Health and must describe the performance and outcomes of the pilot program and include a summary of the information in the annual reports for all pilot program years.

(e) State, county, or municipal 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, 2023 ~~2021~~.

Section 2. This act shall take effect July 1, 2018.

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

Remove everything before the enacting clause and insert: An act relating to an infectious disease elimination pilot program; 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 Broward County and Palm Beach County; establishing the pilot program criteria; providing that the possession, distribution, or exchange 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, volunteer, or participant may be prosecuted; requiring the pilot program to collect certain data for reporting purposes; prohibiting the collection of personal identifying information from program participants; requiring the university and its affiliates to submit quarterly and annual reports to the Department of Health; requiring the university and its affiliates to submit a final report containing certain information and summaries to the department; prohibiting state,

county, or municipal funds from being used to operate the pilot program; requiring the pilot program to be funded through private grants and donations; providing for expiration of the pilot program; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCB HHS 18-03 Ratification of an Agency for Health Care Administration Rule
SPONSOR(S): Health & Human Services Committee
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Health & Human Services Committee		Royal	Calamas

SUMMARY ANALYSIS

PCB HHS 18-03 ratifies Rule 59A-4.1265, F.A.C., so that the rule may go into effect.

Under ch. 120, F.S., the Administrative Procedures Act, the formal rulemaking process begins by an agency giving notice of the proposed rule. The notice is published by the Department of State in the Florida Administrative Register and must provide certain information, including the text of the proposed rule, a summary of the agency's statement of estimated regulatory costs (SERC), if one is prepared, and how a party may request a public hearing on the proposed rule. Section 120.541, F.S. requires that any rule with an adverse economic impact exceeding $1 million over the first 5 years the rule is in effect must be ratified by the legislature to be effective.

Rule 59A-4.1265, F.A.C., requires, by July 1, 2018, currently licensed nursing homes to maintain an alternative power source, such as a generator, that can air-condition an area of no less than 30 net sq. ft. per resident at a temperature of 81 degrees Fahrenheit or lower for at least 96 hours. The rule requires the nursing home to keep 72 hours of fuel on-site. The rule allows facilities under common control that are located on a single campus to share fuel, alternative power sources, and resident space. The rule also allows the Agency for Health Care Administration to grant an extension to comply with the requirements until January 1, 2019 for nursing homes that can show delays caused by necessary construction, delivery of order equipment, zoning or other regulatory approval processes.

The SERC developed for Rule 59A-4.1265, F.A.C., shows that the rule will create an adverse economic impact of $121,380,545 over the first 5 years the rule is in effect. Because the rule has an adverse economic impact on the nursing home industry exceeding $1 million over the first 5 years it is in effect, it must be ratified by the Legislature to be effective.

The bill will have a negative fiscal impact on nursing homes that need to acquire an alternative power source to meet the requirements of the rule. The bill has a negative fiscal impact on state government and no fiscal impact on local governments.

The scope of the bill is limited to this rulemaking procedure and does not adopt the substance of the rule into statute.

The bill is effective upon coming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Rulemaking Authority and Legislative Ratification

Rulemaking authority is delegated by the Legislature[1] through statute and authorizes an agency to "adopt, develop, establish, or otherwise create"[2] a rule.[3] To adopt a rule an agency must have a general or specific grant of authority from the Legislature to implement a specific law through rulemaking.[4] The grant of rulemaking authority itself need not be detailed.[5] The specific statute being interpreted or implemented through rulemaking must provide specific standards and guidelines to preclude the administrative agency from exercising unbridled discretion in creating policy or applying the law.[6]

The Florida Administrative Procedures Act, Ch. 120, F.S., governs the rulemaking process. The formal rulemaking process begins by an agency giving notice of the proposed rule.[7] The notice is published by the Department of State in the Florida Administrative Register[8] and must provide certain information, including the text of the proposed rule, a summary of the agency's statement of estimated regulatory costs (SERC), if one is prepared, and how a party may request a public hearing on the proposed rule.

A SERC must be prepared if the proposed rule will have a negative impact on small business or if the proposed rule is likely to directly or indirectly increase the total regulatory costs by more than $200,000, within one year of the rule's implementation.[9] The SERC must include an economic analysis projecting a proposed rule's adverse effect on specified aspects of the state's economy or increase in regulatory costs.[10] The SERC must analyze a rule's potential impact over the 5 year period from when the rule goes into effect. The economic analysis should show whether the rule, directly or indirectly is:

- Likely to have an adverse impact on economic growth, private-sector job creation or employment, or private-sector investment;[11]
- Likely to have an adverse impact on business competitiveness,[12] productivity, or innovation;[13]
- Likely to increase regulatory costs, including any transactional costs.[14]

The law distinguishes between a rule being "adopted" and becoming enforceable or "effective."[15] A rule must be filed for adoption before it may go into effect[16] and cannot be filed for adoption until completion

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[1] *Southwest Florida Water Management District v. Save the Manatee Club, Inc.,* 773 So. 2d 594 (Fla. 1st DCA 2000).
[2] Section 120.52(17), F.S.
[3] A rule is an agency statement of general applicability interpreting, implementing, or prescribing law or policy, including the procedure and practice requirements of an agency as well as certain types of forms. *See* s. 120.52(16), F.S., and *Florida Department of Financial Services v. Capital Collateral Regional Counsel-Middle Region,* 969 So. 2d 527, 530 (Fla. 1st DCA 2007).
[4] Section 120.52(8), F.S., and s. 120.536(1), F.S.
[5] *Save the Manatee Club, Inc., supra* note 1 at 599.
[6] *Sloban v. Florida Board of Pharmacy,*982 So. 2d 26, 29-30 (Fla. 1st DCA 2008); *Board of Trustees of the Internal Improvement Trust Fund v. Day Cruise Association, Inc.,* 794 So. 2d 696, 704 (Fla. 1st DCA 2001).
[7] Section 120.54(3)(a)1, F.S..
[8] Sections 120.54(3)(a)2., 120.55(1)(b)2, F.S.
[9] Section 120.54(1)(b), F.S.
[10] Section 120.541(2)(a), F.S.
[11] Section 120.541(2)(a)1., F.S.
[12] Including the ability of those doing business in Florida to compete with those doing business in other states or domestic markets.
[13] Section 120.541(2)(a) 2., F.S.
[14] Section 120.541(2)(a) 3., F.S.
[15] Section 120.54(3)(e)6. Before a rule becomes enforceable, thus "effective," the agency first must complete the rulemaking process and file the rule for adoption with the Department of State.
[16] Section 120.54(3)(e)6., F.S.

of the rulemaking process.[17] A rule may be adopted but cannot go into effect if the analysis shows the projected impact of the proposed rule in any one of these areas will exceed $1 million in the aggregate for the 5 year period.[18] Such a rule must be ratified by the Legislature before it may go into effect.[19] Ratification is accomplished through passage of a bill that ratifies the rule.

Regulation of Nursing Homes

Nursing homes are regulated by the Agency for Health Care Administration (AHCA) under the Health Care Licensing Procedures Act (Act) in part II of chapter 408, F.S., which contains uniform licensing standards for 29 provider types, including nursing homes. In addition, nursing homes must comply with the requirements contained in the individual authorizing statutes of part II of chapter 400, F.S., which includes unique provisions for licensure beyond the uniform criteria. There are currently 685 licensed nursing homes in Florida with 83,853 total beds across all facilities.[20]

Section 400.23, F.S. requires rules adopted by AHCA for the regulation of nursing homes include criteria by which a reasonable and consistent quality of resident care may be ensured. Section 400.23, F.S. requires AHCA to adopt rules for housing conditions that will ensure the health, safety, and comfort of residents and the equipment essential to the health and welfare of the residents in nursing homes.

Nursing Home Medicaid Reimbursement

Medicaid is the health care safety net for low-income Floridians. Medicaid is a partnership of the federal and state governments established to provide coverage for health services for eligible persons. The program is administered by the Agency for Health Care Administration (AHCA) and financed by federal and state funds. AHCA delegates certain functions to other state agencies, including the Department of Children and Families (DCF), the Department of Health, the Agency for Persons with Disabilities, and the Department of Elderly Affairs (DOEA).

Currently, Florida Medicaid reimbursement for nursing home services uses a cost-based methodology. Each nursing home has its reimbursement rate per diem established based upon allowable nursing home costs as reported in an annual cost report. The nursing homes are reimbursed their per diem for each day a Medicaid resident is in the nursing home. The nursing home rates are based on unaudited, historical cost reports submitted prior to services being rendered. The reimbursement rates are adjusted post-payment for some facilities each year based on audited cost reports. The cost report audit and rate adjustment processes can take several years for full reconciliation and finalization of payment.

During the 2017 Legislative Session, the Legislature required the AHCA to implement a prospective payment system for nursing homes effective October 1, 2018. A prospective payment system is a reimbursement system in which rates are determined in advance of payment and considered final upon payment. A fully prospective payment system will eliminate the need for retroactive rate adjustments, allowing nursing facilities and AHCA to record final reimbursement amounts in a more expedient manner. In addition, a payment method in which rates are more uniform across facilities will provide more incentives for nursing facilities to control costs.

Emergency Rule 59AER 17-1, F.A.C.: Nursing Home Emergency Power Plan

Agencies may adopt emergency rules if they find that an immediate danger to the public health, safety, or welfare requires emergency action.[21] Emergency rules are effective as of the date they are filed for

[17] Section 120.54(3)(e), F.S.
[18] Section 120.541(3), F.S.
[19] Section 120.541(3), F.S.
[20] Agency for Health Care Administration, Revised Statement of Estimated Regulatory Costs for Proposed Rule 59A-4.1265, F.A.C., on file with the Health and Human Services Committee.
[21] Section 120.54(4), F.S.

adoption.[22] Emergency rules expire 90 days after their effective date, but may be renewed if the agency has initiated rulemaking to adopt the rule and either a proposed rule challenge is pending or the proposed rule is awaiting ratification by the legislature.[23]

On September 16, 2017, AHCA filed Emergency Rule 59AER 17-1, F.A.C. to require nursing homes to acquire a generator and sufficient amount of fuel to ensure that temperatures in the facility could be maintained at 80 degrees or less for at least 96 hours in the event of a power outage. The rule required nursing homes to comply within 60 days of the effective date of the rule. The rule authorized AHCA to revoke the license of a nursing home that failed to comply with rule and to levy a fine of $1000 per day for a violation of the rule. As of January 5, 2018, 108 nursing homes have indicated they are in compliance with the emergency rule.[24]

Permanent Rule 59A-4.1265, F.A.C.: Emergency Environmental Control for Nursing Homes

Notice of Proposed Rule

On November 14, 2017, AHCA filed a Notice of Proposed Rule that required nursing homes to secure alternative power sources. The proposed rule required nursing homes to install and maintain an alternative power source, such as a generator, that can air-condition an area of no less than 50 net sq. ft. per resident at a temperature of 81 degrees Fahrenheit or lower for at least 96 hours. The proposed rule required the nursing home to keep sufficient fuel on site to maintain the required temperature for at least 96 hours. The proposed rule allowed piped gas as a fuel source. The proposed rule also stated that local ordinances that conflicted with the fuel requirement preempted the proposed rule. The proposed rule required currently licensed nursing homes to comply with its terms by July 1, 2018.

Statement of Estimated Regulatory Costs

AHCA prepared a SERC that estimated a total new one-time cost of $186,001,674.58 for nursing homes to comply with the proposed rule.[25] AHCA based its estimate on a nursing home trade association's estimated cost of $315,000 for a 120-bed facility to comply with the proposed rule.[26] As of November 2, 2017, 102 nursing homes had complied with the emergency rule.[27] AHCA excluded the nursing homes that reported compliance with the emergency rule requirements from its estimate.[28]

AHCA divided the $315,000 estimate by 120 beds to determine the cost per bed for a facility to comply with proposed rule, which resulted in an estimated cost of $2,626.66 per bed. To determine the total one-cost for all nursing homes, AHCA multiplied the estimated cost per bed of $2,626.66 by the number of beds in the remaining nursing homes not in compliance with the emergency rule (70,813).

Number of Beds in Nursing Homes Not in Compliance with Emergency Rule	Cost per Nursing Home Bed	Total Cost
70,813	$2,626.66	$186,001,674.58

[22] Id.
[23] Id.
[24] Supra, FN 20.
[25] Id.
[26] Id.
[27] Id.
[28] Id.

Rule Challenge

On December 15, 2017, LeadingAge Florida[29] filed petition challenging the proposed rule at the Division of Administrative Hearings.[30] In response, AHCA filed a Notice of Change to the proposed rule on January 19, 2017. LeadingAge Florida voluntarily withdrew its challenge and the case was dismissed on January 23, 2018.[31]

Notice of Change

Changes made to the proposed rule require facilities to store 72 hours of fuel on-site rather than 96 hours of fuel. However, the facilities must still be able to maintain the required temperature of 81 degrees Fahrenheit or lower for at least 96 hours. The changes to the proposed rule also require facilities to air-condition an area of no less than 30 net sq. ft. per resident rather than 50 net sq. ft. per resident.

The changes to the proposed rule allows facilities under common control that are located on a single campus to share fuel, alternative power sources, and resident space.

The proposed rule still requires nursing homes to comply by July 1, 2018 but changes to the proposed rule allow AHCA to grant an extension to comply with the requirements until January 1, 2019 for nursing homes that can show delays caused by necessary construction, delivery of order equipment, zoning or other regulatory approval processes.

Revised Statement of Estimated Regulatory Costs

Based on the Notice of Change, AHCA prepared a revised SERC that estimated a new one-time cost of $108,224,945 for nursing homes to comply with the proposed rule.[32] AHCA used an average of estimates provided by the nursing home industry, a national generator supplier, and nursing homes that submitted petitions for variance from the emergency rule. As of January 5, 2018, 108 nursing homes were in compliance with the emergency rule. AHCA excluded those nursing homes from its estimate.

Nursing Home Industry Estimate

Using estimates provided by the nursing home trade association, AHCA estimated a new one-time cost of $125,205,935 for nursing homes to comply with the proposed rule.

The nursing home trade association surveyed 177 of its 550 members. Of the 177 members surveyed, 107 provided an estimate of $315,000 for a 120-bed facility to fully install a generator to maintain the required temperature throughout the entire facility. The remaining 70 members surveyed provided estimates of $60,000 to $80,000 for smaller generators or supplementary cooling units.

AHCA divided the $315,000 estimate by 120 beds to determine the cost per bed for a facility to comply with proposed rule, which resulted in an estimated cost of $2,626.66 per bed. To determine the total one-cost for all nursing homes, AHCA multiplied the estimated cost per bed of $2,626.66 by the number of beds in the remaining nursing homes not in compliance with the emergency rule (70,229), which resulted in an estimated cost of $184,467,705.14.

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[29] LeadingAge Florida is a not-for-profit corporation comprised of approximately 250 elder care organizations operating in Florida, including more than 100 nursing homes and assisted living facilities. Petition for Determination of Invalidity of Proposed Rule, *Florida Association of Homes and Services for the Aging, Inc., D/B/A LeadingAge Florida v. Agency for Health Care Administration*, Case No. 17-6832RP (Fla. DOAH 2017).

[30] *Florida Association of Homes and Services for the Aging, Inc., D/B/A LeadingAge Florida v. Agency for Health Care Administration*, Case No. 17-6832RP (Fla. DOAH 2017).

[31] Id.

[32] Agency for Health Care Administration, Revised Statement of Estimated Regulatory Costs for Proposed Rule 59A-4.1265, F.A.C., January 11, 2018, on file with the Health and Human Services Committee.

AHCA then multiplied the $60,000 estimate by the number of facilities not in compliance, which resulted in an estimated cost of $34,620,000.

AHCA then used a proportional average of both estimates to determine the estimated costs for nursing homes to comply with the proposed rule. AHCA multiplied the estimated cost of $184,467,705.14 by the percentage of nursing homes that provided the $315,000 estimate (60.452%), which resulted in an estimated cost of $11,514,417. AHCA then multiplied the estimated cost of $34,620,000 by the percentage of nursing homes that provided the $60,000 to $80,000 estimate (39.548%), which resulted in an estimated cost of $13,691,518. AHCA then added the two estimated costs together, which resulted in a new one-time estimated cost of $125,205,935.

Generator Supplier Estimate

A national generator supplier provided an estimated cost of $145,000 for a 350KW stationary generator to power a 120-bed nursing home. AHCA multiplied the estimated cost by the number of nursing homes not in compliance with the emergency rule (577), which resulted in a new one-time estimated cost of $84,068,900 for nursing homes to comply with the proposed rule.

Petitions for Variance Estimate

In response to the emergency rule requirements, 591 nursing homes filed petitions for variance requesting additional time to comply with the requirements. Sixty-five of the petitions included estimates for installation of generators. AHCA excluded 9 petitions that included exceptionally high or low estimates that were inconsistent with the majority of the estimates. Based on the estimates provided in the remaining petitions, the average cost for installation of a generator comply with the emergency rule was $200,000. AHCA multiplied the average cost by the number of facilities not in compliance with the emergency rule (577), which resulted in a new one-time estimated cost of $115,400,000 for nursing homes to comply with the proposed rule.

Final Estimate for New One-time Costs

AHCA then added the three estimated costs together ($125,205,935 + $84,068,900 + $115,400,000) and divided by three, which resulted in a final new one-time estimated cost of $108,224,945 for nursing homes to comply with the proposed rule.

Nursing Home Industry Estimate	Generator Supplier Estimate	Petitions for Variance Estimate	Final New One-Time Cost Estimate
$125,205,935	$84,068,900	$115,400,000	$108,224,945

Recurring Costs

Based on estimates provided by the national generator supplier, yearly maintenance for a generator would cost $4,560 per nursing home. Yearly maintenance includes three quarterly inspections and one annual oil and filter change. AHCA multiplied the yearly maintenance cost the number of facilities not in compliance with the emergency rule (577), which resulted in recurring costs of $2,631,120 per year for nursing homes to comply with proposed rule. Recurring costs for the first five years the rule is in effect would total $13,155,600.

Adding the new-one time estimated costs of $108,224,945 plus the recurring costs of $13,155,600 for the first five years the rule is in effect creates an adverse economic impact of $121,380,545 over the first 5 years the rule is in effect.

Medicaid Costs

AHCA estimates total Medicaid costs of $66 million for initial costs for nursing home to comply with the rule.[33] The state's estimated share of these costs would be $25 million.[34] AHCA estimates a total of $1.5 million in Medicaid costs per year for the recurring costs for nursing homes to comply with the rule.[35] The state's estimated share of these costs is $597,000.[36]

Adoption

On February 5, 2018, AHCA filed Rule 59A-4.1265, F.A.C. with the Department of State for adoption. However, ratification of the rule by the legislature is required for the rule to be effective.

Effect of Proposed Change

The bill ratifies Rule 59A-4.1265, F.A.C., solely to meet the condition for effectiveness imposed by s. 120.541(3), F.S., and expressly limits ratification to the effectiveness of the rule. The bill directs that the act shall not be codified in the Florida Statutes, but only noted in the historical comments to the rule by the Department of State.

The bill is effective upon becoming law.

B. SECTION DIRECTORY:

Section 1: Ratifies Rule 59A-4.1265, F.A.C.
Section 2: Provides that the act goes into effect upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   AHCA will experience an increase in workload due to inspections to ensure compliance by nursing homes with the rule's requirements. AHCA estimates that it needs two FTE positions to handle the increase in workload.[37] AHCA has requested a transfer of four FTE positions from its Medicaid unit to the Division of Health Quality Assurance, which licenses and regulates nursing homes.[38] Two of the FTE positions will be utilized to handle the increased workload.

   AHCA estimates total Medicaid costs of $66 million for the initial costs for nursing homes to comply with the rule. The state's estimated share of these costs would be $25 million. AHCA estimates a total of $1.5 million in Medicaid costs per year for the recurring costs for nursing homes to comply with the rule. The state's estimated share of these costs is $597,000.

[33] E-mail correspondence with the Agency for Health Care Administration, on file with the Health and Human Services Committee.
[34] Id.
[35] Id.
[36] Id.
[37] *Governor's Budget Recommendation for Fiscal Year 2018-19*, on file with the Health and Human Services Committee.
[38] Id.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill will have a negative fiscal impact on nursing homes that need to acquire an alternative power source to meet the requirements of the rule. Over the first five years the rule is in effect, nursing homes that need to meet the requirements of the rule will experience an adverse economic impact of $121,380,545.

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:

B. RULE-MAKING AUTHORITY:

The bill meets the final statutory requirement for the board to exercise its rulemaking authority concerning the standards of care for office surgery. No additional rulemaking authority is required.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to ratification of Agency for Health Care Administration rules; ratifying a specified rule relating to emergency environmental control for nursing homes for the sole and exclusive purpose of satisfying any condition on effectiveness pursuant to s. 120.541(3), F.S., which requires ratification of any rule meeting any specified thresholds for likely adverse impact or increase in regulatory costs; providing applicability; providing an effective date.

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

Section 1. (1) The following rule is ratified for the sole and exclusive purpose of satisfying any condition on the effectiveness imposed under s. 120.541(3), Florida Statutes: Rule 59A-4.1265, Florida Administrative Code, titled "Emergency Environmental Control for Nursing Homes" as filed for adoption with the Department of State pursuant to the certification package dated February 2, 2018.

(2) This act serves no other purpose and may not be codified in the Florida Statutes. After this act becomes law, its enactment and effective dates shall be noted in the Florida Administrative Code, the Florida Administrative Register, or both, as appropriate. This act does not alter rulemaking

authority delegated by prior law, does not constitute legislative preemption of or exception to any provision of law governing adoption or enforcement of the rule cited, and is intended to preserve the status of any cited rule as a rule under chapter 120, Florida Statutes. This act does not cure any rulemaking defect or preempt any challenge based on lack of authority or a violation of the legal requirements governing the adoption of any rule cited.

Section 2. This act shall take effect upon becoming a law.