

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 Care Appropriations Subcommittee			
3) Health & Human Services Committee			

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:

- Provide maximum security of the exchange site and equipment;
- Account for the number, disposal, and storage of needles and syringes;
- Adopt measures 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;
- 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.

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 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.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

STORAGE NAME: h0579a.HQS

DATE: 1/25/2018

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Needle and Syringe Exchange Programs

Syringe services programs (SSPs)¹ 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).² Additionally, these programs may help to:³

- 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. population⁴ has injected illicit drugs.⁵ 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.⁶

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.⁷ 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.⁸

¹ Also referred to as syringe exchange programs (SEPs), needle exchange programs (NEPs), or needle and syringe exchange programs (NSEPs).

² 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).

³ 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).

⁴ This population represents persons aged 13 years or older in 2011.

⁵ 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).

⁶ 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).

⁷ *Supra* note 5. (citing Brad Drda et al., San Francisco Safe Needle Disposal Program, 1991—2001, 42 J. Am Pharm Assoc. S115—6 (2002).

⁸ 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).

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.⁹ 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.¹⁰ There are approximately 350 SSP sites operating in the U.S.¹¹

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.¹² 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.¹³

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.¹⁴ 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:¹⁵

- 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;
- 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.¹⁶ 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, 2021.¹⁷

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.¹⁸

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

⁹ 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.

¹⁰ *Id.*

¹¹ 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.

¹² 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).

¹³ *Id.* at 255 (finding “44 syringes/1000 census blocks in San Francisco, and 371 syringes/1000 census blocks in Miami.”).

¹⁴ Chapter 2016-68, Laws of Fla., codified at s. 381.0038(4), F.S.

¹⁵ Section 381.0038(4)(a), F.S.

¹⁶ Section 381.0038(4)(d), F.S.

¹⁷ Section 381.0038(4)(f), F.S.

¹⁸ Section 381.0038(4)(e), F.S.

backpacking services.¹⁹ As of July 31, 2017, the program has enrolled 409 participants, had 2,426 exchanges, and provided 44,497 syringes in exchange for 50,509 syringes.²⁰ Additionally, the program achieved the following results:²¹

- 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 naloxone²² to participants and family members, resulting in 73 overdose reversals.

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.²³ 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.

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 bill²⁶ 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 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.

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.²⁹ Examples of sharps include:³⁰

¹⁹ 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.

²⁰ *Id.* The program has recovered a surplus of 6,012 syringes through routine exchanges and neighborhood cleanup initiatives.

²¹ *Id.*

²² 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).

²³ Section 381.0038(4)(c), F.S.

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.

²⁸ Pub. L. No. 114-113.

²⁹ 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).

³⁰ *Id.*

- 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.³¹ The most common infections from such injuries are Hepatitis B (HBV), Hepatitis C (HCV), and Human Immunodeficiency Virus (HIV).³²

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.³³

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.³⁴

- 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.³⁵

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.³⁶ The penalty for such crime is imprisonment for not more than three years and a fine.³⁷

³¹ Id.

³² *Supra* note 23.

³³ 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.

³⁴ Section 893.147(2), F.S.

³⁵ 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.

³⁶ 21 U.S.C. § 863(a).

³⁷ 21 U.S.C. § 863(b).

Persons authorized by local, state, or federal law to possess or distribute drug paraphernalia are exempt from the federal drug paraphernalia statute.³⁸

Effect of Proposed

HB 579 expands the existing Miami-Dade Infectious Disease Elimination pilot program to authorize 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 and the prohibition against the use of state, county, or municipal funds.

The bill includes a severability clause³⁹ 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 use.⁴⁰ 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.

³⁸ 21 U.S.C. § 863(f)(1).

³⁹ 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).

⁴⁰ 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).

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.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:

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

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.

⁴¹ Id.