

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL: PCS/CS/SB 242 (331366)

INTRODUCER: Appropriations Subcommittee on Health and Human Services; Health Policy Committee; and Senator Braynon and others

SUBJECT: Infectious Disease Elimination Pilot Program

DATE: November 18, 2015 **REVISED:** _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Lloyd</u>	<u>Stovall</u>	<u>HP</u>	<u>Fav/CS</u>
2.	<u>Brown</u>	<u>Pigott</u>	<u>AHS</u>	<u>Recommend: Fav/CS</u>
3.	_____	_____	<u>FP</u>	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

PCS/CS/SB 242 creates the Miami-Dade Infectious Disease Elimination Act (IDEA), which authorizes the University of Miami and its affiliates to establish a single sterile needle and syringe exchange pilot program in Miami-Dade County as a means to prevent the transmission of blood-borne diseases. The bill provides duties and requirements for the operation of the pilot program.

The bill prohibits state, county, or municipal funds from being used to operate the pilot program. Instead, the pilot program must be funded through grants and donations from private resources.

The pilot program expires on July 1, 2021.

The bill has no fiscal impact. The bill has an effective date of July 1, 2016.

II. Present 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 the reuse of contaminated needles and syringes by injection-drug-users (IDUs).

Intravenous Drug Use in Florida

In 2013, the majority of Florida counties with high rates of persons living with HIV/AIDS (PLWHA), and with a high IDU-associated risk, were in the southeast or central parts of the state.¹ The Department of Health (DOH) reports that 50 to 90 percent of HIV-infected IDUs are also co-infected with Hepatitis C Virus.² The chart below displays data from 2013 of the 11 Florida counties with the highest incidence of PLWHA with an IDU-associated risk.³

County	Total PLWHA Cases	Total IDU	Percent IDU
Miami-Dade	26,445	3,240	12%
Broward	17,214	2,132	12%
Palm Beach	7,964	1,481	19%
Orange	7,508	1,304	17%
Hillsborough	6,262	1,198	19%
Duval	5,584	999	18%
Pinellas	3,675	728	20%
Lee	1,777	310	18%
St. Lucie	1,550	309	20%
Volusia	1,408	340	24%
Brevard	1,300	273	21%
State Totals	101,977	17,368	17%

Intravenous Drug Use in Miami-Dade County

In a 2011 study, researchers from the University of Miami estimated that there are more than 10,000 IDUs in Miami and that one in five of these IDUs are HIV positive while one in three are Hepatitis C positive.⁴ The researchers also found that IDUs in Miami—a city without a needle and syringe exchange program—had over 34 times the adjusted odds of disposal of a used syringe in a public location relative to IDUs in San Francisco—a city with multiple exchange programs.⁵

Needle and Syringe Exchange Programs

In the mid-1980s, the National Institute on Drug Abuse (NIDA) undertook a research program to develop, implement, and evaluate the effectiveness of intervention strategies to reduce risk behaviors and prevent the spread of HIV/AIDS, particularly among IDUs, their sexual partners, and offspring. The studies found that comprehensive strategies—in the absence of a vaccine or

¹ Florida Dep't of Health, *HIV Infection Among Those with an Injection Drug Use-Associated Risk, Florida, 2014* (power point slide 18) (revised Jan. 29, 2015), available at <http://www.floridahealth.gov/diseases-and-conditions/aids/surveillance/documents/hiv-aids-slide-sets/2014/idu-2014.pdf> (last visited Sept. 19, 2015).

² Florida Dep't of Health, *HIV Disease and Hepatitis C Virus (HCV) Co-Infection – Florida, 2013* (Revised Sept. 3, 2014) (on file with the Senate Committee on Health Policy).

³ *Supra* note 1. Percent IDU adjusted to conform to previous data charts.

⁴ 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." *Drug and Alcohol Dependence*, June 2012, Vol. 123, Issue 1, pp. 255-259, available at <http://www.ncbi.nlm.nih.gov/pubmed/22209091> (last visited Sept. 21, 2015).

⁵ *Id.*

cure for AIDS—are the most cost effective and reliable approaches to prevent new blood-borne infections. The strategies NIDA recommends are community-based outreach, drug abuse treatment, and sterile syringe access programs, including needle and syringe exchange programs (NSEPs). In general, these strategies are referred to as harm reduction.⁶

Needle and syringe exchange programs provide free sterile needles and syringe units and collect used needles and syringes from IDUs to reduce transmission of blood-borne pathogens, including HIV, hepatitis B virus, and hepatitis C virus (HCV). In addition, the programs help to:

- Increase the number of drug users who enter and remain in available treatment programs;
- Disseminate HIV risk reduction information and referrals for HIV testing and counseling and drug treatment;
- Reduce injection frequency and needle-sharing behaviors;
- Reduce the number of contaminated syringes in circulation in a community; and
- Increase the availability of sterile needles, thereby reducing the risk that new infections will spread.⁷

The first sanctioned NSEP in the world began in Amsterdam, the Netherlands, in 1984. The first sanctioned program to operate in North America originated in Tacoma, Washington, in 1988. As of June 2014, there are 194 NSEPs in 33 states, the District of Columbia, the Commonwealth of Puerto Rico, and the Indian Nations.⁸

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.⁹

Examples of sharps include:

- 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;
- 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; and

⁶ National Institute of Drug Abuse, National Institutes of Health, U.S. Department of Health and Human Services, *Principles of HIV Prevention in Drug-Using Populations: A Research-Based Guide* (March 2002), available at [http://www.nhts.net/media/Principles%20of%20HIV%20Prevention%20\(17\).pdf](http://www.nhts.net/media/Principles%20of%20HIV%20Prevention%20(17).pdf) (last visited Sept. 21, 2015).

⁷ *Id.*, at 18. See also World Health Organization, *Effectiveness of Sterile Needle and Syringe Programming in Reducing HIV/AIDS Among Injecting Drug Users* (2004) pp. 28–29, available at <http://www.who.int/hiv/pub/idu/pubidu/en/> (last visited Sept. 21, 2015).

⁸ North American Syringe Exchange Network, *Syringe Services Program Coverage in the United States* (June 2014), available at http://www.amfar.org/uploadedFiles/amfarorg/On_the_Hill/2014-SSP-Map-7-17-14.pdf (last visited Sept. 21, 2015).

⁹ U.S. Food and Drug Administration, *Needles and Other Sharps (Safe Disposal Outside of Health Care Settings)*, (Jan. 27, 2014) available at: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/Sharps/> (last visited Sept. 21, 2015).

- Connection needles/sets - needles that connect to a tub to transfer fluids in and out of the body.¹⁰

Used needles and other sharps pose a dangerous risk to people and animals if not properly disposed as they can spread disease and cause injury. On November 8, 2011, the Federal Drug Administration (FDA) launched a new web site for patients and caregivers on the safe disposal of sharps.¹¹ The most common infections from such injuries are Hepatitis B (HBV), Hepatitis C (HCV), and Human Immunodeficiency Virus (HIV).¹² The FDA's guidelines for disposal are to never place loose needles or other sharps into household or public trash cans or recycling bins, and to never flush them down toilets.¹³

Federal Ban on Funding Needle and Syringe Exchange Programs

In 1988, Congress enacted an initial ban on the use of federal funds for NSEPs which remained in place until 2009. In 2009, Congress passed the 2010 Consolidated Appropriations Act, which 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.¹⁴

However, on December 23, 2011, President Barack Obama signed the 2012 omnibus spending bill that reinstated the ban on the use of federal funds for NSEPs, which reversed the 111th Congress's 2009 decision to allow federal funds to be used for NSEPs.¹⁵ The ban on federal funding for NSEPs remains in effect.

Florida Comprehensive Drug Abuse Prevention and Control Act

In Florida, the term "drug paraphernalia" is defined as all equipment, products, and materials of any kind which are used, intended for use, or designed for use in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, transporting, injecting, ingesting, inhaling, or otherwise introducing into the human body, a controlled substance in violation of ch. 893, F.S., or s. 877.111, F.S.¹⁶

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 this chapter; or

¹⁰ *Id.*

¹¹ U.S. Food and Drug Administration, *Improperly Discarded "Sharps" Can Be Dangerous*, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm278763.htm#1> (last visited Sept. 21, 2015).

¹² *Supra*, note 10.

¹³ *Id.*

¹⁴ Matt Fisher, Center for Strategic and International Studies, *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 Sept. 21, 2015).

¹⁵ *Id.*

¹⁶ Section 893.145, F.S.

- 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 this provision commits a first degree misdemeanor.¹⁷

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:

- 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 this act, or
- To inject, ingest, inhale, or otherwise introduce into the human body a controlled substance in violation of this act.

Any person who violates this provision commits a third degree felony.¹⁸

A court, jury, or other authority, when determining in a criminal case whether an object constitutes drug paraphernalia, must consider specified facts surrounding the connection between the item and the individual arrested for possessing drug paraphernalia. A court or jury is required to consider a number of factors in determining whether an object is drug paraphernalia, such as proximity of the object in time and space to a controlled substance, the existence of residue of controlled substances on the object, and expert testimony concerning its use.¹⁹

Federal Law Exemption

Any person authorized by local, state, or federal law to manufacture, possess, or distribute drug paraphernalia is exempt from the federal drug paraphernalia statute.²⁰

III. Effect of Proposed Changes:

Section 1 titles the bill as the “Miami-Dade Infectious Disease Elimination Act (“IDEA”).”

Section 2 amends s. 381.0038, F.S., to create a sterile needle and syringe exchange pilot program in Miami-Dade County.

The bill authorizes the University of Miami and its affiliates to 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 is designed to 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.

¹⁷ A first degree misdemeanor is punishable by up to 1-year imprisonment in a county jail, a fine of up to \$1,000, or both. *See* ss. 775.082 and 775.083, F.S.

¹⁸ A third degree felony is punishable by up to 5 years in state prison, a fine not to exceed \$5,000, or both. *See* ss. 775.082 and 775.083, F.S.

¹⁹ Section 893.146, F.S.

²⁰ 21 U.S.C. § 863(f)(1).

The bill provides that the pilot program must 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 required to control the use and dispersal of needles and syringes.

The pilot program must operate a one-for-one exchange, whereby participants receive one sterile needle and syringe unit in exchange for each used one. In addition to the needle and syringe exchange, the pilot program must make available:

- Educational materials;
- HIV, AIDS, and viral hepatitis counseling and testing;
- Referral services to provide education regarding HIV, AIDS, viral hepatitis, and other blood-borne disease transmission; and
- Drug-abuse prevention and treatment counseling and referral services.

The bill specifies that the possession, distribution, or exchange of needles or syringes as part of the pilot program is not a violation of any law. However, a pilot program staff member, volunteer, or participant is not immune for criminal prosecution for:

- Possession of needles or syringes that are not a part of the pilot program; or
- Redistribution of needles or syringes in any form, if acting outside the pilot program.

The pilot program must collect data for annual and final reporting purposes, including 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 deemed necessary for the pilot program.

The bill specifies that personal identifying information may not be collected from a participant for any purpose.

State, county, or municipal funds may not be used to operate the pilot program, and the pilot program must be funded through grants and donations from private resources and funds.

The bill provides that the pilot program will expire July 1, 2021.

Section 3 creates an undesignated section of Florida law to provide a severability clause, providing that if any provision of this act or its application to any person or circumstances is held invalid, the invalidity does not affect other provisions or applications of the bill that can be given effect without the invalid provision or application, and to this end the provisions of the bill are severable.

Section 4 provides an effective date of July 1, 2016.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Under PCS/CS/SB 242, the University of Miami will be responsible for securing funding through grants and donations from private sources. According to the Department of Health, the needle exchange site must obtain a Biomedical Waste Operating Permit as a sharps collection program in accordance with Chapter 64E-16, Florida Administrative Code, through the Department's Miami-Dade Environmental Health office.

C. Government Sector Impact:

The pilot program may reduce state and local government expenditures for the treatment of blood-borne diseases associated with intravenous drug use in Miami-Dade County. As one example, the state and local governments currently pay for medical expenditures through a number of programs for patients with AIDS, such as Medicaid, the AIDS Drug Assistance Program, and the AIDS Insurance Continuation Program. In 2010 dollars, the lifetime treatment of an HIV infection is estimated to cost \$379,668.²¹

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill requires the pilot program to collect various data for the purpose of annual reports and the program's final report, including "other data deemed necessary for the pilot program." The

²¹ Centers for Disease Control, *HIV Cost-effectiveness*, <http://www.cdc.gov/hiv/prevention/ongoing/costeffectiveness/> (last visited Oct. 27, 2015).

bill does not provide guidance as to standards under which data may be deemed necessary or which entity may deem data to be necessary. Furthermore the bill does not identify to whom the annual and final reports are to be submitted.

VIII. Statutes Affected:

This bill substantially amends section 381.0038 of the Florida Statutes.

IX. Additional Information:

- A. **Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

Recommended CS/CS by Appropriations Subcommittee on Health and Human Services on November 18, 2015:

The proposed committee substitute changes the pilot program’s expiration date from July 1, 2020, to July 1, 2021.

CS by Health Policy on November 2, 2015:

The CS added county and municipal funds as other sources of public funding that may not be used to operate the pilot program. The CS also removed the requirement for the Office of Program Policy Analysis and Government Accountability to submit a report on the pilot program.

- B. **Amendments:**

None.