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 Committee on Fiscal Policy

BILL:	CS/CS/SB 242
INTRODUCER:	Fiscal Policy Committee (Recommended by Appropriations Subcommittee on Health and Human Services); Health Policy Committee; and Senators Braynon and Flores
SUBJECT:	Infectious Disease Elimination Pilot Program
DATE:	December 4, 2015 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	**Fav/CS**
2.	Brown	Pigott	AHS	**Recommend: Fav/CS**
3.	Pace	Hrdlicka	FP	**Fav/CS**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 242 creates the Miami-Dade Infectious Disease Elimination Act, 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, such as HIV, AIDS, and viral hepatitis. The bill provides duties and requirements for the operation of the pilot program and requires annual and final reports.

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.

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 the 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 of Total PLWHA Cases
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.[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

[1] Florida Department 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 Nov. 20, 2015).
[2] Florida Department of Health, *HIV Disease and Hepatitis C Virus (HCV) Co-Infection – Florida, 2014* (Revised Aug. 13, 2015), *available at* http://www.floridahealth.gov/diseases-and-conditions/hepatitis/_documents/HepC-HIV-Co-infection.pdf (last visited Dec. 1, 2015).
[3] *Supra* note 1. Percent IDU adjusted to conform to previous data charts. State totals include cases in the Department of Corrections system.
[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, *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3358593/pdf/nihms347112.pdf (last visited Nov. 20, 2015).
[5] *Id*.

behaviors and prevent the spread of HIV/AIDS, particularly among IDUs, their sexual partners, and their offspring. The studies found that comprehensive strategies are the most cost effective and reliable approaches to prevent new blood-borne infections (in the absence of a vaccine or cure for AIDS). The strategies NIDA recommends are community-based outreach, drug abuse treatment, and sterile syringe access programs, including needle and syringe exchange programs.[6] In general, these strategies are referred to as "harm reduction".[7]

Needle and syringe exchange programs (NESPs) 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. 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.[8]

The first sanctioned NSEP in the world began in Amsterdam, the Netherlands, in 1984.[9] The first sanctioned program to operate in North America originated in Tacoma, Washington, in 1988.[10] As of June 2014, there are 194 NSEPs in 33 states, the District of Columbia, the Commonwealth of Puerto Rico, and the Indian Nations.[11]

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

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[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), p. 11, *available at* http://www.nhts.net/media/Principles%20of%20HIV%20Prevention%20(17).pdf (last visited Nov. 20, 2015).

[7] Harm reduction programs aim to assist an individual in reducing harm to himself or herself and others if he or she is not willing to give up the drug addiction. They also operate under the recognition that it is impossible to completely eradicate drug use, and recognize that many drug users fail to totally abstain from intravenous drug use. The goal of such programs is to reduce the risk that IDUs can pose to themselves and others. *See* Peter A. Clark and Matthew Fadus, "Federal Funding for Needle Exchange Programs." Med Sci Monit, 2010; 16(1): p. 3 (Jan. 1, 2010) *available at* http://www.medscimonit.com/fulltxt.php?ICID=878301 (last visited Dec. 1, 2015).

[8] Supra note 6 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 Nov. 20, 2015).

[9] Peter A. Clark and Matthew Fadus, "Federal Funding for Needle Exchange Programs." Med Sci Monit, 2010; 16(1): p. 3 (Jan. 1, 2010) *available at* http://www.medscimonit.com/fulltxt.php?ICID=878301 (last visited Dec. 1, 2015).

[10] *Id.* at 4.

[11] 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 Nov. 20, 2015).

Human Services issued implementation guidelines for programs interested in using federal dollars for NSEPs.[12]

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 Congress's 2009 decision to allow federal funds to be used for NSEPs.[13] 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.[14]

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.[15]

Any person who violates this provision commits a first degree misdemeanor.[16]

It is also 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 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.[17]

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

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[12] 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 Nov. 20, 2015).
[13] *Id*.
[14] Section 893.145, F.S.
[15] Section 893.147(1), F.S.
[16] 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.
[17] Section 893.147(2), 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.

A court or jury is required to consider a number of factors before determining whether an object is "drug paraphernalia," including statements by anyone in control of the item concerning its use and the proximity of the item to controlled substances. However, the innocence of anyone in control of an item as to a violation of any of the drug paraphernalia crimes does not prevent a finding that an item is drug paraphernalia.[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 must offer 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.

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

[19] Section 893.146, F.S.
[20] 21 U.S.C. § 863(f)(1).

- 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. 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 deemed necessary for the pilot program.

An annual report is due to the DOH by July 1 every year until the program expires. A final report is due to the DOH on August 1, 2021, and must summarize the annual reports and contain information on program performance and outcomes. 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; instead the pilot program must be funded through grants and donations from private resources and funds.

The pilot program expires on July 1, 2021.

Section 3 is a severability clause that provides that if any provision of this bill or its application to any person or circumstance is held invalid, the invalidity will not affect other provisions or applications of the bill that can be given effect without the invalid provision or application.

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 the bill, 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.[21]

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. For example, state and local governments currently pay for medical expenditures for some 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 was estimated to cost $379,668.[22]

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 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.)

CS/CS by Fiscal Policy on December 3, 2015:
The committee substitute clarifies that an annual and final report are due to the DOH on certain dates.

[21] Department of Health, 2015 Agency Bill Analysis SB 1040, Jan. 29, 2015 (on file with the Senate Fiscal Policy Committee).
[22] Centers for Disease Control, *HIV Cost-effectiveness, available at* http://www.cdc.gov/hiv/prevention/ongoing/costeffectiveness/ (last visited Nov. 20, 2015).

As recommended 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.