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.)

-	Р	repared By: The Profession	nal Staff of the Comr	nittee on Rules		
BILL:	CS/SB 408					
INTRODUCER:	Health Policy Committee and Senators Braynon and Sobel					
SUBJECT:	Needle and Syringe Exchange Pilot Program					
DATE:	March 25,	2014 REVISED:				
ANALYST		STAFF DIRECTOR	REFERENCE	ACTION		
. Peterson		Stovall	HP	Fav/CS		
. Erickson		Cannon	CJ	Favorable		
3. Peterson		Phelps	RC	Favorable		

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 408 creates the "Miami-Dade Infectious Disease Elimination Act (IDEA)." The IDEA requires the Department of Health (DOH) to establish a needle and syringe exchange pilot program in Miami-Dade County to prevent the transmission of HIV/AIDS, viral hepatitis, and other blood-borne diseases. The bill specifies the duties of the pilot program. The pilot program must be funded through private grants and donations.

The bill specifies that possession, distribution, or exchange of needles or syringes through the pilot program is not a violation of criminal law; however, possession or redistribution of syringes or needles outside of the program by staff, volunteers, or participants remains a violation subject to criminal prosecution.

The pilot program expires on July 1, 2019, or, if operated by a designee, 5 years after the entity is designated, and requires the Office of Program Policy Analysis and Government Accountability (OPPAGA) to submit a report to the Legislature that includes data on the pilot program and a recommendation on whether the pilot program should continue.

II. Present Situation:

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 human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS), particularly among injection drug users (IDUs), their sexual partners, and offspring. The studies found that comprehensive strategies—in the absence of a vaccine or 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 syringe exchange programs (SEPs). In general, these strategies are referred to as harm reduction.

Syringe exchange programs provide free sterile syringes and collect used 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; and³
- Increase the availability of sterile needles, thereby reducing the risk that new infections will spread.⁴

¹ This analysis uses the terminology SEP, interchangeably with the term "needle exchange program" (NEP).

² 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%200f%20HIV%20Prevention%20(17).pdf (last visited Feb. 11, 2014). *See also* World Health Organization, *Treatment of injecting drug users with HIV/AIDS: promoting access and optimizing service delivery* (2006), *available at* http://www.who.int/substance_abuse/publications/treatment_idus_hiv_aids.pdf (last visited Feb. 11, 2014); Centers for Disease Control, *Integrated Prevention Services for HIV Infection, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis for Persons Who Use Drugs Illicitly: Summary Guidance from CDC and the U.S. Department of Health and Human Services (Nov. 12, 2012), <i>available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6105a1.htm (last visited Feb. 11, 2014); World Health Organization, United Nations Office on Drugs and Crime, and UNAIDS, *WHO, UNODC, UNAIDS Technical Guide for Countries to Set Targets for Universal Access to HIV Prevention, Treatment and Care for Injecting Drug Users,* 10 – 26 (2012 Revision), *available at* http://opps.who.int/iris/bitstream/10665/77969/1/9789241504379 eng.pdf (last visited Feb. 11, 2014); Institute of Medicine of the National Academies, *Preventing HIV Infection Among Injecting Drug Users in High Risk Countries* (September 2006), *available at* http://iom.edu/Reports/2006/Preventing-HIV-Infection-among-Injecting-Drug-

³ Researchers from the University of Miami recently found that IDUs in Miami—a city without an SEP—were 34 times more likely to dispose of a used syringe in a public location than were IDUs in San Francisco—a city with multiple SEPs. Tookes, HE, Kral, AH, Wenger, LD, Cardenas, GA, Martinez, AN, Sherman, RL, Pereyra, M, Forrest, DW, LalLota, M, Metsch, LR. "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 Feb. 11, 2014).

⁴ National Institute of Drug Abuse, *supra* note 2, at 18. *See also* U.S. Department of Health and Human Services, David Satcher, MD, Assistant Secretary for Health and Surgeon General, *Evidence-based findings on the efficacy of syringe exchange programs: an analysis of the scientific research completed since April 1998 (March 17, 2000), <i>available at*

The first sanctioned SEP began in Amsterdam, the Netherlands, in 1984. The first sanctioned program to operate in North America originated in Tacoma, Washington in 1988. Programs have since developed throughout the United States.⁵ As of July 2013, thirty states, plus the District of Columbia and Puerto Rico, have a combined total of 214 SEPs.⁶

In 1988, Congress enacted a ban on the use of federal funds for SEPs. The ban remained in place until 2009, but was reinstated again at the end of 2011 as part of the omnibus spending bill that continued operations of the federal government through 2012.

Intravenous Drug Use in Florida

The majority of Florida counties with high rates of persons living with HIV/AIDS (PLWHA) with an IDU-associated risk through 2012 are primarily in the southeast or central part of the state. Researchers from the University of Miami recently estimated that there are more than 10,000 IDUs in Miami and that one in five of these IDUs are HIV positive and one in three are HCV positive. The DOH estimates that 50 - 90 percent of HIV-infected IUDs are also coinfected with HCV.

The chart below contains data from 2012 of 11 counties with the highest incidence of PLWHA with an IDU-associated risk.¹⁰

County	Total PLWHA Cases	Total IDU	Percent IDU
Miami-Dade	25,544	3,274	13%
Broward	16,593	2,103	13%
Palm Beach	7,769	1,484	19%

http://home.mchsi.com/~apclc/8fedstudies2.pdf (last visited Feb. 11, 2014). In his report the Surgeon General noted, "The data indicate that the presence of a syringe exchange program does not increase the use of illegal drugs among participants in syringe exchange programs, and in many cases, a decrease in injection frequency has been observed among those attending these programs." World Health Organization, Effectiveness of Sterile Needle and Syringe Programming in Reducing HIV/AIDS Among Injecting Drug Users (2004) 28 – 29, available at http://www.who.int/hiv/pub/idu/pubidu/en/ (last visited Feb. 11, 2014) (Concluding specifically that injecting paraphernalia legislation is a barrier to effective HIV control among IDUs).

⁵ Sandra D. Lane, R.N., Ph.D., M.P.H., *Needle Exchange: A Brief History, a Publication from The Kaiser Forums, available at* http://hpcpsdi.rutgers.edu/facilitator/SAP/downloads/articles%20and%20data/History+of+Needle+Exchange.pdf (last visited Feb. 11, 2014).

⁶ North American Syringe Exchange Network, *Syringe Exchange Program Coverage in the United States* (July 2013), available at

http://www.amfar.org/uploadedFiles/ amfarorg/Articles/In The Community/2013/July%202013%20SEP%20Map%20.pdf (last visited Feb. 11, 2014).

⁷ Florida Department of Health, *HIV Infection Among Those with an Injection Drug Use-Associated Risk, Florida*, 2012 (PowerPoint slide) (Revised Sept. 17, 2013), *available* at http://www.floridahealth.gov/diseases-and-conditions/aids/surveillance/documents/HIV-AIDS-slide%20sets/IDU_2012.pdf (last visited Feb. 11, 2014). The PowerPoint reflects data as of June 30, 2013.

⁸ Tookes et al., *supra* note 3.

⁹ Florida Department of Health, *HIV Disease and Hepatitis C Virus (HCV) Co-Infection – Florida*, 2011 (Revised Dec. 11, 2012) (on file with the Senate Health Policy Committee).

¹⁰ Supra note 7.

County	Total PLWHA Cases	Total IDU	Percent IDU
Orange	7,149	1,291	18%
Hillsborough	5,898	1,144	19%
Duval	5,372	1,009	19%
Pinellas	3,564	723	20%
Lee	1,677	305	18%
St. Lucie	1,508	302	20%
Volusia	1,358	324	24%
Brevard	1,256	268	21%
STATE TOTAL	98,291	17,289	18%

Among those with HIV, drug users have been found to experience significant barriers to accessing care. Specifically, they receive HIV care at lower rates than other populations; have greater difficulty accessing treatment and being prescribed medications, and even when treatment is available, may fail to connect with the health care system due to mistrust, fear of prosecution, stigmatization, and a chaotic lifestyle; and may be discriminated against in the system due to the perception that they will not adhere to a medication regimen or that HIV has been self-inflicted, and thus treatment is not deserved.¹¹

Florida Comprehensive Drug Abuse Prevention and Control Act

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.¹²

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

Any person who violates this provision commits a first degree misdemeanor.¹³

¹¹ World Health Organization, *Treatment of injecting drug users with HIV/AIDS: promoting access and optimizing service delivery*, p. 1 (2006), *available at http://www.who.int/substance_abuse/publications/treatment_idus_hiv_aids.pdf* (last visited Feb 11, 2014).

¹² Section 893.145, F.S.

¹³ A first degree misdemeanor is punishable by up to one-year imprisonment in a county jail, a fine of up to \$1,000, or both. *See* ss. 775.082 and 775.083, F.S.

This section of law also provides that 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. 14

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 addition to other logically relevant 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.¹⁵

III. Effect of Proposed Changes:

Section 1 names the act the "Miami-Dade Infectious Disease Elimination Act (IDEA)."

Section 2 adds a new subsection to s. 381.0038, F.S., which requires the DOH to establish a sterile needle and syringe exchange pilot program in Miami-Dade County. The pilot program is created to prevent the transmission of the HIV/AIDS and other blood-borne diseases by offering free exchange of clean, unused needles and hypodermic syringes for used needles and hypodermic syringes in a one-for-one exchange. The pilot program must be administered by the DOH or its designee. The bill identifies the entities that the DOH is authorized to designate to operate the program at a fixed location or through a mobile health unit:

- A licensed hospital;
- A licensed health care clinic;
- A substance abuse treatment program;
- An HIV or AIDS service organization; or
- Another nonprofit entity designated by the DOH.

The program must do all of the following:

• Provide for maximum security of exchange sites and equipment, including: an accounting of the number of needles and syringes in use and in storage; safe disposal of returned needles;

¹⁴ 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.

¹⁵ Section 893.146, F.S.

and any other measure that may be required to control the use and dispersal of sterile needles and syringes.

- Strive for one-to-one exchange (one sterile needle and syringe unit for each used one).
- Make available the following: educational materials; HIV counseling and testing; referral services to provide education regarding HIV/AIDS and viral hepatitis transmission; and drug use prevention and treatment.

The program must be funded through grants and donations from private resources and funds, without the use of state funds.

The possession, distribution, or exchange of needles or syringes as part of a pilot SEP established by the DOH or its designee is not a violation of ch. 893, F.S., or any other law. However, a SEP staff member, volunteer, or participant is not immune from criminal prosecution for possessing needles or syringes that are not part of the exchange pilot program or for redistributing needles or syringes if acting outside the program.

The pilot program must collect data regarding the following: number of participants served; the number of needles and syringes exchanged and distributed; the number of participants entering drug counseling and treatment; the number of participants receiving HIV/AIDS or viral hepatitis testing; and demographic profiles of participants served. However, no personal identifying information may be collected from a participant for any purpose.

The pilot program expires on July 1, 2019, or, if operated by a designee, 5 years after the entity is designated. Six months before the pilot program expires, the OPPAGA must submit a report to the Legislature that includes the collected data and a recommendation on whether the pilot program should continue.

Section 3 adds a severability clause, which provides that if any provision of this act or its application to a person is invalid, the invalidity would not affect other provisions or applications of the act which can be given effect without the invalid provision, and the provisions of this act are severable.

Section 4 provides an effective date of July 1, 2014.

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:

The private sector would benefit from any cost savings resulting from avoided treatment costs, consistent with the discussion below, in proportion to its share of covered costs.

C. Government Sector Impact:

The DOH indicates that an exchange program site will be required to obtain a permit as a sharps collection program under Chapter 64E-16, F.A.C. The DOH anticipates that permitting costs can be absorbed by current resources.

Currently, no data exist to estimate the potential fiscal impact of the pilot program. However, the CDC indicates that HIV prevention interventions, such as syringe exchange programs, are intended to prevent infection in people who are HIV-negative. Such programs can be evaluated to determine the number of infections prevented that would have otherwise occurred had the intervention not been provided.

The lifetime treatment cost of an HIV infection can be used as a conservative threshold value for the cost of averting one infection. Currently, the lifetime treatment cost of an HIV infection is estimated at \$379,668 (in 2010 dollars), therefore a prevention intervention is deemed cost-saving if its cost-effectiveness ratio (cost of the intervention/number of infections averted) is less than \$379,668 per infection averted.¹⁶

The State of Florida pays for HIV/AIDS treatment through Medicaid, the AIDS Drug Assistance Program, and the AIDS Insurance Continuation Program, among others. If 10 percent of the reported PLWHA with an IDU-associated risk living in Miami-Dade County had avoided infection, this would represent a savings in treatment costs of approximately \$124 million.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 381.0038 of the Florida Statutes.

¹⁶ Centers for Disease Control, *HIV Cost-effectiveness* http://www.cdc.gov/hiv/prevention/ongoing/costeffectiveness/ (last visited Feb. 11, 2014).

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on February 4, 2014:

The CS adds a short title and modifies the program repeal date to be either July 1, 2019, or, if operated by a designee, 5 years from the date the entity is designated.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.