

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 491 Infectious Disease Elimination Pilot Program

SPONSOR(S): Health Quality Subcommittee; Pafford and others

TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 408

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	13 Y, 0 N, As CS	Dunn	O'Callaghan
2) Government Operations Subcommittee	10 Y, 0 N	Stramski	Williamson
3) Judiciary Committee	14 Y, 0 N	Ham-Warren	Havlicak
4) Health & Human Services Committee	17 Y, 0 N	Dunn	Calamas

SUMMARY ANALYSIS

The bill amends s. 381.0038, F.S., to create 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 (pilot program) in Miami-Dade County. The pilot program is to offer free, clean, and unused needles and hypodermic syringes as a means to prevent the transmission of HIV/AIDS and other blood-borne diseases among intravenous drug users, their sexual partners, and offspring. The pilot program must be administered by DOH or a designee, who may operate the pilot program at a fixed location or by using a mobile health unit. The designee may be a licensed hospital, a licensed health care clinic, a substance abuse treatment program, an HIV/AIDS service organization, or another nonprofit entity.

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 any measure to control the use and dispersal of sterile needles and syringes;
- Strive for a one sterile needle and syringe unit to one used unit exchange ratio; and
- Make available 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 bill provides that 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. 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.

The bill requires the collection of data for annual and final reporting purposes but prohibits the collection of any personal identifying information from a participant. The pilot program expires on July 1, 2019, or 5 years after DOH designates an entity to operate the program. Six months prior to expiration, the Office of Program Policy Analysis and Government Accountability is required to submit a report to the Legislature that includes data on the pilot program and a recommendation on whether the pilot program should continue.

The bill prohibits the use of state funds to operate the pilot program and specifies the use of grants and donations from private sources to fund the program. The bill grants DOH the authority to adopt rules to implement the pilot program. The bill includes a severability clause.

The bill may have a positive fiscal impact on state government or local governments. See FISCAL COMMENTS.

The bill provides an effective date of July 1, 2014.

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

STORAGE NAME: h0491g.HHSC

DATE: 4/10/2014

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current 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 reuse of contaminated needles and syringes by injection-drug users (IDUs).

Federal Ban on Funding

In 2009, Congress passed the FY 2010 Consolidated Appropriations Act, which contained language that 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.¹

However, on December 23, 2011, President Obama signed the FY 2012 omnibus spending bill that, among other things, reinstated the ban on the use of federal funds for NSEPs; this step reversed the 111th Congress's decision to allow federal funds to be used for NSEPs.²

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.

Examples of sharps include:³

- 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. This is generally used for patients on home hemodialysis.

On November 8, 2011, the Federal Drug Administration (FDA) launched a new website⁴ for patients and caregivers on the safe disposal of sharps that are used at home, at work, and while traveling.⁵

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

¹ Matt Fisher, *A History of the Ban on Federal Funding for Syringe Exchange Programs*, SMARTGLOBALHEALTH.ORG (Feb. 6, 2012), <http://www.smartglobalhealth.org/blog/entry/a-history-of-the-ban-on-federal-funding-for-syringe-exchange-programs/> (last visited April 7, 2014).

² *Id.*

³ Food and Drug Administration, *Needles and Other Sharps (Safe Disposal Outside of Health Care Settings)*, (Jan. 27, 2014), <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/Sharps/ucm20025647.htm> (last visited April 7, 2014).

⁴ *Id.*

⁵ *Id.*

conditions. The most common infections from such injuries are Hepatitis B (HBV), Hepatitis C (HCV), and Human Immunodeficiency Virus (HIV).⁶ Moreover, injections of illicit drugs have been estimated to represent approximately one-third of the estimated 2 to 3 billion injections occurring outside of health-care settings in the U.S. each year, second only to insulin injections by persons with diabetes.⁷

For these reasons, communities are trying to manage the disposal of sharps within the illicit drug population. In San Francisco in 2000, approximately 2 million syringes were recovered at NSEPs, 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.⁸ Other NSEPs 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.⁹

National Data & Survey Results

According to the Centers for Disease Control and Prevention (CDC), NSEPs 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 Often, programs also provide other public health services, such as HIV testing, risk-reduction education, and referrals for substance-abuse treatment.¹¹

In 2002, staff from the Beth Israel Medical Center in New York City and the North American Syringe Exchange Network mailed surveys asking the directors of 148 NSEPs about syringes exchanged and returned, services provided, budgets, and funding. The survey found for the first time in 8 years, the number of NSEPs, the number of localities with NSEPs, and public funding for NSEPs decreased nationwide; however, the number of syringes exchanged and total budgets across all programs continued to increase.¹²

In 2011, the Beth Israel Medical Center conducted another survey of NSEPs in the U.S.¹³ The results revealed that the most frequent drug being used by participants was heroin, followed by cocaine, and that usually the problems NSEPs encountered had to do with the lack of resources and staff shortages.¹⁴

A 2012 study compared improper public syringe disposal between Miami, a city without NSEPs, and San Francisco, a city with NSEPs.¹⁵ 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.¹⁶

⁶ *Id.*

⁷ Centers for Disease Control, *Update: Syringe Exchange Programs --- United States, 2002*, MMWR WEEKLY, July 15, 2005, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5427a1.htm> (last visited April 7, 2014) (citing American Association of Diabetes Educators, American Diabetes Association, American Medical Association, American Pharmaceutical Association, Association of State and Territorial Health Officials, National Alliance of State and Territorial AIDS Directors, *Safe Community Disposal of Needles and Other Sharps, Houston, TX: Coalition for Safe Community Needle Disposal* (2002)).

⁸ *Id.* (citing Brad Orda et al., *San Francisco Safe Needle Disposal Program, 1991—2001*, 42 J. AM PHARM ASSOC. S115—6 (2002), available at <http://japha.org/article.aspx?articleid=1035735> (last visited April 7, 2014)).

⁹ Centers for Disease Control, *Update: Syringe Exchange Programs --- United States, 2002*, *supra* note 7.

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ North American Syringe Exchange Network, *2011 Beth Israel Survey, Results Summary, (PowerPoint slide) available at* <http://www.nasen.org/news/2012/nov/29/2011-beth-israel-survey-results-summary/> (last visited April 7, 2014).

¹⁴ *Id.*

¹⁵ 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 April 7, 2014).

¹⁶ *Id.* at 255 (finding “44 syringes/1000 census blocks in San Francisco, and 371 syringes/1000 census blocks in Miami.”).

A separate 2012 study, examining the results of a needle exchange program in the District of Columbia shows an 80 percent decline between 2007 (149 cases) and 2011 (30 cases) in the number of HIV cases in which injection drug use was reported as transmission mode.¹⁷

Heroin Use in Florida

An estimated 1 million people in the U.S. are living with HIV/AIDs, and it has been estimated that one-third of those cases are linked directly or indirectly to injection drug use, including the injection of heroin.¹⁸ Recently the National Institute on Drug Abuse reported an epidemic of heroin use in South Florida and particularly in Miami-Dade County.¹⁹ The number of heroin-related deaths in Miami-Dade County jumped to 33 in 2012 from 15 in 2011, an 120 percent increase. Statewide, Florida has also seen an upswing in heroin deaths, which rose to 117 in 2012 from 62 in 2011, an increase of 89 percent.²⁰

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 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 the above provision is guilty of a misdemeanor of the first degree.²¹

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.²²

- 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 the above provision is guilty of a felony of the third degree.²³

Federal Drug Paraphernalia Statute

Persons authorized by state law to possess or distribute drug paraphernalia are exempt from the federal drug paraphernalia statute.²⁴

¹⁷ The District of Columbia Department of Health, *2012 Annual Epidemiology and Surveillance Report, Section 2: Newly Diagnosed HIV Cases (2012)*, available at <http://doh.dc.gov/page/2012-annual-epidemiology-and-surveillance-report>.

¹⁸ National Institute on Drug Abuse, *Drug abuse is a significant risk factor for HIV/AIDS in the U.S.*, (Oct. 2005) available at <http://www.drugabuse.gov/publications/topics-in-brief/linked-epidemics-drug-abuse-hiv-aids> (last visited April 7, 2014).

¹⁹ James N. Hall, *Drug Abuse Patterns and Trends in Miami-Dade and Broward Counties, Florida—Update: January 2014*, <http://www.drugabuse.gov/> (forthcoming March 2014) (on file with House Health Quality Subcommittee).

²⁰ Florida Department of Law Enforcement, *Drugs Identified in Deceased Persons by Florida Medical Examiners, 2012 Report*, (2013), available at <http://www.news-press.com/assets/pdf/A4212345924.PDF> (last visited April 7, 2014).

²¹ A second degree misdemeanor is punishable by up to 60 days in county jail and a \$500 fine. Sections 775.082 and 775.083, F.S.

²² Section 893.147(2), F.S.

²³ 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.

Effect of Proposed Changes

The bill amends s. 381.0038, F.S., to require DOH to establish a 5-year needle and syringe exchange pilot program in Miami-Dade County. The pilot program is to offer free, clean, and unused needles and hypodermic syringes as a means to prevent the transmission of HIV/AIDS and other blood-borne diseases among intravenous drug users and their sexual partners and offspring. The pilot program must be administered by DOH or a designee, who may operate the pilot program at a fixed location or by using a mobile health unit. The designee may be a licensed hospital, a licensed health care clinic, a substance abuse treatment program, an HIV/AIDS service organization, or another nonprofit entity.

The exchange program must:

- 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;
- Strive for a 1 sterile to 1 used exchange ratio; and
- Make available 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 bill provides that 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. 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.

The bill requires the collection of data for annual and final reporting purposes, but prohibits the collection of any personal identifying information from a participant. The pilot program expires on July 1, 2019, or if operated by a designee, 5 years after DOH designates an entity to operate the program. Six months prior to expiration, the Office of Program Policy Analysis and Government Accountability is required to submit a report to the Legislature that includes data on the pilot program and a recommendation on whether the pilot program should continue.

The bill prohibits the use of state funds to operate the pilot program and specifies the use of grants and donations from private sources to fund the program.

The bill provides DOH the authority to promulgate rules to implement the pilot program.

The bill includes a severability clause²⁵ and provides an effective date of July 1, 2014.

B. SECTION DIRECTORY:

Section 1. Names the act the “Miami-Dade Infectious Disease Elimination Act (IDEA).”

Section 2. Amends s. 381.0038, F.S., requiring DOH to establish a needle and syringe exchange program.

Section 3. Creates an unnumbered section to provide a severability clause.

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

²⁴ 21 U.S.C. § 863(f)(1).

²⁵ 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).

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

See FISCAL COMMENTS.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

See FISCAL COMMENTS.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

The pilot program required by the bill may significantly reduce state and local government expenditures for the treatment of blood borne diseases associated with intravenous drug use for individuals in Miami-Dade County.²⁶ The reduction in expenditures for such treatments depends on the extent to which the needle and syringe exchange pilot program reduces transmission of blood-borne diseases among intravenous drug users, their sexual partners, offspring, and others who might be at risk of transmission.

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:

The bill provides DOH the authority to promulgate rules to implement the provisions of the bill.

²⁶ 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. The lifetime treatment cost of an HIV infection is estimated at \$379,668 (in 2010 dollars). Centers for Disease Control, *HIV Cost-effectiveness*, (Apr. 16, 2013) available at <http://www.cdc.gov/hiv/prevention/ongoing/costeffectiveness/> (last visited April 7, 2014). Miami-Dade County has 3,274 reported cases of individuals living with HIV/AIDS that have an IDU-associated risk. Florida Department of Health, *HIV Infection Among Those with an Injection Drug Use-Associated Risk, Florida, 2012* (PowerPoint slide) (Sept. 17, 2013), available at http://www.floridahealth.gov/diseases-and-conditions/aids/surveillance/_documents/HIV-AIDS-slide%20sets/IDU_2012.pdf (last visited April 7, 2014) (noting that HIV IDU infection risk includes IDU cases, men who have sex with men (MSM)/IDU, heterosexual sex with IDU, children of IDU mom). If 10 percent of those individuals with an IDU-associated risk had avoided infection, this would represent a savings in treatment costs of approximately \$124 million.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 18, 2014, the Health Quality Subcommittee adopted an amendment and reported the bill favorably as a committee substitute. The amendment:

- Substitutes the term “drug-abuse” for “drug-use” for clarification.
- Provides an alternative expiration date for the pilot program, in case the expiration of the pilot program cannot be based on the date an entity is designated to operate the pilot program.
- Makes technical changes by correcting certain punctuation marks.

This analysis is drafted to the committee substitute.