

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 81 Infectious Disease Elimination Pilot Program

SPONSOR(S): Judiciary Committee; Health Quality Subcommittee; Edward and others

TIED BILLS: None **IDEN./SIM. BILLS:** CS/CS/SB 242

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	11 Y, 1 N, As CS	Siples	O'Callaghan
2) Judiciary Committee	17 Y, 1 N, As CS	Aziz	Havlicak
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The bill amends s. 381.0038, F.S., to create the Miami-Dade Infectious Disease Elimination Act (IDEA). The IDEA authorizes the University of Miami and its affiliates 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 University of Miami must operate the pilot program at fixed locations on its property or the property of its affiliates.

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;
- Operate a one sterile needle and syringe unit to one used unit exchange ratio; and
- Make available educational materials and referrals to education regarding the transmission of HIV, viral hepatitis, and other blood-borne diseases; provide referrals to drug abuse prevention and treatment; and provide or refer for HIV and viral hepatitis screening.

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 quarterly, annual, and final reporting purposes, but prohibits the collection of any personal identifying information from a participant. The pilot program expires on July 1, 2021. The bill requires the pilot program to issue quarterly reports to the Department of Health in Miami-Dade County, and annual reports to the Department of Health, including a final report on the performance and outcomes of the pilot program.

The bill prohibits the use of state, county, or municipal funds to operate the pilot program and requires the use of grants and donations from private sources to fund the 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, 2016.

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' 2009 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.³

Examples of sharps include:⁴

- 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 U.S. Food and Drug Administration (FDA) launched a new website 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*, 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 October 10, 2015).

² *Id.*

³ Food and Drug Administration, *Needles and Other Sharps (Safe Disposal Outside of Health Care Settings)*, available at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/Sharps/ucm20025647.htm> (last visited October 10, 2015).

⁴ *Id.*

⁵ Food and Drug Administration, *FDA launches website on safe disposal of used needles and other "sharps"*, FDA News Release, Nov. 8, 2011, available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm278851.htm> (last visited on October 10, 2015).

conditions. The most common infections from such injuries are Hepatitis B (HBV), Hepatitis C (HCV), and Human Immunodeficiency Virus (HIV).⁶

Approximately 2.6% of the U.S. population⁷ has injected illicit drugs.⁸ 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 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.⁹ 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.¹⁰

National Data & Survey Results

In 2010, 8 percent (3,900) of the estimated 47,500 new HIV infections in the U.S. were attributed to injection drug use.¹¹ 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.¹² Often, programs also provide other public health services, such as HIV testing, risk-reduction education, and referrals for substance-abuse treatment.¹³

Based on findings of a survey conducted by staff from the Beth Israel Medical Center in New York City and the North American Syringe Exchange Network, there were 184 NSEPs operating in 36 states, the District of Columbia, and Puerto Rico as of March 2009,¹⁴ compared to 148 NSEPs in 2002 and 68 NSEPs in 1995.¹⁵ The survey found that the proportion of NSEP budgets coming from public sources increased from 62% during 1994-1995 to 79% in 2008.¹⁶

In 2011, the Beth Israel Medical Center conducted another survey of NSEPs in the U.S.¹⁷ 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.¹⁸

⁶ *Supra* fn. 3.

⁷ This population represents persons aged 13 years or older in 2011.

⁸ Public Library of Science; Lansky, A., Finlayson, T., Johnson, C., 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*; May 19, 2014; •DOI: 10.1371/journal.pone.0097596; available at <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0097596> (last visited on October 15, 2015).

⁹ *Id.* (citing Brad Drda 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 October 11, 2015).

¹⁰ Centers for Disease Control and Prevention, *Update: Syringe Exchange Programs --- United States, 2002*, *supra* note 7.

¹¹ Centers for Disease Control and Prevention, *HIV and Injection Drug Use*, April 2015, available at http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CB0QFjAAahUKEWj8nbnvLnbnvIAhUEFR4KHUQuAPU&url=http%3A%2F%2Fwww.cdc.gov%2Fhiv%2Fpdf%2Fg-1%2Fcdc-hiv-idu-fact-sheet.pdf&usq=AFQjCNHXNVbqd729aWoMirXcVhqtQsAJ9Q&sig2=s88dqAr_jEgG8X3gJINBVg&bvm=bv.104819420.d.dmo (last visited on October 11, 2015).

¹² Centers for Disease Control and Prevention, *Syringe Exchange Programs---United States, 2008*, November 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 October 15, 2015).

¹³ *Id.* See Table 3.

¹⁴ *Supra* fn. 12.

¹⁵ Centers for Disease Control and Prevention, *Update: Syringe Exchange Programs---United States, 2002*, July 15, 2005, 54(27); 673-676, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5427a1.htm> (last visited on October 15, 2015).

¹⁶ *Supra* fn. 12.

¹⁷ 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 October 11, 2015).

¹⁸ *Id.*

A separate 2014 report, examining the results of a needle exchange program in the District of Columbia shows an 81 percent decline between 2008 and 2012 in the number of HIV cases in which injection drug use was reported as transmission mode.¹⁹

A 2012 study compared improper public syringe disposal between Miami, a city without NSEPs, and San Francisco, a city with NSEPs.²⁰ 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.²¹

Heroin Use in Florida

An estimated 1.2 million people in the U.S. are living with HIV/AIDS,²² 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.²³ In 2014, the National Institute on Drug Abuse reported an epidemic of heroin use in South Florida and particularly in Miami-Dade County.²⁴ The number of heroin-related deaths in Miami-Dade County jumped to 60 in 2014 from 40 in 2013 and 32 in 2012. Statewide, Florida has experienced a steady upswing in heroin deaths, which rose to 408 in 2014 from 199 in 2013 and 108 in 2012.²⁵

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 misdemeanor of the first degree.²⁶

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.²⁷

- 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.

¹⁹ The District of Columbia Department of Health, *2013 Annual Epidemiology and Surveillance Report, Section 2: Newly Diagnosed HIV Cases (2014)*, available at <http://doh.dc.gov/page/2013-annual-epidemiology-and-surveillance-report> (last visited October 11, 2015).

²⁰ 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 October 11, 2015).

²¹ *Id.* at 255 (finding “44 syringes/1000 census blocks in San Francisco, and 371 syringes/1000 census blocks in Miami.”).

²² Centers for Disease Control and Prevention, *HIV in the United States: At a Glance*, accessible at: <http://www.cdc.gov/hiv/statistics/basics/ataglance.html> (last visited October 11, 2015).

²³ Health Resources and Services Administration, *Innovative Programs for HIV Positive Substance Users*, available at <http://www.drugabuse.gov/publications/topics-in-brief/linked-epidemics-drug-abuse-hiv-aids> (last visited October 11, 2015).

²⁴ James N. Hall, *Drug Abuse Patterns and Trends in Miami-Dade and Broward Counties, Florida—Update: January 2014*, available at <http://www.drugabuse.gov/about-nida/organization/workgroups-interest-groups-consortia/community-epidemiology-work-group-cewg/meeting-reports/highlights-summaries-january-2014/miami> (last visited October 11, 2015).

²⁵ Florida Department of Law Enforcement, Medical Examiners Commission, *Drugs Identified in Deceased Persons by Florida Medical Examiners, 2014 Annual Report*, (September 2015), available at <http://www.fdle.state.fl.us/Content/getdoc/0f1f79c0-d251-4904-97c0-2c6fd4cb3c9f/MEC-Publications-and-Forms.aspx> (last visited October 11, 2015).

²⁶ 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.

²⁷ Section 893.147(2), F.S.

Any person who violates the above provision is guilty of a felony of the third degree.²⁸

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.²⁹ The penalty for such crime is imprisonment for not more than three years and a fine.³⁰ Persons authorized by state law to possess or distribute drug paraphernalia are exempt from the federal drug paraphernalia statute.³¹

EFFECT OF PROPOSED CHANGES

The bill amends s. 381.0038, F.S., to allow the University of Miami and its affiliates 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 University of Miami must operate the pilot program at fixed locations on its property or the property of its affiliates.

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;
- Operate a 1 sterile to 1 used needle and syringe exchange ratio; and
- Make available educational materials and referrals to education regarding the transmission of HIV, viral hepatitis, and other blood-borne diseases; provide referrals to drug abuse prevention and treatment; and provide or refer for HIV and viral hepatitis screening.

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 data collected must include:

- 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 HIV, AIDS, or viral hepatitis testing;
- The rates of HIV, AIDS, viral hepatitis, or other blood borne disease before the pilot program began and every subsequent year thereafter; and
- Other data deemed necessary for the pilot program.

The pilot program expires on July 1, 2021. The bill requires the pilot program to issue quarterly reports to the Department of Health in Miami-Dade County. The quarterly reports must be submitted by October 15, January 15, April 15, and July 15 of each year. The first quarterly report is due on October

²⁸ 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.

²⁹ 21 U.S.C. § 863(a).

³⁰ 21 U.S.C. § 863(b).

³¹ 21 U.S.C. § 863(f)(1).

15, 2016. The bill also requires annual reports to the Department of Health, including a final report on the performance and outcomes of the pilot program.

The bill prohibits the use of state, county, or municipal funds to operate the pilot program and requires the use of grants and donations from private sources to fund the program.

The bill includes a severability clause³² and provides an effective date of July 1, 2016.

B. SECTION DIRECTORY:

Section 1. Creates an unnumbered section to name the act the “Miami-Dade Infectious Disease Elimination Act (IDEA).”

Section 2. Amends s. 381.0038, F.S., relating to education.

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

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

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

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.³³ The reduction in expenditures for such treatments depends on the extent to which the

³² 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).

³³ 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 and Prevention, *HIV Cost-effectiveness*, (Apr. 16, 2013) available at <http://www.cdc.gov/hiv/prevention/ongoing/costeffectiveness/> (last visited October 11, 2015). 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 October 11, 2015) (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.

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:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On October 20, 2015, the Health Quality Subcommittee adopted two amendments and reported the bill favorably as a committee substitute. The first amendment restricted the operation of the pilot program to fixed locations on the property of the University of Miami or its affiliates. The second amendment prohibited the pilot program from using not only state funds, but also county or municipal funds.

On February 10, 2016, the Judiciary Committee adopted one amendment and reported the bill favorably as a committee substitute. The amendment provides the pilot program will issue quarterly reports to the Department of Health in Miami-Dade County, and annual reports to the Department of Health. This analysis is drafted to the committee substitute as passed by the Judiciary Committee.