

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 Health Policy

BILL: SB 800

INTRODUCER: Senator Braynon

SUBJECT: Infectious Disease Elimination Pilot Programs

DATE: January 12, 2018

REVISED: _____

| | ANALYST | STAFF DIRECTOR | REFERENCE | ACTION |
|----|---------|----------------|-----------|--------------------|
| 1. | Lloyd | Stovall | HP | Pre-meeting |
| 2. | _____ | _____ | AHS | _____ |
| 3. | _____ | _____ | AP | _____ |

I. Summary:

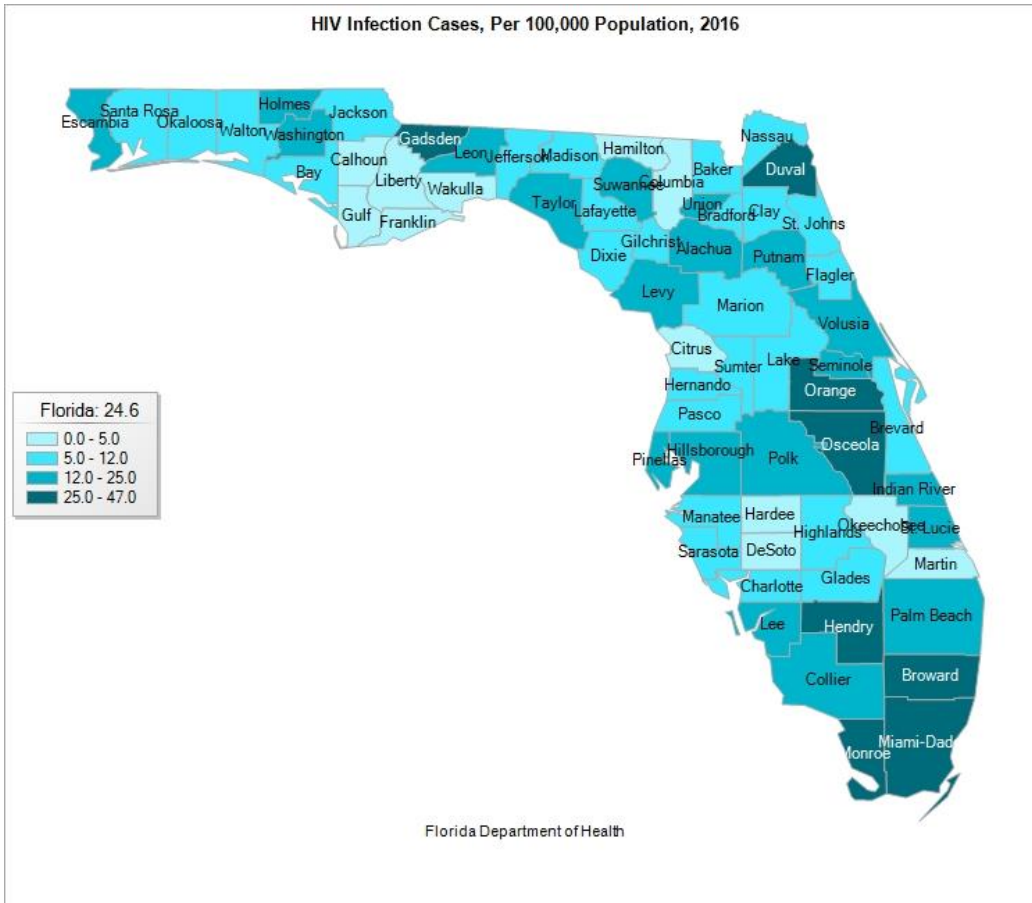
SB 800 expands the existing Miami-Dade sterile needle and syringe exchange pilot program, creating a state pilot program, and renames the section as the “Florida Statewide Infectious Disease Elimination Act.” The bill authorizes the Department of the Health (DOH) to establish additional pilot sites upon request from eligible entities, provides program requirements, modifies what types of entities are eligible to operate a program, and extends the program termination date to July 1, 2023.

The effective date of the bill is July 1, 2018.

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). The map below shows the number of HIV infection cases, per 100,000 population for 2016.¹

¹ Florida Department of Health, HIV Section, FLCharts.com, *Division of Public Health Statistics and Performance Management*, <http://www.flhealthcharts.com/charts/OtherIndicators/NonVitalHIVAIDSViewer.aspx?cid=0471> (last viewed Jan. 11, 2018).



Intravenous Drug Use in Florida

Of the total individuals living with an HIV infection in Florida, 4,972 individuals were newly diagnosed during 2016.² Florida is second in the nation, behind only California, with both the percentage of the national total (12 percent) and the number of newly diagnosed HIV infections in 2016.³ The vast majority of those infected are exposed through male to male sexual contact (60 percent) while 4 percent are infected through intravenous drug use (IDU).⁴ Statistics show Florida’s HIV-infected population is 78 percent male.⁵

The DOH reports that 60 to 90 percent of HIV-infected IDUs are also co-infected with Hepatitis C Virus.⁶ Hepatitis C is a liver disease caused by a virus that spreads through contact with

² Centers for Disease Control and Prevention, *HIV Surveillance Report, 2015 (most recent available)*, vol. 27, Table 18a., <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2015-vol-27.pdf> (November 2016) (last visited Jan. 11, 2018).

³ Kaiser Family Foundation, *The HIV/AIDS Epidemic in the United States: The Basics* (December 2017), <http://files.kff.org/attachment/Fact-Sheet-HIV-AIDS-in-the-United-States-The-Basics>, (last visited Jan. 11, 2018).

⁴ Florida Department of Health, *HIV Cases Diagnosed in 2016 by Selected Demographics and Risk Factors in the U.S. and Florida*, http://www.floridahealth.gov/diseases-and-conditions/aids/surveillance/_images/County_HIV_Trends_2007-2016pdf.pdf (last visited Jan. 11, 2018).

⁵ *Id.*

⁶ Florida Department of Health, *Hepatitis, Hepatitis C and HIV Co-Infection*, <http://www.floridahealth.gov/diseases-and-conditions/hepatitis/co-infection.html> (last visited: Jan. 11, 2018).

infected blood and can cause cirrhosis of the liver, liver cancer, and death.⁷ The Hepatitis C virus can be acquired through:

- Injection of shared drug equipment;
- A blood transfusion before 1992;
- An occupational needle stick,
- A long-term hemodialysis,
- An infected mother to her infant, and
- Sexual transmission.⁸

In 2016, 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.⁹ The chart below displays data from 2016 of the 11 Florida counties with the highest incidence of PLWHA with an IDU-associated risk.¹⁰

| County | Total PLWHA Cases | Total IDU | Percent IDU |
|---------------------|-------------------|---------------|-------------|
| Miami-Dade | 26,946 | 2,873 | 11% |
| Broward | 20,020 | 2,188 | 11% |
| Orange | 8,663 | 1,389 | 16% |
| Palm Beach | 8,198 | 1,323 | 16% |
| Hillsborough | 6,691 | 1,229 | 18% |
| Duval | 6,199 | 981 | 16% |
| Pinellas | 4,589 | 830 | 18% |
| Lee | 2,238 | 333 | 15% |
| Volusia | 1,698 | 410 | 24% |
| St. Lucie | 1,610 | 284 | 18% |
| Brevard | 1,566 | 307 | 20% |
| State Totals | 114,608 | 17,886 | 16% |

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 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

⁷ Florida Dep't of Health, *Hepatitis C Palm Card*, <http://www.floridahealth.gov/diseases-and-conditions/hepatitis/documents/educational-materials/documents/hcv-palmscard.pdf>

⁸ *Id.*

⁹ 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 Jan. 11, 2018).

¹⁰ Florida Department of Health, *Senate Bill 800 2017 Bill Analysis – SB 800 (Nov. 13, 2017) p. 2*, (on file with the Senate Committee on Health Policy).

treatment, and sterile syringe access programs, including needle and syringe exchange programs (NSEPs). In general, these strategies are referred to as harm reduction.¹¹

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 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.¹²

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 May 2015, there were 228 NSEPs in 35 states, the District of Columbia, the Commonwealth of Puerto Rico, and the Indian Nations.¹³

Miami's Needle and Syringe Exchange Program

Florida's first legal needle exchange program was approved by the legislature in 2016.¹⁴ The pilot program is limited to Miami-Dade County and must be funded with private funds, grants, and donations. No state, county, or municipal funds may be used to operate the pilot program. The pilot is limited to a single sterile needle and syringe exchange program in the county and must operate from a mobile unit. The legislation requires the University of Miami to offer the exchange of free, clean, unused needles and hypodermic syringes for used needles and hypodermic syringes.¹⁵ The pilot program must provide educational materials, secure the used needles, and collect required data.¹⁶ The pilot program is scheduled to expire on July 1, 2021.

The Miami NSEP costs more than \$500,000 annually and receives funding from private organizations such as the MAC AIDS Fund, Gilead Pharmaceuticals, the Elton John AIDS

¹¹ 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 Jan. 11, 2018).

¹² *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 Jan. 11, 2018).

¹³ North American Syringe Exchange Network, *Directory* (Updated May 2015), available at <https://nasen.org/> (last visited Jan. 11, 2018).

¹⁴ Chapter 2016-68, Laws of Fla. (creating the Miami-Dade Infectious Disease Elimination Act, amending s. 381.0038, F.S., effective July 1, 2016).

¹⁵ Section 381.0038(4), F.S.

¹⁶ Section 381.0038(4)(a), F.S.

Foundation, and the AIDS Healthcare Foundation as well as support from the University of Miami.¹⁷

Program officials indicate that in the first year, the Miami NSEP has reached more than 500 injection drug users, collected more than 85,000 used needles and reversed at least 235 overdoses.¹⁸ A total of 232 participants have tested HCV positive.¹⁹

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.²⁰

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 “finger stick” 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
- Connection needles/sets - needles that connect to a tub to transfer fluids in and out of the body.²¹

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. The most common infections from such injuries are Hepatitis B (HBV), HCV, and HIV.²² 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.²³ Many Florida counties have their own sharps disposal programs through the county health department.²⁴

¹⁷ Sammy Mack, “The Most Pro-Life Thing:” *HIV Activists Push to Expand Miami’s Needle Exchange Statewide*, HEALTH NEWS FLORIDA, (Jan. 8, 2018) <http://health.wusf.usf.edu/post/most-pro-life-thing-hiv-activists-push-expand-miamis-needle-exchange-statewide>.

¹⁸ *Id.*

¹⁹ *Supra*, note 10, at 3.

²⁰ 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 Jan. 11, 2018).

²¹ *Id.*

²² *Supra*, note 10.

²³ *Id.*

²⁴ Florida Department of Health, *Environmental Health –Needle Collection Programs*, <http://www.floridahealth.gov/environmental-health/biomedical-waste/needle-collection-programs.html> (last visited Jan. 11, 2018).

Federal Funding for Needle and Syringe Exchange Programs

On December 23, 2011, President Barack Obama signed the 2012 omnibus spending bill that reinstated a 1988 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.²⁵ However, on December 18, 2015, President Obama signed the Consolidated Appropriations Act, 2016 (Pub. L. 114-113), which modified the restriction on the use of federal funds for syringe services programs (SSPs) for persons who inject drugs to allow the use of federal funds for certain services.²⁶

The Department of Health and Human Services defines SSPs as the provision of sterile needles and syringes and other drug preparation equipment and disposal services as well as some or all of the following services:

- Comprehensive sexual and injection risk reduction counselling;
- HIV, viral hepatitis, other sexually transmitted diseases (STDs) and tuberculosis (TB) screening, other STDs and TB prevention care and treatment services, referral and linkage to HIV, viral hepatitis A virus (HAV) and HPV vaccinations; and
- Referral to integrated and coordinated substance abuse disorder, mental health services, physical health care, social services, and recovery support services.²⁷

While the federal law continues to prohibit the use of federal funds to purchase sterile needles and syringes, it does allow the use of federal funds by the state or local health department for other needs of the SSPs.²⁸ In order to receive funds from the DHHS, a state must first consult with the Centers for Disease Control and provide evidence that their jurisdiction is experiencing or at risk for significant increases in hepatitis infections or an HIV outreach due to injection drug use.²⁹ As of December 2017, 30 states and seven counties have been determined of such a status by the CDC. Florida is not included in that list.³⁰ Examples of what federal funds may be used for under this determination include:

- Personnel;
- Testing kits for HCV and HIV;
- Syringe disposal services;
- Provision of naloxone;
- Condoms to reduce sexual risk of sexual transmission of HIV, viral hepatitis, and other STDs,
- Communication and outreach activities and
- Educational materials.³¹

²⁵ *Id.*

²⁶ U.S. Department of Health and Human Services, *Implementation Guidance to Support Certain Components of Syringe Services Programs, 2016*, <https://www.hiv.gov/sites/default/files/hhs-ssp-guidance.pdf> (last visited Jan. 11, 2018).

²⁷ *Id.*

²⁸ *Id.*

²⁹ Centers for Disease Control and Prevention, *CDC Consultation on Determination of Need Requests*, <https://www.cdc.gov/hiv/risk/ssps-jurisdictions.html> (last visited Jan. 11, 2018).

³⁰ *Id.*

³¹ *Supra*, note 25.

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.³²

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 ch. 893, F.S.

Any person who violates this provision commits a first degree misdemeanor.³³

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.³⁴

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.³⁵

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.³⁶

³² Section 893.145, F.S.

³³ 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.

³⁴ 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.

³⁵ Section 893.146, F.S.

³⁶ 21 U.S.C. § 863(f)(1).

III. Effect of Proposed Changes:

Section 1 names the act the “Florida Infectious Disease Elimination Act (IDEA).”

Section 2 amends s. 381.0038, F.S., which modifies the existing single-county, Miami-Dade sterile needle and syringe exchange pilot program to establish a statewide program through the DOH, rather than the University of Miami. The bill allows the program to be administered either by the DOH or one of the participating, eligible entities. No state, county, or municipal funds may be used to operate the program.

The bill permits a pilot program to continue to be established at a mobile health unit or at one of several new location types:

- A hospital licensed under chapter 395;
- A health care clinic licensed under chapter 400;
- A substance abuse treatment program;
- An HIV or AIDS service organization; or
- Another nonprofit entity designated by the DOH.

Quarterly and annual reports must be submitted to the DOH under the revised pilot program, rather than to the local DOH office in Miami-Dade County. A final report will be due from all programs by August 1, 2023.

The expiration date for all pilot programs is extended to July 1, 2023.

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

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:

SB 800 continues the requirement that all pilot program sites must raise funds from private donations, grants, and other non-government sources. The University of Miami was also required to obtain a Biomedical Waste Operating permit as a sharps collection program in accordance with Chapter 64E-16, Florida Administrative Code, through the DOH's Miami-Dade's Environmental Health office.³⁷ This expense would be required for any entity that elects to participate in this program.

Private sector health care providers may also see an impact in emergency rooms through a reduction in the treatment of individuals related to drug-related overdoses, earlier linkage to substance abuse and mental health treatment programs, and prevention of mother to child HIV transmissions.³⁸

C. Government Sector Impact:

The pilot programs may reduce state and local government expenses for the treatment of blood-borne diseases associated with intravenous drug use on those counties or areas that elect to participate in the program. 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. The lifetime cost of HIV treatment is estimated to be \$379,668 in 2010 dollars.³⁹ The initial market prices of HCV ranged from \$84,000 to \$96,000 in 2014, but had fallen to \$40,000 for Medicaid programs.⁴⁰

The DOH did not provide a specific fiscal impact for the bill, but indicated it was uncertain how the DOH could provide administrative support to receive reports, summarize, and provide state level program update without state funding.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

³⁷ Department of Health, *Senate Bill 1040 Analysis* (Jan. 29, 2015) (on file with Senate Committee on Fiscal Policy).

³⁸ Centers for Disease Control and Prevention, *Syringe Services Programs*, <https://www.cdc.gov/hiv/risk/ssps.html> (last visited Jan. 11, 2018).

³⁹ Centers for Disease Control and Prevention, *HIV Cost-effectiveness*, <https://www.cdc.gov/policy/hst/hi5/cleansyringes/index.html> (last visited Jan. 11, 2018).

⁴⁰ *Id.*

VIII. Statutes Affected:

This bill substantially amends section 381.0038 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:

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

None.

B. Amendments:

None.

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