

**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.)

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Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

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BILL: SB 800

INTRODUCER: Senator Braynon

SUBJECT: Infectious Disease Elimination Pilot Programs

DATE: January 23, 2018

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Lloyd</u>	<u>Stovall</u>	<u>HP</u>	<b>Favorable</b>
2.	<u>Gerbrandt</u>	<u>Williams</u>	<u>AHS</u>	<b>Pre-meeting</b>
3.	_____	_____	<u>AP</u>	_____

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**I. Summary:**

SB 800 expands the existing sterile needle and syringe exchange pilot program to be implemented statewide. The bill authorizes the Department of the Health (DOH) to establish additional pilot programs upon request from eligible entities, provides program requirements, modifies the types of entities that are eligible to operate a program, and extends the program expiration date to July 1, 2023.

The Department of Health anticipates increased workload associated with implementation of the bill. Depending upon the increase in workload for the Department of Health, such costs may be absorbed within existing resources. However, state, county and municipal funds may not be used to operate a pilot program.

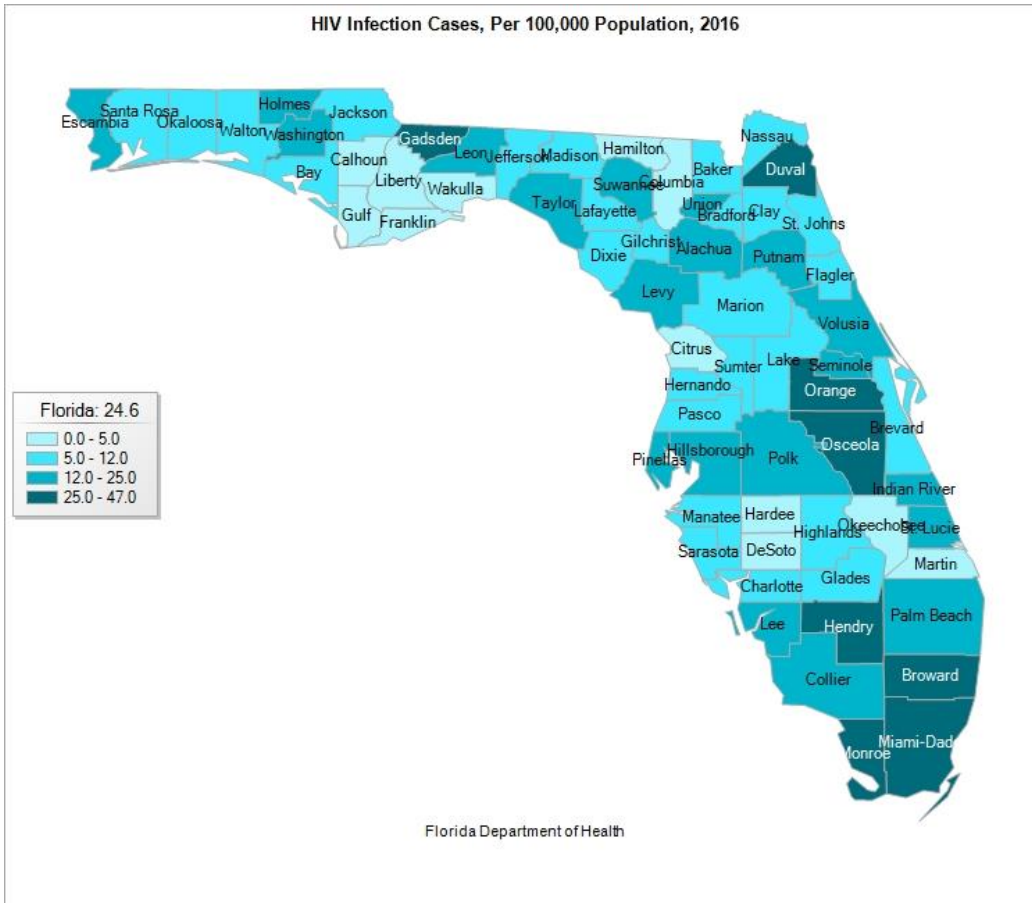
The effective date of the bill is July 1, 2018.

**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 in Florida, per 100,000 population for 2016.<sup>1</sup>

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<sup>1</sup> 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. 20, 2018).



### Intravenous Drug Use in Florida

In 2016, 4,940 individuals were newly diagnosed with HIV in Florida.<sup>2</sup> Florida is second in the nation, behind California, with both the percentage of the national total (12 percent) and the number of newly diagnosed HIV infections in 2016.<sup>3</sup> 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.<sup>4</sup> Statistics show Florida’s HIV-infected population is 78 percent male.<sup>5</sup>

The DOH reports that 60 to 90 percent of HIV-infected IDUs are also co-infected with Hepatitis C Virus (HCV).<sup>6</sup> Hepatitis C is a liver disease caused by a virus that spreads through contact with infected blood and can cause cirrhosis of the liver, liver cancer, and death.<sup>7</sup> The Centers for

<sup>2</sup> 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. 20, 2018).

<sup>3</sup> *Id.*

<sup>4</sup> 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](http://www.floridahealth.gov/diseases-and-conditions/aids/surveillance/images/County_HIV_Trends_2007-2016pdf.pdf) (last visited Jan. 20, 2018).

<sup>5</sup> *Id.*

<sup>6</sup> 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. 20, 2018).

<sup>7</sup> Florida Department of Health, *Hepatitis C Palm Card*, <http://www.floridahealth.gov/diseases-and-conditions/hepatitis/documents/educational-materials/documents/hcv-palmcard.pdf> (last visited Jan. 201, 2018).

Disease Control and Prevention report that injection drug use is the most common risk factor for HCV infection.<sup>8</sup>

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

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%
<b>State Totals</b>	<b>114,608</b>	<b>17,886</b>	<b>16%</b>

### 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 treatment, and sterile syringe access programs, including needle and syringe exchange programs. In general, these strategies are referred to as harm reduction.<sup>11</sup>

Needle and syringe exchange programs provide free sterile needles and syringes 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:

<sup>8</sup> 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).

<sup>9</sup> 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 Jan. 20, 2018).

<sup>10</sup> 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).

<sup>11</sup> 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. 20, 2018).

- 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.<sup>12</sup>

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.<sup>13</sup>

### ***University of Miami Needle and Syringe Exchange Pilot Program***

Florida's first legal needle exchange program was approved by the legislature in 2016.<sup>14</sup> 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. Currently, the pilot is limited to a single sterile needle and syringe exchange program in Miami-Dade County and must operate from a fixed location or through a mobile health unit. The pilot program is required to offer the free exchange of clean, unused needles and hypodermic syringes for used needles and hypodermic syringes.<sup>15</sup> The pilot program must provide educational materials, secure the used needles, and collect certain data.<sup>16</sup> The pilot program is scheduled to expire on July 1, 2021.

The University of 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 Foundation, and the AIDS Healthcare Foundation as well as support from the University of Miami.<sup>17</sup>

Program officials indicate that in the first year, the Miami NSEP has reached more than 500 IDU's, collected more than 85,000 used needles and reversed at least 235 overdoses.<sup>18</sup> A total of 232 participants have tested HCV positive.<sup>19</sup>

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<sup>12</sup> *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. 20, 2018).

<sup>13</sup> North American Syringe Exchange Network, *Directory* (Updated May 2015), available at <https://nasen.org/> (last visited Jan. 20, 2018).

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

<sup>15</sup> Section 381.0038(4), F.S.

<sup>16</sup> Section 381.0038(4)(a), F.S.

<sup>17</sup> 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> (last visited Jan. 20, 2018).

<sup>18</sup> *Id.*

<sup>19</sup> *Supra*, note 10, at 3.

### ***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.<sup>20</sup>

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.<sup>21</sup>

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, HCV, and HIV.<sup>22</sup> The FDA’s guidelines for disposal are to never place loose needles or other sharps into household or public trashcans or recycling bins, and to never flush them down toilets.<sup>23</sup> Many Florida counties have their own sharps disposal programs through the county health department.<sup>24</sup>

### ***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.<sup>25</sup> 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.<sup>26</sup>

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<sup>20</sup> 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. 20, 2018).

<sup>21</sup> *Id.*

<sup>22</sup> *Supra*, note 10.

<sup>23</sup> *Id.*

<sup>24</sup> Florida Department of Health, *Environmental Health –Needle Collection Programs*, <http://www.floridahealth.gov/environmental-health/biomedical-waste/needle-collection-programs.html> (last visited Jan. 20, 2018).

<sup>25</sup> *Id.*

<sup>26</sup> 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. 20, 2018).

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 and tuberculosis screening, other STDs and TB prevention care and treatment services, referral and linkage to HIV, viral hepatitis A virus and HPV vaccinations; and
- Referral to integrated and coordinated substance abuse disorder, mental health services, physical health care, social services, and recovery support services.<sup>27</sup>

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<sup>28</sup> of the SSPs.<sup>29</sup> In order to receive funds from the Department of Health and Human Services, a state must first consult with the Centers for Disease Control and provide evidence that their jurisdiction is experiencing or is at risk for significant increases in hepatitis infections or an HIV outbreak due to injection drug use.<sup>30</sup> As of December 2017, 30 states and seven counties have been determined of such a status. Florida is not included in that list.<sup>31</sup>

### **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.<sup>32</sup>

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.<sup>33</sup>

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<sup>27</sup> *Id.*

<sup>28</sup> Other needs include personnel, virus testing, syringe disposal services, naloxone provision, condom dissemination, outreach activities, and educational materials. *See supra*, note 25.

<sup>29</sup> *Id.*

<sup>30</sup> 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. 20, 2018).

<sup>31</sup> *Id.*

<sup>32</sup> Section 893.145, F.S.

<sup>33</sup> 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.*

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.<sup>34</sup>

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.<sup>35</sup>

#### ***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.<sup>36</sup>

### **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., to authorize the DOH to establish a sterile needle and syringe exchange pilot program, upon request from an eligible entity, rather than a single program established in Miami-Dade County. Each pilot program must be administered by the DOH or the department may designate an eligible entity to operate the pilot program. An eligible entity may include:

- 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.

The bill prohibits state, county, or municipal funds from being used to operate a pilot program. Instead, a pilot program must be funded through grants and donations from private resources. The bill requires each pilot program to collect data and submit quarterly and annual reports to the DOH. A final report is due from all pilot programs by August 1, 2023.

The bill extends the expiration date for all pilot programs to July 1, 2023.

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<sup>34</sup> 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.

<sup>35</sup> Section 893.146, F.S.

<sup>36</sup> 21 U.S.C. § 863(f)(1).



**Section 3** includes a severability clause which provides that if any provision of this act or its application to any person or 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.

**Section 4** provides that the bill takes effect July 1, 2018.

#### **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 bill continues the requirement that all pilot programs must obtain funds from private donations, grants, and other non-government sources. Any entity that elects to participate in the pilot program must obtain a Biomedical Waste Operating Permit in accordance with Ch. 64-E, Florida Administrative Code.

Private sector health care providers may see a positive impact in emergency room utilization through a reduction in the treatment of individuals with drug-related overdoses, earlier linkage between IDU's and substance abuse and mental health treatment programs, and prevention of mother to child HIV transmission.<sup>37</sup>

C. Government Sector Impact:

The pilot programs may reduce state and local government expenditures for the treatment of blood-borne diseases associated with intravenous drug use in those counties in which an eligible entity has elected to participate in the pilot program.

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<sup>37</sup> Centers for Disease Control and Prevention, *Syringe Services Programs*, <https://www.cdc.gov/hiv/risk/ssps.html> (last visited Jan. 20, 2018).



The Department of Health anticipates increased workload associated with implementation of the bill. Depending upon the increase in workload for the Department of Health, such costs may be absorbed within existing resources. However, as noted above, state funds may not be used to operate a pilot program.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends section 381.0038 of the Florida Statutes.

The bill creates two undesignated sections of Florida law.

**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.