

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: CS/SB 366

INTRODUCER: Health Policy Committee and Senators Braynon, Pizzo and Book

SUBJECT: Infectious Disease Elimination Programs

DATE: February 20, 2019

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Brown	HP	Fav/CS
2.			AHS	
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 366 establishes the Infectious Disease Elimination Act (IDEA) and modifies s. 381.0038, F.S. The bill eliminates references to the current sterile needle and syringe exchange pilot program in Miami-Dade County except to authorize its continuation until the Miami-Dade County Board of County Commissioners authorizes the program under the IDEA or July 1, 2021, whichever occurs first.

Under the bill, through adoption of a county ordinance and satisfaction of the specified program requirements, county commissions may establish sterile needle and syringe exchange programs. An exchange program may not operate unless authorized and approved by the county commission. Programs must cooperate with the Department of Health (DOH) and the local county health department. Programs are prohibited from using state funds; however, programs may be funded with county funds or through private donations.

In authorizing an exchange program, a county commission must contract with one of the following entities to operate the program: a hospital licensed under chapter 395, F.S., a health care clinic licensed under part X of chapter 400, an accredited medical school associated with a university in the state, a licensed addictions receiving facility as defined in s. 397.311, F.S., or a 501(c)(3) HIV/AIDS service organization.

The bill includes a civil liability immunity clause for any law enforcement officer acting in good faith in arresting or charging a person who is later found to be immune from prosecution based on the conditions specified in IDEA.

A severability clause is included in CS/SB 366, providing that if any provision of the act or its application to any person or circumstance is found invalid, that invalidity does not affect the validity of the remaining provisions of the act.

The CS provides the DOH with rulemaking authority for data collection and reporting requirements.

The effective date of the bill is July 1, 2019.

II. Present Situation:

HIV/AIDS

The first cases of human immunodeficiency virus (HIV) were reported in 1981 and since then, approximately 77 million people have been infected with the virus.¹ HIV is a virus that is transmitted through certain body fluids and weakens the body's immune system. Over time, the body is unable to fight off infections and disease. No effective cure currently exists but with proper medical care, it can be controlled.²

HIV can eventually lead to the development of AIDS or acquired immunodeficiency syndrome.³ The term *diagnosis of HIV infection* is defined by the Centers for Disease Control and Prevention (CDC) as a diagnosis of HIV infection regardless of the state of the disease (stage 0, 1, 2, 3 (AIDS), or unknown), and refers to all person with a diagnosis of HIV infection.⁴

The CDC's *HIV Surveillance Report* compares Florida to other states, the region, and nation. For example, in the South, a year-by-year and a cumulative death rate is given from 2012 through 2016. The surveillance reports provide one-year figures that show both the rate per 100,000 in population, raw totals, three-year rolling rates, raw totals for infection rates, and death totals. Cause of death or cause for infection are also broken out by state and by certain metropolitan statistical areas (MSA)⁵. The cumulative three-year death total for the South⁶ is 134,957.⁷ An

¹ Kaiser Family Foundation, *The Global HIV/AIDS Epidemic*, (Jan 28, 2019) available at <https://www.kff.org/global-health-policy/fact-sheet/the-global-hiv-aids-epidemic/> (last visited Feb. 12, 2019).

² Centers for Disease Control and Prevention, *About HIV/AIDS*, (last updated: October 31, 2018) available at <https://www.cdc.gov/hiv/basics/whatishiv.html> (last visited Feb. 13, 2019).

³ Kaiser Family Foundation, *supra* note 1.

⁴ Centers for Disease Control and Prevention, *Diagnosis of HIV Infection in the United States and Dependent Areas, 2016*; vol. 28 (Nov. 2017), p. 5, available at <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2016-vol-28.pdf> (last visited Feb. 13, 2019).

⁵ Formerly referred to as standard metropolitan statistical areas (SMSA).

⁶ The CDC's South Region includes Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia.

⁷ Centers for Disease Control and Prevention, *HIV Surveillance Report, Table 19b: Deaths of persons with diagnosed HIV infection ever classified as stage 3 (AIDS), by year of death and selected characteristics, 2012-2016 and cumulative – United*

HIV infection diagnosis rate attributed to injected drug use for the period of 2012 to 2017 in the South for men is 77 and 103 for women.⁸

For 2016, 4,708 adults and adolescents in Florida, plus 18 children (those under age 13) for a total of 4,726 in 2016 were newly diagnosed with HIV in Florida. This number increased in 2017 to 4,783 newly diagnosed adults or adolescents and 17 children for a total of 4,800.⁹ The Florida Department of Health’s (DOH) annual report shows 116,944 persons of all ages living with an HIV diagnosis in Florida as of the end of the year, 2017.¹⁰

The Miami-Ft. Lauderdale-Palm Beach MSA had the highest prevalence of newly-diagnosed individuals with HIV infection in the nation. The prevalence rate translates to a total of 53,269 individuals who have been newly diagnosed with an HIV infection. For 2017, the Miami MSA is also ranked first in the nation for HIV infection diagnoses with a total of 2,177.¹¹ The table below shows the information in comparison to other Florida MSAs.

Diagnoses of HIV Infection, 2017 and Persons Living with Diagnoses HIV Infection (Prevalence)¹²					
MSA	Diagnosis – 2017			Prevalence of HIV Infection, 2016	
	Number	Rate	Rank	Number	Rate
Cape Coral-Ft. Myers	81	11.0	49	2,103	2,91.1
Deltona-Daytona Beach-Ormond Beach	94	14.5	29	1,804	283.3
Jacksonville	353	23.5	7	6,759	457.8
Lakeland–Winter Haven	94	13.7	36	2,247	3,36.9
Miami-Ft. Lauderdale-Palm Beach	2,177	35.3	1	53,269	8,72.2
North Port-Sarasota-Bradenton	83	10.3	57	1,901	2,41.1
Orlando-Kissimmee-Sanford	718	28.6	2	11,316	4,61.3
Palm Bay-Melbourne-Titusville	55	9.3	62	14,979	2,59.0
Tampa-St. Petersburg-Clearwater	561	18.1	14	12,308	405.3

State and 6 dependent areas, <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2017-vol-29.pdf> (last visited Feb. 12, 2019).

⁸ Centers for Disease Control and Prevention, HIV Surveillance Report, *Tab 8b: Diagnosis of HIV Infection attributed to injection drug use, by selected characteristics, 2012-2017-United States and 6 dependent areas*, <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2017-vol-29.pdf> (last visited Feb. 12, 2019).

⁹ Centers for Disease Control and Prevention, *HIV Surveillance Report – Diagnoses of HIV Infection in the United States and Dependent Areas, 2017*, Table 26 – Diagnoses of HIV Infection, by area of residence, 2016 and 2017 – United States and 6 dependent areas <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2017-vol-29.pdf> (November 2018) (last visited Feb. 12, 2019).

¹⁰ Florida Dep’t of Health, *Persons Living with an HIV Diagnosis in Florida, 2017*, http://www.floridahealth.gov/diseases-and-conditions/aids/surveillance/documents/fact-sheet/FloridaFactsheet_20180830.pdf (last visited Feb. 12, 2019).

¹¹ Centers for Disease Control and Prevention, *HIV Surveillance Report – Diagnoses of HIV – Infection in the United States and Dependent Areas*, Table 30, Diagnosis of HIV Infection, 2017, and persons living with diagnosed infection prevalence, year-end 2016, by metropolitan statistical area of residence – United States and Puerto Rico <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2017-vol-29.pdf> (November 2018)(last visited Feb. 12, 2019).

¹² Florida Dep’t of Health, *supra* note 13.

Diagnoses of HIV Infection, 2017 and Persons Living with Diagnoses HIV Infection (Prevalence) ¹²					
MSA	Diagnosis – 2017			Prevalence of HIV Infection, 2016	
	Number	Rate	Rank	Number	Rate
State ^{13,14}	4,949	24.1		116,944	568.9
<i>Explanation:</i>		<i>Per 100,000 population</i>	<i>Based on rate</i>		<i>Per 100,000 population</i>

The vast majority of Floridians who received an HIV diagnosis in 2017 report their mode of HIV exposure as male to male contact (61 percent), followed by heterosexual contact either female (19 percent) or male (13 percent) with male and female injection drug use at 2 percent each.¹⁵ A combination of male-to-male contact and injection drug use was also at 2 percent. The age range with the most persons receiving an HIV diagnosis in 2017 was between 20-29 (30 percent) followed closely by ages 30 to 39 (27 percent).¹⁶ In 2017, males were much more likely to receive an HIV diagnosis than a female, by more than three to one. Males represented 78 percent of the HIV diagnoses and females 22 percent.¹⁷

HIV Diagnosis in Florida, 2016 and 2017 ¹⁸ (Based on CDC Surveillance Reports)									
	2016				2017 (preliminary data)				Total Rate
	Adults (>13)	Adults (>13)*	Children	Child Rate*	Adults (>13)	Adults (>13)	Children	Child Rate*	
Florida	4,708	26.6	18	0.6	4,783	26.6	17	0.6	22.9
National	40,012	14.6	130	0.2	38,640	14.0	99	0.2	11.8

**Rates are per 100,000 population.*

On the continuum of HIV/AIDS care, an individual can move from receiving an initial diagnosis to a virally suppressed status. In Florida for 2017, 25 percent of those living with an HIV diagnosis were not in care.

¹³ Florida Dep’t of Health, flhealthcharts.com, *HIV Cases*, <http://www.flhealthcharts.com/charts/OtherIndicators/NonVitalHIVAIDSViewer.aspx?cid=0471>, (report generated on Feb. 12, 2019).

¹⁴ Florida Dep’t of Health, flhealthcharts.com, *Persons Living with HIV (PLWH)*, <http://www.flhealthcharts.com/charts/OtherIndicators/NonVitalHIVAIDSViewer.aspx?cid=0471> (report generated on Feb. 12, 2019).

¹⁵ Florida Dep’t of Health, *supra* note 12.

¹⁶ Florida Dep’t of Health, *supra* note 12.

¹⁷ Florida Dep’t of Health, *supra* note 12.

¹⁸ Centers for Disease Control and Prevention, *supra* note 4.

2017 – Florida’s Continuum of Care ¹⁹ From the beginning (a diagnosis to viral suppression)					
Status	Living with HIV Diagnosis	Ever in Care	In Care	Retained in Care	Virally Suppressed
Florida	116,944	108,461	87,184	79,831	71,955
% of Whole	100%	93%	75%	68%	62%
Documented care			Less than or equal to 1 medical visit for HIV in 2017	Less than or equal to 2 medical visits for HIV in 2017; greater than 3 mos. apart in 2017	Suppression of HIV viral load as measured by level of virus in blood.

The CDC recommends that anyone at increased risk of an HIV infection,²⁰ including injection drug users (IDUs), undergo HIV testing at least annually. Individuals between the ages of 13 and 64 who are not at risk should be tested for HIV at least once as part of their normal health care routine.²¹

National HIV/AIDS Strategy

Additionally, the CDC has four strategy goals aimed at achieving its overall mission:

*The United States will become a place where new HIV infections are rare and when they do occur, every person, regardless of age, gender, race/ethnicity, sexual orientation, gender identity or socio-economic circumstance, will have unfettered access to high quality, life extending care, free from stigma and discrimination.*²²

The mission is supported by four strategy goals that focus on reducing the number of new infections, increasing access to care, reducing health disparities and inequities, and achieving a more coordinated response. The 13 national HIV indicators include three which were identified as under development. The 10 other national indicators are:

- Increase the percentage of people living with HIV who know their status to at least 90 percent.
- Reduce number of new diagnoses by 25 percent.
- Reduce the percentage of young gay and bisexual men who have engaged in HIV-risk behaviors by 10 percent.

¹⁹ Florida Dep’t of Health, *supra* note 12.

²⁰ Those at increased risk for HIV include: men who have sex with men; individuals who have sex with an HIV-positive partner; individuals who have had more than one sexual partner since their last HIV test; individuals who have injected drugs and shared needles or the water or cotton with others; individuals who have been treated for hepatitis or tuberculosis; individuals who have traded sex for money; individuals who have been treated for another sexually transmitted disease; or individuals who have had sex with someone who can answer yes to any of the above questions or whose sexual history is unknown. See Centers for Disease Control and Prevention, *HIV Risk Reduction Tool*, <https://www.cdc.gov/hivrisk/how-know/testing.html> (last visited Feb. 13, 2019).

²¹ Centers for Disease Control and Prevention, *Testing*, <https://www.cdc.gov/hiv/basics/testing.html> (last visited Feb. 13, 2019).

²² United States Dep’t of Health and Human Services, Secretary’s Minority AIDS Initiative Fund, The Office of National AIDS Policy, *National HIV/AIDS Strategy*, <https://www.hiv.gov/federal-response/national-hiv-aids-strategy/overview> (last visited Feb. 14, 2019).

- Increase the percentage of newly-diagnosed persons who are linked to HIV medical care within one month after HIV diagnosis to at least 85 percent.
- Increase the percentage of persons with diagnosed HIV infection who are retained in medical care (two or more visits at least 3 months apart) to at least 90 percent.
- Increase the percentage of persons who are virally suppressed to at least 80 percent.
- Reduce the percentage of persons in HIV medical care who are homeless to no more than 5 percent.
- Reduce the death rate among persons with diagnosed HIV infection by at least 33 percent.
- Reduce disparities in the rate of new diagnoses by at least 15 percent in the following groups: gay and bisexual men, young Black and bisexual men, Black females, and persons living in the Southern United States.
- Increase the percentage of youth and persons who inject drugs with diagnosed HIV infections who are virally suppressed to at least 80 percent.²³

Twenty-eight federal offices under the coordinating efforts of the Office of the National AIDS Policy in the White House and the Director of the Health and Human Services Office of HIV/AIDS and Infectious Disease Policy work to implement the National HIV/AIDS Strategy. The coordinating group meets on a regular basis to provide feedback and advice, review outcomes, and discuss research findings. The first set of policies was released in 2010 and the most recent list of 13 was updated in 2015 with its goals set for 2020.²⁴

Florida IDEA Pilot Program

In 2016, the IDEA, or the Miami-Dade Infectious Disease Elimination Act²⁵ was enacted by the Legislature and implemented by the University of Miami (UM) as a sterile needle and syringe exchange pilot program. The pilot program is prohibited by state law from accepting public funds. The pilot program currently receives funds from the Gilead COMPASS Initiative (Commitment to Partnership in Addressing HIV/AIDS in Southern States)²⁶ to support the program's screening component.²⁷ Funding is also obtained through grants from the MAC AIDS Fund, the Elton John AIDS Foundation, the Fishman Family Foundation, the Comer Family Foundation, and the Health Foundation of South Florida.²⁸

Needle and syringe exchange programs 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

²³ United States Dep't of Health and Human Services, Secretary's Minority AIDS Initiative Fund, The Office of National AIDS Policy, *National HIV/AIDS Strategy*, <https://www.hiv.gov/federal-response/national-hiv-aids-strategy/overview> (last visited Feb. 14, 2019).

²⁴ United States Dep't of Health and Human Services, Secretary's Minority AIDS Initiative Fund, *Strategy Implementation*, <https://www.hiv.gov/federal-response/national-hiv-aids-strategy/overview> (last visited Feb. 14, 2019)

²⁵ Chapter 2016-68, Laws of Fla., (amending s. 381.0038, F.S, effective July 1, 2016).

²⁶ COMPASS Initiative, *Who We Are* <https://www.gileadcompass.com/whoweare/> (last visited Feb. 12, 2019).

²⁷ Sammy Mack, *New HIV Cases and an Investigation on a Closed Street: Doctor Explains Situation under 836 Overpass* HEALTHNEWS FLORIDA (Nov. 8, 2018), available at <http://health.wusf.usf.edu/post/new-hiv-cases-and-investigation-closed-street-doctor-explains-situation-under-836-overpass#stream/0> (last visited Feb. 12, 2019).

²⁸ University of Miami Miller School of Medicine, *Senator Bill Nelson Tours Miller School's Needle Exchange, Sees Opioid Epidemic First Hand* (July 16, 2018), <http://med.miami.edu/news/senator-bill-nelson-tours-miller-schools-needle-exchange-sees-opioid-epidemic> (last visited Feb. 12, 2019).

IDUs. Florida's IDEA pilot program in Miami-Dade provides one-for-one needle exchange as well as prevention services at its main site and on its mobile unit. Services include providing basic wound care, bandages, antibiotics, sanitizers, and condoms. Rapid and anonymous testing for HIV and Hepatitis C is also offered at both the main site and on its mobile unit. For those that need referrals to rehabilitation and treatment, the pilot program will provide assistance linking individuals with community stakeholders who can provide those services.²⁹

In addition to the services above, the pilot program offers two different kits. One is a *Safe Injection Pack* which is intended to reduce the need for sharing of needles and other related items, which the program hopes will lead to a decrease in the spread of HIV and Hepatitis C. The kit includes cottons, cookers, ties, sterile water, alcohol swabs, and portable sharps containers.³⁰ The other kit is the *Naloxone Pack* which includes Narcan, a prescription medication used to treat drug overdoses.

According to its August 1, 2018 annual report, the IDEA pilot program has:

- Enrolled over 800 participants.
- Exchanged 173,532 clean needles for 186,167 used needles.
- Distributed over 1,300 boxes of Narcan.
- Made 682 overdose referrals.
- Administered 600 HIV tests and 500 Hepatitis C tests.
- Added five mobile sites with 141 enrollees.
- Been selected as one of two international site for a multi-year grant which will allow 250 random patients to receive a direct-acting anti-viral medication on site.³¹

The IDEA pilot program annual report also notes that during the first half of the 2017, there were 133 fatal overdoses compared with 217 for the second half of 2016.³² The overall death rate in Miami-Dade related to HIV/AIDS has also lowered while the pilot program has been in operation.

Intravenous Drug Use in Florida

At the end of 2016, there were a total of 114,772 diagnosed persons living with HIV in Florida.³³ The modes of exposure for adults (age 13 and above) in 2016 are shown in the table below.

²⁹ IDEA Exchange, *Services*, <http://ideaexchangeflorida.org/services/> (last visited Feb. 12, 2019).

³⁰ *Id.*

³¹ Miami-Dade County Commission Agenda Item, *Resolution Urging the Florida Legislature to Authorize Additional Institutions to Collaborate with the University of Miami in the Operation of the Miami-Dade Infectious Disease Elimination Act Needle and Syringe Exchange Pilot Program*, Agenda Item 11(A)(19) (September 5, 2018), available at <http://www.miamidade.gov/govaction/legistarfiles/Matters/Y2018/181939.pdf> (last visited Feb. 12, 2019).

³² *Id.*

³³ Florida Dep't of Health, *FL HealthCHARTS.com Statistical Brief, HV Trends in Florida 2007 Through 2016* (July 2018), available at <http://www.flhealthcharts.com/charts/StatisticalBriefs.aspx>.

Adult (Age 13+) Diagnosed Persons Living with HIV, Year End 2016, Florida ³⁴		
Mode of Exposure	Male Count (%)	Female Count (%)
Men who have sex with Men (MSM)	56,829 (69%)	NA
Injection Drug Use	5,300 (6%)	3,977 (13%)
Heterosexual Contact	15,625 (19%)	26,894 (85%)
Other Risk	775 (1%)	874 (3%)
State Total:	82,863	31,745

During this same time period, the state’s total number of deaths from HIV was 864. This is a decrease over a nine-year period from 1,526 in 2007 to 864 in 2016.³⁵ However, within these rates there are differences between races and ethnicities. For example, the age-adjusted death rate due to HIV was nine times higher for non-Hispanic blacks compared to non-Hispanic whites. Among non-Hispanic blacks, the age-adjusted resident death rate due to HIV decreased by 56 percent from 2007, decreased by 49 percent for non-Hispanic whites, Hispanics by 58 percent, and other races by 55 percent.³⁶

Resident Deaths Due to HIV by Count and Rate per 100,000 Population, 2007-2016, Florida ³⁷										
Year	White Non-Hispanic		Black Non-Hispanic		Hispanic		Other ³⁸		State Total	
	Count	Rate	Count	Rate	Count	Rate	Count	Rate	Count	Rate
2007	389	3.5	917	35.3	202	5.3	18	2	1,526	8.3
2016	244	1.8	482	15.7	112	2.2	26	0.9	864	3.9

A study conducted at the University of Miami and Jackson Health System from July 1, 2013, through June 30, 2014, reviewed the charts of patients hospitalized for injection drug use-related infections. Records from the emergency room and inpatient hospitalizations were researched for drug abuse and use, infection, and hospitalization during this time period.³⁹ The findings over the 12 month period included:

- 349 IDUs hospitalized with 423 total admissions for injection-related infections.
 - 59 percent abused cocaine.
 - The median hospital charge for an injection-related infection was \$39,896 with a range in claims from \$14,158 to \$104,912.
- Only 8 percent of the population had private insurance; 41 percent had Medicaid, 15 percent had Medicare, and 36 percent were uninsured.
- Of those hospitalized, 64 percent had skin and soft tissue infections (SSTIs) resulting from dirty or unsterile needles.

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

³⁸ Other includes American Indian/Alaska Native, Asian/Pacific Islander, and multi-racial.

³⁹ Hansel Tookes, Chanelle Diaz, et al., *A Cost Analysis of Hospitalizations for Infections Related to Drug Use at a County Safety-Net Hospital in Miami, Florida*, (2015), PLOS ONE 10(6): e0129360, <https://doi.org/10.1371/journal.pone.0129360> (last visited February 12, 2019).

- Opiate abuse was diagnosed in 37 percent of patients.⁴⁰
- Total costs over one year from hospitalizations relating to bacterial infections linked to dirty needles: \$11.4 million⁴¹

The study notated above occurred prior to the implementation of Miami-Dade's needle exchange pilot program.

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.⁴²

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 this provision commits a first degree misdemeanor.⁴³

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 the Florida Comprehensive Drug Abuse Prevention and Control Act⁴⁴, or
- To inject, ingest, inhale, or otherwise introduce into the human body a controlled substance in violation of the Florida Comprehensive Drug Abuse Prevention and Control Act.

Any person who violates this provision commits a third degree felony.⁴⁵

⁴⁰ *Id.*

⁴¹ Christine Dimattei, *Miami Doctor Behind Florida's New Needle-Exchange Programs Says It Will Save Lives*, (WLRN radio broadcast March 30, 2016)(transcript available at <http://www.wlrn.org/post/miami-doctor-behind-floridas-new-needle-exchange-program-says-it-will-save-lives>).

⁴² Section 893.145, F.S.

⁴³ 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.

⁴⁴ The act referred to is the Florida Comprehensive Drug Abuse Prevention and Control Act.

⁴⁵ 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.

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.⁴⁶

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 the skin.⁴⁷ Examples of sharps include:

- Needles: hollow needles used to inject drugs or medications 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: includes epinephrine and insulin pens or syringes with pre-filled 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/set: needles that connect to a tube used to transfer fluids in and out of the body.⁴⁸

Used needles and other sharps pose a dangerous risk to people and animals if not properly disposed of, as they can spread disease and cause injury. The most common infections from such actions are Hepatitis B (HBV), Hepatitis C (HCV), and HIV.⁴⁹

A National HIV Behavioral Surveillance Report on HIV Infection, Risk, Prevention, and Testing Behaviors among Persons Who Inject Drugs, conducted in 20 cities in 2015, produced data from 10,485 participants, including participants from Miami and was released in 2016. Approximately one in three of the report participants reported using a syringe used by someone else with 25 percent indicating that the syringe had been used by an HIV-positive IDU. Fifty-two percent of the respondents indicated they had received syringes from a syringe services program or syringe exchange program during the past 12 months; however the range of participation varied greatly with the HIV-negative group by city, from 2 percent to 90 percent.

For the Miami site, 412 participants, or 88.6 percent of the survey respondents, indicated they had had at least one HIV test performed. Of those that had an HIV test performed, 300 participants, or 64.5 percent, had most recently had a test within the past 12 months, as recommended by the CDC. The national averages in the report were 91.4 percent had ever had a test done and 57.1 percent had done so within the past 12 months.

Safe disposal of syringes is also an important component to decrease the number of accidental transmission of infections and the re-use of spoiled syringes. Only 18 percent of IDUs reported

⁴⁶ Section 893.146, F.S.

⁴⁷ United States Food and Drug Administration, *Safely Using Sharps* (page last updated August 30, 2018), available at <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/Sharps/default.htm>, (last visited Feb. 13, 2019).

⁴⁸ U.S. Food and Drug Administration, *supra* note 24.

⁴⁹ *Id.*

the use of safe disposal methods for used syringes. The U.S. Food and Drug Administration's guidelines for disposal are to never place loose needles or other sharps in household or public trashcans or recycling bins, and to never flush them down toilets.⁵⁰ Many Florida counties and municipalities have their own sharps disposal programs through their respective county health departments.⁵¹

Needle and Syringe Exchange Programs in Other States

Sixteen other states have passed laws authorizing needle and syringe exchanges.⁵² California has passed legislation permitting the sale of syringes and needles as non-prescription items for personal use if sold by a pharmacy, doctor, or by an authorized syringe exchange program.⁵³ As of January 1, 2015, California removed the prior limits on the number of the non-prescription sale of hypodermic needles and syringes by pharmacies and physicians that an adult may purchase and possess⁵⁴

Louisville, Kentucky, has a syringe exchange program operated by Volunteer America in a mobile RV that also provides wound supplies, safe injection supplies, biohazard containers/sharps containers, HIV/HCV testing and referrals for care, naloxone testing and referrals for care, safe injection education, and referrals for drug treatment, medical care, and community resources.⁵⁵ Kentucky's program also permits local health departments to operate outreach programs whereby individuals can exchange used hypodermic needs and syringes for clean needles and syringes.⁵⁶

The Kentucky guidelines also discuss the different syringe and needle exchange transaction models:

- Needs Based Negotiation: The program does not set a limit on the number of syringes a participant can receive regardless of the number of returned syringes. The number of new,

⁵⁰ U.S. Food and Drug Administration, *Do's and Don'ts – Safe Disposal of Needles and Other Sharps Used at Home, Work, or While Traveling*, <https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/Sharps/UCM278775.pdf> (last visited February 13, 2019).

⁵¹ Florida Dep't of Health, *A Safe Way to Throw Away Needles*, <http://www.floridahealth.gov/environmental-health/biomedical-waste/documents/HomeDisposal.pdf> (last visited Feb. 13, 2019).

⁵² Centers for Disease Control and Prevention, *Access to Clean Syringe – Improving Access to Prevent Spread of HIV and HCV*, <https://www.cdc.gov/policy/hst/hi5/cleansyringes/index.html> (last visited February 11, 2019).

⁵³ California Department of Public Health, Office of AIDS, *Fact Sheet – For Syringe Exchange Programs and Law Enforcement, Non-Prescription Sale and Provision of Syringes (January, 2017)* https://www.cdph.ca.gov/Programs/CID/DOA/CDPH%20Document%20Library/Fact%20Sheet%20-%20What%20the%20Law%20Says_ADA.pdf (last visited Feb. 11, 2019).

⁵⁴ California Department of Public Health, Office of AIDS, *California Legal Code Related to Access to Sterile Needles and Syringes* (updated January 2017), available at https://www.cdph.ca.gov/Programs/CID/DOA/CDPH%20Document%20Library/CA%20Legal%20Code_Jan%202017_AD_A.pdf.

⁵⁵ Louisville, Kentucky Office of Addiction Services, *Syringe Exchange*, https://louisvilleky.gov/sites/default/files/health_and_wellness/educationalmaterials/2017julysepbrochure2.pdf (last visited Feb. 11, 2019).

⁵⁶ Kentucky Public Health, *Kentucky Harm Reduction and Syringe Exchange Program (HRSEP) Guidelines for Local Health Departments Implementing Needle Exchange Programs* (May 11, 2015), available at https://louisvilleky.gov/sites/default/files/health_and_wellness/clinics/2015_kydp_hrsep_guidelines_long_version.pdf (last visited Feb. 11, 2019).

sterile syringes given out is based on the participant's need, frequency of injection, and the length of time until the participant can next visit the program. Some programs may place an upper limit on the number of sterile syringes distributed per individual.

- **Strict One-for-One Exchange:** Provides the participant with the exact same number of sterile syringes as the participant brings in for disposal. If the participant did not bring in any syringes or needles, the participant would not receive any new, sterile syringes or needles in return.
- **One-for-One-Plus Exchange:** Modifies the strict one-for-one exchange by providing a pre-determined number of needles that can be obtained beyond the one-for-one ratio. A voucher system could also be used for the additional syringes or needles.⁵⁷

In Maine, the Church of Safe Injection distributes free supplies, including syringes and Narcan, a drug which can reduce an opioid overdose. The Church of Safe Injection operates in several states and is one of six programs certified in Maine.⁵⁸ It is also illegal in Maine to possess hypodermic needles unless you are a certified needle exchange.⁵⁹ For the time period of November 2014, through October 2015, Maine's six certified sites collected 545,475 contaminated needles from 4,264 individuals. By state law and administrative rule, certified needle exchange sites may only exchange needles on a strict one-for-one exchange policy, may only exchange needles with individuals age 18 and older who are enrolled in their program, and may only exchange ten clean hypodermic needles at a time.⁶⁰

Federal Status of Needle Exchange Programs

Syringe service programs are described as an effective component of a comprehensive, integrative approach to a community-based HIV prevention program in CDC and U.S. Department of Health and Human Services guidance documents.⁶¹ 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 sterile needle or syringe programs, which reversed the 111th Congress' 2009 decision to allow federal funds to be used for such programs.⁶² However, on December 18, 2015, President Obama signed the Consolidated Appropriations Act of 2016 (Pub. L. 114-113), which modified the restriction on the use of federal funds for needle exchange programs for persons who inject drugs to allow the use of federal funds for certain services.⁶³

⁵⁷ *Id.*

⁵⁸ Deborah Becker, 'Church of Safe Injection' Offers Needles, Naloxone to Prevent Opioid Overdoses, NPR.org, https://www.npr.org/sections/health-shots/2019/02/12/693653562/church-of-safe-injection-offers-needles-naloxone-to-prevent-opioid-overdoses?utm_medium=RSS&utm_campaign=shotshealthnews (February 12, 2019) (last visited Feb 12, 2019).

⁵⁹ *Id.*

⁶⁰ State of Maine, Dep't of Human Services, Maine Center for Disease Control and Prevention, Chapter 252: Rules Governing the Implementation of Hypodermic Apparatus Exchange Programs, *see* <https://www.maine.gov/dhhs/mecdc/infectious-disease/hiv-std/provider/documents/nep-rules.pdf> (last visited Feb. 14, 2019).

⁶¹ Centers for Disease Control and Prevention, *Syringe Services Programs*, <https://www.cdc.gov/hiv/risk/ssps.html> (last visited Feb. 13, 2019).

⁶² Centers for Disease Control and Prevention, *U.S. Department of Health and Human Services Implementation Guide to Support Certain Component of Syringe Services Programs, 2016*, (Mar. 29, 2016), available at <https://www.cdc.gov/hiv/pdf/risk/hhs-ssp-guidance.pdf>, (last visited Feb. 13, 2019).

⁶³ *Id.*

The Consolidated Act, 2016, allows:

SEC. 520. Notwithstanding any other provision of this Act, no funds appropriated in this Act shall be used to purchase sterile needles or syringes for the hypodermic injection of any illegal drug: Provided, That such limitation does not apply to the use of funds for elements of a program other than making such purchases if the relevant State or local health department, in consultation with the Centers for Disease Control and Prevention, determines that the State or local jurisdiction, as applicable, is experiencing, or is at risk for, a significant increase in hepatitis infections or an HIV outbreak due to injection drug use, and such program is operating in accordance with State and local law.⁶⁴

Additionally, under the Consolidated Appropriations Act of 2016, needle exchange programs must be part of a comprehensive service program that includes:

- Comprehensive sexual and injection risk reduction counselling.
- HIV, viral hepatitis, other sexually transmitted diseases and tuberculosis screening, other sexually transmitted diseases and tuberculosis prevention care and treatment services, referral and linkage to HIV, viral hepatitis A virus and human papillomavirus vaccinations.
- Referral to integrated and coordinated substance abuse disorder, mental health services, physical health care, social services, and recovery support services.
- Provision of naloxone to reverse opioid overdoses.
- Provision of sterile needles, syringes, and other drug preparation equipment purchased with non-federal funds and disposal services.⁶⁵

While the federal government does continue to prohibit the use of federal funds to purchase sterile needles and syringes for exchange programs, it does allow the use of federal funds by the state or local health department for other needs of such programs.⁶⁶ In order to receive such funds from the Department of Health and Human Services, a state must first consult with the CDC and provide evidence that its jurisdiction is experiencing or is at risk for significant increases in hepatitis infections or an HIV outbreak due to injection drug use.⁶⁷ As of February 6, 2019, 37 states, the District of Columbia, one territory, six counties, and one city have demonstrated adequate need, according to federal law, and are thereby authorized to use federal funds to purchase needles or syringes.⁶⁸

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.⁶⁹

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ Other needs include personnel, virus testing, syringe disposal services, naloxone provisions, condom dissemination, outreach activities, and educational materials.

⁶⁷ U.S. Department of Health and Human Services, *supra* note 59.

⁶⁸ Centers for Disease Control and Prevention, *Syringe Service Program Determination of Need*, (Feb. 8, 2019) available at <https://www.cdc.gov/hiv/risk/ssps-jurisdictions.html> (last visited Feb. 13, 2019).

⁶⁹ 21 U.S.C. § 863(f)(1).

III. Effect of Proposed Changes:

Section 1 provides that the act may be cited as the “Infectious Disease Elimination Act (IDEA).”

Section 2 amends subsection (4) of section 381.0038, F.S., to authorize sterile needle and syringe exchange programs in counties other than Miami-Dade rather than limiting such programs to a single pilot program at the University of Miami.

CS/SB 366 allows a county commission to authorize a sterile needle and syringe program within its county boundaries. The program may operate at one or more fixed or mobile locations. The bill prohibits a needle and syringe exchange program from being established unless authorized by the county commission through a county ordinance.

The stated goal for the sterile needle and syringe exchange program is the prevention of disease transmission. The bill defines an “exchange program” as a sterile needle and syringe program established by a county commission.

Before a program can be established, a county commission must complete a number of steps:

1. Authorize the program through a county ordinance.
2. Enter into a letter of agreement with the Department of Health (DOH) in which the county commission agrees that any needle and syringe exchange program will operate in accordance with the provisions of the IDEA.
3. Enlist the local county health department to provide ongoing advice, consultation, and recommendations for the operation of the program.
4. Contract with one of the following entities to operate the program:
 - a. A hospital licensed under chapter 395.
 - b. A health care clinic licensed under part X of chapter 400.
 - c. An accredited medical school associated with a university in the state.
 - d. A licensed addictions receiving facility as defined in s. 397.311, F.S.⁷⁰
 - e. A 501(c) (3) HIV/AIDS service organization.

An exchange program is required to:

- Develop an oversight and accountability system with measurable objectives to track the program’s progress towards its goals and report routinely to the county commission and the DOH.
- Incorporate into its accountability system mechanisms to address issues of compliance or noncompliance with contractual obligations.
- Provide for maximum security of sites where needles and syringes are exchanged as with the current pilot program, including an accounting of the number of needles and syringes in use, the number in storage, safe disposal of returned needles, and other measures.
- Operate a one-to-one exchange; however, a waiver of this requirement may be granted under exigent circumstances.

⁷⁰ A licensed addictions receiving facility is defined as a secure, acute care facility that provides, at a minimum, detoxification and stabilization services; is operated 24 hours per day, 7 days per week; and is designated by the department to serve individuals found to be substance abuse impaired as described in s. 397.675, F.S., who meet the placement criteria for this component.

- Require the program operator to offer educational materials whenever needles or syringes are exchanged.
- Provide onsite counseling or referrals for drug abuse prevention, education, and treatment, and provide onsite HIV and viral hepatitis screening, and, if such services are not provided onsite, referrals for same services must be available within 72 hours of a referral. The county commission may adjust the 72-hour time period in rural areas if the availability of providers warrants such an adjustment.
- Provide kits containing an emergency opioid antagonist,⁷¹ as defined in s. 381.887, F.S., or if unable to provide kits directly, then provide a referral to a program that can provide a kit.
- Collect data for annual reporting purposes, including the number of people served, services provided, types of services provided, and number of needles and syringes exchanged and received.

The DOH is required to compile annual reports of exchange programs and submit the compilation to the Governor, President of the Senate, and the Speaker of the House of Representatives annually by October 1st. The bill provides the DOH with rulemaking authority for the parameters for data collection and reporting.

Immunity is provided, notwithstanding chapter 893 or any other law, to any program staff member, volunteer, or participant, from criminal prosecution for possession of a needle or syringe that is obtained or surrendered as part of this program. The extension of this immunity protects volunteers, staff members, or participants who are handling needles and syringes that are being turned in or exchanged pursuant to the terms of the program.

The bill prohibits state funds being used to operate an exchange, but funding by the county or through grants and donations from private resources or funds is allowed.

The bill provides that a law enforcement officer who acts in good faith by arresting or charging an individual with a needle or syringe who is thereafter found to be immune from prosecution is granted immunity from any civil liability that may be incurred because of his or her actions.

Section 3 authorizes the continued operation of the Miami-Dade pilot program, as authorized under chapter 2016-68, Laws of Florida, until the Miami-Dade County Board of County Commissioners establishes an exchange program under this act or until July 1, 2021, whichever occurs first.

Section 4 contains a severability clause so that if any provision of the act is found to be invalid, that invalidity does not affect the ability of the other provisions of the act to go into effect. If that provision is severed, the other provisions of this act can be given effect.

Section 5 provides an effective date of July 1, 2019.

⁷¹ An “emergency opioid antagonist” means naloxone hydrochloride or any similarly acting drug that block the effects of opioids administered from outside the body and that is approved by the United States Food and Drug Administration for the treatment of an opioid overdose.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Areas that elect to participate in this program may see a reduction in the number of infectious diseases consistent with the results seen in the pilot program in Miami-Dade County.

C. Government Sector Impact:

Local governments may elect to provide funding for a sterile needle and syringe program; however, the bill specifically prohibits the use of state funding. The program is voluntary and requires the county commission to opt-in through adoption of an ordinance and satisfaction of statutory requirements. There is no requirement for any minimum funding level.

Local law enforcement are also impacted as the bill provides limited immunity to program staff, volunteers, and participants who are in possession of a syringe or needle that was obtained through the program or was surrendered to the program. If the syringe

or needle was obtained in this manner, then the individual may be immune from prosecution under chapter 893, Drug Abuse Prevention and Control statutes.^{72,73} Additionally, for those local governments that elect to participate, they may see a reduction in other health care expenditures related to the treatment of blood-borne diseases associated with intravenous drug use. For example, local governments pay a portion of costs for some patients with AIDS who are enrolled in Medicaid, the AIDS Drug Assistance Program, and the AIDS Insurance Continuation Program. The lifetime cost per individual for HIV treatment is estimated to be \$379,668 in 2010 dollars.⁷⁴

Studies of the New York City needle syringe exchange program showed an estimated savings of \$1,300 to \$3,000 per individual and a drop in the HIV prevalence rate from 50 percent to 17 percent in the time period of 1990 to 2002.⁷⁵

In 2015, for those who do not have insurance and for whom the hospital or other local charity programs or local government must pay, a study which involved the Miami-Dade area found that the median hospital charge for an injection-related infection was \$39,896 with a range in claims from \$14,158 to \$104,912.⁷⁶

The DOH and the county commission are required to enter into a letter of agreement before an exchange program is established. In the letter of agreement, the county agrees that the program will abide by all of the provisions of the IDEA. Included in that oversight role is the collection of annual data from the program sites for the compilation of the annual report for submission to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

In addition, the county commission must also enlist its county health department to provide ongoing advice, consultation, and recommendations for the program. The local county health department could play an ongoing advisory and oversight role in the program.

⁷² Under s. 893.147(3)(b), F.S., it is unlawful for any person to sell or otherwise deliver hypodermic syringes, needles, or other objects which may be used, are intended for use, or are designed for use in parenterally injecting substances into the human body to any person under 18 years of age, except that hypodermic syringes, needles, or other such objects may be lawfully dispensed to a person under 18 years of age by a licensed practitioner, parent, or legal guardian or by a pharmacist pursuant to a valid prescription for same. Any person who violates the provisions of this paragraph is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. For a misdemeanor of the first degree, it may be punishable by a term of imprisonment of not more than one year or a fine of not more than \$1,000.

⁷³ Drug paraphernalia is defined in statute under s. 893.145, F.S., and means 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 this chapter or s. 877.111. Drug paraphernalia is deemed to be contraband which shall be subject to civil forfeiture. The term includes, but is not limited to...(11) Hypodermic syringes, needles, and other objects used, intended for use, or designed for use in parenterally injecting controlled substances into the human body.

⁷⁴ Centers for Disease Control, *Improving access to prevent the spread of HIV and HCV*, (page last updated Aug. 5, 2016) available at <https://www.cdc.gov/policy/hst/hi5/cleansyringes/index.html> (last visited Feb. 8, 2019).

⁷⁵ *Id.*

⁷⁶ Hansel Tookes, Chanelle Diaz, et al., *Supra* note 46.

The bill prohibits the use of any state funds to operate an exchange program. The DOH has questioned in the past how it could effectively administer the program or complete any comprehensive reports without any state funds to conduct its administrative duties or promulgate rules.⁷⁷ The DOH is authorized, but not required, to promulgate rules related to the collection of data and the compilation of the annual report.

VI. Technical Deficiencies:

None

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 381.0038 of the Florida Statutes.

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 19, 2019:

The CS modifies the sterile needle and syringe exchange program and provides a process by which a county commission may authorize an exchange program. A program’s goal of disease prevention is specifically stated. The CS also defines the term “exchange program” as a sterile needle and syringe exchange program established by a county commission and provides that an exchange program may not operate unless it has been approved by the county commission in accordance with the IDEA.

The CS provides specific requirements for the county commission before an exchange program may be established. Those requirements for the county commission include specific adoption of a county ordinance approving the program, approval of the program’s needle and syringe exchange program operator, coordination with the DOH and county health department, and development of an accountability and tracking system.

Exchange programs have several operational requirements under the CS including:

- Operate a one-to-one exchange; however, the CS permits the county commission to grant a waiver of this requirement for exigent circumstances.
- Offer educational materials to program participants whenever needles or syringes are exchanged.
- Provide onsite counseling or referrals for drug abuse prevention, education, treatment, and provide onsite HIV and viral hepatitis screening or referrals. If not available on

⁷⁷ Florida Dep’t of Health, *Senate Bill 800 Analysis* (November 13, 2017) (on file with Senate Committee on Health Policy).

site, must be available within 72 hours. The CS also provides for a rural exception if providers are not readily available.

- Provide kits or refer to a program that can provide the kits containing an opioid antagonist.
- Collect and submit data to the county commission and the DOH.

The CS also recognizes the existence of the pilot program in Miami-Dade County and authorizes its continuation until the Miami-Dade County Board of County Commissioners establishes an exchange program as defined under the IDEA or until July 1, 2021, whichever occurs first.

B. Amendments:

None.