

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 171 Infectious Disease Elimination Programs
SPONSOR(S): Health Quality Subcommittee, Jones and others
TIED BILLS: IDEN./SIM. **BILLS:** SB 366

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	9 Y, 1 N, As CS	Siples	McElroy
2) Judiciary Committee	14 Y, 0 N	Rochester	Poche
3) Health & Human Services Committee			

SUMMARY ANALYSIS

In 2016, the Legislature authorized the University of Miami to operate a needle and syringe exchange pilot program in Miami-Dade County. The pilot program offers free, clean, unused needles and syringes to intravenous drug users as a means to prevent the transmission of blood-borne diseases, such as HIV, AIDS, and viral hepatitis. The pilot program must:

- Operate on a one sterile needle and syringe unit to one used unit exchange ratio;
- Account for the number, disposal, and storage of needles and syringes;
- Adopt measures to control the use and dispersal of sterile needles and syringes;
- Provide maximum security of the exchange site and equipment;
- Make available educational materials and referrals to educational resources regarding the transmission of HIV, AIDS, viral hepatitis, and other blood-borne diseases;
- Provide HIV and viral hepatitis testing; and
- Provide or refer for drug abuse prevention and treatment.

Staff and participants of the pilot program are exempt from prosecution under the Florida Comprehensive Drug Abuse Prevention and Control Act, or any other law for the possession, distribution, and exchange of needles or syringes. However, individuals acting outside the scope of the program are not immune from prosecution.

CS/HB 171 extends the program statewide by authorizing county commissions to establish a sterile needle and exchange program by adopting county ordinances and meeting certain program requirements, including consulting with local county health departments and contracting with certain entities to operate such programs. The bill also establishes minimum operational requirements for exchange programs.

The bill provides civil immunity to any law enforcement officer who, acting in good faith, arrests or charges program staff, volunteers, or participants for unlawful possession or distribution of needles or syringes and who later determines that such person is immune from criminal prosecution because he or she was operating under the authority of a needle and syringe exchange program.

The bill requires exchange programs to annually report certain data to the Department of Health (DOH) and their respective county commissions. DOH must compile such data into an annual report to the Governor and the Legislature. The bill retains current law prohibiting the use of state, county and municipal funds in the operation of the program.

The bill may have an insignificant, negative fiscal impact on DOH for the administrative duties required under the bill's provisions. The bill may have an indeterminate, positive fiscal impact on state or local governments, resulting from lower transmission rates of blood-borne diseases. The bill may have an indeterminate, negative fiscal impact on county governments related to passing an ordinance, contracting with eligible entities, and monitoring such contracts for compliance.

The bill provides an effective date of July 1, 2019.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

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.¹ Examples of sharps include:²

- Needles – hollow needles used to inject drugs (medication) under the skin.
- Syringes – devices used to inject medication into or withdraw fluid from the body.
- Lancets, also called “fingerstick” devices – instruments with a short, two-edged blade used to get drops of blood for testing. Lancets are commonly used in the treatment of diabetes.
- Auto Injectors, including epinephrine and insulin pens – syringes pre-filled with fluid medication designed to be self-injected into the body.
- Infusion sets – tubing systems with a needle used to deliver drugs to the body.
- Connection needles/sets – needles that connect to a tube used to transfer fluids in and out of the body, generally used for patients on home hemodialysis.

According to the FDA, used needles and other sharps are dangerous to people and animals if not disposed of safely because they can injure people and spread infections that cause serious health conditions.³ The most common infections from such injuries are hepatitis B, hepatitis C, and HIV.⁴

Injection Drug Use

Approximately 2.6 percent of the U.S. population⁵ has injected illicit drugs.⁶ During the last decade, there has been increase in drug injection that has been attributed to the use of prescription opioids and heroin among individuals who started using opioids with oral analgesics and transitioned to injection.⁷

HIV and Hepatitis

Injection drug use facilitates the transmission of blood-borne infections, particularly HIV, hepatitis B and C, as well as bacteria that can cause heart infections.⁸ HIV can survive on a used needle for up to 42 days and about one in ten new HIV cases in this country can be attributed to injection drug use.⁹ If the current rate continues one in 23 women who inject drugs and 1 in 36 men who inject drugs will be

¹ Food and Drug Administration, *Safely Using Sharps (Needles and Syringes) at Home, at Work, and on Travel*, (last rev. Aug. 30, 2018), <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/Sharps/default.htm> (last visited Apr. 1, 2019).

² Id.

³ Id.

⁴ Id.

⁵ This population represents persons aged 13 years or older in 2011.

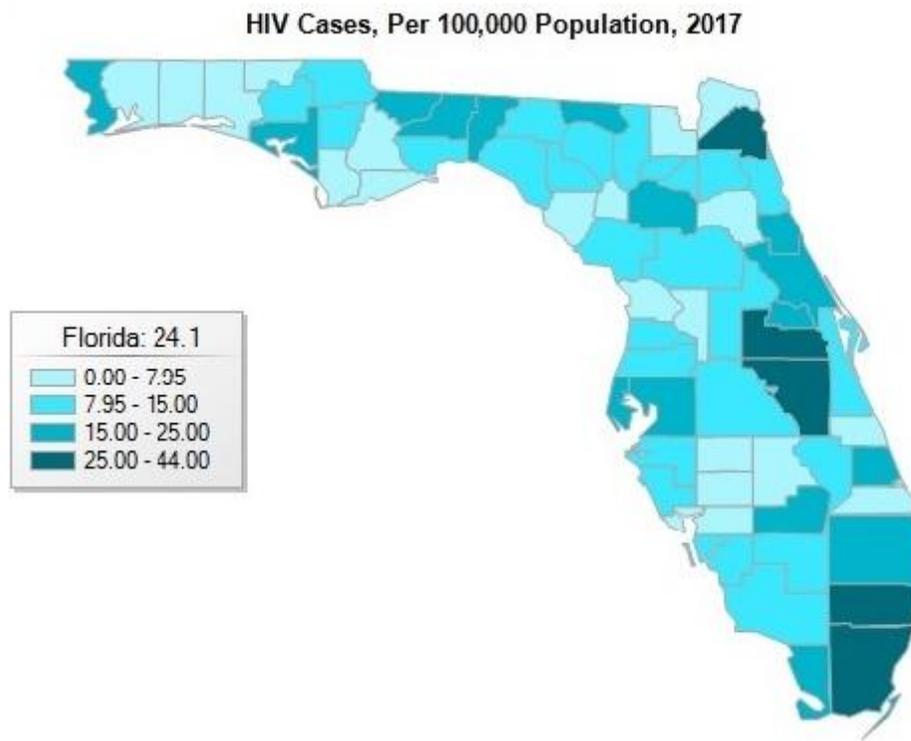
⁶ A. Lansky, T. Finlayson, C. Johnson, et. al.; *Estimating the Number of Persons Who Inject Drugs in the United States by Meta-Analysis to Calculate National Rates of HIV and Hepatitis C Virus Infections*; PLoS ONE, May 19, 2014; 9(5), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4026524/pdf/pone.0097596.pdf> (last visited on Apr. 1, 2019).

⁷ Centers for Disease Control and Prevention, *Syringe Service for Persons Who Inject Drugs in Urban, Suburban, and Rural Areas – United States, 2013*, Morbidity and Mortality Weekly Report (MMWR) (Dec. 11, 2015), 64(48); 1337-1341, <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6448a3.htm> (last visited Apr. 1, 2019).

⁸ Centers for Disease Control and Prevention, *Persons Who Inject Drugs (PWID)*, (last rev. July 19, 2018), <https://www.cdc.gov/pwid/index.html> (last visited Apr. 1, 2019).

⁹ Centers for Disease Control and Prevention, *Injection Drug Use and HIV Risk*, (last rev. Nov. 9, 2018), <https://www.cdc.gov/hiv/risk/idu.html> (last visited Apr. 1, 2019).

diagnosed with HIV in their lifetime.¹⁰ In 2017, there were 4,949 cases of HIV infection reported.¹¹ The counties with most new cases reported were Broward, Duval, Miami-Dade, Orange, and Osceola.¹²



Of the new cases reported in 2017, 192 were transmitted due to injection drug use and 103 were attributed to men who have sex with men and inject drugs.¹³

People who inject drugs are also at risk for viral hepatitis infection, as it is one of the most common blood-borne infections in the country.¹⁴ Both Hepatitis B and Hepatitis C are contagious liver diseases that range in severity from a mild illness lasting a few days to a serious, chronic illness.¹⁵ Acute Hepatitis B and C virus infections are frequently associated with injection drug use and the sharing of needles.¹⁶ It is estimated that 60-90 percent of those who contracted HIV from injection drug use are also infected with viral hepatitis.¹⁷ Hepatitis B is vaccine-preventable; however, there is no vaccine for Hepatitis C. In the last few years, there has been an upward trend in the number of individuals diagnosed with acute Hepatitis B and Hepatitis C; however, the incidence of chronic infections has remained stable for Hepatitis B and has dropped for Hepatitis C:¹⁸

¹⁰ Centers for Disease Control and Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Division of HIV/AIDS Prevention, *HIV and Injection Drug Use*, (Nov. 2016), <https://www.cdc.gov/hiv/pdf/risk/cdc-hiv-idu-fact-sheet.pdf> (last visited Apr. 1, 2019).

¹¹ Department of Health, FL Health Charts, *HIV Cases*, (as of June 30, 2018), <http://www.flhealthcharts.com/charts/OtherIndicators/NonVitalHIVAIDSViewer.aspx?cid=9866> (last visited Apr. 1, 2019).

¹² Id.

¹³ Id. Male to male sexual contact was the overall primary mode of transmission.

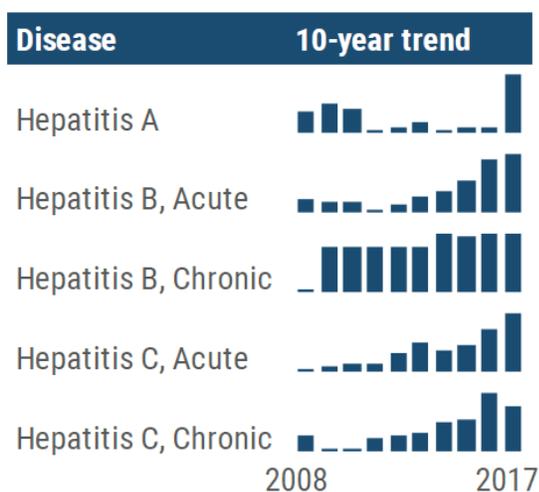
¹⁴ Centers for Disease Control and Prevention, *People who Inject Drugs and Viral Hepatitis*, (last rev. Jan. 7, 2019), <https://www.cdc.gov/hepatitis/populations/idu.htm> (last visited Apr. 1, 2019).

¹⁵ U.S. Department of Health and Human Services, *Learn about Viral Hepatitis*, (last rev. Aug. 8, 2018), <https://www.hhs.gov/hepatitis/learn-about-viral-hepatitis/index.html> (last visited Apr. 1, 2019).

¹⁶ Id.

¹⁷ Department of Health, *Diseases and Conditions: Hepatitis: Co-Infection*, <http://www.floridahealth.gov/diseases-and-conditions/hepatitis/co-infection.html> (last visited Apr. 1, 2019).

¹⁸ Department of Health, Division of Disease Control and Health Protection, Bureau of Epidemiology, *2017 Florida Morbidity Statistics Report*, <http://www.floridahealth.gov/diseases-and-conditions/disease-reporting-and-management/disease-reporting-and-surveillance/data-and-publications/documents/2017-annual-morbidity-statistics-report.pdf> (last visited Apr. 1, 2019).



Florida Comprehensive Drug Abuse Prevention and Control Act

Section 893.147, F.S., regulates the use or possession of drug paraphernalia. Currently, it is unlawful for any person to use, or to possess with intent to use, drug paraphernalia:

- To plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, or conceal a controlled substance in violation of ch. 893, F.S.; or
- To inject, ingest, inhale, or otherwise introduce into the human body a controlled substance in violation of ch. 893, F.S.

Any person who violates the above provision is guilty of a first degree misdemeanor.¹⁹

Moreover, it is unlawful for any person to deliver, possess with intent to deliver, or manufacture with intent to deliver drug paraphernalia, knowing, or under circumstances where one reasonably should know, that it will be used:²⁰

- To plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, or conceal a controlled substance in violation of ch. 893, F.S.; or
- To inject, ingest, inhale, or otherwise introduce into the human body a controlled substance in violation of ch. 893, F.S.

Any person who violates the above provision is guilty of a third degree felony.²¹

Drug paraphernalia is any equipment, products, or materials that are used, intended for use, or designed for use to illegally plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, package, repackage, store, contain, conceal, transport, inject, ingest, inhale, or otherwise introduce a controlled substance into the human body.²² This would include hypodermic syringes, needles, and other objects for paternally injecting controlled substances into the human body.²³

¹⁹ A first-degree misdemeanor is punishable by a term of imprisonment not to exceed 1 year and a \$1,000 fine. Sections 775.082 and 775.083, F.S.

²⁰ Section 893.147(2), F.S.

²¹ A third degree felony is punishable by up to five years imprisonment and a \$5,000 fine. Sections 775.082 and 775.083, F.S.

²² Section 893.145, F.S.

²³ Section 893.145(11), F.S.

Federal Drug Paraphernalia Statute

Under federal law, it is unlawful for any person to sell or offer for sale drug paraphernalia, use the mails or any other facility of interstate commerce to transport drug paraphernalia or to import or export drug paraphernalia.²⁴ The penalty for such crime is imprisonment for not more than three years and a fine.²⁵ Persons authorized by local, state, or federal law to possess or distribute drug paraphernalia are exempt from the federal drug paraphernalia statute.²⁶

Needle and Syringe Exchange Programs

Syringe services programs (SSPs)²⁷ provide sterile needles, syringes, and other injection equipment and facilitate the disposal of used needles and syringes to reduce the transmission of human immunodeficiency virus (HIV) and other blood-borne infections associated with reuse of contaminated needles and syringes by injection-drug users (IDUs).²⁸ Additionally, these programs may help to:²⁹

- Increase the number of drug users who enter treatment for substance use disorder;
- Reduce needlestick injuries among first responders by providing proper disposal;
- Reduce overdose deaths by providing education on overdose prevention and safer injection practices;
- Provide referrals to medical, mental health, and social services; and
- Provide other tools, such as counseling, condoms, and vaccinations, to prevent HIV, hepatitis C, and sexually transmitted infections.

According to the Centers for Disease Control and Prevention (CDC), SSPs can help prevent blood-borne pathogen transmission by increasing access to sterile syringes among IDUs and enabling safe disposal of used needles and syringes.³⁰ There are approximately 224 SSP sites operating in the U.S.³¹

A 2012 study compared improper public syringe disposal between Miami, a city without an SSP at the time, and San Francisco, a city with SSPs.³² Using visual inspection walk-throughs of high drug-use public areas, the study found that Miami was eight times more likely to have syringes improperly disposed of in public areas.³³

Federal Funding of NSEPs

In 2009, Congress passed the FY 2010 Consolidated Appropriations Act, which contained language that removed a ban on federal funding of NSEPs.³⁴ In July 2010, the U.S. Department of Health and Human Services issued implementation guidelines for programs interested in using federal dollars for

²⁴ 21 U.S.C. § 863(a).

²⁵ 21 U.S.C. § 863(b).

²⁶ 21 U.S.C. § 863(f)(1).

²⁷ Also referred to as syringe exchange programs (SEPs), needle exchange programs (NEPs), or needle and syringe exchange programs (NSEPs).

²⁸ Centers for Disease Control and Prevention, *Syringe Services Programs – United States, 2008*, Morbidity and Mortality Weekly Report (MMWR) (Nov. 19, 2010), 59(45): 1488-1491, <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5945a4.htm/Syringe-Exchange-Programs-United-States-2008> (last visited Apr. 1, 2019).

²⁹ Centers for Disease Control and Prevention, *Reducing Harms from Injection Drug Use & Opioid Use Disorder with Syringe Services Programs*, (Aug. 2017), <https://www.cdc.gov/hiv/pdf/risk/cdchiv-fs-syringe-services.pdf> (last visited Apr. 1, 2019).

³⁰ Id.

³¹ North American Syringe Exchange Network, *Directory of Syringe Exchange Programs*, <https://nasen.org/map/> (last visited Apr. 1, 2019). The directory provides a list of SSP sites in each state; an SSP may operate more than one site.

³² Hansel E. Tookes, et al., *A Comparison of Syringe Disposal Practices Among Injection Drug Users in a City with Versus a City Without Needle and Syringe Programs*, 123 *Drug & Alcohol Dependence* 255 (2012), <http://www.ncbi.nlm.nih.gov/pubmed/22209091> (last visited Apr. 1, 2019).

³³ Id. at 255 (finding “44 syringes/1000 census blocks in San Francisco, and 371 syringes/1000 census blocks in Miami.”).

³⁴ Pub. L. No. 111-117.

NSEPs.³⁵ On December 23, 2011, President Obama signed the FY 2012 omnibus spending bill³⁶ that, among other things, reinstated the ban on the use of federal funds for NSEPs; reversing the 111th Congress' 2009 decision that permitted federal funds to be used for NSEPs.³⁷

On December 18, 2015, President Obama signed into law the Consolidated Appropriations Act, which prohibits the use of federal funds for the purchase of sterile needles or syringes used to inject illegal drugs.³⁸ However, the act allows funds to be used for other elements of the program if the state or local health department, in consultation with the CDC, determines that the state or local jurisdiction is, or at risk of, experiencing a significant increase in hepatitis or HIV infection due to intravenous drug use. Federal funds may be used on items, such as personnel costs, HIV and hepatitis testing kits, provision of naloxone, educational materials, and syringe disposal services.³⁹

Miami-Dade Infectious Disease Elimination Act (IDEA)

In 2016, the Legislature passed the Miami-Dade Infectious Disease Elimination Act (IDEA), authorizing the University of Miami and its affiliates to establish a needle and syringe exchange pilot program (pilot program) in Miami-Dade County.⁴⁰ The pilot program offers free, clean, and unused needles and hypodermic syringes to IDUs to prevent the transmission of blood-borne diseases.

The University of Miami is authorized to operate the pilot program at a fixed location or through a mobile health unit. The pilot program is required to:⁴¹

- Operate a one sterile needle and syringe unit to one used unit exchange ratio;
- Account for the number, disposal, and storage of needles and syringes;
- Adopt any measure to control the use and dispersal of sterile needles and syringes;
- Provide maximum security of the exchange site and equipment;
- Make available educational materials and referrals to education regarding the transmission of HIV, AIDS, viral hepatitis, and other blood-borne diseases;
- Provide HIV and viral hepatitis testing; and
- Provide or refer for drug abuse prevention and treatment.

The University of Miami must collect data for quarterly, annual, and final reporting purposes, but may not collect any personal identifying information from a participant.⁴² The pilot program must issue an annual report to the Department of Health (DOH), as well as a final report on the performance and outcomes of the pilot program to DOH by August 1, 2021. The pilot program expires on July 1, 2021.⁴³

The pilot program is expressly prohibited from using state, county, or municipal funds for its operation, and must use grants and donations from private sources to fund the program.⁴⁴

The pilot program began operating on December 1, 2016, as the IDEA Exchange at a fixed location; and as of May 2017, the program began offering services through a mobile unit and provides

³⁵ Matt Fisher, *A History of the Ban on Federal Funding for Syringe Exchange Programs*, The Global Health Policy Center (Feb. 6, 2012), <http://www.smartglobalhealth.org/blog/entry/a-history-of-the-ban-on-federal-funding-for-syringe-exchange-programs/> (last visited Apr. 1, 2019).

³⁶ Pub. L. No. 112-74.

³⁷ *Supra* note 35.

³⁸ Pub. L. No. 114-113.

³⁹ Department of Health and Human Services, *Department of Health and Human Services Implementation Guidance to Support Certain Components of Syringe Services Programs*, (Mar. 29, 2016), <https://www.cdc.gov/hiv/pdf/risk/hhs-ssp-guidance.pdf> (last visited Apr. 1, 2019).

⁴⁰ Chapter 2016-68, Laws of Fla., codified at s. 381.0038(4), F.S.

⁴¹ Section 381.0038(4)(a), F.S.

⁴² Section 381.0038(4)(d), F.S.

⁴³ Section 381.0038(4)(f), F.S.

⁴⁴ Section 381.0038(4)(e), F.S.

backpacking services.⁴⁵ As of December 31, 2018, the program has enrolled 1002 participants, has made 8,998 exchanges, and provided 247,220 unused syringes in exchange for 259,838 used syringes.⁴⁶ Additionally, the program achieved the following results:⁴⁷

- Referred 66 individuals for substance use disorder treatment;
- Administered 913 HIV tests, which resulted in 64 positive diagnoses;
- Administered 708 hepatitis C tests, which resulted in 298 positive diagnoses; and
- Distributed 1,910 naloxone⁴⁸ kits to participants and family members, with 1,075 overdose reversals being reported.⁴⁹

Staff, volunteers, and participants of the pilot program are immune from prosecution for the possession, distribution, or exchange of needles or syringes under the Florida Comprehensive Drug Abuse Prevention and Control Act under ch. 893, F.S., or any other law.⁵⁰ Since the pilot program staff, volunteers, and participants are authorized to possess needles and syringes when acting under the authority of the pilot program, such possession would also be exempt from the federal drug paraphernalia statute.⁵¹ However, pilot program staff, volunteers, and participants are not immune from prosecution under state and federal law for the possession or redistribution of needles or syringes in any form if acting outside of the pilot program.

Effect of Proposed Changes

Establishment of Needle and Syringe Exchange Programs

CS/HB 171 expands the current pilot program by allowing a county commission to authorize a needle and syringe exchange program (exchange program) to operate within its boundaries by adopting a county ordinance. The county commission must also enter into an agreement with DOH that the exchange program will operate in accordance with Florida law, consult with the local county health department for advice and recommendations, and contract with an approved entity to operate the exchange program including:

- A hospital licensed under ch. 395, F.S.;
- A health care clinic licensed under ch. 400, F.S.;
- An accredited medical school;
- A licensed addictions receiving facility;⁵² and
- A nonprofit HIV/AIDS service organization.

The goal of an exchange program must be the prevention of disease transmission. An exchange program may not operate unless authorized and approved by the county commission.

⁴⁵ IDEA Exchange, Department of Medicine, University of Miami Miller School of Medicine, *IDEA Exchange Quarterly Report*, (Jan. 15, 2019). Backpacking services are services provided on foot.

⁴⁶ Id. The program has recovered a surplus of syringes through routine exchanges and neighborhood cleanup initiatives.

⁴⁷ Id.

⁴⁸ Naloxone is an opioid antagonist used to reverse the effects of an opioid overdose by counteracting the depression of the central nervous system and respiratory, allowing an overdose victim to breathe normally. See Harm Reduction Coalition, *Understanding Naloxone*, <http://harmreduction.org/issues/overdose-prevention/overview/overdose-basics/understanding-naloxone/> (last visited Apr. 1, 2019).

⁴⁹ Each kit contains two doses of naloxone.

⁵⁰ Section 381.0038(4)(c), F.S.

⁵¹ *Supra* note 26.

⁵² Section 397.311(26), F.S., defines an “addictions receiving facility” as a secure, acute care facility that provides, at a minimum, detoxification and stabilization services; operated 24 hours per day, 7 days per week; and is designated by the department to serve individuals found to be substance use-impaired.

Exchange Program Requirements

The bill requires that an exchange program:

- Develop an oversight and accountability system that:
 - Ensures compliance with statutory and contractual requirements;
 - Has measurable objectives for meeting program goals, tracks the progress in achieving those objectives, requires a routine report on the progress of meeting the objectives and goals;
 - Tracks compliance with contractually obligations and applies consequences for noncompliance; and
 - Is approved by the county commission;
- Provide for maximum security of the exchange sites that includes accounting for the number, disposal, and storage of needles and syringes;
- Operate a one sterile to one used needle or syringe exchange ratio;
- Make available educational materials and referrals to education resources regarding the transmission of HIV, viral hepatitis, and other blood-borne diseases and must offer such materials to program participants each time an exchange is made;
- Provide onsite counseling or referrals for drug abuse prevention, education, and treatment, and onsite testing or referrals for testing for HIV and viral hepatitis. If such services are only offered by referral, the services must be available to the participant within 72 hours after the referral. The bill authorizes a county commission in a rural county to adjust the 72-hour requirement in its contract with the program operator, as needed; and
- Provide or refer to an entity that can provide kits containing an emergency opioid antagonist.

The bill retains current law prohibiting an exchange program from using state, county, or municipal funds for its operation.

Reporting Requirements

The bill requires a program operator to annually report, by August 1, to DOH and the county commission:

- The number of participants served;
- The number of needles and syringes exchanged and distributed;
- The demographic profiles of the participants served;
- The number of participants entering drug counseling or treatment;
- The number of participants receiving testing for HIV, AIDS, viral hepatitis, or other blood-borne diseases; and
- Other data required under DOH rule.

The program operator may not include any personally identifiable information in the data it reports to DOH. DOH must compile the data it receives from all the exchange programs in a report to the Governor and the Legislature by October 1 of each year.

Miami-Dade Infectious Disease Elimination Pilot Program

The bill authorizes the continued operation of the Miami-Dade pilot program until the Miami-Dade Board of County Commissioners establishes an exchange program or July 1, 2021.

Law Enforcement Immunity

The bill retains the immunity from criminal prosecution for the possession or distribution of needles or syringes when acting under the authority of the program. The bill provides civil immunity to a law enforcement officer who, acting in good faith, arrests or charges a person for unlawful possession of

needles or syringes and if it is later determined that such person is immune from prosecution under the bill provisions.

The bill includes a severability clause⁵³ and provides an effective date of July 1, 2019.

B. SECTION DIRECTORY:

Section 1: Creates a short title.

Section 2: Amends s. 381.0038, F.S., relating to education, sterile needle and exchange pilot program.

Section 3: Creates an unnumbered section authorizing the Miami-Dade pilot program to continue to operate under certain conditions.

Section 4: Creates an unnumbered section providing for severability.

Section 5: Provides an effective date of July 1 2019.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

In those counties in which a pilot program is operated, the state may realize a cost savings related to the expenditures for the treatment of blood-borne diseases associated with intravenous drug use.⁵⁴ The reduction in expenditures for such treatments depends on the extent to which the needle and syringe exchange pilot program reduces the transmission of blood-borne diseases among IDUs, their sexual partners, offspring, and others who might be at risk of transmission.

2. Expenditures:

The bill may have an insignificant, negative fiscal impact on DOH related to establishing agreements with counties that opt to establish an exchange program, and complying with the bill's reporting requirements.⁵⁵

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

A local government entity may realize a cost savings related to the reduction of expenditures for the treatment of blood-borne diseases associated with intravenous drug use, if there is a needle and syringe exchange program located in its jurisdiction.⁵⁶ The reduction in expenditures for such treatments depends on the extent to which the needle and syringe exchange program reduces the transmission of blood-borne diseases among IDUs, their sexual partners, offspring, and others who might be at risk of transmission.

⁵³ A "severability clause" is a provision of a contract or statute that keeps the remaining provisions in force if any portion of that contract or statute is judicially declared void or unconstitutional. Courts may hold a law constitutional in one part and unconstitutional in another. Under such circumstances, a court may sever the valid portion of the law from the remainder and continue to enforce the valid portion. See *Carter v. Carter Coal Co.*, 298 U.S. 238 (1936); *Florida Hosp. Waterman, Inc. v. Buster*, 984 So.2d 478 (Fla. 2008); *Ray v. Mortham*, 742 So.2d 1276 (Fla. 1999); and *Wright v. State*, 351 So.2d 708 (Fla. 1977).

⁵⁴ The State of Florida and county governments incur costs for HIV/AIDS treatment through a variety of programs, including Medicaid, the AIDS Drug Assistance Program, and the AIDS Insurance Continuation Program. See generally, Department of Health, *HIV/AIDS*, <http://www.floridahealth.gov/diseases-and-conditions/aids/index.html> (last visited Apr. 1, 2019). The average lifetime treatment cost of an HIV infection is estimated at \$379,668 (in 2010 dollars). Centers for Disease Control and Prevention, *HIV Cost-Effectiveness*, (March 8, 2017), <https://www.cdc.gov/hiv/programresources/guidance/costeffectiveness/index.html> (last visited Apr. 1, 2019).

⁵⁵ Department of Health, *2019 Agency Legislative Bill Analysis for HB 171*, (Jan. 9, 2019).

⁵⁶ *Id.*

2. Expenditures:

The bill may have an indeterminate, negative fiscal impact on a county commission that opts to enact an ordinance and contract with an eligible entity to provide needle and syringe exchange services, including costs to monitor contract compliance.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

DOH has sufficient rulemaking authority to implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 26, 2019, the Health Quality Subcommittee adopted a strike-all amendment and reported the bill favorably as a committee substitute. The strike-all amendment:

- Authorized a county commission to adopt an ordinance to operate a sterile needle and syringe exchange program.
- Required a county to enter into an agreement with DOH affirming that it will consult with the county health department and only contract with authorized entities to operate an exchange program.
- Established criteria for needle exchange programs.
- Required exchange programs to:
 - Offer educational materials to program participants each time needles are exchanged;
 - Provide onsite counseling and referrals or at another facility within 72 hours, if onsite services are not available;
 - Provide kits with an opioid antagonist or refer to a program that provides such kits;
 - Collect and submit data to DOH and the county commission.
- Required DOH to submit an annual report to the Governor and Legislature.
- Provided civil immunity to a law enforcement officer who, in good faith, arrests or charges a person who is later determined to be in lawful possession of a needle or syringe obtained from an authorized exchange program.
- Authorized the continuation of the pilot program in Miami-Dade County until the county commission establishes an exchange program or until July 1, 2021.

The analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.