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 Appropriations											
BILL:	PCS/SB 544 (455298)										
INTRODUCER:	Appropriations Committee (Recommended by Appropriations Subcommittee on Health and Human Services); and Senator Boyd										
SUBJECT:	Drug-related Overdose Prevention										
DATE:	January 20	6, 2022	REVISED:								
ANALYST		STAFF DIRECTOR		REFERENCE	ACTION						
. Looke		Brown		HP	Favorable						
2. Howard		Money		AHS	Recommend: Fav/CS						
3. Howard		Sadberry		AP	Pre-meeting						

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

PCS/SB 544 amends section 381.887, Florida Statutes, to expand access to emergency opioid antagonists by:

- Allowing pharmacists to order, as well as dispense, emergency opioid antagonists with an autoinjection delivery system or intranasal delivery system;
- Providing that specified persons who are authorized to possess, store, and administer emergency opioid antagonists are immune from any civil or criminal liability resulting from the administration of such emergency opioid antagonists; and
- Adding specified personnel of a law enforcement agency or other agencies to the list of persons who are authorized to possess, store, and administer emergency opioid antagonists.

The bill also amends section 395.1041, Florida Statutes, to require hospital emergency departments, urgent care centers, and basic (BLS) and advanced life support (ALS) providers to report the treatment of actual or suspected overdose victims under certain circumstances.

The bill amends section 381.981, Florida Statutes, requiring the Florida Public Health Institute, Inc., to include emergency opioid antagonists as part of substance abuses in their statutorily required health awareness campaigns.

The Department of Health (department) will incur costs for ongoing maintenance, additional storage and software licensing for their reporting systems for hospital emergency departments,

urgent care centers and life support services to report data which can be absorbed within existing resources.

The bill provides an effective date of July 1, 2022.

II. Present Situation:

History of the Opioid Crisis in Florida

According to the National Institute on Drug Abuse:¹

- "In the late 1990s, pharmaceutical companies reassured the medical community that patients would not become addicted to prescription opioid pain relievers, and health care providers began to prescribe them at greater rates" and
- "This subsequently led to widespread diversion and misuse of these medications before it became clear that these medications could indeed be highly addictive."

Between the early 2000s and the early 2010s, Florida was infamous as the "pill mill capital" of the country. At the peak of the pill mill crisis, doctors in Florida bought 89 percent of all the oxycodone sold in the country.²

Between 2009 and 2011, the Legislature enacted a series of reforms to combat prescription drug abuse. These reforms included strict regulation of pain management clinics; creating the Prescription Drug Monitoring Program (PDMP); and stricter regulation on selling, distributing, and dispensing controlled substances.³ "In 2016, the opioid prescription rate was 75 per 100 persons in Florida. This rate was down from a high of 83 per 100." ⁴

As reported at the time by the Florida Attorney General's Opioid Working Group:

Drug overdose is now the leading cause of non-injury related death in the United States. Since 2000, drug overdose death rates increased by 137 percent, including a 200 percent increase in the rate of overdose deaths involving opioids. In 2015, over 52,000 deaths in the U.S. were attributed to drug poisoning, and over 33,000 (63 percent) involved an opioid. In 2015, 3,535 deaths occurred in Florida where at least one drug was identified as the cause of death. More specifically, 2,535 deaths were caused by at least one opioid in 2015. Stated differently, seven lives per day were lost to opioids in Florida in 2015. Overall, the state had a rate of opioid-caused deaths of 13 per 100,000. The three counties with the

¹ National Institute on Drug Abuse, *Opioid Overdose Crisis* (Rev. Jan. 2019), *available at https://www.drugabuse.gov/drugsabuse/opioids/opioid-overdose-crisis* (last visited Nov. 29, 2021).

² Lizette Alvarez, *Florida Shutting 'Pill Mill' Clinics*, The New York Times (Aug. 31, 2011), *available at* http://www.nytimes.com/2011/09/01/us/01drugs.html (last visited Nov. 29, 2021).

³ See Chapters 2009-198, 2010-211, and 2011-141, Laws of Fla.

⁴ Attorney General's Opioid Working Group, *Florida's Opioid Epidemic: Recommendations and Best Practices*, 7 (Mar. 1, 2019), *available at* https://myfloridalegal.com/webfiles.nsf/WF/TDGT-B9UTV9/\$file/AG+Opioid+Working+Group+Report+Final+2-28-2019.pdf (last visited Nov. 29, 2021).

highest opioid death rate were Manatee County (37 per 100,000), Dixie County (30 per 100,000), and Palm Beach County (22 per 100,000).⁵

Early in 2017, the federal Centers for Disease Control and Prevention (CDC) declared the opioid crisis an epidemic.⁶ Shortly thereafter, on May 3, 2017, Governor Rick Scott signed Executive Order 17-146 declaring the opioid epidemic a public health emergency in Florida.⁷

House Bill 21 (2018)

In 2018, the Florida Legislature passed CS/CS/HB 21 (Chapter 2018-13, Laws of Florida) to combat the opioid crisis. CS/CS/HB 21:

- Required additional training for practitioners on the safe and effective prescribing of controlled substances;
- Restricted the duration of prescriptions for Schedule II opioid medications to three days or up to seven days if medically necessary;
- Reworked the PDMP statute to require that prescribing practitioners check the PDMP prior to prescribing a controlled substance and to allow the integration of PDMP data with electronic health records and the sharing of PDMP data between Florida and other states; and
- Provided for additional funding for treatment and other issues related to opioid abuse.

Status of the Opioid Crisis after HB 21

There is some evidence that the passage of HB 21 reduced opioid use in Florida. For example, one study that reviewed pharmacy prescriptions claims for a health plan serving more than 45,000 Floridians found that on average, the number of enrollees per month that began opioid use between April of 2019 and August of 2019 dropped from 5.5 per 1,000 patients to 4.6 per 1,000 patients.⁸

Unfortunately, with the onset of the COVID-19 pandemic, the incidence of opioid use disorder and resulting overdose deaths has once again risen. A report from Project Opioid details provisional data from the department showing that deaths from drug overdoses have increased by 43 percent between 2019 and 2020, from 56 deaths per 100,000 in 2019 to 94 deaths per 100,000 in 2020. Additionally, fentanyl, an extremely potent opioid drug, is the leading cause of overdose deaths in Florida, and the incidence of fentanyl overdose deaths increased by 38 percent, from 2,348 in 2019 to 3,244 in 2020.

⁵ *Id*.

⁶ See Exec. Order No. 17-146, available at https://www.flgov.com/wp-content/uploads/2017/05/17146.pdf. (last visited Mar. 12, 2021).

⁷ *Id*.

⁸ Juan M. Hincapie-Castillo, et al., Changes in Opioid Use After Florida's Restriction Law for Acute Pain Prescriptions, JAMA Netw Open. 2020 Feb; 3(2): e200234, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7049083/, (last visited Nov. 29, 2021).

⁹ Project Opioid, A Pandemic Fueling an Epidemic in Florida in 2020, available at https://projectopioid.org/wp-content/uploads/2020/12/PO-2020-Data-Study-Final New-Section.pdf (last visited Nov. 29, 2021).

Opioid Antagonists

Opioid receptor antagonists block one or more of the opioid receptors in the central or peripheral nervous system. The two most commonly used, centrally-acting opioid receptor antagonists are naloxone and naltrexone. Naloxone comes in intravenous, intramuscular, and intranasal formulations and is FDA-approved for the use in an opioid overdose and the reversal of respiratory depression associated with opioid use. Naltrexone is available in both oral and long-acting injectable formulations and is FDA-approved for the treatment of opioid and/or alcohol maintenance treatment. The most commonly used peripheral opioid receptor antagonist is methylnaltrexone, which is a potent competitive antagonist acting at the digestive tract and is also FDA-approved for the treatment of opioid-induced constipation.¹⁰

The Florida Public Health Institute, Inc.

The Florida Public Health Institute (Institute) is a not-for-profit corporation established by s. 381.98, F.S., with the purpose of advancing the knowledge and practice of public health, including promoting health awareness in Florida. The Institute is tasked with procuring funds to complement, supplement, and enhance the missions of the various organizations, entities, and departments that provide public health initiatives by serving as the lead corporation in the state for promoting public health awareness. The Institute is required to enter into partnerships with providers of continuing education for health care practitioners, including, but not limited to, hospitals and state and local medical organizations, to ensure that practitioners are aware of the most recent and complete diagnostic and treatment tools.

Additionally, s. 381.981, F.S., requires the Institute to, in consultation with the department, coordinate monthly health awareness campaigns with national, state, and local health care organizations and government entities, targeting a wide range of the public, including: parents; teachers and other school employees; students in 4th through 12th grades, colleges, and universities; state agency employees; county and local government employees; patients of county health departments; Medicaid recipients; health care professionals and providers; and the public in general. The health campaigns must include the following diseases in at least one monthly campaign every 24 months:

- Cancer, including breast, prostate, cervical, ovarian, colorectal, and skin cancer and leukemia.
- Heart disease.
- Stroke.
- Lung disease, including asthma and smoking-relating disease.
- Neurological disorders and disease, including Alzheimer's disease, Parkinson's disease, and epilepsy.
- Gastrointestinal disease.
- Kidney disease.
- Diabetes.

¹⁰ Opioid Antagonists, Theriot, Jonathan, et. al., (last updated July 23, 2021), available at https://www.ncbi.nlm.nih.gov/books/NBK537079/#:~:text=3%5D%5B4%5D-, The%20two%20most%20commonly%20used%20centrally%20acting%20opioid%20receptor%20antagonists, depression%20associated%20with%20opioid%20use. (last visited Nov. 29, 2021).

- Liver disease.
- Autoimmune disorders.
- Birth defects and prenatal care.
- Obesity and malnutrition.
- Sexually transmissible disease.
- Hepatitis A, hepatitis B, and hepatitis C.
- Arthritis.
- Vaccine-preventable diseases.
- Infectious diseases, including HIV/AIDS.
- Substance abuse.
- Mental illness.
- Lupus.
- Osteoporosis.

III. Effect of Proposed Changes:

This bill amends s. 381.887, F.S., to:

- Include the prescribing, ordering and dispensing of emergency opioid antagonists within the purpose of the section, which is to provide for the emergency treatment for suspected opioid overdose;
- Authorize a pharmacist to order, and dispense pursuant to that order, an emergency opioid
 antagonist with an autoinjection delivery system or intranasal application delivery system to
 a patient or caregiver;¹¹
- Add personnel of a law enforcement agency or other agencies to the list of persons authorized to possess, store, and administer emergency opioid antagonists under the section. The bill specifies that such personnel includes, but is not limited to, correctional probation officers and child protective investigators who, while acting within the scope or course of employment, come into contact with controlled substances or persons at risk of experiencing an opioid overdose; and
- Provide immunity from any civil or criminal liability to the listed persons authorized to possess, store, and administer emergency opioid antagonists under the section for the administering of emergency opioid antagonists.¹²

The bill amends s. 381.981, F.S., requiring the Florida Public Health Institute, Inc., to include emergency opioid antagonists as part of substance abuses in their statutorily required health awareness campaigns.

The bill also amends s. 395.1041, F.S., to require a hospital emergency department or urgent care center to report the treatment of a person in response to an actual or suspected overdose to the department if the patient was not transported to the hospital by a BLS or ALS provider and to require a BLS or ALS provider to report when it treats and releases or transports to a medical

¹¹ Section 381.887, F.S., defines "patient" as a person who is at risk of experiencing an opioid overdose, and defines "caregiver" as a family member, friend, or person in a position to have recurring contact with a person at risk of experiencing an opioid overdose.

¹² These persons include emergency responders as well as crime laboratory personnel for the statewide criminal analysis laboratory system and their supervisors.

facility a person in response to an emergency call for a suspected or actual overdose of a controlled substance. The provider must use an appropriate reporting method with secure access, including, but not limited to, the Washington/Baltimore High Intensity Drug Trafficking Overdose Detection Mapping Application Program or other program identified by the department rule and must use its best effort to report such incidents within 120 hours of discovering the incident.

The bill provides an effective date of July 1, 2022.

IV. Constitutional Issues:

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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:

PCS/SB 544 may have an indeterminate negative fiscal impact on BLS providers, ALS providers, hospital emergency departments, and urgent care centers that are required to report specified incidents of treatment of patients suffering from suspected or actual overdoses of controlled substances.

C. Government Sector Impact:

The Department of Health has existing reporting systems for hospital emergency departments, urgent care centers and life support services to report data; however,

ongoing maintenance, additional data storage and software licensing will be needed. The cost is estimated to be \$64,000 recurring and can be absorbed with existing resources.¹³

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 381.887, 381.981, and 395.1041.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes: (Summarizing differences between the Committee Substitute and the prior version of the bill.)

PCS (455298) by Appropriations Committee (Recommended by Appropriations Subcommittee on Health and Human Services):

The committee substitute:

- Removes the requirement that the Florida Public Health Institute, Inc., in consultation with the Department of Health (department), educate the public regarding the use of emergency opioid antagonists as part of its statutory duty to educate the public regarding substance abuse; however, the Florida Public Health Institute must include emergency opioid antagonists in their educational information about preventing, detecting, treating, and curing disease awareness campaigns.
- Modifies the list of persons authorized to possess, store, and administer emergency opioid antagonists to include personnel of a law enforcement agency or other agency and that such personnel include, but is not limited to, correctional probation officers and child protective investigators.
- Removes the technical adjustments to s. 401.253, F.S.

B. Amendments:

None.

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

¹³ Department of Health, Senate Bill 544, 2022 Agency Legislative Analysis (January 11, 2022) (on file with the Senate Appropriations Subcommittee on Health and Human Services).