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.)

	Р	repared By:	The Profession	al Staff of the Comn	nittee on Rules		
BILL:	SB 542						
INTRODUCER:	Senators Boyd and Brodeur						
SUBJECT:	Emergenc	y Opioid A	antagonists				
DATE:	April 18, 2023 REVISED:						
ANALYST		STAFF	DIRECTOR	REFERENCE		ACTION	
l. Brick		Bouck		HE	Favorable		
2. Davis		Cibula		JU	Favorable		
3. Brick		Twogood		RC	Favorable		

I. Summary:

SB 542 is a response to the escalating opioid epidemic. The bill requires each Florida College System institution and state university to store a supply of emergency opioid antagonists in each residence hall or dormitory residence owned or operated by the institution.

Emergency opioid antagonists are drugs approved by the U.S. Food and Drug Administration to rapidly reverse the effects of an opioid overdose. The emergency opioid antagonists must be easily accessible to campus law enforcement officers who are trained in their administration.

The bill provides civil or criminal immunity for campus law enforcement officers trained to administer the opioid antagonist as well as for the employing institution when the officer administers or attempts to administer the antagonist in accordance with the bill.

The bill takes effect July 1, 2023.

II. Present Situation:

Opioids

Opioids belong to a class of drugs that occur naturally in the opium poppy plant. While scientists create some prescription opioids directly from the poppy plant, other prescription opioids are created in laboratories using the plant's chemical structure. Opioids are generally prescribed by physicians to treat pain that ranges from moderate to severe. Some of the common prescription opioids are hydrocodone, oxycodone, oxymorphone, morphine, codeine, and fentanyl. Fentanyl

¹ National Institute of Health, National Institute on Drug Abuse, *What Are Prescription Opioids?* https://nida.nih.gov/publications/drugfacts/prescription-opioids.

is a synthetic opioid that is described as being 50 to 100 times more powerful than morphine.² While many opioids are prescription medications, many others, such as heroin, are illegal drugs.

Because opioids contain chemicals that relax the body and provide a high, they can become highly addictive which can lead to misuse, overdose, and often death. When a user overdoses on an opioid, the breathing slows and in some instances, even stops. When the amount of oxygen that travels to the brain is significantly reduced, the result can be a coma, permanent brain damage, or even death.³

Opioid Epidemic

Centers for Disease Control and Prevention Statistics - Nationwide

The Centers for Disease Control and Prevention (CDC), reports that more than 250 Americans die each day from drug overdoses. During the 12-month period between February 2021 and January 2022, more than 107,000 Americans died from drug overdoses. Of the 250 overdose deaths that occur each day, it is estimated that opioids are responsible for 188 of those deaths. The CDC also reports that 40 percent of the overdose deaths occurred when the victim was not alone, but when a bystander was there with the victim.

Florida Department of Law Enforcement Statistics - Florida

According to the most recent data supplied by the Florida Department of Law Enforcement (FDLE), 6,442 people died in Florida from opioid-caused deaths in 2021. This is a 6 percent increase over the 6,089 opioid-caused deaths reported in 2020.⁷ Of the 2021 reported deaths, 235 were between the ages of 18 and 23. The age categories and deaths are as follows⁸:

18 year olds – 15 deaths

19 year olds - 26 deaths

20 year olds – 45 deaths

21 year olds – 43 deaths

22 year olds – 49 deaths

23 year olds – 57 deaths

Total deaths 235

² Centers for Disease Control and Prevention, The National Institute for Occupational Safety and Health, *Fentanyl and Work*, https://www.cdc.gov/niosh/topics/fentanyl/.

 $^{^{3}}$ Id.

⁴ <u>Fighting Fentanyl: The Federal Response to a Growing Crisis</u>: Hearing Before the Senate Health, Education, Labor, and Pensions Committee, July 26, 2022 (statement of Christopher M. Jones, Acting Director of National Center for Injury Prevention and Control, Centers for Disease Control and Prevention). https://www.cdc.gov/washington/testimony/2022/t20220726.htm.

⁵ Dr. Nora Volkow, *Five Areas Where "More Research" Isn't Needed to Curb the Overdose Crisis*, National Institute on Drug Abuse (Aug. 31, 2022) https://nida.nih.gov/about-nida/noras-blog/2022/08/five-areas-where-more-research-isnt-needed-to-curb-overdose-crisis.

⁶ See Fighting Fentanyl, *supra* note 4.

⁷ Florida Department of Law Enforcement, *Drugs Identified in Deceased Persons by Florida Medical Examiners*, 2021 Annual Report, ii, (Dec. 2022), https://www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2021-Annual-Drug-Report-FINAL.aspx.

⁸ Email from Vickie Koenig, Deputy Director, Criminal Justice Professionalism, Florida Department of Law Enforcement (March 16, 2023) (on file with the Senate Committee on Judiciary).

Executive Orders

As a result of the opioid epidemic increasing in Florida in 2017, Governor Scott declared Florida to be in a state of emergency. Subsequent Executive Orders extended the state of emergency through April 2, 2019. 10

On April 1, 2019, Governor DeSantis created a Statewide Task Force on Opioid Abuse to research and assess the nature of opioid drug abuse in Florida and develop a statewide strategy to identify best practices to combat the opioid epidemic through education, treatment, prevention, recovery, and law enforcement.¹¹

Emergency Opioid Antagonists

In the simplest of terms, an opioid antagonist is a medicine that quickly reverses the effects of an opioid overdose. The antagonist works by attaching to opioid receptors to reverse and block the effect of opioids. In the case of an opioid overdose, an antagonist is capable of restoring normal breathing in someone whose breathing has slowed dramatically or even stopped because of the overdose.¹²

According to information published by the National Library of Medicine, naloxone and naltrexone are two of the most frequently used opioid receptor antagonists approved by the United States Food and Drug Administration. Naloxone has been a proven medicine and is deemed to be an essential tool in hospital emergency rooms and ambulance emergency kits. It reverses both heroin and opioid overdoses within minutes of its administration and can save a life if given in time. Research shows that when naloxone and overdose education are available to community members, overdose deaths decrease in those communities.

Administration of Naloxone

Laypersons administering naloxone have a 75 to 100 percent success rate in reversing the effects of an opioid overdose. ¹⁶ Naloxone may be administered to a person through a vein, through a

⁹ Office of the Governor, Executive Order Number 17-146, May 3, 2017 (Opioid Epidemic).

¹⁰ Office of the Governor, Executive Order Number 19-36, February 1, 2019 (Opioid Epidemic Extension).

¹¹ Office of the Governor, *Executive Order Number 19-97*, April 1, 2019 ((Establishing the Office of Drug Control and the Statewide Task Force on Opioid Abuse to Combat Florida's Substance Abuse Crisis).

¹² National Institute on Drug Abuse, *Naloxone Drug Facts* (Jan. 2022) https://nida.nih.gov/publications/drugfacts/naloxone.

¹³ Jonathan Theriot, et. al., National Institute of Health, National Library of Medicine, *Opioid Antagonists*, (July 19, 2022) 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.

¹⁴ John Strang et al., *Take-Home Naloxone for the Emergency Interim Management of Opioid Overdose: The Public Health Application of an Emergency Medicine*, 79(13) Drugs 1395-1418 (2019), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6728289/. Naltrexone is FDA-approved and often prescribed as a maintenance treatment for opioid and alcohol use disorders.

¹⁶ Rachael Rzasa Lynn and J. L. Galinkin, *Naloxone dosage for opioid reversal: current evidence and clinical implications*, 9(1) Therapeutic Advances in Drug Safety 63-88 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5753997/.

muscle, or through the nasal passage, and is approved by the Food and Drug Administration to treat an opioid overdose and to reverse respiratory depression that accompanies opioid use.¹⁷

Cost

The cost of naloxone varies widely from less than a dollar per unit for a simple ampoule or vial, to several thousand dollars for certain intramuscular auto-injectors. On average, naloxone costs approximately \$30 per dose kit. He Florida Department of Children and Families, as part of its overdose prevention program, purchases Narcan at \$75 per kit with two doses in each kit. Emergent Biosolutions has produced an FDA- approved naloxone nasal spray called Narcan. Emergent Biosolutions offers up to four free cartons of Narcan to degree-granting postsecondary institutions.

Regulation

Naloxone is a derivative of thebaine, ²³ a Schedule II controlled substance in Florida. ²⁴ Schedule II substances may only be dispensed with a prescription from a licensed health care practitioner, ²⁵ but emergency responders, crime lab personnel, and personnel of a law enforcement agency are authorized by law to possess, store, and administer emergency opioid antagonists as necessary and are immune from any civil liability or criminal liability as a result of administering an emergency opioid antagonist. ²⁶ The U.S. Surgeon General has developed standards to encourage the distribution of over-the-counter naloxone. ²⁷

 $^{^{17}}$ Jonathan Theriot, et. al., National Institute of Health, National Library of Medicine, $Opioid\ Antagonists$, (July 19, 2022) $\frac{\text{https://www.ncbi.nlm.nih.gov/books/NBK537079/\#:}\sim:\text{text}=3\%5D\%5B4\%5D-, The\%20two\%20most\%20commonly\%20used}{\%20centrally\%20acting\%20opioid\%20receptor\%20antagonists, depression\%20associated\%20with\%20opioid\%20use}.$

¹⁸ John Strang et al., *Take-Home Naloxone for the Emergency Interim Management of Opioid Overdose: The Public Health Application of an Emergency Medicine*, 79(13) Drugs 1395-1418 (2019), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6728289/.

¹⁹ Florida Department of Education, HB 39 2023 Agency Legislative Bill Analysis (Feb. 9, 2023) (on file with the Senate Committee on Judiciary).

²⁰ Email, Florida Department of Children and Families (Mar. 6, 2023) (on file with the Senate Committee on Judiciary).

²¹ Id. Emergent Biosolutions bought Adapt Pharma, who originally produced Narcan.

²² Emergent Biosolutions, *Free Narcan Nasal Spray to Eligible Schools, available at* https://californiamat.org/wpcontent/uploads/2022/01/Schools.PP-NAR4-US-00483-Professional-Educator-One-Pager-2021-Update.pdf.

²³ National Center for Biotechnology Information, *PubChem Compound Summary for CID 5284596*, *Naloxone*, PubChem https://pubchem.ncbi.nlm.nih.gov/compound/Naloxone and Sun Dongbang, et al., National Library of Medicine, *Assymetric Synthesis of Naltrexone*, Chemical Science, Oct. 23, 2018, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6326069/.

²⁴ Section 893.03(2)(a)1.s., F.S.

²⁵ Section 893.04(1)(f), F.S. "Practitioner" means a physician licensed under chapter 458, a dentist licensed under chapter 466, a veterinarian licensed under chapter 474, an osteopathic physician licensed under chapter 459, an advanced practice registered nurse licensed under chapter 464, a naturopath licensed under chapter 462, a certified optometrist licensed under chapter 463, a psychiatric nurse as defined in s. 394.455, F.S., a podiatric physician licensed under chapter 461, or a physician assistant licensed under chapter 458 or chapter 459, provided such practitioner holds a valid federal controlled substance registry number. Section 893.02(23), F.S.

²⁶ Section 381.887, F.S. The Department of Health has issued a Statewide Standing Order for Naloxone. The order authorizes pharmacists who maintain a current active license, practicing in a pharmacy in the state that maintains a current active pharmacy permit to dispense naloxone formulations to emergency responders for administration to persons exhibiting signs of opioid overdose. Those emergency responders include law enforcement, firefighters, paramedics, and emergency medical technicians. The approved options for administration are Intramuscular Injection Naloxone and Intranasal Spray Naloxone.
²⁷ U.S. Food & Drug Administration, <u>Statement from FDA Commissioner Scott Gottlieb, M.D.</u>, on Unprecedented New Efforts to Support Development of Over-the-counter Naloxone to Help Reduce Opioid Overdose Deaths, (Jan 17, 2019)

Subject to statutory exceptions, it is illegal for a drug manufacturer or wholesale distributor in Florida to distribute a prescription drug to a person without a prescription.²⁸ One statutory exception authorizes a public school to purchase a supply of epinephrine auto-injectors from a wholesale distributor or manufacturer.²⁹

In addition, a manufacturer or wholesale distributor of naloxone may sell a prescription drug to:

- A licensed pharmacist or any person under the licensed pharmacist's supervision while acting within the scope of the licensed pharmacist's practice;
- A licensed practitioner authorized by law to prescribe prescription drugs or any person under the licensed practitioner's supervision while acting within the scope of the licensed practitioner's practice;
- A qualified person who uses prescription drugs for lawful research, teaching, or testing, and not for resale;
- A licensed hospital or other institution that procures such drugs for lawful administration or dispensing by practitioners;
- An officer or employee of a federal, state, or local government; or
- A person that holds a valid permit issued by the Department of Business and Professional Regulation, which authorizes that person to possess prescription drugs.³⁰

Similar Emergency Opioid Antagonists in the Statutes

In 2015, the Legislature passed the "Emergency Treatment and Recovery Act" in an effort to stem the rising number of opioid overdose deaths. The purpose of the bill was to authorize "health care practitioners to prescribe and dispense opioid antagonists to patients, caregivers, and first responders." The patient or his or her caregiver may store the opioid antagonist for later use on someone that he or she believed in good faith was experiencing an opioid overdose, regardless of whether that person had a prescription for an emergency opioid antagonist.

The act authorized emergency responders, including law enforcement officers, paramedics, and emergency medical technicians to possess, store, and administer the emergency opioid antagonists as clinically indicated. The legislation initially provided civil liability immunity protections for certain professionals involved in prescribing, dispensing and storing the opioid antagonists. The current statute has been expanded and now also provides immunity from civil or criminal liability for the administration of the opioid protagonist by emergency responders, law enforcement officers, paramedics, and emergency medical technicians.³³

 $[\]underline{https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-unprecedented-new-efforts-support-development-over.}$

²⁸ Section 499.005(14), F.S.

²⁹ Section 1002.20(3)(i)2., F.S.

³⁰ Section 499.03(1), F.S.

³¹ Chapter 2015-123, ss. 1-3, Laws of Florida; Section 381.887, F.S.

³² CS/CS/SB 758, Florida Senate Bill Analysis and Fiscal Impact Statement by the Committee on Appropriations (April 20, 2015) https://www.flsenate.gov/Session/Bill/2015/758/Analyses/2015s0758.ap.PDF

³³Section 381.887(4), F.S.

The Good Samaritan Act

The Good Samaritan Act provides immunity from civil liability for people who act in an emergency situation to render aid when certain factors are present. The act states, in part, that any person, including those licensed to practice medicine, who gratuitously and in good faith renders emergency care or treatment either in direct response to emergency situations at the scene of an emergency outside of a hospital, doctor's office, or other place having proper medical equipment, without objection from the injured victim or victims are immune from liability for any civil damages as a result of that care or treatment or as a result of any act or failure to act in providing or arranging further medical treatment where the person acts as an ordinary reasonably prudent person would have acted under the same or similar circumstances.³⁴

Dormitories and Residence Halls

All 12 state universities in the State University System of Florida own or operate a residence hall or dormitory available to students. In the 28 state colleges in the Florida College System, there are 12 residence halls or dormitories available to students. However, only three of these residence halls or dormitories are owned or operated by a state college. They are located at Chipola College, College of the Florida Keys, and Florida Gateway College.³⁵

III. Effect of Proposed Changes:

SB 542 requires each Florida College System (FCS) institution and state university to have a supply of emergency opioid antagonists with an autoinjection or intranasal application delivery system in each residence hall or dormitory residence owned or operated by the institution. The emergency opioid antagonists are available for administration to a person believed to be experiencing an opioid overdose.

The bill defines an "emergency opioid antagonist" to mean naloxone hydrochloride or any similarly acting drug approved by the United States Food and Drug Administration that blocks the effects of opioids and is administered from outside the body for the treatment of an opioid overdose. The emergency opioid antagonist must be placed in a clearly marked location within each residence hall or dormitory residence in a manner that is easily accessible to campus law enforcement officers who are trained in the administration of emergency opioid antagonists.³⁶

The bill provides civil and criminal immunity to any campus law enforcement officer trained in the administration of emergency opioid antagonists, who administers or attempts to administer an emergency opioid antagonist as authorized under laws related to emergency treatment for suspected opioid overdose and the Good Samaritan Act. The institution that employs the officer who acts in accordance with the provisions of the bill is also granted civil and criminal immunity.

³⁴ Section 768.13(2)(a), F.S.

³⁵ Florida Department of Education, HB 39 2023 Agency Legislative Bill Analysis (Feb. 9, 2023) (on file with the Senate Committee on Judiciary).

³⁶ Campus law enforcement may include personnel employed by the institution, or county or municipal officers who act as campus law enforcement on a contractual basis.

The bill requires the State Board of Education and the Board of Governors to adopt rules and regulations, in cooperation with the Department of Health, to administer the requirements related to the supply and administration of emergency opioid antagonists pursuant to the bill.

The bill encourages public and private partnerships to cover the cost associated with the purchase and placement of emergency opioid antagonists.

Providing increased access to emergency opioid antagonists through a dormitory or residence hall accessible by law enforcement trained in its use, may help decrease the risk of death for FCS institution and state university students and others who experience an opioid overdose.

The bill takes effect July 1, 2023.

IV. Constitutional Issues:

Δ

A.	Municipality/County Mandates Restrictions:						
	None.						
_							

В. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

٧. **Fiscal Impact Statement:**

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

> The bill does not require the appropriation of state funds. Florida College System institutions and state universities that secure a supply of emergency opioid antagonists

may incur costs related to the purchase and storage of the emergency opioid antagonist. The costs are indeterminate.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends s. 1004.0971 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:

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

None.

B. Amendments:

None.

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