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: Th | he Profes | ssional Staff of | the Committee on E | ducation Postsec | condary |
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| SB 542 | | | | | |
| Senator Boyd | | | | | |
| Emergency Opioid Antagonists | | | | | |
| March 6, 2023 | 3 | REVISED: | | | |
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I. Summary:

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 in the event of an opioid overdose. The emergency opioid antagonist must be easily accessible to campus law enforcement officers who are trained in the administration of emergency opioid antagonists and provides immunity from civil or criminal liability for administering an emergency opioid antagonist in accordance with the bill.

The bill takes effect July 1, 2023.

II. Present Situation:

Opioid Epidemic

An opioid overdose may cause a person to lose consciousness, stop breathing, and die.¹ In 2017, the number of overdose deaths involving opioids was 6 times higher nationwide than it was in 1999.² In that same year in Florida, opioids killed 4,280 people, including 25 children under the age of 18, indicating a 9 percent increase in the overall death toll over the preceding year.³ As a

¹ U.S. Food & Drug Administration, *Statement From FDA Commissioner Scott Gottlieb, M.D.*, on Unprecedented New Efforts to Support Development of Over-The-Counter Naloxone to Help Reduce Opioid Overdose Deaths (Jan. 17, 2019), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-unprecedented-new-efforts-support-development-over (last visited Mar. 2, 2023).

² National Institute on Drug Abuse, *Drug Overdose Death Rates*, https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates (last visited Mar. 1, 2023).

³ Florida Department of Law Enforcement, Medical Examiners Commission, *Drugs Identified in Deceased Persons by Florida Medical Examiners*, 2017 Annual Report (Nov. 2018), available at https://www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2017-Annual-Drug-Report.aspx, at ii.

result of the opioid epidemic, Governor Scott declared Florida to be in a state of emergency.⁴ Subsequent Executive Orders extended the state of emergency through April 2, 2019.⁵

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.⁶ Deaths from opioid overdoses in Florida increased by 6 percent from 2020 to 2021, to 6,442.⁷

Emergency Opioid Antagonists

An emergency opioid antagonist is a drug such as naloxone hydrochloride or any similarly acting drug that blocks 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. Naltrexone is another commonly used opioid antagonist. Naloxone is a well-established essential medicine for the treatment of a life-threatening opioid overdose in emergency medicine. Naloxone is a safe antidote to a suspected overdose and can save a life when given in time. Research shows that when naloxone and overdose education are available to community members, overdose deaths decrease in those communities.

Administration

Laypersons administering naloxone have a 75 to 100 percent success rate in reversing the effects of an opioid overdose. ¹² Naloxone may be administered to a person through a vein, through a muscle, or through the nasal passage, and is FDA-approved for the use in an opioid overdose and

⁴ Office of the Governor, Executive Order Number 17-146, May 3, 2017 (Opioid Epidemic).

⁵ Office of the Governor, Executive Order Number 19-36, February 1, 2019 (Opioid Epidemic Extension).

⁶ 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).

⁷ FDLE, Medical Examiners Commission, *Drugs Identified in Deceased Persons by Florida Medical Examiners: 2021 Annual Report, available* at https://www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2021-Annual-Drug-Report-FINAL.

⁸ Theriot, Jonathan, et. al., *Opioid Antagonists* (last updated 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. (last visited Mar. 1, 2023).

⁹ 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/.

¹⁰ U.S. Department of Health and Human Services, Office of the Surgeon General, *U.S. Surgeon General's Advisory on Naloxone and Opioid Overdose* (Apr. 5, 2018), *available at* https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html (last visited Mar. 2, 2023).

¹¹ *Id.*

¹² 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), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5753997/.

the reversal of respiratory depression associated with opioid use. ¹³ Naltrexone is available in both oral and long-acting injectable formulations. ¹⁴

Naloxone may cost less than a dollar per unit for a simple vial, to several thousand dollars for certain intramuscular auto-injectors. ¹⁵ On average, Naloxone costs approximately \$30 per carton, which includes two doses of Narcan. ¹⁶ The Florida Department of Children and Families, as part of its overdose prevention program, purchases Narcan at \$75 per carton. ¹⁷ Emergent Biosolutions has produced an FDA- approved naloxone nasal spray called Narcan. ¹⁸ Emergent Biosolutions offers up to two free cartons of Narcan to degree-granting postsecondary institutions. ¹⁹

Regulation

Naloxone and naltrexone are derivatives of thebaine, ²⁰ a Schedule II controlled substance in Florida. ²¹ Schedule II substances may only be dispensed with a prescription from a licensed health care practitioner, ²² 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. ²³ The U.S. Surgeon General has developed standards to encourage the distribution of over-the-counter naloxone. ²⁴

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.²⁵ One such statutory exception authorizes a public school to purchase a supply of epinephrine auto-injectors from a

¹³ Jonathan Theriot, et. al., *Opioid Antagonists*, (last updated July 23, 2021), StatPearls Pub. 2022-Jan, *available at* https://www.ncbi.nlm.nih.gov/books/NBK537079/#:~:text=3%5D%5B4%5D-

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¹⁴ *Id*.

¹⁵ 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/.

¹⁶ Florida Department of Education, 2023 Staff Analysis of HB 39 (Jan. 11, 2023).

¹⁷ Email, Florida Department of Children and Families (Mar. 6, 2023).

¹⁸ *Id.* Emergent Biosolutions bought Adapt Pharma, who originally produced Narcan.

¹⁹ Emergent Biosolutions, *Free Narcan Nasal Spray to Eligible Schools, available at* https://californiamat.org/wp-content/uploads/2022/01/Schools.PP-NAR4-US-00483-Professional-Educator-One-Pager-2021-Update.pdf.

²⁰ National Center for Biotechnology Information, *PubChem Compound Summary for CID 5284596*, *Naloxone*, PubChem https://pubchem.ncbi.nlm.nih.gov/compound/Naloxone (last visited Mar. 2, 2023); *and* Sun Dongbang, et al., *Assymetric synthesis of naltrexone*, Chem Sci 2018 Oct 23 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6326069/ (last visited Mar. 1, 2023).

²¹ Section 893.03(2)(a)1.s., F.S.

²² 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.

²³ Section 381.887, F.S.

²⁴ U.S. Food & Drug Administration, *supra* note 1.

²⁵ Section 499.005(14), F.S.

wholesale distributor or manufacturer.²⁶ 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.²⁷

The Good Samaritan Act

The Good Samaritan Act provides 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 outside of a hospital, doctor's office, or other place having proper medical equipment, without objection of the injured victim or victims are immune from liability for any civil damages as a result of such 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.²⁸

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.²⁹

III. Effect of Proposed Changes:

SB 542 requires each Florida College System (FCS) institutions 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 for the administration of emergency opioid antagonists 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 that blocks 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. The emergency opioid antagonist must be placed in a clearly marked location

²⁶ Section 1002.20(3)(i), F.S.

²⁷ Section 499.03(1), F.S.

²⁸ Section 768.13(2)(a), F.S.

²⁹ Florida Department of Education, 2023 Staff Analysis of HB 39 (Jan. 11, 2023).

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.³⁰

The bill provides civil and criminal immunity to any campus law enforcement officer trained in the administration of emergency opioid antagonists, and the institution that employs such officer, 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 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 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 such emergency opioid antagonists.

Providing increased access to an emergency opioid antagonist 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:

| 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. |
| | |

³⁰ 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.

V. 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.