

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: SB 120

INTRODUCER: Senators Pizzo and Book

SUBJECT: Naloxone in Schools

DATE: January 27, 2020

REVISED: _____

| | ANALYST | STAFF DIRECTOR | REFERENCE | ACTION |
|----|--------------|----------------|-----------|--------------------|
| 1. | <u>Brick</u> | <u>Sikes</u> | <u>ED</u> | Favorable |
| 2. | <u>Looke</u> | <u>Brown</u> | <u>HP</u> | Pre-meeting |
| 3. | _____ | _____ | <u>RC</u> | _____ |

I. Summary:

SB 120 authorizes a K-12 public school to purchase the opioid antagonist naloxone and allows trained personnel to administer the drug to a student who overdoses on an opioid. The bill requires a participating school district to adopt a protocol developed by a licensed physician and provides liability protections for the physician and school district personnel relating to injuries arising from naloxone use administered by trained school personnel who comply with the protocol.

The bill takes effect July 1, 2020.

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 six times higher nationwide than it was in 1999² and, in 2018, opioids killed 3,727 people in Florida.³ As a result of the opioid epidemic, Governor Rick Scott declared Florida to be in a state of emergency.⁴ Subsequent Executive

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), available at <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-unprecedented-new-efforts-support-development-over> (last visited Jan. 14, 2020).

² Centers for Disease Control and Prevention, *Opioid Overdose* (2018), available at <https://www.cdc.gov/drugoverdose/epidemic/index.html> (last visited Jan. 14, 2020).

³ Florida Department of Law Enforcement, Medical Examiners Commission, *Drugs Identified in Deceased Persons by Florida Medical Examiners, 2018 Annual Report*, available at <https://www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2018-Annual-Drug-Report.aspx> (last visited Jan. 14, 2020).

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

Orders extended the state of emergency through April 2, 2019.⁵ On April 1, 2019, Governor Ron 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

Naloxone

Background

Naloxone is a well-established essential medicine for the treatment of life-threatening opioid overdose in emergency medicine.⁷ Naloxone is a safe antidote to a suspected overdose and can save a life when given in time.⁸ Research shows that when naloxone and overdose education are available to community members, overdose deaths decrease in those communities.⁹ Laypersons administering naloxone have a 75 to 100 percent success rate in reversing the effects of an opioid overdose.¹⁰

Regulation

Naloxone is a derivative of thebaine,¹¹ a Schedule II controlled substance in Florida.¹² Schedule II substances may only be dispensed with a prescription from a licensed practitioner,¹³ but emergency responders are authorized by law to possess, store, and administer emergency opioid antagonists as necessary.¹⁴ The U.S. Surgeon General developed standards to encourage the distribution of over-the-counter naloxone.¹⁵

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.¹⁶ One such statutory exception authorizes a public school to purchase a supply of epinephrine auto-injectors from a

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 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 (July 27, 2019), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6728289/> (last visited Jan. 14, 2020).

⁸ 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 Jan. 14, 2020).

⁹ *Id.*

¹⁰ Rachael Rzasa Lynn, 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/> (last visited Jan. 14, 2020).

¹¹ National Institute of Health, U.S. National Library of Medicine, *Naloxone*, <https://pubchem.ncbi.nlm.nih.gov/compound/Naloxone> (last visited Jan. 14, 2020).

¹² Section 893.03(2)(a)1.s., F.S.

¹³ Section 893.04(1)(f), F.S. "Practitioner" means a physician licensed under ch. 458, a dentist licensed under ch. 466, a veterinarian licensed under ch. 474, an osteopathic physician licensed under ch. 459, an advanced practice registered nurse licensed under ch. 464, a naturopath licensed under ch. 462, a certified optometrist licensed under ch. 463, a psychiatric nurse as defined in s. 394.455, F.S., a podiatric physician licensed under ch. 461, or a physician assistant licensed under ch. 458 or ch. 459, provided such practitioner holds a valid federal controlled substance registry number. Section 893.02(23), F.S.

¹⁴ Section 381.887, F.S.

¹⁵ U.S. Food & Drug Administration, *supra* note 1.

¹⁶ Section 499.005(14), F.S.

wholesale distributor or manufacturer.¹⁷ In addition, a manufacturer or wholesale distributor of naloxone may sell a prescription drug to:¹⁸

- 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.

Administration

Naloxone may be administered to a person through a vein, through a muscle, or through the nasal passage.¹⁹ Naloxone may cost less than a dollar per unit for a simple vial, to several thousand dollars for certain intramuscular auto-injectors.²⁰

ADAPT Pharma, Inc., has produced an FDA-approved naloxone nasal spray called Narcan.²¹ The Florida Department of Children and Families, as part of its overdose prevention program, purchases Narcan at \$75 per carton. Each carton contains two doses of Narcan.²² The Narcan Nasal Spray School Program, offered through ADAPT Pharma, offers up to two cartons of Narcan to every high school at no cost.²³ New approved naloxone nasal sprays cost between \$30 and several hundred dollars per carton.²⁴

School Health

District school board personnel may assist students in the administration of certain medication and medical services.²⁵ County health departments, district school boards, and local school health advisory committees jointly develop school health services plans, which must include provisions for meeting emergency needs at each school.²⁶ Each school must ensure that at least

¹⁷ Section 1002.20(3)(i), F.S.

¹⁸ Section 499.03(1), F.S.

¹⁹ Strang, *supra* note 7.

²⁰ *Id.*

²¹ *Id.*

²² Fla. Dep't of Children and Families, *Patterns and Trends of the Opioid Epidemic in Florida*, 20 (2018), available at <http://www.floridahealth.gov/statistics-and-data/e-forcse/fl-seow-annual-report-2018.pdf> (last visited Jan. 14, 2020).

²³ Narcan Nasal Spray, *Community Programs*, available at <https://www.narcan.com/community/education-awareness-and-training-resources/> (last visited Jan. 14, 2020).

²⁴ Strang, *supra* note 7.

²⁵ Section 1006.062, F.S.

²⁶ Sections 381.0056(4)(a)12. and 1006.062(6), F.S.

two school staff members are currently certified by nationally recognized certifying agencies to provide first aid and cardiopulmonary resuscitation.²⁷

At least four states enacted bills to expand naloxone access in schools in 2019.²⁸

III. Effect of Proposed Changes:

SB 120 authorizes a school to purchase a supply of the opioid antagonist naloxone from a wholesale distributor, or enter into an arrangement with a wholesale distributor or manufacturer for naloxone at fair-market, free, or reduced prices. A participating school district must adopt a protocol developed by a licensed physician for the administration of the drug by school personnel who are trained to recognize an opioid overdose and to administer naloxone. The school must maintain the naloxone in a secure location on the premises of a participating school.

The bill exempts a school district, its employees and agents, and the physician who provides the standing protocol, from liability for any injury arising from the use of naloxone so long as the naloxone is administered by trained school personnel who follow the standing protocol and whose professional opinion is that the student is having an opioid overdose. The liability protections apply unless the trained school personnel's action is willful and wanton and apply regardless of whether:

- The parents or guardians of the student to whom the naloxone is administered have been provided notice or have signed a statement acknowledging that the school district is not liable; or
- Authorization has been given by the student's parents or guardians or by the student's physician, physician's assistant, or advanced practice registered nurse.

The bill takes effect July 1, 2020.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

²⁷ Fla. Admin. Code R. 64F-6.004.

²⁸ Minnesota, Oregon, South Dakota, and Washington. Alyssa Rafa, Education Commission of the States, *Education Policy Responses to the Opioid Crisis* (2019), available at <https://www.ecs.org/education-policy-responses-to-the-opioid-crisis/>, at 3, (last visited Jan. 14, 2020).

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:

None.

C. Government Sector Impact:

SB 120 may have an indeterminate, negative fiscal impact on school districts. The costs to school districts depend on whether or not the district decides to purchase the medication and whether the medication is purchased at fair-market or reduced prices. ADAPT Pharma will provide two cartons of Narcan nasal spray (four doses) free of charge to high schools through the Narcan Nasal Spray School Program.²⁹

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 1002.20 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.

²⁹ *Supra* note 23.

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