# 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.)

	Prep	ared By: Th	ne Professional	Staff of the Commit	tee on Education	
BILL:	SB 120					
INTRODUCER:	Senators Pizzo and Book					
SUBJECT:	Naloxone in Schools					
DATE:	November 8, 2019 REVISED:					
ANALYST		STAFF DIRECTOR		REFERENCE	ACT	ION
. Brick		Sikes		ED	Pre-meeting	
2.				HP		
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# I. Summary:

SB 120 authorizes a K-12 public school to purchase the opioid antagonist naloxone and 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 from injuries arising from naloxone use that complies 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.<sup>1</sup> In 2017, the number of overdose deaths involving opioids was 6 times higher nationwide than it was in 1999.<sup>2</sup> In Florida, opioids killed 4,280 people, including 25 children under the age of 18, indicating a nine percent increase in the overall death toll over the preceding year.<sup>3</sup> As a result of the opioid epidemic, Governor Scott declared Florida to be in a state of emergency.<sup>4</sup> Subsequent

<sup>&</sup>lt;sup>1</sup> 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), <a href="https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-unprecedented-new-efforts-support-development-over">https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-unprecedented-new-efforts-support-development-over</a> (last visited Oct. 29, 2019).

<sup>&</sup>lt;sup>2</sup> Centers for Disease Control and Prevention, *Opioid Overdose* (2018), *available at* https://www.cdc.gov/drugoverdose/epidemic/index.html (last visited Nov. 6, 2019).

<sup>&</sup>lt;sup>3</sup> Florida Department of Law Enforcement, Medical Examiners Commission, *Drugs Identified in Deceased Persons by Florida Medical Examiners*, 2017 Annual Report, *available at* <a href="https://www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2017-Annual-Drug-Report.aspx">https://www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2017-Annual-Drug-Report.aspx</a>.

<sup>&</sup>lt;sup>4</sup> Office of the Governor, Executive Order Number 17-146, May 3, 2017 (Opioid Epidemic).

Executive Orders extended the state of emergency through April 2, 2019.<sup>5</sup> 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.<sup>6</sup>

### **Naloxone**

## **Background**

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

## Regulation

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

<sup>&</sup>lt;sup>5</sup> Office of the Governor, Executive Order Number 19-36, February 1, 2019 (Opioid Epidemic Extension).

<sup>&</sup>lt;sup>6</sup> 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).

<sup>&</sup>lt;sup>7</sup> 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/

<sup>&</sup>lt;sup>8</sup> 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* <a href="https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html">https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html</a> (last visited Nov. 6, 2019).

<sup>9</sup> *Id.* 

<sup>&</sup>lt;sup>10</sup> 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* <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5753997/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5753997/</a>.

<sup>&</sup>lt;sup>11</sup> National Institute of Health, U.S. National Library of Medicine, *Naloxone*, <a href="https://pubchem.ncbi.nlm.nih.gov/compound/Naloxone">https://pubchem.ncbi.nlm.nih.gov/compound/Naloxone</a> (last visited Oct. 29, 2019).

<sup>&</sup>lt;sup>12</sup> Section 893.03(2)(a)1.s., F.S.

<sup>&</sup>lt;sup>13</sup> 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.

<sup>&</sup>lt;sup>14</sup> Section 381.887, F.S.

<sup>&</sup>lt;sup>15</sup> U.S. Food & Drug Administration, *supra* note 1.

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. One such statutory exception authorizes a public school to purchase a supply of epinephrine auto-injectors from a wholesale distributor or manufacturer. 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. <sup>19</sup> Naloxone may cost less than a dollar per unit for a simple vial, to several thousand dollars for certain intramuscular auto-injectors. <sup>20</sup>

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

#### **School Health**

District school board personnel may assist students in the administration of certain medication and medical services.<sup>25</sup> County health departments, district school boards, and local school health advisory committees jointly develop school health services plans, which must include

<sup>&</sup>lt;sup>16</sup> Section 499.005(14), F.S.

<sup>&</sup>lt;sup>17</sup> Section 1002.20(3)(i), F.S.

<sup>&</sup>lt;sup>18</sup> Section 499.03(1), F.S.

<sup>&</sup>lt;sup>19</sup> Strang, *supra* note 7.

 $<sup>^{20}</sup>$  *Id*.

<sup>&</sup>lt;sup>21</sup> Id

<sup>&</sup>lt;sup>22</sup> Florida Department of Children and Families, *Patterns and Trends of the Opioid Epidemic in Florida*, at 20 (2018), *available at* http://www.floridahealth.gov/statistics-and-data/e-forcse/fl-seow-annual-report-2018.pdf.

<sup>&</sup>lt;sup>23</sup> Narcan Nasal Spray, *Community Programs*, *available at* <a href="https://www.narcan.com/community/education-awareness-and-training-resources/">https://www.narcan.com/community/education-awareness-and-training-resources/</a> (last visited Oct. 30, 2019).

<sup>&</sup>lt;sup>24</sup> Strang, *supra* note 7.

<sup>&</sup>lt;sup>25</sup> Section 1006.062, F.S.

provisions for meeting emergency needs at each school.<sup>26</sup> Each school must ensure that at least two school staff members are currently certified by nationally recognized certifying agencies to provide first aid and cardiopulmonary resuscitation.<sup>27</sup>

At least four states enacted bills to expand naloxone access in schools in 2019.<sup>28</sup>

# III. Effect of Proposed Changes:

SB 120 authorizes a K-12 public school to purchase the opioid antagonist naloxone and 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 from injuries arising from naloxone use that complies with the protocol.

The bill authorizes a participating school district 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 district must maintain the naloxone in a secure location on the premises of a participating school.

The bill exempts a school district, its employees, 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 administration of naloxone pursuant to this bill may prevent the death of a student who experiences an opioid overdose on a school campus.

The bill takes effect July 1, 2020.

<sup>&</sup>lt;sup>26</sup> Sections 381.0056(4)(a)12. and 1006.062(6), F.S.

<sup>&</sup>lt;sup>27</sup> Rule 64F-6.004, F.A.C.

<sup>&</sup>lt;sup>28</sup> Minnesota, Oregon, South Dakota, and Washington. Alyssa Rafa, Education Commission of the States, *Education Policy Responses to the Opioid Crisis* (2019), *available at* <a href="https://www.ecs.org/education-policy-responses-to-the-opioid-crisis/">https://www.ecs.org/education-policy-responses-to-the-opioid-crisis/</a>, at 3, (last visited Nov. 5, 2019).

# IV. Constitutional Issues:

IV.	Cons	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.					
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	A.	Tax/Fee Issues:					
		None.					
	B.	Private Sector Impact:					
		None.					
	C.	Government Sector Impact:					
		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. <sup>29</sup>					
VI.	Technical Deficiencies:						
	None.						
VII.	Relat	Related Issues:					
	None.						

 $<sup>^{29}</sup>$  Florida Department of Education,  $Legislative\ Bill\ Analysis\ for\ SB\ 120$  (Sept. 30, 2019).

#### VIII. **Statutes Affected:**

This bill substantially amends s. 1002.20, F.S.

#### **Additional Information:** IX.

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.