

**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.)

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Prepared By: The Professional Staff of the Committee on Education

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BILL: SB 538

INTRODUCER: Senator Polsky

SUBJECT: Use of Epinephrine Auto-injectors on Public K-20 Campuses

DATE: February 15, 2021

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Brick	Bouck	ED	<b>Favorable</b>
2.			HP	
3.			AP	

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## I. Summary:

SB 538 adds requirements related to the purchase and maintenance of a supply of epinephrine auto-injectors by K-12 public schools, Florida College System (FCS) institutions, and state universities. The bill makes mandatory provisions that are optional under current law related to the purchase and maintenance of a supply of epinephrine auto-injectors in K-12 public schools. Specifically, the bill requires K-12 public schools, FCS institutions, and state universities to:

- Purchase a supply of epinephrine auto-injectors and maintain them in a secure location in each school's or public postsecondary institution's cafeteria.
- Adopt a protocol developed by a licensed physician for the administration of epinephrine auto-injectors by the school's or public postsecondary institution's personnel.

The bill provides liability protections for FCS institutions and state universities who meet specified conditions and administer epinephrine to an individual in an emergency.

The bill takes effect July 1, 2021.

## II. Present Situation:

### Epinephrine Use

Anaphylaxis is a severe, whole-body allergic reaction to a chemical that has become an allergen.<sup>1</sup> The human body releases chemicals during anaphylaxis that can cause shock, resulting in a sudden drop in blood pressure and the release of histamines, which may restrict breathing.<sup>2</sup>

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<sup>1</sup> U.S. National Library of Medicine, National Institute of Health, *Anaphylaxis*, <http://www.nlm.nih.gov/medlineplus/ency/article/000844.htm> (last visited Feb. 12, 2021).

<sup>2</sup> Mayo Foundation for Medical Education and Research, *First Aid: Anaphylaxis*, <http://www.mayoclinic.org/first-aid/first-aid-anaphylaxis/basics/art-20056608> (last visited Feb. 12, 2021).

Symptoms of anaphylaxis include rapid, weak pulse; skin rash; nausea; and vomiting.<sup>3</sup> Common causes include certain medications, some foods, insect bites or stings, and exposure to latex.<sup>4</sup> Food allergies are also the most common cause of anaphylaxis cases in children.<sup>5</sup>

An epinephrine auto-injector is a prescription medication in a specific dose-for-weight device that is packaged for self-delivery in the event of a life-threatening allergic reaction.<sup>6</sup> An epinephrine injection is used along with emergency medical treatment to treat anaphylaxis. Epinephrine is in a class of medications called alpha- and beta-adrenergic agonists (sympathomimetic agents). It works by relaxing the muscles in the airways and tightening the blood vessels.<sup>7</sup> Anaphylaxis requires an immediate injection of epinephrine. If anaphylaxis isn't treated right away, it can be fatal.<sup>8</sup>

### ***Regulation***

Subject to statutory exceptions, it is illegal for a drug manufacturer<sup>9</sup> or wholesale distributor<sup>10</sup> in Florida to distribute a prescription drug to a person without a prescription.<sup>11</sup> One such statutory exception authorizes a public school to purchase a supply of epinephrine auto-injectors from a wholesale distributor or manufacturer.<sup>12</sup> In addition, a manufacturer or wholesale distributor of epinephrine auto-injectors may sell a prescription drug to:<sup>13</sup>

- 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.

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<sup>3</sup> Mayo Foundation for Medical Education and Research, *First Aid: Anaphylaxis*, <http://www.mayoclinic.org/first-aid/first-aid-anaphylaxis/basics/art-20056608> (last visited Feb. 12, 2021).

<sup>4</sup> Mayo Clinic, *Anaphylaxis - Definition*, <http://www.mayoclinic.org/diseases-conditions/anaphylaxis/basics/definition/con-20014324> (last visited: Feb. 12, 2021).

<sup>5</sup> *Id.*

<sup>6</sup> Rule 6A-6.0251, F.A.C.

<sup>7</sup> National Institute of Health, Medline Plus, *Epinephrine Injection*, <https://medlineplus.gov/druginfo/meds/a603002.html> (last visited Feb. 11, 2021).

<sup>8</sup> Mayo Clinic, *supra* note 4.

<sup>9</sup> “Manufacturer” is defined in s. 499.003(29), F.S.

<sup>10</sup> “Wholesale distributor” means a person, other than a manufacturer, a manufacturer’s co-licensed partner, a third-party logistics provider, or a repackager, who is engaged in wholesale distribution. Section 499.003(49), F.S.

<sup>11</sup> Section 499.005(14), F.S.

<sup>12</sup> Section 1002.20(3)(i), F.S.

<sup>13</sup> Section 499.03(1), F.S.

## Epinephrine in Schools

Federal law provides a financial incentive for schools to maintain a supply of epinephrine auto-injectors and permit trained personnel to administer it.<sup>14</sup> A state receives priority under the federal Children's Asthma Treatment Grants Program<sup>15</sup> if the state attorney general certifies adequate civil liability protections exist for personnel trained to administer epinephrine to a student, and the state requires K-12 public schools to:

- Permit trained personnel of the school to administer epinephrine to any student of the school reasonably believed to be having an anaphylactic reaction;
- Maintain a supply of epinephrine in a secure location that is easily accessible to trained personnel of the school for the purpose of administration to any student of the school reasonably believed to be having an anaphylactic reaction; and
- Have in place a plan for having on the premises of the school during all operating hours of the school one or more individuals who are trained personnel of the school.

Twelve states currently require schools to maintain a supply of epinephrine auto-injectors.<sup>16</sup> K-12 public and private schools in Florida may purchase and maintain a supply of epinephrine auto-injectors in a secure, locked location on school premises for use if a student has an anaphylactic reaction.<sup>17</sup> A participating school district or private school is required to adopt a protocol developed by a licensed physician for administration of the epinephrine by school personnel. The epinephrine auto-injectors may be administered by school personnel or self-administered by the student.<sup>18</sup>

A student may carry an epinephrine auto-injector to self-administer epinephrine with written authorization from a physician and parent.<sup>19</sup> For each student authorized to carry an epinephrine auto-injector, the school nurse must develop an annual child-specific action plan for an anticipated health emergency in the school setting.<sup>20</sup>

K-12 public schools, their employees, and physicians who provide the standing protocol, are exempted from liability for any injury arising from the use of an epinephrine auto-injector so long as the epinephrine auto-injector is administered by trained school personnel who follow the standing protocol and whose professional opinion is that the individual is having an anaphylactic

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<sup>14</sup> The School Access to Emergency Epinephrine Act of 2013, Pub. Law 113-48, H.R. 2094, 113th Cong. (Nov. 13, 2013).

<sup>15</sup> 42 U.S.C. s. 280g.

<sup>16</sup> Food Allergy and Anaphylaxis Connection Team, *Government Relations*, <https://www.foodallergyawareness.org/government-relations/school-access-to-emergency-epinephrine-act/>, (last visited Feb. 12, 2021). The states with laws that require schools to maintain a supply of epinephrine are Arizona, California, Connecticut, Delaware, Maryland, Michigan, Nebraska, New Jersey, North Carolina, Nevada, Utah, and Virginia.

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

<sup>18</sup> *Id.*

<sup>19</sup> Rule 6A-6.0251, F.A.C.

<sup>20</sup> *Id.* The annual plan is developed in cooperation with the student, parent, healthcare provider, and school personnel for the student with life threatening allergies and must specify that the emergency number 911 will be called immediately for an anaphylaxis event. It must also describe a plan of action if the student is unable to perform self-administration of the epinephrine auto-injector.

reaction.<sup>21</sup> The liability protections apply unless the trained school personnel's action is willful and wanton and apply:<sup>22</sup>

- Even if the individual to whom the epinephrine is administered has not been provided notice or has not signed a statement acknowledging that the school is not liable; or
- Regardless of whether authorization has been given by the parent or legal guardian of the student.

### III. Effect of Proposed Changes:

SB 538 adds requirements related to the purchase and maintenance of a supply of epinephrine auto-injectors by K-12 public schools, Florida College System (FCS) institutions, and state universities. The bill makes mandatory provisions that are optional under current law related to the purchase and maintenance of a supply of epinephrine auto-injectors in K-12 public schools. Specifically, the bill requires K-12 public schools, FCS institutions, and state universities to:

- Purchase a supply of epinephrine auto-injectors and maintain them in a secure location in each school's or public postsecondary institution's cafeteria.
- Adopt a protocol developed by a licensed physician for the administration of epinephrine auto-injectors by the school's or public postsecondary institution's personnel.

The bill provides liability protections for FCS institutions and state universities who meet specified conditions and administer epinephrine to an individual in an emergency.

The bill adds to s. 381.88, F.S., state universities and FCS institutions to the list of entities specifically authorized to make a stock supply of epinephrine auto-injectors available to individuals who have not been certified to administer the auto-injector, if:<sup>23</sup>

- The supply of epinephrine auto-injectors was prescribed by an authorized health care practitioner;
- The epinephrine auto-injectors are stored in a locked, secure container and are made available only upon remote authorization by an authorized health care practitioner;
- Administration of the auto-injector only occurs after consultation with the authorized health care practitioner by audio, televideo, or other similar means of electronic communication; and
- Administration of the auto-injector is limited to when a person is believed in good faith to be experiencing a severe allergic reaction.

The bill modifies s. 1002.20, F.S., to make mandatory, rather than optional, provisions related to epinephrine in K-12 public schools. The bill also creates s. 1004.0963, F.S., to add similar requirements for state universities and FCS institutions to maintain a supply of epinephrine. The bill requires each state university, FCS institution, and K-12 public school to:

- Purchase a supply of epinephrine auto-injectors from a wholesale distributor or enter into an arrangement with a wholesale distributor or manufacturer for the epinephrine auto-injectors at fair market, free, or reduced prices for use in the event a student has an anaphylactic reaction.

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<sup>21</sup> Section 1002.20(3)(i)3., F.S.

<sup>22</sup> *Id.*

<sup>23</sup> Section 381.885(4), F.S.

- Maintain auto-injectors in a secure location in each public school's cafeteria or state university or FCS institution cafeterias. Schools retain the authority under current law and state universities and FCS institutions are authorized, to maintain auto-injectors in other secure locations on the public school's, state university's, or FCS institution's premises. The bill defines "cafeteria" as a space to eat or that serves food and that has a capacity of 50 or more persons, including dining halls on a state university or FCS institution campus.

The bill requires each state university or FCS institution to adopt a protocol developed by a licensed physician for the administration by the state university's or FCS institution's personnel who are trained to recognize an anaphylactic reaction and to administer an epinephrine auto-injection.

The bill aligns liability protections for state universities and FCS institutions with existing liability protections for the administration of epinephrine in K-12 public schools. The bill exempts an FCS institution or state university, their employees, agents, and the physician who provides the standing protocol from liability for any injury arising from the use of an epinephrine auto-injector so long as the epinephrine auto-injector is administered by trained school personnel who follow the standing protocol and whose professional opinion is that the individual is having an anaphylactic reaction. The liability protections apply unless the trained school personnel's action is willful and wanton and apply:

- Even if the individual to whom the epinephrine is administered has not been provided notice or has not signed a statement acknowledging that the state university or FCS institution is not liable; or
- Regardless of whether authorization has been given by the individual or the individual's parent or legal guardian if the individual is under the age of 18.

The administration of an epinephrine auto-injector pursuant to this bill may prevent the death of a student who experiences anaphylaxis on a school or public postsecondary institution campus.

The bill does not have an impact on state expenditures or revenues. However, the bill adds requirements for school districts, state universities, and FCS institutions to purchase and maintain a supply of epinephrine auto-injectors.

The bill takes effect July 1, 2021.

#### **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.

**V. Fiscal Impact Statement:****A. Tax/Fee Issues:**

None.

**B. Private Sector Impact:**

None.

**C. Government Sector Impact:**

According to the Florida Board of Governors of the State University System, state universities may incur an estimated expense of approximately \$696.52 for the purchase of each two-pack of epinephrine auto-injectors, which require periodic replacement.<sup>24</sup> K-12 public schools and Florida College System (FCS) institutions may incur similar expenses. The total expenses will depend on the number of qualifying cafeterias on public school, state university, and FCS institution sites.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends the following sections of the Florida Statutes: 381.88 and 1002.20.

This bill creates section 1004.0963 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.

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<sup>24</sup> Board of Governors, *Legislative Bill Analysis for SB 538* (2021), at 2.

B. Amendments:

None.

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

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