

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 99 Use of Epinephrine Auto-injectors on Public K-20 Campuses

**SPONSOR(S):** Gottlieb, Nixon and others

**TIED BILLS:** None **IDEN./SIM. BILLS:** SB 538

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Post-Secondary Education & Lifelong Learning Subcommittee	17 Y, 0 N	Bauman	Kiner
2) Early Learning & Elementary Education Subcommittee			
3) Appropriations Committee			
4) Education & Employment Committee			

### SUMMARY ANALYSIS

HB 99 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 modifies current law, which permits K-12 public schools to purchase and maintain a supply of epinephrine auto-injectors, to mandate K-12 public schools purchase and maintain a supply of epinephrine auto-injectors. The epinephrine auto-injectors must be maintained in a secure location in the school's cafeteria and may be contained in other secure locations on the school's premises. The bill defines "cafeteria" as a space to eat or that serves food with a capacity of at least 50 people.

The bill also requires each state university or Florida College System (FCS) institution to purchase a supply of epinephrine auto-injectors, which must be maintained in a secure location in each of the cafeterias on campus. The bill specifies that the definition of "cafeteria" includes dining halls.

The bill requires state universities and FCS institutions to adopt a protocol developed by a licensed physician for trained personnel to administer epinephrine auto-injections. 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 adds state universities and FCS institutions to the definition of "authorized entity," which provides specific authorization to make a stock supply of epinephrine auto-injectors available to certain individuals who may administer an epinephrine auto-injection in an emergency situation.

The bill has indeterminate fiscal impact. See Fiscal Comments.

The bill provides an effective date of July 1, 2021.

# FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

### A. EFFECT OF PROPOSED CHANGES:

#### **Anaphylaxis and the Use of Epinephrine**

Anaphylaxis is a severe, whole-body allergic reaction to a chemical that has become an allergen.<sup>1</sup> During anaphylaxis, the human body releases chemicals that can cause shock, a sudden drop in blood pressure, and difficulty breathing.<sup>2</sup> Symptoms of anaphylaxis include rapid, weak pulse; skin rash; nausea; and vomiting.<sup>3</sup> Common causes include certain medications, foods, insect bites or stings, and exposure to latex.<sup>4</sup> Food allergies are the most common cause of anaphylactic responses in children.<sup>5</sup>

An epinephrine auto-injector is a prescription medication in a specific dose-for-weight device that is packaged for administration 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 that work by relaxing the muscles in the airways and tightening the blood vessels.<sup>7</sup> Anaphylaxis requires an immediate injection of epinephrine and follow-up trip to the emergency room.<sup>8</sup> If anaphylaxis isn't treated right away, it can be fatal.<sup>9</sup>

Reporting on the frequency of anaphylactic events in schools suggests that approximately 20-25 percent of epinephrine administrations in schools involve individuals whose allergy was unknown at the time.<sup>10</sup> There are fewer studies and reports regarding the frequency of anaphylactic events among students at higher education institutions; however, existing studies consider the attitudes of undergraduate students toward food allergies and highlight data indicating adolescents and teenagers are more likely to take risks pertaining to their food allergies and increases in food allergy prevalence in late teens and young adults as indicative of students' anaphylactic risks on college campuses.<sup>11</sup>

#### *Regulation of Epinephrine*

In Florida, it is illegal for a drug manufacturer<sup>12</sup> or wholesale distributor<sup>13</sup> to distribute a prescription drug to a person without a prescription.<sup>14</sup> However, Florida law provides an exception to this prohibition for public schools and authorizes schools to purchase a supply of epinephrine auto-injectors from a

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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 March 16, 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 March 16, 2021).

<sup>3</sup> *Id.*

<sup>4</sup> Mayo Clinic, *Anaphylaxis - Definition*, <http://www.mayoclinic.org/diseases-conditions/anaphylaxis/basics/definition/con-20014324> (last visited March 16, 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 March 16, 2021).

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

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

<sup>10</sup> See Food Allergy Research & Education, *Facts and Statistics: Who is at greatest risk?*, <https://www.foodallergy.org/resources/facts-and-statistics> (last visited March 22, 2021); Scott Sicherer et al., *Clinical Report—Management of Food Allergy in the School Setting*, American Academy of Pediatrics 1232 (2010), available at <https://pediatrics.aappublications.org/content/pediatrics/early/2010/11/29/peds.2010-2575.full.pdf>.

<sup>11</sup> See Matthew J. Greenhawt et al., *Food allergy and food allergy attitudes among college students*, Journal of Allergy and Clinical Immunology 323 (2009); Ali Hassan et al., *Food allergy among university students: uncharted territory*, Allergy, Asthma & Clinical Immunology (2020).

<sup>12</sup> “Manufacturer” is defined in s. 499.003(29), F.S.

<sup>13</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>14</sup> Section 499.005(14), F.S.

wholesale distributor or manufacturer.<sup>15</sup> Florida law also allows a manufacturer or wholesale distributor of epinephrine auto-injectors to sell a prescription drug to:<sup>16</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.

## Epinephrine in Schools

### *Federal Law*

Federal law provides a financial incentive for K-12 schools to maintain a supply of epinephrine auto-injectors and permit trained personnel to administer epinephrine auto-injectors.<sup>17</sup> A state receives priority under the federal Children's Asthma Treatment Grants Program<sup>18</sup> if the state attorney general certifies that adequate civil liability protections exist for personnel trained to administer epinephrine to students and the state requires its K-12 public schools to:<sup>19</sup>

- Permit trained school personnel 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 school personnel; and
- Have a plan for at least one individual who is trained school personnel for epinephrine administration on the school premises during all operating hours.

### *Florida Law*

K-12 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>20</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.<sup>21</sup> The epinephrine auto-injectors may be administered by school personnel or self-administered by the student.<sup>22</sup>

A student may carry an epinephrine auto-injector to self-administer epinephrine with written authorization from a physician and parent.<sup>23</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

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<sup>15</sup> Section 1002.20(3)(i), F.S.

<sup>16</sup> Section 499.03(1), F.S.

<sup>17</sup> The School Access to Emergency Epinephrine Act of 2013, Pub. Law 113-48, H.R. 2094, 113th Cong. (Nov. 13, 2013).

<sup>18</sup> 42 U.S.C. s. 280g.

<sup>19</sup> 42 U.S.C. s. 280g(1)(F)-(G).

<sup>20</sup> Section 1002.20(3)(i)2., F.S.

<sup>21</sup> *Id.*

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

<sup>23</sup> Rule 6A-6.0251, F.A.C. See Section 1002.20(3)(i)1., F.S.

emergency in the school setting.<sup>24</sup> The State Board of Education, in cooperation with the Florida Department of Health, is required to adopt rules for the use of epinephrine auto-injectors.<sup>25</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 if the epinephrine auto-injector is administered by trained school personnel who follows the protocol and reasonably believes that the student is having an anaphylactic reaction.<sup>26</sup> Florida law provides that the liability protections apply:<sup>27</sup>

- Even if the student’s parent has not been provided notice or has not signed a statement acknowledging that the school district is not liable; and
- Regardless of whether authorization has been given by the student’s parent or the student’s physician.

However, the liability protections do not apply if the trained school personnel’s action is willful and wanton.<sup>28</sup>

### *Other States’ Laws*

All 50 states have laws permitting the use of epinephrine in schools.<sup>29</sup> Twelve states currently require K-12 schools to maintain a supply of epinephrine auto-injectors.<sup>30</sup> A handful of states have legislation specifically allowing post-secondary education institutions to maintain a supply of epinephrine but none require post-secondary education institutions to stock and maintain epinephrine.<sup>31</sup>

### **Effect of Proposed Changes**

HB 99 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 requires K-12 public schools to purchase and maintain a supply of epinephrine auto-injectors. The epinephrine auto-injectors must be maintained in a secure location in the school’s cafeteria and may be contained in other secure locations on the school’s premises. The bill defines “cafeteria” as a space to eat or that serves food with a capacity of at least 50 people.

The bill also requires each state university or FCS institution to purchase a supply of epinephrine auto-injectors. The epinephrine auto-injectors must be maintained in a secure location in each of the cafeterias on a state university’s or FCS institution’s campus. The bill specifies that the definition of “cafeteria” includes dining halls. The bill also provides that state universities or FCS institutions may maintain epinephrine auto-injectors in other secure locations on campus.

The bill models epinephrine auto-injection requirements for state universities and FCS institutions on the requirements for participating K-12 public schools under current law. The bill requires state universities and FCS institutions to adopt a protocol developed by a licensed physician for trained

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<sup>24</sup> Rule 6A-6.0251, F.A.C. The annual action plan is developed in cooperation with the student, parent, healthcare provider, and school personnel for the student with life threatening allergies. The plan 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.

<sup>25</sup> Section 1002.20(3)(i)1., F.S.

<sup>26</sup> Section 1002.20(3)(i)3., F.S.

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> Ashley A. Noble, *Increasing Access to Epinephrine*, National Conference of State Legislatures, April 2016, <https://www.ncsl.org/research/health/increasing-access-to-epinephrine.aspx>.

<sup>30</sup> Food Allergy and Anaphylaxis Connection Team, *School Access to Emergency Epinephrine Federal Legislation*, <https://www.foodallergyawareness.org/government-relations/school-access-to-emergency-epinephrine-act/> (last visited March 16, 2021). The states with laws that require K-12 schools to maintain a supply of epinephrine are Arizona, California, Connecticut, Delaware, Maryland, Michigan, Nebraska, New Jersey, North Carolina, Nevada, Utah, and Virginia.

<sup>31</sup> States with epinephrine stocking legislation specific to post-secondary education institutions include Indiana, Maryland, New Hampshire, New Jersey, Texas, and Virginia. Food Allergy Research & Education, *College and University Access to Epinephrine*, <https://www.foodallergy.org/college-and-university-access-epinephrine> (last visited March 16, 2021).

personnel to administer epinephrine auto-injections. The bill also provides liability protections for state universities and FCS institutions, their employees and agents, and the physician providing the protocol.

The bill establishes that the specified parties are not liable for any injury arising from the use of an epinephrine auto-injector provided the injection is administered by trained school personnel who follow the protocol and whose professional opinion is that the individual is having an anaphylactic reaction. The liability protections apply:

- Even if the individual receiving the epinephrine auto-injection has not been provided notice or has not signed a statement acknowledging that the state university or FCS institution is not liable; and
- Regardless of whether authorization has been given by the individual, the individual's parent if the individual is under age 18, or the individual's physician.

If the trained personnel's action in administering the epinephrine auto-injection is willful and wanton, the liability protections will not apply.

The bill adds state universities and FCS institutions to the definition of "authorized entity," which provides specific authorization to make a stock supply of epinephrine auto-injectors available to certain individuals for administration in an emergency situation.

#### B. SECTION DIRECTORY:

**Section 1.** Amends s. 381.88, F.S., providing that state universities and Florida College System institutions are considered authorized entities for specified purposes relating to the emergency use of epinephrine auto-injectors.

**Section 2.** Amends s. 1002.20, F.S., requiring, rather than authorizing, public schools to purchase or acquire a supply of epinephrine auto-injectors for specified purposes; requiring such epinephrine auto-injectors be maintained in a specified location; defining the term "cafeteria".

**Section 3.** Creates s. 1004.0963, F.S., requiring state universities and Florida College System institutions to purchase or acquire a supply of epinephrine auto-injectors for specified purposes; providing requirements for such supplies of epinephrine auto-injectors; defining the term "cafeteria"; requiring state universities and Florida College System institutions to develop specified protocols; providing requirements for such protocols; providing liability for the use of such epinephrine auto-injectors.

**Section 4.** Provides an effective date of July 1, 2021.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

#### A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

#### B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

See Fiscal Comments.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

State Universities, FCS institutions, and school districts will incur expenses for the purchase and maintenance of a supply of epinephrine auto-injectors.<sup>32</sup> The cost of epinephrine auto-injectors ranges from \$100-\$700 depending upon dosage, brand, pharmacy, and insurance plan.<sup>33</sup> According to the current state contract with Henry Schein, a healthcare products distributor, a 2-pack of epinephrine auto-injectors costs \$696.52.<sup>34</sup> Epinephrine auto-injectors have a shelf-life of approximately 18 months, so the packs must be replaced on a recurring basis.<sup>35</sup> According to the Department of Education, it does not appear that any company provides free epinephrine auto-injectors to public schools.<sup>36</sup> The total cost is dependent upon the number of qualifying “cafeterias” for mandated epinephrine auto-injector placement. Additionally, there will be costs for epinephrine auto-injector storage and training for school personnel.<sup>37</sup>

### III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

None.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

### IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

None.

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<sup>32</sup> See Board of Governors, *Legislative Bill Analysis for HB 99 (2021)*, at 2; Florida Department of Education, *Legislative Bill Analysis for HB 99 (2021)*, at 4-5.

<sup>33</sup> *Id.*

<sup>34</sup> Board of Governors, *Legislative Bill Analysis for HB 99 (2021)*, at 2.

<sup>35</sup> *Id.*

<sup>36</sup> Florida Department of Education, *Legislative Bill Analysis for HB 99 (2021)*, at 5.

<sup>37</sup> See Board of Governors, *Legislative Bill Analysis for HB 99 (2021)*, at 2; Florida Department of Education, *Legislative Bill Analysis for HB 99 (2021)*, at 4-5.