

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 Appropriations

BILL: CS/SB 1196

INTRODUCER: Education Pre-K - 12 Committee and Senators Bean and Hutson

SUBJECT: Emergency Allergy Treatment in Schools

DATE: February 24, 2016

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Graf	Klebacha	ED	Fav/CS
2.	Sikes	Elwell	AED	Recommend: Favorable
3.	Sikes	Kynoch	AP	Pre-meeting

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1196 modifies the definition of an authorized entity for the purposes of emergency allergy treatment and authorizes public and private schools to enter into agreements with wholesale distributors or manufacturers to obtain epinephrine auto-injectors. Specifically, the bill:

- Expands the definition of an authorized entity to include private schools and their employees, agents, and the physician who provides the standing protocol for school epinephrine auto-injectors; changes the purposes for which public and private schools and their employees, agents, and physician are considered an authorized entity; and extends immunity from liability to such schools and their employees, agents, and physician.
- Clarifies that public and private schools may obtain 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.

The bill has no fiscal impact.

The bill takes effect July 1, 2016.

II. Present Situation:

The law provides for parents of students to receive accurate and timely information regarding their child's academic progress and be informed about ways to help their child succeed in

school.¹ Students and parents are afforded numerous rights including, but not limited to, epinephrine² use and supply.³ Additionally, through the “Emergency Allergy Treatment Act,” certain authorized entities⁴ may also obtain and administer epinephrine auto-injectors.⁵

Epinephrine Use

A student who has experienced or is at risk for life-threatening allergic reactions is authorized to carry an epinephrine auto-injector and self-administer epinephrine by auto-injector while in school, participating in school-sponsored activities, or in transit to or from school or school-sponsored activities, if the school secures authorization from the student’s parent and physician.⁶

Epinephrine Supply

Public and Private Schools

Public and private schools may purchase from a wholesale distributor⁷ and maintain in a locked, secure location on its premises a supply of epinephrine auto-injectors for use if a student experiences an anaphylactic reaction.⁸ The participating school district or private school, as applicable, must adopt a protocol developed by a licensed physician for a trained school personnel to administer an epinephrine auto-injection.⁹ The supply of epinephrine auto-injectors may be provided to and used by a student, who is authorized to self-administer epinephrine by auto-injector, or by trained school personnel.¹⁰

Other Authorized Entities

The law specifies that an authorized entity that acquires a stock supply of epinephrine auto-injectors, in accordance with the law, is authorized to make the auto-injectors available to individuals, other than certified individuals, who may administer the auto-injector to a person

¹ Section 1002.20, F.S.

² “Epinephrine injection is used along with emergency medical treatment to treat very serious allergic reactions caused by insect bites or stings, foods, medications, latex, and other causes.” The injection comes as a pre-filled automatic injection device containing a liquid solution to inject under the skin or into the muscle in the outer side of the thigh. It is usually injected as needed at the first sign of a serious allergic reaction. Typically, automatic injection devices contain enough solution for one dose of epinephrine. U.S. Department of Health and Human Services, National Institutes of Health, *Epinephrine Injection*, <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a603002.html> (last visited Jan. 28, 2016).

³ Section 1002.20(3), F.S.

⁴ An “authorized entity” means an entity or organization at or in connection with which allergens capable of causing a severe allergic reaction may be present. The term includes, but is not limited to, restaurants, recreation camps, youth sports leagues, theme parks and resorts, and sports arenas. A school is considered an authorized entity under the “Emergency Allergy Treatment Act,” only for the purposes of conducting educational training programs related to the recognition of allergic symptoms and proper administration of epinephrine auto-injectors. Section 381.88(1)(b) and (5), F.S.

⁵ Sections 381.88(2)(b) and 381.885, F.S.

⁶ Section 1002.20(3)(i)1., F.S.; *see also* Rule 6A-6.0251, F.A.C.

⁷ A “wholesale distributor” means any person engaged in wholesale distribution of prescription drugs in or into this state, including, but not limited to, manufacturers; repackagers; own-label distributors; jobbers; private-label distributors; brokers; warehouses, including manufacturers’ and distributors’ warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; exporters; retail pharmacies; and the agents thereof that conduct wholesale distributions. Section 499.003(54), F.S.

⁸ Sections 1002.20(3)(i)2. and 1002.42(17)(a), F.S.

⁹ *Id.*

¹⁰ *Id.*

believed in good faith to be experiencing a severe allergic reaction if the epinephrine auto-injectors are stored in a locked, secure container and are made available only upon remote authorization after consulting an authorized health care practitioner, as specified.¹¹

Epinephrine Liability

School Districts and Private Schools

The school district or private school, as applicable, and its employees and agents, including the physician who provides the standing protocol for school epinephrine auto-injectors, are not liable for any injury arising from the use of an epinephrine auto-injector administered by trained school personnel who follow the adopted protocol and whose professional opinion is that the student is having an anaphylactic reaction:¹²

- Unless the trained school personnel's action is willful and wanton;
- Notwithstanding that the parents or guardians of the student to whom the epinephrine is administered have not been provided notice or have not signed a statement acknowledging that the school district is not liable; and
- Regardless of whether authorization has been given by the student's parents or guardians or by the student's physician, physician's assistant, or advanced registered nurse practitioner.

Other Individuals

Additionally, the law affords civil liability immunity protections to certain individuals (e.g., authorized health care practitioner, a dispensing health care practitioner or pharmacist and an uncertified person who administers epinephrine auto-injectors in accordance with the law) who possess, administer, or store an epinephrine auto-injector, in accordance with the law.¹³

III. Effect of Proposed Changes:

This bill modifies the definition of authorized entity for the purposes of emergency allergy treatment and authorizes public and private schools to enter into agreements with wholesale distributors or manufacturers¹⁴ to obtain epinephrine auto-injectors at an affordable price.

¹¹ Section 381.885(4), F.S.

¹² Section 1002.20(3)(i)3, F.S.

¹³ Section 381.885(5), F.S.

¹⁴ A "manufacturer" means: (a) a person who prepares, derives, manufactures, or produces a drug, device, or cosmetic; (b) the holder or holders of a New Drug Application (NDA), and Abbreviated New Drug Application (ANDA), Biologics License Application (BLA), or a New Animal Drug Application (NADA), provided such application has become effective or is otherwise approved consistent with s. 499.023; (c) a private label distributor for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged; (d) a person registered under the federal act as a manufacturer of a prescription drug, who is described in paragraph (a), (b), or (c), who has entered into a written agreement with another prescription drug manufacturer that authorizes either manufacturer to distribute the prescription drug identified in the agreement as the manufacturer of that drug consistent with the federal act and its implementing regulations; (e) a member of an affiliated group that includes, but is not limited to, persons described in paragraph (a), (b), (c), or (d), which member distributes prescription drugs, whether or not obtaining title to the drugs, only for the manufacturer of the drugs who is also a member of the affiliated group as defined in s. 1504 of the Internal Revenue Code of 1986, as amended. The manufacturer must disclose the names of all its affiliated group members to the department; or (f) a person permitted as a third party logistics provider, only while providing warehousing, distribution, or other logistics services on behalf of a person described in paragraph (a), (b), (c), (d), or (e). The term "manufacturer" does not include a

Authorized Entity

The bill expands the definition of authorized entity to include private schools and their employees, agents, and the physician who provides the standing protocol for school epinephrine auto-injectors. Currently, public schools and their employees and agents including the physician, as specified, are considered an authorized entity.¹⁵

Additionally, the bill changes the purposes for which public and private schools will be considered as authorized entity. Current law specifies that public schools are considered authorized entity only for the purposes of conducting educational training programs which must include recognition of symptoms of allergic reactions and the administration of epinephrine auto-injectors.¹⁶ The bill changes that purpose by authorizing public and private schools to acquire a stock supply of epinephrine auto-injectors in accordance with the law and make the auto-injectors available to individuals, other than certified individuals, who may administer the auto-injectors to a person believed in good faith to be experiencing a severe allergic reaction, as specified.¹⁷ The bill also expands immunity from liability to the public and private schools and their employees, agents, and physician, as specified.

Epinephrine Supply

The bill authorizes additional ways to obtain epinephrine auto-injectors by permitting schools to enter into arrangements with wholesale distributors or manufacturers. Current law already authorizes public and private schools to purchase a supply of epinephrine auto-injectors from wholesale distributors.

The bill clarifies that public and private schools may obtain 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 if a student experiences an anaphylactic reaction. Such arrangements may involve third party entities other than the wholesale distributors and manufacturers. Accordingly, such manufacturers and third party entities, in addition to the wholesale distributors, may be considered agents of school districts and private schools, as applicable, and may be granted immunity from liability for an injury arising from the use of an epinephrine auto-injector.

The bill eliminates the requirement that the supply of epinephrine auto-injectors obtained by public and private schools must be kept locked on the school premises but continues to maintain current law requiring the schools to maintain the epinephrine auto-injectors in a secure location on the school premises.¹⁸

The bill takes effect July 1, 2016.

pharmacy that is operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter. Section 499.003(30), F.S.

¹⁵ Section 1002.20(3)(i), F.S.

¹⁶ Section 381.88(5), F.S.

¹⁷ Section 381.885(4), F.S.

¹⁸ Sections 1002.20(3)(i)2. and 1002.42(17)(a), F.S.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 381.88, 1002.20, and 1002.42.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Education Pre-K - 12 on February 2, 2016:

The committee substitute maintains the substance of the bill with one modification that removes a requirement that epinephrine auto-injectors obtained by public and private schools must be kept locked.

B. Amendments:

None.

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