

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 1122

INTRODUCER: Senator Bean

SUBJECT: Emergency Allergy Treatment

DATE: March 10, 2014

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	Pre-meeting
2.			AHS	
3.			AP	

I. Summary:

SB 1122 renames the Insect Sting Emergency Treatment Act to the Emergency Allergy Treatment Act (act) and expands the scope to include all emergency allergy reactions.

The educational training for certification of those who may administer epinephrine must be conducted by a nationally recognized organization or the Department of Health (DOH) approved person or entity, rather than a physician. The list of those that may attain a certificate of training changes to a non-exhaustive list of eligible persons from an exclusive list. Eligible persons include, but are not limited to, camp counselors, scout leaders, school teachers, forest rangers, tour guides, and chaperones who successfully complete the training program.

The act replaces references to outdated epinephrine delivery devices and specifies the use and prescription of epinephrine auto-injectors, as follows:

- An authorized health care practitioner may prescribe epinephrine auto-injectors in the name of an authorized entity for storage and use at a later date.
- An authorized certificate holder may provide or administer an epinephrine auto-injector to a person who the certificate holder believes in good faith is suffering a severe allergic reaction regardless of whether or not the person has a prescription for an auto-injector or has previously been diagnosed with an allergy.
- An authorized entity may make auto-injectors available to individuals other than a certified individual if the epinephrine auto-injector is accessed upon remote authorization by an authorized health care provider.

The act provides immunity from civil liability to an authorized health care provider, authorized entity, individual who holds a certificate, a noncertified individual, and a trainer. An authorized entity doing business in Florida is not liable for injuries or related damages that result from the administration of an epinephrine auto-injector by its employees or agents outside of the state if the entity would not have been liable in this state or the other state.

The DOH is authorized to establish rules for the maintenance and supply of the epinephrine auto-injectors.

II. Present Situation:

Anaphylaxis is a severe, whole body allergic reaction to a chemical that has become an allergen.¹ 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 restrict breathing.² Symptoms of anaphylaxis include rapid, weak pulse; skin rash; nausea; and vomiting.³ Common causes include certain medications, some foods, insect bites or stings, and exposure to latex.⁴ Food allergies alone affect approximately 3.8 percent of all United States children and the prevalence of such allergies has increased by 18 percent from 1997 - 2007.⁵ Food allergies are also the most common cause of anaphylaxis in the emergency room.⁶

Anaphylaxis is an emergency situation that requires immediate medical attention. If anaphylaxis is not treated, it will lead to unconsciousness and possible death. Symptoms can vary but can include hives, itching, flushing, swelling of the lips, tongue and roof of the mouth as well as tightness of the throat, chest, dizziness, and headaches.

Initial treatment of anaphylaxis includes the administration of epinephrine, also known as adrenaline. Epinephrine is classified as a sympathomimetic drug, meaning its effects mimic those of the stimulated sympathetic nervous system, which stimulates the heart and narrows the blood vessels. It is available through a prescription from a physician.

Many individuals with severe allergies that have resulted in, or can result in, anaphylaxis carry a pre-filled, auto-injector that contains one dose of epinephrine such as an EpiPen or Twinject.⁷ Epinephrine acts quickly to improve breathing, stimulate the heart to improve breathing by relaxing muscles in the airways, and tighten the blood vessels to reduce swelling of the face, lips and throat. The effects of epinephrine are rapid, but not long-lasting.⁸ When injected, epinephrine eases the symptoms until professional medical treatment is obtained.

In 2012, the Legislature authorized pharmacists to administer, in the event of an allergic reaction, epinephrine using an auto injection delivery system within the framework of an established

¹ U.S. National Library of Medicine, National Institute of Health, *Anaphylaxis*, <http://www.nlm.nih.gov/medlineplus/ency/article/000844.htm> (last visited Mar. 6, 2014).

² Mayo Foundation for Medical Education and Research, *First Aid: Anaphylaxis*, <http://www.mayoclinic.org/first-aid/first-aid-anaphylaxis/basics/art-20056608> (last visited Mar. 6, 2014).

³ *Id.*

⁴ Mayo Clinic, *Anaphylaxis - Definition*, <http://www.mayoclinic.org/diseases-conditions/anaphylaxis/basics/definition/con-20014324> (last visited: Mar. 6, 2014).

⁵ McWilliams, Laurie, et al, *Future Therapies for Food Allergy*, landesbioscience.com, Human Vaccines and Immunotherapeutics, (October 2012), available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3660769/pdf/hvi-8-1479.pdf> (last visited Mar. 6, 2014).

⁶ *Id.*

⁷ U.S. National Library of Medicine, National Institute of Health, *Epinephrine Injection*, <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a603002.html> (last visited: Mar. 6, 2014).

⁸ *Id.*

protocol with a physician. The action was included in legislation that expanded pharmacists' existing authority to administer certain vaccinations under a protocol with a supervising physician.⁹ The legislation further required any participating pharmacist to complete a 3-hour continuing education course as part of his or her re-licensure or recertification on the safe and effective administration of vaccines and epinephrine.¹⁰

For public and private schools, the 2013 Legislature authorized the purchase and maintenance of a supply of epinephrine auto-injectors in a secure, locked location on its premises for use if a student has an anaphylactic reaction.¹¹ Any 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 self-administered by the student or by the school personnel.

The state Board of Education rule for the use of epinephrine auto-injectors is based solely on self-administration.¹² The rule provides that the 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. Written authorization is required from the physician and parent for the student to carry an epinephrine auto-injector and to self-administer epinephrine. The rule requires a school nurse to develop an annual child-specific action plan for an anticipated health emergency in the school setting.¹³

In November 2013, Congress passed and the President signed the *School Access to Emergency Epinephrine Act*.¹⁴ The federal legislation provides a financial incentive to schools to maintain a supply of the medication and permit trained personnel to administer it. Participating schools will be given additional preference for receiving federal asthma-treatment grants. The federal act also requires that the state Attorney General certify that the state's liability protections are adequate for school personnel. Currently, five states require schools to stock epinephrine or will require in the next school year.¹⁵

The marketer and distributor of the EpiPen, Mylan Specialty, offers four free auto-injectors to qualifying public and private kindergarten, elementary, middle and high schools in the United States with a valid prescription.¹⁶

⁹ Chapter Law 2012-60, s. 1, Laws of Florida.

¹⁰ Chapter Law 2012-60, s. 3, Laws of Florida.

¹¹ Chapter Law 2013-63, ss. 1 and 3, Laws of Florida.

¹² Rule 6A-6.0251, F.A.C.; Effective March 24, 2008.

¹³ *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.

¹⁴ Pub. Law 113-48, H.R. 2094, 113th Cong. (Nov. 13, 2013)

¹⁵ The five states that require epinephrine are Maryland, Michigan, Nebraska, Nevada and Virginia. Another 26 states permit schools to stock epinephrine but do not mandate stocking.

¹⁶ See EpiPen4Schools Program, <http://epipen4schools.com/> (last visited Mar. 6, 2014).

III. Effect of Proposed Changes:

Section 1 amends s. 381.88, F.S. This section, and newly created s. 381.885, F.S., may be cited as the Emergency Allergy Treatment Act. Section 381.88, F.S., was previously the Insect Sting Emergency Treatment Act. Definitions for the re-titled act are created for:

- Administrator
- Authorized entity
- Authorized health care practitioner
- Department
- Epinephrine auto-injector
- Self-administration

Under this section, references to “insect stings” are revised to “allergic” reactions to reflect the broader scope of the bill. References to the prescription or administration of epinephrine throughout this act are clarified to specifically identify the epinephrine auto-injector.

The educational training program required for a layperson to obtain a certificate to obtain, produce, or administer epinephrine must be conducted by a nationally recognized organization with experience in training laypersons in emergency health treatment or an entity approved by the DOH, rather than a physician licensed in this state.

The list of eligible persons to whom a certificate of training under this section may be awarded is clarified to include, but not be limited to, a camp counselor, a scout leader, school teacher, forest ranger, tour guide, or chaperone who successfully complete the training program. The current list is an exclusive list of eligible entities.

Under the bill, a certificate holder is authorized to:

- Receive a prescription for epinephrine auto-injectors from either an authorized health care practitioner or the DOH,
- Possess the prescribed epinephrine auto injector; and,
- Administer the prescribed epinephrine auto-injector to a person experiencing a severe allergic reaction when a physician is not immediately available.

Section 2 creates s. 381.885, F.S., to permit an authorized health care practitioner to prescribe epinephrine auto-injectors to an authorized entity and pharmacists to dispense the prescription in the name of the authorized entity. The authorized entity is permitted to acquire and maintain a supply of epinephrine auto-injectors in accordance with its instructions and any rules established by the DOH. The authorized entity is also permitted to designate employees or agents who hold a certificate that is issued under s. 381.88, F.S., to be responsible for the storage, maintenance, and oversight of the epinephrine auto-injector supply.

This section provides authorization for individuals who hold a certificate from the training program to use the epinephrine auto-injectors to:

- Provide to a person who the certified individual believes in good faith is experiencing a severe allergic reaction for that person’s immediate self-administration; or,

- Administer the epinephrine auto-injector to a person who the certified individual believes in good faith is experiencing a severe allergic reaction.

Provision of the epinephrine auto-injector by the certified individual under either scenario may occur regardless of whether the affected person has a prescription or has been previously diagnosed with an allergy.

An authorized entity that acquires a stock supply of epinephrine auto-injectors pursuant to a prescription from an authorized health care practitioner may also make the auto-injectors available to non-certified individuals. These non-certified individuals may administer the auto-injector in the following circumstances:

- Non-certified individual believes in good faith person is experiencing severe allergic reaction;
- The auto-injector is stored in a locked, secure container; and,
- The auto-injectors can only be accessed upon remote authorization by an authorized health care provider after consultation with the authorized health care practitioner by audio, televideo or other electronic communication. The bill provides that this consultation is not the practice of telemedicine or a violation of professional practice standards.

The administration of epinephrine auto-injector under this section is specifically identified as not the practice of medicine.

Under the bill, immunity from liability for civil damages relating to administration or self-administration of an epinephrine auto-injector, the failure to administer an epinephrine auto-injector or any other act or omission committed in good faith is provided to the following individuals or entities:

- An authorized health care practitioner who prescribes epinephrine auto-injectors to an authorized entity or to a certificate holder pursuant to s. 381.88, F.S.;
- An authorized entity that possess or makes auto-injectors available;
- An individual that who holds a certificate pursuant to s. 381.88, F.S.;
- A noncertified individual provided epinephrine auto-injectors by an authorized entity upon an authorized health care practitioner's authorization under s. 381.885(4), F.S.; and,
- Any person who conducts training under s. 381.88, F.S.

Immunity from liability is also provided to authorized entities doing business in this state for injuries or related damages that relate to the provision of epinephrine auto-injectors by its employees or agents outside this state if the entity or its employees or agents would not have been liable for such injuries or related damages had the provision or administration occurred in this state.

The immunity granted under SB 1122 does not reduce, limit or eliminate any other immunity or defense that may be available under state law, including the immunity provided under s. 768.13, F.S. This section is known as Florida's *Good Samaritan Act* and provides, in part:

(2)(a) Any person, including those licensed to practice medicine, who gratuitously and in good faith renders emergency care or treatment either

in direct response to emergency situations related to and arising out of a public health emergency declared pursuant to s. 381.00315, a state of emergency which has been declared pursuant to s. 252.36, or at the scene of an emergency outside of a hospital, doctor's office, or other place having proper medical equipment, without objection of the injured victim or victims thereof, shall not be held liable for any civil damages as a result of such care or treatment or as a result of any act or failure to act in providing or arranging further medical treatment where the person acts as an ordinary reasonably prudent person would have acted under the same or similar circumstances.

(b)1. Any health care provider, including a hospital licensed under chapter 395, providing emergency services pursuant to obligations imposed by 42 U.S.C. s. 1395dd, s. 395.1041, s. 395.401, or s. 401.45 shall not be held liable for any civil damages as a result of such medical care or treatment unless such damages result from providing, or failing to provide, medical care or treatment under circumstances demonstrating a reckless disregard for the consequences so as to affect the life or health of another.

Section 3 provides the effective date of the act is July 1, 2014.

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:

The bill identifies "authorized entities" as any entity or organization where allergens could be capable of causing a reaction. This could include restaurants, camps, youth sports, private schools, theme parks, and sports arenas. Businesses and organizations achieving certification would be eligible to stock and maintain the epinephrine auto-injectors for use by their customers or administration by their certified employees or agents on affected clients.

Immunity from civil liability has also been provided under the bill to certified organizations and certificate holders to encourage participation.

There is a cost to acquire the epinephrine auto-injectors and it is unclear who would bear the cost of the prescription. At least one distributor of the medication provides a limited, free supply of auto-injectors to schools.

C. Government Sector Impact:

The DOH is required to establish rules for the storage of epinephrine auto-injector supplies by authorized entities and approve entities or individuals for the educational training program. The DOH is also identified as an entity that may prescribe epinephrine auto-injectors to certificate holders. There may be a fiscal impact to implement and conduct these activities; however, the DOH has not filed an impact statement to identify these costs.

Other governmental agencies that may be impacted would be any local municipalities or school boards that elect certification as an authorized entity for storage and maintenance of epinephrine auto-injectors. School districts, individual schools, parks and recreation departments would be likely entities that would participate in the program.

There is a cost to acquire the epinephrine auto-injectors and it is unclear who would bear the cost of the prescription. At least one distributor of the medication provides a limited, free supply of auto-injectors to schools.

VI. Technical Deficiencies:

Lines 87 and 88 should be:

~~thereof to possess and administer,~~ to possess and in an emergency situation when a physician is not immediately available.

On line 75, the bill contains a cross-reference to subsection (4) that is no longer accurate as the educational training program is now under subsection (5).

There could be an additional conflict between subsections (4) and (5). Subsection (5) requires DOH approval by the training program but does not address the DOH being authorized to conduct its own training program, however, subsection (4) says the DOH can also perform the training program but does not address approval of that program.

VII. Related Issues:

There are three other state statutes that address administration of epinephrine auto-injectors:

- Section 1002.20, F.S., relating to epinephrine supplies and authorization for student self-administration in public schools;

- Section 1002.42, F.S., relating to epinephrine supplies and authorization for student self-administration in private schools; and,
- Section 465.189, F.S.; relating to pharmacist administration of vaccines and epinephrine auto-injections.

All of these statutes require the third party (the school or the pharmacist) to have an approved protocol with a supervising physician prior to administration of epinephrine auto-injectors. For the school related statutes, the statute addresses only self-administered injections by a student authorized to self-administer and by rule, the state Board of Education has required written authorization from the physician and the student's parent for the student to carry and self-administer epinephrine.

The bill describes a school as an authorized entity only for the purposes of subsection (5), the training program. Section 1002.20(3)(i), F.S., already authorizes schools to purchase epinephrine auto-injectors from wholesale distributors and to maintain a supply of injectors in a secure, locked location for student use. It is unclear if the intent of this language is to limit the role of the schools to only being an authorized entity for training and preclude them as sites for storage, administration or distribution to certified individuals as created under this bill. A certificate of training may still be issued to a school teacher under the bill, yet the schools appear to be limited to student self-administration under s. 1002.20, F.S., since they are authorized entities only for training.

For pharmacists administering epinephrine auto-injectors, the statute also requires continuing education credit on the safe and effective administration of vaccines and epinephrine auto-injection as part of their biennial relicensure or recertification. It is unclear that if a pharmacist, who is not precluded under SB 1122 from being recognized as an authorized entity or certificate holder, would be required to meet complete both the continuing education requirements under s. 465.009(6)(a), F.S., and the education training program or if completion of one of requirements would be sufficient.

Additionally, on lines 123 - 127, the person suffering the adverse allergic reaction is not required to provide consent, if capable of providing. The student self-administration requirements specifically require parental and physician authorization for the epinephrine auto-injector. In any other situation where medical care is rendered, authorization for medical treatment is required, if capable.

On lines 160 - 167, the act provides immunity from civil liability for a broad range of individuals, including activity by an employee of an authorized entity doing business in this state that may occur outside of the state. In order to enjoy these broad protections under Florida law, the individual should have some additional nexus to Florida beyond what is currently provided in the bill.

VIII. Statutes Affected:

This bill substantially amends the section 381.88 of the Florida Statutes.
This bill creates section 381.885 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.

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