

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: PCS/CS/SB 1122 (578150)

INTRODUCER: Appropriations Committee (Recommended by Appropriations Subcommittee on Health and Human Services); Health Policy Committee; and Senator Bean and others

SUBJECT: Emergency Allergy Treatment

DATE: April 21, 2014

REVISED: _____

| | ANALYST | STAFF DIRECTOR | REFERENCE | ACTION |
|----|------------------|----------------|------------|--------------------|
| 1. | <u>Lloyd</u> | <u>Stovall</u> | <u>HP</u> | <u>Fav/CS</u> |
| 2. | <u>Brown/Loe</u> | <u>Pigott</u> | <u>AHS</u> | <u>Fav/CS</u> |
| 3. | <u>Brown/Loe</u> | <u>Kynoch</u> | <u>AP</u> | <u>Pre-meeting</u> |

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

PCS/CS/SB 1122 renames the Insect Sting Emergency Treatment Act to the Emergency Allergy Treatment 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 an individual or entity approved by the Department of Health (DOH), rather than a physician. 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The bill replaces references to outdated epinephrine delivery devices and specifies the use and prescription of epinephrine auto-injectors.

The bill provides immunity from civil liability to certain persons who possess, administer, or store an epinephrine auto-injector in compliance with the Emergency Allergy Treatment Act under specified parameters.

The bill has an insignificant fiscal impact.

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 may 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 to 2007.⁵ Food allergies are also the most common cause of anaphylaxis cases in hospital emergency rooms.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, tightness of the throat and 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 by stimulating the heart to improve breathing, relaxing muscles in the airways, and tightening 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 protocol with a physician. This provision 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

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.*

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

a three-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 school 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 administered by school personnel or self-administered by the student.

The state Board of Education's 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 Barack Obama signed the School Access to Emergency Epinephrine Act.¹⁴ The federal legislation provides a financial incentive for 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 a state attorney general certify that the state's liability protections are adequate for school personnel. Currently, five states require or will require schools to stock epinephrine 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

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

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).

- 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 are clarified to specifically identify the epinephrine auto-injector.

Under the bill, 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 completes 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 authorizes 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 the auto-injectors’ instructions and any additional requirements 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.

The bill 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.

Use of the epinephrine auto-injector by the certified individual under either scenario may occur under the bill 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 via 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, that a 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-injectors under this section is specifically identified as not the practice of medicine.

The bill provides immunity from civil liability to any person, as defined in s. 1.01,¹⁷ who possesses, administers, or stores an epinephrine auto-injectors under the bill, including:

- An authorized health care practitioner;
- A dispensing health care practitioner or pharmacist;
- Any person certified under the Emergency Allergy Treatment Act;
- Any non-certified individual who receives an epinephrine auto-injectors from an authorized entity for purposes of administering it to another person suffering from a severe allergic reaction; and
- A trainer who conducts an educational training program for recognizing the symptoms of a severe allergic reaction and administering an epinephrine auto-injectors.

The immunity granted under CS/CS/SB 1122 is, by reference, identical to 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

¹⁷ Section 1.01, F.S., defines "person" to include individuals, children, firms, associations, joint adventures, partnerships, estates, trusts, business trusts, syndicates, fiduciaries, corporations, and all other groups or combinations.

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 that the bill's effective date 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:

Under PCS/CS/SB 1122, private "authorized entities," such as restaurants, camps, youth sports, private schools, theme parks, and sports arenas could incur costs to stock and maintain the epinephrine auto-injectors. This is voluntary and the cost is indeterminate.

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

C. Government Sector Impact:

The DOH is required to establish rules and indicates that these costs can be absorbed within existing resources.

Other governmental agencies that may be impacted are 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 likely be entities that 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:

None.

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. The school-related statutes address 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 s. 381.88(5), F.S., which refers to the bill's provisions for educational training programs. 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 the bill 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 bill also requires continuing education credit on the safe and effective administration of vaccines and epinephrine auto-injection as part of their biennial re-licensure or recertification. It is unclear whether a pharmacist – who is not precluded under the bill from being recognized as an authorized entity or certificate holder – would be required to complete both the continuing education requirements under s. 465.009(6)(a), F.S., and the education training program, or whether completion of one of the requirements would be sufficient.

In lines 123 to 127, the person who is believed to be suffering an adverse allergic reaction is not required to provide consent for treatment, if he or she is capable. 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 the person who is believed to need treatment is capable.

VIII. Statutes Affected:

This bill substantially amends 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.)

Recommended CS/CS by Appropriations Subcommittee on Health and Human Services on April 2, 2014:

The CS revises the bill's civil liability immunity provisions and makes the bill's liability protections identical to those under s. 768.13, F.S.

CS by Health Policy on March 11, 2014:

The CS makes technical corrections to update a cross reference that was re-numbered and to clarify who is authorized to possess and administer a prescription of an epinephrine auto-injector to a person suffering a severe allergic reaction.

B. Amendments:

None.