

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1131 Emergency Allergy Treatment

SPONSOR(S): Health Quality Subcommittee; Hudson

TIED BILLS: **IDEN./SIM. BILLS:** SB 1122

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	12 Y, 0 N, As CS	Poche	O'Callaghan
2) Health & Human Services Committee		Poche	Calamas

SUMMARY ANALYSIS

An allergy is a disease of the immune system that causes an overreaction to substances called allergens. An allergy is also described as a hypersensitivity disorder in which the immune system reacts to substances in the environment that are normally harmless. An antigen is any substance that causes the human immune system to produce antibodies against it. An antigen may be a foreign substance from the environment, such as pollen, pet dander, or food, which can enter the body through inhalation, ingestion, injection, or absorption. If an antigen causes an allergic reaction when it enters the body, it is considered an allergen.

Anaphylaxis is a severe, whole body allergic reaction to an allergen. 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. Symptoms of anaphylaxis include a rapid and weak pulse, skin rash, nausea and vomiting. The number of people with severe allergies has increased significantly during that last ten years, with the current incidence rate estimated to be 49.8 per 100,000 persons. The only treatment for anaphylaxis caused by an allergy is the administration of epinephrine, usually through an auto-injector (EAI), which provides a premeasured dose of the medication based on body weight. An epinephrine auto-injector is only available by prescription.

House Bill 1131 amends the law governing insect sting emergency treatment in s. 381.88, F.S., by creating new and expanding existing provisions related to emergency allergy treatment and making EAI's available in more public places. The bill permits certain authorized entities, such as restaurants and youth sports leagues, to obtain a prescription for EAI's. Authorized entities may stock and store EAI's, and authorized entities' employees who have completed certain training and are certified may provide an EAI to a person suffering a severe allergic reaction for self-administration, administer an EAI to a person suffering a severe allergic reaction, or provide an EAI to a person to administer it to another person suffering a severe allergic reaction. The bill makes any act or omission committed under the Emergency Allergy Treatment Act, consisting of ss. 381.88, F.S., and 381.885, F.S., subject to the civil liability immunity protections of the Good Samaritan Act in s. 768.13, F.S.

The bill does not appear to have a fiscal impact on state or local governments.

The bill provides an effective date of July 1, 2014.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Allergies

An allergy is a disease of the immune system that causes an overreaction to substances called allergens.¹ An allergy is also described as a hypersensitivity disorder in which the immune system reacts to substances in the environment that are normally harmless.² An antigen is any substance that causes the human immune system to produce antibodies against it.³ An antigen may be a foreign substance from the environment, such as pollen, pet dander, or food, which can enter the body through inhalation, ingestion, injection, or absorption.⁴ If an antigen causes an allergic reaction when it enters the body, it is considered an allergen. Common allergies include indoor allergies, outdoor allergies, food allergies, latex allergies, insect allergies, skin allergies, and eye allergies.⁵

Symptoms

The following are examples of symptoms associated with common allergic diseases.⁶

- Allergic rhinitis (“hay fever,” “seasonal,” or “nasal” allergy)
 - Nasal stuffiness
 - Sneezing
 - Nasal itching
 - Itching of the roof of the mouth
 - Itching of the ears
- Latex allergy
 - Hand dermatitis
 - Sneezing and other respiratory distress
 - Coughing
 - Wheezing
 - Shortness of breath
- Insect sting or bite allergy
 - Pain, itching, and swelling at site of sting
- Allergic conjunctivitis (eye allergy)
 - Itchy and watery eyes
 - Eyelid distress

¹ Asthma and Allergy Foundation of America, *Allergy Overview-What Causes Allergies*, available at <http://aafa.org/display.cfm?id=9&cont=79> (last viewed on March 16, 2014).

² U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, *Trends in Allergic Conditions Among Children: United States, 1997-2011*, NCHS Data Brief No. 121, page 1, May 2013, available at www.cdc.gov/nchs/data/databriefs/db121.pdf (last viewed on March 16, 2014).

³ U.S. Dept. of Health and Human Services, National Institutes of Health, U.S. National Library of Medicine, MedlinePlus, *Antigen*, available at www.nlm.nih.gov/medlineplus/ency/article/002224.htm (last viewed on March 16, 2014).

⁴ See supra, FN 1.

⁵ Id.

⁶ Asthma and Allergy Foundation of America, *Allergy Overview-What Are Allergies*, available at <http://aafa.org/display.cfm?id=9&cont=78> (last viewed on March 16, 2014).

Allergies in Children

Allergic conditions are among the most common medical conditions affecting children in the United States.⁷ The most common allergies in children include food allergies, skin allergies, and respiratory allergies.⁸ The prevalence of food and skin allergies have increased in children aged 0 to 17 years from 1997 to 2011.⁹ For food allergies, the prevalence rose from 3.4 percent in 1997 to 1999 to 5.1 percent in 2009 to 2011.¹⁰ For skin allergies, the prevalence rose from 7.4 percent in 1997 to 1999 to 12.5 percent in 2009 to 2011.¹¹

Food Allergies

As many as 15 million people in the United States have one or more food allergies- 9 million adults and 6 million children, which translates 4 percent of all adults and 8 percent of all children.¹² Eight foods account for 90 percent of all food allergic reactions:

- Milk
- Eggs
- Peanuts
- Tree nuts, such as walnuts and pecans
- Wheat
- Soy
- Fish, such as salmon
- Shellfish, such as shrimp and lobster

In infants and children, egg, milk, peanut, tree nuts, soy and wheat are the most common food allergies, while adults have the most common food allergies to shellfish, peanut, tree nuts, and fish.¹³ According to the National Institute of Allergy and Infectious Disease, children usually outgrow an allergy to egg, milk, and soy. Children do not outgrow a peanut allergy. People who develop an allergy as an adult will usually have the allergy for life.

Symptoms of food allergies appear from within a few minutes to two hours after a person has ingested the food which she or he is allergic.¹⁴ Food allergic reactions can include:

- Hives
- Flushed skin or rash
- Tingling or itchy sensation in the mouth
- Face, tongue, or lip swelling
- Vomiting and/or diarrhea
- Abdominal cramps

⁷ See supra, FN 2 (citing, e.g., Friedman, AH, Morris, TL. *Allergies and anxiety in children and adolescents: A review of the literature*. J Clin Psychol Med Settings 13(3):318-31, 2006.).

⁸ Id.

⁹ Id.

¹⁰ Id. at page 2.

¹¹ Id.

¹² Food Allergy Research and Education, *Food Allergy Facts and Statistics for the U.S.*, available at www.foodallergy.org/document.doc?id=194 (citing, e.g., Gupta, RS, Springston, MR, et al. *The prevalence, severity, and distribution of childhood food allergy in the United States*. J. Pediatrics.2011; 128.doi: 10.1542/peds.2011-0204, and Liu, AH, Jaramillo, R, et al. *National prevalence and risk factors for food allergy and relationships to asthma: Results from the National Health and Nutrition Examination Survey 2005-2006*. J Allergy ClinImmunol.2010; 126: 798-806)(last viewed on March 16, 2014).

¹³ U.S. Dept. of Health and Human Services, National Institutes of Health, National Institute of Allergy and Infectious Diseases, *Common Food Allergies in Infants, Children, and Adults*, available at www.niaid.nih.gov/topics/foodallergy/understanding/Pages/foodAllergy8Allergens.aspx (last viewed on March 16, 2014).

¹⁴ U.S. Food and Drug Administration, *Food Allergies-What You Need to Know*, page 2, available at www.fda.gov/downloads/Food/ResourcesForYou/Consumers/UCM220117.pdf (last viewed on March 16, 2014).

- Coughing or wheezing
- Dizziness and/or lightheadedness
- Swelling of the throat and vocal cords
- Difficulty breathing
- Loss of consciousness¹⁵

More severe allergic reactions can result in anaphylaxis, a life-threatening condition discussed in more detail below. Each year in the United States, it is estimated that anaphylaxis caused by food allergies result in 30,000 emergency room visits, 2,000 hospitalizations, and 150 deaths.¹⁶

There is no cure for food allergies. Only avoidance of food allergens and timely recognition and management of allergic reactions can prevent serious health problems.¹⁷

Anaphylaxis

Anaphylaxis is a severe, whole body allergic reaction to an allergen.¹⁸ 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.¹⁹ Symptoms of anaphylaxis include a rapid and weak pulse, skin rash, nausea and vomiting.²⁰ The number of persons with a severe allergy has increased significantly during the last ten years, with the current incidence rate estimated to be 49.8 per 100,000 persons.²¹

Anaphylaxis is an emergency situation that requires immediate medical attention. If anaphylaxis is not treated, it will lead to unconsciousness and possible death. Initial treatment of anaphylaxis includes the administration of epinephrine, also known as adrenaline, to improve breathing by relaxing muscles in the airways, stimulate the heart, and tighten the blood vessels to reduce swelling. 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 an EpiPen²² or Auvi-Q.²³ Both products are epinephrine auto-injectors (EAI)s which consist of a syringe prefilled with an appropriate dose of epinephrine and a retractable needle that is protected by a safety guard to prevent injury or reuse. There are two dosages available for the EpiPen and Auvi-Q; for children weighing between 33 and 66 pounds, the dosage is .15 mg and for children and adults weighing more than 66 pounds, the dosage is .30 mg.²⁴ Once injected into the outer thigh, epinephrine eases the symptoms of anaphylaxis until professional medical treatment is received.

¹⁵ Id.

¹⁶ Id.

¹⁷ See supra, FN 12.

¹⁸ U.S. Dept. of Health and Human Services, National Institutes of Health, U.S. National Library of Medicine, National Center for Biotechnology Information, *Anaphylaxis*, available at: <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001847/> (last viewed March 16, 2014).

¹⁹ Food Allergy Research and Education, *About Food Allergies-About Anaphylaxis*, available at www.foodallergy.org/anaphylaxis (last viewed on March 16, 2014); see also U.S. Dept. of Health and Human Services, National Institutes of Health, National Institute of Allergy and Infectious Diseases, *Food Allergy: What is Anaphylaxis?*, available at www.niaid.nih.gov/topics/foodallergy/understanding/Pages/anaphylaxis.aspx (last viewed on March 16, 2014).

²⁰ Id.

²¹ Stephanie Guerlain, PhD, et al., *A comparison of 4 epinephrine autoinjector delivery systems: usability and patient preference*, NIH Public Access Author Manuscript, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2892620/> (citing Decker WW, Campbell, RL, Luke A, et al., *The etiology and incidence of anaphylaxis in Rochester, Minnesota: a report from the Rochester Epidemiology Project*, J Allergy Clin Immunol., 2008;122:1161-1165)(last viewed on March 16, 2014).

²² EpiPen and EpiPen Jr are manufactured for Mylan Specialty, L.P., a Pfizer company.

²³ Auvi-Q is manufactured by Sanofi.

²⁴ Mylan Specialty, L.P., *Epipen and Epipen Jr Patient Information*, available at www.epipen.com/~media/BBAC09E9BE9346A3B9C81EC175B7FD3E.ashx (last viewed on March 16, 2014); see also

Recent Florida Laws about EAls

In 2012, the Legislature passed House Bill 509,²⁵ which authorizes a pharmacist to administer epinephrine using an EAI in the event of an allergic reaction from a vaccine.²⁶ Pharmacists who obtain certification and are authorized to provide vaccines are required to complete a 3-hour continuing education course every two years on the safe and effective administration of vaccines.²⁷ The 3-hour course must be offered by a statewide professional association of physicians in this state and is considered part of the 30-hour continuing education requirement for biennial licensure renewal and recertification.²⁸ If a pharmacist fails to take the 3-hour course, the authorization to administer vaccines or epinephrine is revoked.²⁹

In 2013, the Legislature passed Senate Bill 284,³⁰ which gives an option to public and private schools to purchase and store EAls on campus.³¹ A school that stores EAls must adopt a physician's protocol for administering the device.³² The law provides that except for willful and wanton conduct, trained school employees and the physicians who develop the school's protocol on administering the EAls are protected from liability that may result from administering EAls.³³

Good Samaritan Act

The Good Samaritan Act, found in s. 768.13, F.S., provides immunity from civil liability for those who render emergency care and treatment to individuals in need of assistance. The statute provides immunity from liability for civil damages to any person who:

- Gratuitously and in good faith renders emergency care or treatment either in direct response to emergency situations or at the scene of an emergency, without objection of the injured victim, if that person acts as an ordinary reasonably prudent person would have acted under the same or similar circumstances.³⁴
- Participates in emergency response activities of a community emergency response team if that person acts prudently and within scope of his or her training.³⁵
- Gratuitously and in good faith renders emergency care or treatment to an injured animal at the scene of an emergency if that person acts as an ordinary reasonably prudent person would have acted under the same or similar circumstances.³⁶

Sanofi, *Auvi-Q Patient Brochure*, available at www.auvi-q.com/media/pdf/Patient-Brochure.pdf (last viewed on March 16, 2014).

²⁵ Ch. 2012-60, Laws of Fla.

²⁶ S. 465.189(3), F.S.

²⁷ S. 465.009(6)(a), F.S.

²⁸ Id.

²⁹ S. 465.009(6)(c), F.S.

³⁰ Ch. 2013-63, Laws of Fla.

³¹ S. 1002.20(3)(i)2., F.S. (public schools) and s. 1002.42(17)(a), F.S. (private schools).

³² Id.

³³ S. 1002.20(3)(i)3., F.S. (public schools) and s. 1002.42(17)(b), F.S. (private schools).

³⁴ Section 768.13(2)(a), F.S.

³⁵ Section 768.13(2)(d), F.S.

³⁶ Section 768.13(3), F.S.

Effect of Proposed Changes

House Bill 1131 amends the law governing insect sting emergency treatment by creating new and expanding existing provisions in s. 381.88, F.S., related to emergency allergy treatment, and by creating s. 381.885, F.S. Together, these laws are to be referred to as the “Emergency Allergy Treatment Act” (“the Act”).

The bill defines several terms for the purposes of the Act, including “administer,” “authorized health care practitioner,” “department,” and “self-administration.” The following definitions are important for the operation of the Act:

- “Authorized entity” is defined as 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. The term also includes a school for the purposes of the educational training programs for recognizing the symptoms of a severe allergic reaction and administering an epinephrine auto-injector.
- “Epinephrine auto-injector” is defined as a single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body. Examples of EAI are the EpiPen and the Auvi-Q, discussed above.

Section 381.88, F.S., provides for the certification of individuals who administer life-saving treatment to persons who have a severe adverse reaction to an insect sting. The bill deletes references to insect stings and includes the more general term “allergic reactions.” Current law only authorizes physicians to conduct educational training programs to teach people to recognize the symptoms of a reaction to an insect sting and the proper administration of epinephrine. The bill authorizes, instead, a nationally recognized organization that trains individuals in emergency health treatment or an entity or individual approved by the Department of Health (DOH) to conduct the training programs. The bill also slightly changes the requirements for training, which must prepare persons to recognize the symptoms of a reaction to food, insect stings, and other allergens and administer an EAI.

The bill expands the category of persons who may receive a certificate of training to include a person who has, or reasonably expects to have, responsibility for or contact with at least one other person. This provision would allow anyone who works around at least one other person to obtain a certificate of training in recognizing a severe allergic reaction and administering an EAI, if necessary. Current law restricts the category of persons who may receive a certificate to only those who are responsible for someone who has severe adverse reactions to insect stings, which requires a measure of prior knowledge.

The bill permits the holder of a certificate of training to receive a prescription for EAI from a physician or the department. The bill also authorizes a certificate holder to possess an EAI and administer it when a person is experiencing a severe allergic reaction.

The bill creates s. 381.885, F.S., relating to EAI and the emergency administration of EAI. The new section of law permits an authorized health care practitioner to prescribe, and a pharmacist to dispense, EAI to authorized entities. The law permits a certificate holder, either on the premises of an authorized entity or in connection with an authorized entity, to provide and administer an EAI to a person if the certificate holder has a good faith belief the person is suffering a severe allergic reaction.

The bill allows an authorized entity to acquire and stock a supply of EAI pursuant to a prescription and in accordance with the EAI instructions for use and any other requirements established by the DOH. An authorized entity is required to designate someone who is a certificate holder to be responsible for the EAI storage, maintenance, and general oversight.

The bill permits an authorized entity to make an EAI available to a non-certified individual for administration to a person believed in good faith to be suffering a severe allergic reaction if the following occurs:

- The EAI is stored in a secure, locked container; and
- The EAI is provided to the non-certified person after remote authorization by an authorized health care practitioner after consulting the practitioner by audio, televideo, or other similar means of electronic communication.

The bill applies the civil liability immunity protections in the Good Samaritan Act³⁷ to any person, as defined in s. 1.01,³⁸ including:

- An authorized health care practitioner;
- A dispensing health care practitioner;
- Any person certified under the Act;
- Any non-certified individual who receives an EAI 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 EAI.

The bill would extend civil liability immunity protections under the Good Samaritan Act to an authorized entity as it is captured within the definition of “person.”

The bill provides an effective date of July 1, 2014.

B. SECTION DIRECTORY:

Section 1: Amends s. 381.88, F.S., relating to insect sting emergency treatment.

Section 2: Creates s. 381.885, F.S., relating to epinephrine auto-injectors; emergency administration.

Section 3: Provides an effective date of July 1, 2014.

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:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

³⁷ S. 768.13, F.S.

³⁸ S. 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.

An authorized entity which opts to stock EAls must ensure at least one individual holds a certificate from an education training program which is evidence the individual can recognize the symptoms of a severe allergic reaction and administer an EAI. Each certificate costs \$25.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or local governments.

2. Other:

The bill grants civil liability immunity protection under the Good Samaritan Act in s. 768.13, F.S., to several individuals and entities involved with the provision or administration of, or the failure to provide or administer, EAls including authorized entities, individuals suffering from a severe allergic reaction, or other individuals who administer EAls to a person suffering from a severe allergic reaction. Immunity provisions may restrict an injured person's ability to seek redress for injury and damages in court.

The state constitution provides that the "courts shall be open to every person for redress of any injury, and justice shall be administered without sale, denial or delay." In *Kluger v. White*, the Florida Supreme Court held that:

[w]here a right of access to the courts for redress for a particular injury has been provided the Legislature is without power to abolish such a right without providing a reasonable alternative to protect the rights of the people of the State to redress for injuries, unless the Legislature can show an overpowering public necessity for the abolishment of such right, and no alternative method of meeting such public necessity can be shown.³⁹

B. RULE-MAKING AUTHORITY:

The DOH has sufficient rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

At line 47, the word "department" is capitalized in current law.

At line 106, to clarify what instructions must be followed regarding the storage of EAls by an authorized entity, it is suggested that the new language be changed to read, "accordance with the epinephrine auto-injector manufacturer's instructions for."

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 18, 2014, the Health Quality Subcommittee adopted two amendments and reported the bill favorable as a committee substitute. The amendments made the following changes to the bill:

- Removed the broad civil liability immunity provisions;

³⁹ See *Kluger v. White*, 281 So.2d 1, 4 (Fla. 1973).

- Provided civil liability immunity protections under the Good Samaritan Act in s. 768.13, F.S., to persons, as defined in s. 1.01, F.S., including:
 - An authorized health care practitioner;
 - A dispensing health care practitioner;
 - Any person certified under the Act;
 - Any non-certified individual who receives an EAI 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 EAI.
- Corrected a cross-reference to subsection (5) within the bill.

The analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.