Date of Hearing: April 3, 2024

ASSEMBLY COMMITTEE ON EDUCATION
Al Muratsuchi, Chair
AB 2714 (Wallis) – As Introduced February 14, 2024

SUBJECT: Pupil health: epinephrine delivery systems

SUMMARY: Replaces references to "emergency epinephrine auto-injectors" with "emergency epinephrine delivery systems" in relation to the authority of schools to store the medication, to have trained volunteers available to administer it to students suffering from anaphylaxis, and for students to carry and self-administer the medication. Specifically, **this bill**:

1) Replaces references to "emergency epinephrine auto-injectors" to "emergency epinephrine delivery systems" in referring to the authority of schools to store the medication, to have trained volunteers available to administer it to students suffering from anaphylaxis, and for students to carry and self-administer the medication.

2) Makes technical and conforming changes.

EXISTING LAW:

1) Requires the governing board of any school district to give diligent care to the health and physical development of pupils, which may include employing properly certified persons for the work. (Education Code (EC) Section 49400)

2) Requires a school district, county office of education (COE), and charter school to provide emergency epinephrine auto-injectors to school nurses or trained volunteers, and allows those individuals to utilize epinephrine auto-injectors to provide emergency medical aid to persons suffering from an anaphylactic reaction. (EC 49414)

3) Authorizes each public and private elementary and secondary school in the state to voluntarily determine, as specified, whether or not to make emergency epinephrine auto-injectors and trained personnel available at its school. (EC 49414)

4) Permits each public and private school to designate one or more volunteers to receive initial and annual refresher training, based on specified standards, regarding the storage and emergency use of an epinephrine auto-injector from the school nurse or other qualified person designated by an authorizing physician or surgeon. (EC 49414)

5) Requires a school nurse, or if the school does not have a school nurse or the school nurse is not onsite or available, a school administrator, to obtain from the school district physician, the medical director of the local health department, or the local emergency medical services director a prescription for epinephrine auto-injectors. (EC 49414)

6) Requires the Superintendent of Public Instruction (SPI) to review, every five years, or sooner, standards of training for the administration of epinephrine auto-injectors by consulting with organizations and providers with expertise in administering epinephrine auto-injectors and administering medication in a school environment. (EC 49414)

7) Sets minimum requirements for the training described above, requiring certain topics about anaphylaxis and procedures for rendering emergency treatment to be included in the training, and for the training to be consistent with guidelines of the federal Centers for Disease Control and Prevention (CDC). (EC 49414)

8) Requires a school district, COE, or charter school to ensure that each employee who volunteers will be provided defense and indemnification by the school district, COE, or charter school for any and all civil liability, as specified and requires that this information be provided in writing and retained in the volunteer's personnel file. (EC 49414)

9) Defines "volunteer," and "trained personnel" as an employee who has volunteered to administer epinephrine auto-injectors to a person suffering, or reasonably believed to be suffering, from anaphylaxis and who has been designated by a school, and has received training. (EC 49414)

10) Requires the Commission on Teacher Credentialing (CTC), upon verification of fingerprint clearance through a criminal background check, to issue an Activity Supervisor Clearance Certificate to individuals working with students in a student activity program sponsored by a school district, including, but not limited to, scholastic programs, interscholastic programs, and extracurricular activities sponsored by a school district or school booster club, including, but not limited to, cheer team, drill team, dance team, and marching band. (EC 49024)

FISCAL EFFECT: The Office of Legislative Counsel has keyed this as a possible state-mandated local program.

COMMENTS:

Need for the bill. According to the author, "The Federal Drug Administration (FDA) is in the process of studying other methods of epinephrine delivery including a nasal spray that would be the first needle-free alternative to epinephrine auto injectors, such as EpiPens, and in the future other methods may be made available. AB 2714 will ensure that students have access to the latest approved epinephrine delivery systems at school, in order to provide students with a safer learning environment by changing epinephrine auto injector to epinephrine delivery system, providing schools with maximum flexibility, as new products become available."

Anaphylaxis is a potentially lethal allergic reaction. Anaphylaxis can happen within minutes when a person is stung by a bee, ingests food such as shellfish or nuts, or comes in contact with something as simple as latex. Reactions can be severe, or even fatal, without prompt use of epinephrine. According to the Mayo Clinic, anaphylaxis requires an injection of epinephrine and a follow-up trip to an emergency room. If untreated, anaphylaxis can be fatal.

Children sometimes do not exhibit overt and visible symptoms after ingesting an allergen, making early diagnosis difficult. Some children may not be able to communicate their symptoms clearly because of their age or developmental challenges. Complaints such as abdominal pain, itchiness, or other discomforts may be the first signs of an allergic reaction. Signs and symptoms can become evident within a few minutes or up to 1–2 hours after ingestion of the allergen, and rarely, several hours after ingestion. Symptoms of breathing difficulty, voice hoarseness, or faintness associated with a change in mood or alertness or rapid progression of symptoms that involve a combination of the skin, gastrointestinal tract, or

cardiovascular symptoms, signal a more severe allergic reaction (anaphylaxis) and require immediate attention. (CDC, 2013)

What is a food allergy? According to the CDC, a food allergy is defined as an adverse health effect arising from a specific immune response that occurs on exposure to a given food. The immune response can be severe and life-threatening. Although the immune system normally protects people from germs, in people with food allergies, the immune system mistakenly responds to food as if it were harmful. One way that the immune system causes food allergies is by making a protein antibody called immunoglobulin E (IgE) in response to the ingested food. The substance in foods that cause this reaction is called the food allergen. When exposed to the food allergen, the IgE antibodies alert cells to release powerful substances, such as histamine, that cause symptoms that can affect the respiratory system, gastrointestinal tract, skin, or cardiovascular system and lead to a life-threatening reaction called anaphylaxis.

Incidence of severe food allergy among children and youth. According to the Asthma and Allergy Foundation of America, approximately 5.6 million children or 7.6% have food allergies. In 2018, 4.8 million children under 18 years of age had food allergies over the previous 12 months. Milk is the most common allergen for children, followed by egg and peanut. (Gupta, 2018)

According to the CDC, food allergies among children increased by 50% between 1997 and 2011. Today one in 13 children has food allergies, and nearly 40% of these children have already experienced a severe allergic reaction. Many of these reactions happen at school.

An international study of food allergies concluded that the best available evidence indicates that food allergy has increased in many Westernized countries. The authors note that of greatest concern is the apparent escalation in prevalence in older children and teenagers, a group in which the risk of death due to food anaphylaxis is highest. (Tang, 2016)

Use of epinephrine to respond to anaphylaxis. An epinephrine auto-injector (commonly called an "epi-pen" because its size and shape is similar to a writing pen) is a disposable medical drug delivery device that delivers a single measured dose of epinephrine, most frequently for the treatment of acute allergic reactions to avoid or treat the onset of anaphylactic shock. Anaphylactic shock can quickly cause death if untreated. Epinephrine auto-injectors can be obtained by prescription only.

California law has been amended to, among other things, permit school districts or COEs to provide emergency epinephrine auto-injectors to trained personnel, and to permit trained personnel to utilize the auto-injectors to provide emergency medical aid to persons suffering from an anaphylactic reaction.

Alternative to epinephrine auto-injector. A pharmaceutical company presented information on an alternative to epinephrine auto-injectors in the form of an epinephrine nasal spray to the FDA's Pulmonary-Allergy Drug Advisory Committee in May 2023. They claimed that the product provides an alternative to those patients afraid of needles or self-injection, and is less complicated and difficult to carry. They were proposing the product for the treatment of allergic reactions including anaphylaxis in both adults and children. At a public meeting on May 11, 2023, the FDA's Pulmonary-Allergy Drugs Advisory Committee voted 16-6 in favor of the

epinephrine nasal spray for use in adults. The Committee also voted 17-5 in favor of its use in children.

This nasal spray has not received FDA approval, as of September 2023, as FDA regulators determined that more data was needed before it could be approved. "I trust that the FDA made the decision in the interest of patient safety. Traditional injectable epinephrine is widely available, proven effective and safe when used as indicated for treatment of systemic reactions to allergens," said Dr. Thomas Scott, an allergist and fellow of the American Academy of Allergy, Asthma and Immunology.

The Asthma and Allergy Network notes that other alternatives to epinephrine auto-injectors are under development including another nasal spray and an under-the-tongue (sublingual) strip containing epinephrine. ***The Committee may wish to consider that,*** given that no alternatives to epinephrine auto-injectors have received FDA approval, this bill may be premature.

Arguments in support. The Allergy and Asthma Network writes, "We believe laws and guidelines established to implement stock epinephrine in schools and other entities should reflect all methods to treat life-threatening allergic reactions, or anaphylaxis. This change is also reflected in the Voice of the Patient Report created by the a coalition of food allergy organizations, people living with food allergies, industry partners and FDA. The Report highlights patients and caregivers who want less-invasive epinephrine options.

Approximately 32 million Americans, including 6 million children, live with severe allergies to food, insect venom, medication and latex. Many are at risk for anaphylaxis, which causes about 1,500 deaths annually. According to federal guidelines by the Centers for Disease Control and Prevention (CDC), epinephrine is the first-line treatment when a person is experiencing a life-threatening allergic reaction. Data further shows death from anaphylaxis occurs more often when there is either a delay before epinephrine is administered or it is not given at all."

Related legislation. AB 1651 (Sanchez) Chapter 588, Statutes of 2023, extends the definition of "volunteer" and "trained personnel" to include the holder of an ASCC who may administer an emergency epinephrine auto-injector, as specified, and requires LEAs, COEs and charter schools to store epinephrine auto-injectors in an accessible location upon the need for emergency use.

AB 2640 (Valladares) Chapter 794, Statutes of 2022, requires the CDE to create the "California Food Allergy Resource Guide" for voluntary use by LEAs to protect pupils with food allergies.

AB 2042 (Villapudua) of the 2021-22 Session would have required the Department of Social Services (DSS), by July 1, 2023, to establish an anaphylactic policy, including guidelines and procedures to be followed by child daycare personnel to prevent a child from suffering from anaphylaxis and to be used during a medical emergency resulting from anaphylaxis; also would have required the DSS to create informational materials on the anaphylactic policy by September 1, 2023 and distribute the materials to child daycare facilities and to post them on the DSS website. This bill was vetoed by the Governor with the following message:

> It is important for all children in a child care setting to be cared for by staff who are trained to assist with their unique needs, including being able to recognize and respond to symptoms of anaphylaxis. While I appreciate the author's attention to this important matter, the bill before me creates a number of implementation concerns, including establishing multiple processes and expanding the memorandum of understanding (MOU) between the State and the CCPU.

I encourage the Legislature to work with the DSS and the Emergency Medical Services Authority, who have the expertise to develop health and safety standards, on a workable alternative that is uniform and addresses these issues.

AB 3342 (Bauer-Kahan) of the 2019-20 Session would have required the DSS to authorize child daycare facilities to keep emergency epinephrine auto-injectors onsite to be administered by trained, volunteer personnel to provide emergency medical aid to a person who is suffering, or reasonably believed to be suffering, from an anaphylactic reaction; would also have required the DSS to develop a training program for the participating personnel, which would include components, including, but not limited to, techniques for recognizing symptoms of anaphylaxis and emergency follow-up procedures. This bill was held in the Assembly Human Services Committee.

AB 1386 (Low) Chapter 374, Statutes of 2016, permits a pharmacy to furnish epinephrine auto-injectors to an authorized entity if they are furnished exclusively for use at or in connection with an authorized entity; an authorized health care provider provides a prescription; and, the records are maintained by the authorized entity for three years. Requires the authorized entity to create and maintain an operations plan related to its use; and, contains specified immunity provisions.

SB 1266 (Huff) Chapter 321, Statutes of 2014, requires school districts, COEs, and charter schools to provide emergency epinephrine auto-injectors to school nurses or trained personnel who have volunteered, as specified. Authorizes school nurses or trained personnel to use the epinephrine auto-injectors to provide emergency medical aid to persons suffering, or reasonably believed to be suffering, from an anaphylactic reaction.

REGISTERED SUPPORT / OPPOSITION:

Support

Allergy and Asthma Network
Allergy Strong
Asthma and Allergy Foundation of America
California Food Allergy Moms
Food Allergy and Anaphylaxis Connection Team
Latino Food Allergy Network
Nessie Bear Memorial Group
Red Sneakers for Oakley

Opposition

None on file

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