Date of Hearing: March 12, 2025

ASSEMBLY COMMITTEE ON EDUCATION Al Muratsuchi, Chair AB 228 (Sanchez) – As Introduced January 13, 2025

SUBJECT: Pupil health: epinephrine delivery systems

SUMMARY: Replaces references to "emergency epinephrine auto-injectors" with "emergency epinephrine delivery systems" as it relates 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. Would take effect immediately as an urgency statute. Specifically, **this bill**:

- 1) Replaces the requirement that school districts, county offices of education (COEs), and charter schools provide emergency epinephrine auto-injectors with the requirement to provide at least one type of United States Food and Drug Administration (FDA)-approved emergency epinephrine delivery system, as specified.
- 2) 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.
- 3) Defines an "epinephrine delivery system" as a disposable delivery system designed for the delivery of a premeasured dose of epinephrine into the human body to prevent or treat a life-threatening allergic reaction.
- 4) Is an urgency statute to enable school districts, COEs, and charter schools to provide FDA-approved epinephrine delivery systems as soon as possible.
- 5) 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, 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)

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

COMMENTS:

Need for the bill. According to the author, "AB 228 will help make campuses safer for students with food allergies and could be the difference in saving a life. No student should feel unsafe on campus, and no parent should have to worry about whether their child's school has the tools to keep them safe. By enacting AB 228, California schools will be permitted to carry new, safe and effective treatments for anaphylaxis that are less invasive than auto-injectors."

Alternative to epinephrine auto-injector. This bill would authorize schools to meet the existing requirement to stock an emergency epinephrine auto-injector by providing at least one type of an FDA-approved emergency epinephrine delivery system, which could include the recently approved nasal spray.

In August 2024, the U.S. Food and Drug Administration (FDA) approved an epinephrine nasal spray for the emergency treatment of allergic reactions, including those involving anaphylaxis in adults and children weighing at least 66 pounds. This is the first epinephrine product that is not administered by injection. The FDA noted that "anaphylaxis is life-threatening, and some people, particularly children, may delay or avoid treatment due to fear of injections. The availability of epinephrine nasal spray may reduce barriers to rapid treatment of anaphylaxis."

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 causes 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.

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.

Arguments in support. The California School Boards Association writes, "AB 228 would replace Education Code references to "epinephrine auto-injectors or auto-injectable epinephrine" with references to "epinephrine delivery systems", as defined. LEAs would be required to provide at least one type of U.S. FDA-approved epinephrine delivery system.

This bill will help ensure schools can continue to provide students with the latest federally approved epinephrine delivery systems to treat instances of anaphylaxis. This bill accounts for the recent and future changes to how epinephrine is referred and can be administered to individuals undergoing an allergic reaction or anaphylaxis."

Related legislation. AB 2714 (Wallis) of the 2023-24 Session was substantially similar to this measure and would have replaced 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. This bill was held in the Assembly Appropriations Committee.

AB 1651 (Sanchez) Chapter 588, Statutes of 2023, extends the definition of "volunteer" and "trained personnel" to include the holder of an Activity Supervisor Clearance Certificate (ASCC) who may administer an emergency epinephrine auto-injector, as specified, and requires a local educational agency (LEA), COE, 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 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 autoinjectors 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

Alameda County Office of Education Allergy & Asthma Network Allergy Strong American Academy of Pediatrics, California Asthma and Allergy Foundation of America California Association of School Police Chiefs California Coalition of School Safety Professionals California Food Allergy Moms California School Boards Association California Teachers Association Latino Food Allergy Network Los Angeles School Police Management Association Los Angeles School Police Officers Association Los Angeles Unified School District Office of The Riverside County Superintendent of Schools Red Sneakers for Oakley

Opposition

None on file

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