

Department of Legislative Services
Maryland General Assembly
2025 Session

FISCAL AND POLICY NOTE
First Reader

House Bill 536 (Delegate Guzzone, *et al.*)
Ways and Means and Health and
Government Operations

Education and Health - Emergency Use Epinephrine - Alterations

This bill replaces the term “auto-injectable epinephrine” with “emergency use epinephrine” throughout the Education, Health-General, and Health Occupations articles and renames the Emergency Use Auto-Injectable Epinephrine Program to the Emergency Use Epinephrine Program, thereby including non-injectable forms of epinephrine in existing programs. The bill defines “emergency use epinephrine” as a portable, disposable drug delivery device or product approved by the U.S. Food and Drug Administration (FDA) that contains a premeasured single dose of epinephrine that is used to treat anaphylaxis in an emergency situation. **The bill takes effect July 1, 2025.**

Fiscal Summary

State Effect: The Maryland Department of Health (MDH) can update resources and regulations with existing budgeted resources, as discussed below. Revenues are not affected.

Local Effect: None.

Small Business Effect: None.

Analysis

Current Law: “Auto-injectable epinephrine” means a portable, disposable drug delivery device that contains a premeasured single dose of epinephrine that is used to treat anaphylaxis in an emergency situation. “Anaphylaxis” means a sudden, severe, and

potentially life-threatening allergic reaction that occurs when an individual is exposed to an allergen.

Education

Each local board of education must establish a policy to authorize the school nurse and other school personnel to administer auto-injectable epinephrine, if available, to a student who is determined to be or perceived to be in anaphylaxis, regardless of whether the student (1) has been identified as having an anaphylactic allergy or (2) has a prescription for epinephrine from a licensed health care practitioner. The policy must also include training for school personnel on how to recognize the symptoms of anaphylaxis; procedures for the emergency administration of auto-injectable epinephrine; proper follow-up emergency procedures; and a provision authorizing a school nurse to obtain and store at a public school auto-injectable epinephrine to be used in an emergency situation. These elements are also required, as appropriate, for any policy voluntarily developed by nonpublic schools; however, nonpublic schools must also establish an ongoing process for oversight and monitoring by a licensed health care practitioner. Each public school must submit a report to MDH of each incident at school or a school-related event that required the administration of auto-injectable epinephrine. MDH must develop and disseminate a standard form that can be used for this reporting.

Child Care Providers

Chapter 273 of 2024 requires the Maryland State Department of Education (MSDE) and MDH to jointly develop guidelines to reduce the risk of exposure to anaphylactic major food allergens in child care settings. The guidelines must identify at least one free training resource on reducing the risk of exposure to anaphylactic major food allergens that is appropriate for child care providers. Based on the guidelines, MSDE must develop a model policy for child care providers that, at a minimum, includes (1) emergency protocols, including comprehensive guidelines for storage and administration of epinephrine; (2) cross-contamination prevention strategies; and (3) notification of a child's anaphylactic allergy to staff who come in contact with the child and child care provider administrators. MSDE must post the guidelines, model policy, and training resources on its website.

Except for any willfully or grossly negligent act, a child care provider (or employee of a provider) who responds in good faith to the anaphylactic reaction of a child in accordance with guidelines or by use of auto-injectable epinephrine is immune from civil liability for any act or omission in the course of responding to the reaction.

Emergency and Allergy Treatment Program

The Emergency and Allergy Treatment Program within MDH authorizes a certificate holder or their agent to administer life-saving treatment to individuals who have severe adverse reactions to allergens or insect stings when physician or emergency medical services are not immediately available in a youth camp.

MDH may issue a certificate, including an endorsement on the operating certificate of a youth camp, to an applicant who (1) operates a youth camp; (2) is at least age 18; and (3) has successfully completed an educational training program, at the applicant's expense, that is approved by MDH. A certificate is valid for up to one year and authorizes a certificate holder to obtain, store, and administer auto-injectable epinephrine.

An agent is an individual at least age 18 who has completed an educational training program approved by MDH and has been appointed by a certificate holder to administer auto-injectable epinephrine in accordance with statutory provisions.

An applicant also has to have a written policy that includes (1) authorization for the certificate holder or their agent to administer auto-injectable epinephrine (if available) to an individual determined, or believed, to be experiencing anaphylaxis, regardless of whether the individual has been previously known to experience anaphylaxis or has a prescription for epinephrine; (2) a requirement that youth camp personnel complete training on recognizing the symptoms of anaphylaxis; (3) procedures for administering auto-injectable epinephrine in an emergency; (4) proper emergency follow-up procedures; (5) authorization for a certificate holder to obtain and store auto-injectable epinephrine for emergency use; and (6) a requirement that each certificate holder implement a notification system to alert campers' parents or guardians of the youth camp's auto-injectable epinephrine policy before the campers attend the camp.

A certificate holder must submit a report to MDH of each incident that occurs while the youth camp is in session that required the administration of auto-injectable epinephrine. MDH must publish a report that summarizes the information obtained from these required reports by January 31 annually.

A licensed physician and registered nurse practitioner are authorized to prescribe and dispense, and a licensed pharmacist may dispense, auto-injectable epinephrine to a certificate holder. A certificate holder may receive, possess, and store auto-injectable epinephrine. Additionally, in emergency situations when physician or emergency medical services are not immediately available, a certificate holder or agent may administer auto-injectable epinephrine to an individual. However, that individual must either be experiencing anaphylaxis, or the certificate holder or agent must believe in good faith that the individual is experiencing anaphylaxis.

A cause of action may not arise against a certificate holder or agent if the certificate holder or agent acts in good faith to administer auto-injectable epinephrine to an individual experiencing or believed by the certificate holder or agent to be experiencing anaphylaxis, unless the certificate holder or agent's conduct amounts to gross negligence, willful or wanton misconduct, or intentionally tortious conduct. A cause of action may not arise against any physician or registered nurse practitioner for any act or omission if the physician prescribes or dispenses auto-injectable epinephrine and the necessary paraphernalia for administration of auto-injectable epinephrine, in good faith, to a person certified by MDH under statute. Likewise, a cause of action may not arise against any pharmacist for any act or omission when the pharmacist in good faith dispenses auto-injectable epinephrine and the necessary paraphernalia for the administration of auto-injectable epinephrine to a person certified by MDH under statute.

Emergency Use Auto-Injectable Epinephrine Program

Chapter 527 of 2018 established the Emergency Use Auto-Injectable Epinephrine Program at Institutions of Higher Education within MDH to authorize qualified individuals (through issuance of a certificate) employed by a food service facility or a recreation and wellness facility at an “eligible institution” to obtain, store, and administer auto-injectable epinephrine to individuals experiencing (or believed to be experiencing) anaphylaxis. Eligible institutions can also obtain and store auto-injectable epinephrine under specified circumstances. There are legal immunities for certificate holders, prescribing physicians, and pharmacists acting in compliance with the program. There are also reporting requirements for certificate holders and MDH. Chapter 478 of 2020 renamed the program to the Emergency Use Auto-Injectable Epinephrine Program and expanded it to include any food service facility in the State that voluntarily participates.

State Fiscal Effect: MDH advises that the Prevention and Health Promotion Administration would need to update existing regulations, procedures, and materials developed for the Emergency Use Auto-Injectable Epinephrine Program. Any necessary updates can be completed with existing budgeted resources.

Additional Comments: In August 2024, the FDA approved Neffy, the first epinephrine nasal spray device, which can treat allergic reactions without injection. Other non-injectable forms of epinephrine are currently in development and awaiting FDA approval.

Additional Information

Recent Prior Introductions: Similar legislation has not been introduced within the last three years.

Designated Cross File: None.

Information Source(s): Maryland Association of County Health Officers; Maryland State Department of Education; Maryland Department of Health; Baltimore City Public Schools; Baltimore County Public Schools; Montgomery County Public Schools; Department of Legislative Services

Fiscal Note History: First Reader - February 4, 2025
km/jc

Analysis by: Eliana R. Prober

Direct Inquiries to:
(410) 946-5510
(301) 970-5510