

Testimony SB0459 FAV.pdf

Uploaded by: Kari Keaton

Position: FAV

Testimony of Kari Keaton
608 Autumn Wind Way, Rockville MD 20850
Finance Committee
February 6, 2024
Position: FAVORABLE SB0459

Dear Chair Beidle and members of the Finance Committee:

I am submitting this testimony today on behalf of my two adult sons, each with multiple life-threatening food allergies, and on behalf of the Metro DC Food Allergy Support Group. I am the facilitator of this support group of several hundred Maryland and DC area food allergy families.

Epinephrine is a very unique kind of medication because it is one you hope you never have to use, however, a person with potentially anaphylactic food allergies must have epinephrine with them at all times. It is the only medicine to control life-threatening allergic reactions.

Prior to August 9, 2024 emergency epinephrine was only available as auto injector devices--EpiPens, Auvi Qs, and other generic auto-injector devices. On August 9, 2024, the FDA approved Neffy, a nasal spray delivery method for emergency epinephrine. Neffy devices are already out in the world and can be used just like auto injectors in the event of anaphylactic allergic reactions.

Previous bills included the term "auto-enjectable epinephrine", but this is no longer valid because there is this new delivery method for epinephrine. It only makes sense to change the wording in all previous instances where "auto-injectable epinephrine" is used with the more accurate term "emergency use epinephrine.

In addition to the Neffy nasal spray delivery method, there is also current research taking place for yet another delivery method for emergency epinephrine--sublingual (dissolve under the tongue) tablets containing epinephrine. By changing the wording in the bills now to "emergency use epinephrine", any new delivery method for epinephrine that is approved by the FDA will be covered in the Maryland laws.

I urge the committee to give a favorable report on SB0459, and thank Senator Gile for introducing the bill.

SB 459 - MDH - FIN - LOS (1).pdf

Uploaded by: Meghan Lynch

Position: FAV



DEPARTMENT OF HEALTH

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

February 6, 2025

The Honorable Pamela Beidle
Chair, Senate Finance Committee
3 East Miller Office Building
Annapolis, MD 21401-1991

**RE: Senate Bill (SB) 459 – Education and Health - Emergency Use Epinephrine -
Alterations – Letter of Support**

Dear Chair Beidle and Committee Members:

The Maryland Department of Health (the Department) respectfully submits this letter of support for Senate Bill 459 – Education and Health - Emergency Use Epinephrine - Alterations. This bill alters all references to “auto-injectable epinephrine” to “emergency use epinephrine” in statutes that impact school health, youth camps, child care, institutions of higher education, and naturopaths, and provides a definition for “emergency use epinephrine.”

The authorization for trained school staff to administer stock epinephrine to students experiencing anaphylaxis is a critical emergency measure when a student does not have access to their own prescribed epinephrine. In the 2023-24 school year, Maryland public schools reported 32,000 students with life-threatening allergies/anaphylaxis who could potentially require administration of stock epinephrine. Within that same year, it was reported that stock auto-injectable epinephrine—the only form allowable by law—was administered 69 times.

The Department supports altering the term “auto-injectable epinephrine” to “emergency use epinephrine” as defined in SB 459. This legislative change will allow school staff to stock and administer alternative epinephrine delivery systems for use in an emergency. Auto-injectable epinephrine requires a needle for medication delivery, and fear of needles is one of the factors associated with underuse of this potentially life-saving medication.¹ The use of FDA-approved non-needle epinephrine delivery systems such as intranasal epinephrine has the potential to increase student and school staff comfort with emergency epinephrine administration, which could be life-saving for students experiencing anaphylaxis.

If you would like to discuss this further, please do not hesitate to contact Sarah Case-Herron, Director of Governmental Affairs at sarah.case-herron@maryland.gov.

¹ Lieberman, J. et al. (2023). Innovations in the treatment of anaphylaxis: A review of recent data. *Annals of Allergy, Asthma & Immunology* 131(2), 185-193. <https://doi.org/10.1016/j.anai.2023.05.033>

Sincerely,

A handwritten signature in blue ink, appearing to read "Laura Herrera Scott". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Laura Herrera Scott, M.D., M.P.H.
Secretary

2025 MASBHC SB 459 Senate Side.pdf

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Position: FAV



Committee: Senate Finance Committee

Bill Number: Senate Bill 459 – Education and Health – Emergency Use – Epinephrine - Alterations

Hearing Date: February 6, 2025

Position: Support

The Maryland Assembly on School-Based Health Care (MASBHC) support *Senate Bill 459 - Education and Health – Emergency Use – Epinephrine – Alterations*. The bill updates the emergency use program for epinephrine in schools to allow for the use of Neffy, a form of epinephrine administered by nasal spray. In August 2024, the Food and Drug Administration (FDA) approved Neffy for use with adults and children weighing more than sixty-six pounds.ⁱ The nasal spray is easier to use than the injectable form of epinephrine, but Maryland law only authorized the use of auto-injectable epinephrine. The legislation will correct that problem by permitting other forms of epinephrine approved by the FDA.

We ask for a favorable vote. If we can provide any information, please contact Robyn Elliott at relliott@policypartners.net.

ⁱ [https://www.fda.gov/news-events/press-announcements/fda-approves-first-nasal-spray-treatment-anaphylaxis#:~:text=For%20Immediate%20Release:%20August%2009,kilograms%20\(about%2066%20pounds\).](https://www.fda.gov/news-events/press-announcements/fda-approves-first-nasal-spray-treatment-anaphylaxis#:~:text=For%20Immediate%20Release:%20August%2009,kilograms%20(about%2066%20pounds).)

2025 MASHN SB 459 Senate Side.pdf

Uploaded by: Robyn Elliott

Position: FAV

Maryland Association of School Health Nurses



Committee: Senate Finance Committee

Bill Number: Senate Bill 459 – Education and Health – Emergency Use – Epinephrine - Alterations

Hearing Date: February 6, 2025

Position: Support

The Maryland Association of School Health Nurses strongly support *Senate Bill 459 - Education and Health – Emergency Use – Epinephrine – Alterations*. The bill updates the statute on the emergency use of epinephrine in schools. Under the emergency use program, school nurse, other school personnel, and certain volunteers (e.g. coaches) may administer auto-injectable epinephrine to students in emergency situations. School health guidelines, developed jointly by the Departments of Education and Health, outline the parameters of the program and include training requirements.

In August 2024, the Food and Drug Administration (FDA) approved a new form of epinephrine that may be administered by nasal spray to adults and children over 66 pounds.ⁱ Called Neffy, this new form of epinephrine is easier to administer. However, Maryland law only authorizes the emergency use of auto-injectable epinephrine. The legislation updates this outdated terminology, allowing for the use of Neffy and other forms of epinephrine that could be approved by the FDA in the future.

We ask for a favorable vote. If we can provide any information, please contact Robyn Elliott at relliott@policypartners.net.

ⁱ [https://www.fda.gov/news-events/press-announcements/fda-approves-first-nasal-spray-treatment-anaphylaxis#:~:text=For%20Immediate%20Release:%20August%2009,kilograms%20\(about%2066%20pounds\).](https://www.fda.gov/news-events/press-announcements/fda-approves-first-nasal-spray-treatment-anaphylaxis#:~:text=For%20Immediate%20Release:%20August%2009,kilograms%20(about%2066%20pounds).)

DG Written Testimony_SB0459.docx.pdf

Uploaded by: Senator Gile

Position: FAV

DAWN D. GILE
Legislative District 33
Anne Arundel County

Finance Committee

Chair

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THE SENATE OF MARYLAND
ANNAPOLIS, MARYLAND 21401

Testimony in Support of SB0459 - Education and Health - Emergency Use Epinephrine - Alterations

Madame Chair, Vice Chair Hayes, and fellow members of the Senate Finance Committee:

This legislation updates an outdated term in state law to ensure that any government-approved epinephrine delivery product can be used during an emergency. The bill changes the statutory term for “auto-injectable epinephrine” (e.g. EpiPen) to “emergency use epinephrine” in all references in state law. This change is needed to include additional government-approved epinephrine delivery products that do not involve bodily injection.

Background

For many Marylanders, epinephrine can mean the difference between life and death during a severe allergic reaction. This is especially true for children – insurance data shows that 63% of claims in Maryland relating to food allergies and anaphylaxis were for children under 18.¹ Food allergies impact about 8% of children in the United States, a proportion that has grown in recent decades.²³ Unfortunately, an estimated 18% of children with a food allergy have had an allergic reaction in a school setting.⁴

For these reasons, state law authorizes the administration of auto-injectable epinephrine by school nurses, child care providers, camp counselors, health professionals, and others if they suspect someone is experiencing a life-threatening allergic reaction. Given the potentially deadly nature of severe food allergies, it is essential that state law is updated to remain current with new innovations in the treatment of anaphylaxis.

In August 2024, the U.S. Food and Drug Administration (FDA) approved Neffy, the first needle-free epinephrine delivery device.⁵ Neffy is a single-dose nasal spray. Epinephrine nasal sprays like Neffy are easier to use than auto-injectors. Many people with anaphylaxis and their caregivers tend to hesitate when using auto-injectors, in part because of worries about injecting a

¹ For 2009-2016, [Food Allergy Research & Education](#)

² “Food Allergies.” Centers for Disease Control and Prevention.

³ Food allergy among U.S. children: trends in prevalence and hospitalizations.” Branum, et al. National Center for Health Statistics. <https://www.cdc.gov/nchs/products/databriefs/db10.htm>

⁴ “Food-allergic reactions in schools and preschools.” Nowak-Wegrzyn, et al. Archives of Pediatrics & Adolescent Medicine. <https://pubmed.ncbi.nlm.nih.gov/11434845/>

⁵ FDA: “FDA Approves First Nasal Spray for Treatment of Anaphylaxis”. August 2024.

needle. Studies show any hesitation or delay in administering epinephrine puts patients at risk for worse outcomes, and even death.⁶ In a study by the Allergy & Asthma Network, 72% of participants reported that they would prefer using an epinephrine nasal spray instead of an auto-injector, and 82% would prefer needle-free epinephrine instead of an injection.⁷ Another product, Anaphylm, is in the final stages of FDA approval and works like a breath strip by dissolving under the tongue.

Given the ease of administering these products relative to an EpiPen and that the manufacturer of Neffy is providing the product free to schools, it is likely that some schools, child care providers, and others who currently keep auto-injectable epinephrine on hand would prefer to use a different product.⁸ For Marylanders to take full advantage of these new devices, state law needs to be updated.

Existing Law

Current state law authorizes the use of auto-injectable epinephrine in a variety of public settings, including in public and non-public schools, in child care facilities and summer camps, at colleges and universities, and by health care professionals. Since 1987, auto-injectable epinephrine (often synonymously called the EpiPen) has been the sole medication available for rapid response to anaphylaxis.

Solution

This bill would update the terminology in all sections of state law so that any FDA-approved epinephrine delivery device or product could be used. SB0459's change to the terminology for epinephrine would expand rapid treatment options for Marylanders. Notably, the bill would take effect in time for the start of the upcoming summer camp season and school year.

Per the Fiscal Note, SB0459 would not require additional state resources.

For these reasons, I respectfully request a favorable report on SB0459.

⁶ <https://allergyasthmanetwork.org/news/epinephrine-nasal-spray-for-anaphylaxis/>

⁷ Ibid.

⁸ <https://ars-pharma.com/neffyinschools/>