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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, Madame Vice Chair, and members of the House Ways and Means 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This legislation updates an outdated term in state law to ensure that any government-approved epinephrine delivery product can be used during an emergency.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. Food allergies impact about 8% of children in the United States, a proportion that has grown in recent decades. Unfortunately, an estimated 18% of children with a food allergy have had an allergic reaction in a school setting.

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. SB0459 is the cross-file of HB0420, which this committee reported favorably and the full House passed unanimously. The third-reader of SB0459 is in the exact same posture as the third-reader of HB0420.

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

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

^{&#}x27; Ibid.

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