

May 28, 2026

District of Columbia Pharmacy and Therapeutics Committee

**RE: Epinephrine, Self-Administered, June 4 Board Meeting**

Submitted to: charlene.fairfax@dc.gov

On behalf of the Asthma and Allergy Foundation of America, we write to you to encourage the D.C. Pharmacy and Therapeutics Committee to provide meaningful access to currently approved and future needle-free forms that become FDA approved for Medicaid enrollees. Epinephrine is the only option for treating severe allergic reactions and anaphylaxis.<sup>1</sup> Because most anaphylaxis occurs away from a medical setting, having access to choose among all forms of this life-saving drug—including auto-injectors and new needle-free forms—is essential.

### **Anaphylaxis and Treatment**

- Nearly 5.1% of Americans have had anaphylaxis, from a range of causes including food allergy, drug allergy, venom allergy, inhalant allergy and immunotherapy, and from mast cell disorders.<sup>2</sup>
- Food anaphylaxis is very common and rising rapidly. Between 40–50% of food allergic children and adults have had a severe reaction, and emergency room visits for food reactions have increased by 124%.<sup>3,4,5</sup> All such patients are prescribed self-administrable epinephrine.
- There has been a longstanding unmet need for needle-free epinephrine treatments as an option for patients. Some patients will hesitate to use an auto-injector (even for their own child), delaying injection on average 9 minutes.
- Administering epinephrine immediately without delay is critical.<sup>6</sup> Delay places the patient at risk for needing additional epinephrine doses, having biphasic (rebound) reactions, and hospital admissions.<sup>7</sup>

### **Needle-free Forms of Epinephrine Address Current Gaps in Anaphylaxis Treatment**

- **Improved portability.** Needle-free forms are significantly smaller and more compact, making them easier to keep in pockets, purses, or small bags. This addresses the 60% of patients who don't always carry auto-injectors due to size and discreet carrying difficulties.<sup>8</sup>

<sup>1</sup> Golden DBK, Wang J, Waserman S, Akin C, Campbell RL, Ellis AK, et al. Anaphylaxis: A 2023 practice parameter update. *Ann Allergy Asthma Immunol.* 2024;132(2):124–76.

<sup>2</sup> Wood RA, Camargo CA Jr, Lieberman P, Sampson HA, Schwartz LB, Zitt M, Collins C, Tringale M, Wilkinson M, Boyle J, Simons FE. Anaphylaxis in America: the prevalence and characteristics of anaphylaxis in the United States. *J Allergy Clin Immunol.* 2014 Feb;133(2):461–7.

<sup>3</sup> Gupta RS, Warren CM, Smith BM, Blumenstock JA, Jiang J, Davis MM, Nadeau KC. The Public Health Impact of Parent-Reported Childhood Food Allergies in the United States. *Pediatrics.* 2018 Dec;142(6):e20181235.

<sup>4</sup> Gupta RS, Warren CM, Smith BM, Jiang J, Blumenstock JA, Davis MM, Schleimer RP, Nadeau KC. Prevalence and Severity of Food Allergies Among US Adults. *JAMA Netw Open.* 2019 Jan 4;2(1):e185630.

<sup>5</sup> Motosue et al., "Increasing Emergency Department Visits for Anaphylaxis, 2005–2014." *J Allergy Clin Immunol Pract.* 2017 Jan – Feb;5(1):171–175.

<sup>6</sup> Rooney E, Tanimoto S, Kaplan H, Lowenthal R. Injectable Devices and Triggers Driving Use: A Patient/Caregiver Survey. *Ann Allergy Asthma Immunol* 2022; 29(5):S16–S17

<sup>7</sup> Shaker MS, Wallace DV, Golden DBK, Oppenheimer J, Bernstein JA, Campbell RL, Dinakar C, Ellis A, Greenhawt M, Khan DA, Lang DM, Lang ES, Lieberman JA, Portnoy J, Rank MA, Stukus DR, Wang J; Collaborators; Riblet N, Bobrownicki AMP, Bontrager T, Dusing J, Foley J, Frederick B, Fregene E, Hellerstedt S, Hassan F, Hess K, Horner C, Huntington K, Kasireddy P, Keeler D, Kim B, Lieberman P, Lindhorst E, McEnany F, Milbank J, Murphy H, Pando O, Patel AK, Ratliff N, Rhodes R, Robertson K, Scott H, Snell A, Sullivan R, Trivedi V, Wickham A; Chief Editors; Shaker MS, Wallace DV; Workgroup Contributors; Shaker MS, Wallace DV, Bernstein JA, Campbell RL, Dinakar C, Ellis A, Golden DBK, Greenhawt M, Lieberman JA, Rank MA, Stukus DR, Wang J; Joint Task Force on Practice Parameters Reviewers; Shaker MS, Wallace DV, Golden DBK, Bernstein JA, Dinakar C, Ellis A, Greenhawt M, Horner C, Khan DA, Lieberman JA, Oppenheimer J, Rank MA, Shaker MS, Stukus DR, Wang J. Anaphylaxis—a 2020 practice parameter update, systematic review, and Grading of Recommendations, Assessment, Development and Evaluation (GRADE) analysis. *J Allergy Clin Immunol.* 2020 Apr;145(4):1082–1123.

<sup>8</sup> Warren CM, Zaslavsky JM, Kan K, Spergel JM, Gupta RS. Epinephrine auto-injector carriage and use practices among US children, adolescents, and adults. *Ann Allergy Asthma Immunol.* 2018 Oct;121(4):479–489.e2.

- **Enhanced usability.** Needle-free forms are more intuitive to use, and require less training to do so, making them easier for laypersons in the community and patients to administer.
- **Safety profile.** A needle-free design removes variables related to injection depth and eliminates the risk of injury from sudden patient movement during administration.
- **Increased patient compliance.** Allergy specialists and patient advocates are hopeful that having the choice of smaller, easier to carry, needle-free options will encourage patients to carry devices consistently and use them earlier during reactions before they become critically severe.
- **Pharmacological performance.** Data from the pivotal studies from needle-free options show that these forms have more optimal pharmacokinetic and pharmacodynamic properties. These enhanced pharmacological properties are highly desirable when treating anaphylaxis, as faster onset and sustained elevation of vital hemodynamic parameters can improve patient outcomes during severe reactions.
- **Economic advantages.** Research shows these devices can be cost-effective based on current market prices and improved patient acceptance when compared with existing therapies.<sup>9,10</sup> The extended shelf life of the needle-free products compared to auto-injectors further enhances economic value by reducing the frequency of prescription refills.
- **Updated clinical management approach.** The needle-free epinephrine products have updated package insert instructions which do not state that all patients should immediately seek emergency care after use, reflective of 2023 Joint Taskforce on Allergy Practice Parameters updated anaphylaxis guidelines. This management pathway has been shown to be more cost-effective than all patients universally presenting for emergency care per a 2018 study.<sup>11,12</sup>

The Asthma and Allergy Foundation of America supports Medicaid Preferred Drug Lists including needle-free epinephrine forms an option for patients at risk for anaphylaxis. Our mission includes advocating for expanded treatment choice, and while many patients may prefer auto-injectors, this should be a matter of patient choice rather than one forced by lack of alternatives. When patients are too hesitant to use needle-based devices during severe reactions, this inaction could lead to costly healthcare utilization including emergency department visits, ambulance transport, and potential hospitalization-- defeating the purpose of containing medication costs.

Sincerely,



Kenneth Mendez  
President and Chief Executive Officer  
Asthma and Allergy Foundation of America

<sup>9</sup> Shaker M, Greenhawt M. Association of Fatality Risk With Value-Based Drug Pricing of Epinephrine Autoinjectors for Children With Peanut Allergy: A Cost-effectiveness Analysis. JAMA Netw Open. 2018 Nov 2;1(7):e184728.

<sup>10</sup> Shaker MS, Oppenheimer J, Rider NL, Golden DBK, Agnostou A, Greenhawt M. A health economic analysis of noninjectable epinephrine compared with intramuscular epinephrine. Ann Allergy Asthma Immunol. 2025 May;134(5):587-593.e1.

<sup>11</sup> Shaker M, Kanaoka T, Feenan L, Greenhawt M. An economic evaluation of immediate vs non-immediate activation of emergency medical services after epinephrine use for peanut-induced anaphylaxis. Ann Allergy Asthma Immunol. 2019 Jan;122(1):79-85.

<sup>12</sup> Golden DBK, Wang J, Wasserman S, Akin C, Campbell RL, Ellis AK, Greenhawt M, Lang DM, Ledford DK, Lieberman J, Oppenheimer J, Shaker MS, Wallace DV, Abrams EM, Bernstein JA, Chu DK, Horner CC, Rank MA, Stukus DR; Collaborators; Burrows AG, Cruickshank H; Workgroup Contributors; Golden DBK, Wang J, Akin C, Campbell RL, Ellis AK, Greenhawt M, Lang DM, Ledford DK, Lieberman J, Oppenheimer J, Shaker MS, Wallace DV, Wasserman S; Joint Task Force on Practice Parameters Reviewers; Abrams EM, Bernstein JA, Chu DK, Ellis AK, Golden DBK, Greenhawt M, Horner CC, Ledford DK, Lieberman J, Rank MA, Shaker MS, Stukus DR, Wang J. Anaphylaxis: A 2023 practice parameter update. Ann Allergy Asthma Immunol. 2024 Feb;132(2):124-176.