

Improving Anaphylaxis Outcomes: Approaches for Enhancing Access to Epinephrine

Hybrid Meeting | Duke in DC Office
December 16, 2025 | 9:00 AM – 4:30 PM ET

Workshop Summary

Introduction and Background

Anaphylaxis is a severe, progressive allergic reaction that can be fatal if not promptly treated with epinephrine. Failure to treat anaphylaxis within minutes can lead to airway obstruction, shock, and multi-organ failure. Despite being the only effective first-line treatment approved by the Food and Drug Administration (FDA), barriers may limit access to and use of epinephrine. For example, patients and caregivers may experience challenges in determining whether and how to administer epinephrine to treat an anaphylactic reaction. Institutional barriers may also inhibit access to and use of epinephrine in community settings, such as schools, workplaces, restaurants, and other public venues. Additionally, procedural barriers may limit patients' ability to obtain authorization from a health care professional to carry epinephrine. These barriers may be magnified in communities with limited health care infrastructure and by the cost of epinephrine products. While federal and state legislation has sought to expand access to epinephrine by directly addressing barriers to use, additional policy and regulatory solutions may be needed to help ensure life-saving treatment for anaphylaxis is readily available during an emergency to improve anaphylaxis outcomes.

On December 16, 2025, the Duke-Margolis Institute for Health Policy, under a cooperative agreement with the FDA, hosted a hybrid public workshop titled *Improving Anaphylaxis Outcomes: Approaches for Enhancing Access to Epinephrine*. Discussion among allergists, pediatricians, patient advocates, and educators centered around expanding epinephrine accessibility and use, including in community settings, to reduce anaphylaxis-related morbidity and mortality. Prospective approaches to improve anaphylaxis outcomes include, but are not limited to, expanding training on use, incentivizing availability in public spaces, enhancing civil liability protections for administrators of epinephrine, and considering development of epinephrine for nonprescription use.

This meeting summary provides an overview of trends, challenges, issues, and recommendations discussed by the FDA and other experts at the meeting. Key takeaways from participants at the meeting included:

- The nuances involved in diagnosing allergic diseases associated with anaphylaxis and the urgency of treatment required during anaphylaxis events.

- The importance of collaborative decision making between patients and providers, patient education, community access to stock epinephrine, and emergency management plans to improve anaphylaxis outcomes.
- The variability in access to epinephrine across community settings such as homes, primary care settings, emergency departments, daycares, schools and universities, airplanes, and other public venues. Approaches to enhance access must take each setting's unique hurdles into consideration.
- To the extent that the benefits of epinephrine used to treat anaphylaxis outweigh the risks to consumers, creative approaches are encouraged for prescription-to-nonprescription switch applications through deeper industry-agency collaboration.
 - FDA presented naloxone as a use case that may help industry stakeholders better prepare for consumer testing evaluations such as label comprehension studies, self-selection studies, actual use studies, and human factors studies that may be necessary to support a nonprescription application.
 - If a drug label cannot, by itself, provide all the information consumers need to appropriately select or use the drug on their own in the nonprescription setting, drug companies may also consider an additional condition for nonprescription use (ACNU).

Diagnosing and Treating Anaphylaxis: Complexity, Uncertainty, and the Need for Early Epinephrine

Panelists explored clinical considerations for the treatment of anaphylaxis and described the nuance of managing allergic diseases. Participants, who were allergists, highlighted that diagnosing Immunoglobulin E-mediated allergic diseases, which may present as anaphylaxis, and deciding which patients require epinephrine prescriptions are highly individualized. Appropriate diagnosis requires evaluating a patient's history of allergic reactions, administering targeted allergy testing, and ruling out conditions that mimic anaphylaxis. Allergic diseases associated with anaphylaxis, particularly to foods, are frequently misdiagnosed. Decisions regarding need to carry epinephrine are based on careful risk assessment.

Participants representing patient advocacy groups pointed out that families and caregivers often struggle to decide when to use epinephrine. This hesitation to administer epinephrine is driven by the costs of epinephrine and need for follow-up emergency care, as well as fear of overreacting or causing harm to their family member. In response, clinicians emphasized a low threshold for epinephrine use, as delayed administration is more dangerous than unnecessary dosing, even for patients with cardiovascular comorbidities.

Considering the nuance of diagnosing allergic diseases and the need for immediate treatment required during anaphylaxis events, participants listed patient education and emergency management plans as essential tools to empower timely intervention. Evidence supports that laypersons can be effectively trained to recognize anaphylaxis and administer epinephrine when provided with clear, well-designed educational materials. Participants also emphasized the need for novel therapeutic approaches, including alternative epinephrine routes of

administration, and digital tools that offer promising advancements in the diagnosis, management, and treatment of allergic diseases and anaphylaxis.

Epinephrine Access in Community Settings: Inequities, Implementation Gaps, and the Role of Training

Since most anaphylaxis events occur outside medical settings, access to epinephrine in community settings is essential. Participants discussed economic, social, policy-related, and psychological barriers to epinephrine use across community settings. Policies and protocols that can overcome these barriers to support better outcomes from anaphylaxis were also centered in the discussion.

Participants, representing patient advocacy groups, noted that socioeconomic disparities shape access, with Medicaid patients and low-income families facing greater barriers due to cost. Notably, a shift from prescription-to-nonprescription status for epinephrine may increase costs for beneficiaries who currently do not have a co-pay for prescription epinephrine products. The FDA does not regulate pricing but acknowledged that nonprescription status could shift costs to patients, including Medicaid beneficiaries. However, FDA noted that “most of the time when something gets switched to nonprescription, both costs to the consumer and overall health care system costs go down for the use of that drug for that therapeutic use.” Special emphasis was given to the need for equity considerations, ensuring that expanded access does not exacerbate disparities in affordability or availability.

Policy adjustments may help address access barriers, which vary across public settings. Participants noted that air travel presents unique risks, with limited data on in-flight reactions and inconsistent dosage forms in emergency medical kits. Though [H.R. 3935](#), which became law in May 2024, requires emergency medical kits in airplanes to be equipped with appropriate medications to treat anaphylaxis, current kits often include epinephrine in syringe-vial form, which is prone to dosing uncertainty and error, rather than easily administered autoinjectors.

In schools and other public settings, stock epinephrine laws vary across states, and implementation is inconsistent across preschools, grade schools, colleges, and public venues like theme parks. Participants discussed challenges schools face related to procurement, liability, staff training, and device standardization. Preschools and daycare settings often require more intensive emergency training due to high staff turnover and limited child communication abilities. Participants noted that data suggest carriage rates are low across all age groups, but especially among adolescents and college students. These lower carriage rates are due, in part, to psychological and social factors such as stigma, inconvenience, and fear of side effects. Consistent policy that supports access to stock epinephrine in public settings is key to reducing morbidity and mortality from anaphylaxis and mitigating cost, coverage, and psychological barriers to access.

FDA’s Role in Expanding Epinephrine Access: Nonprescription Pathways, Labeling Challenges, and Equity Considerations

Presentations from leaders in FDA's Office of Nonprescription Drugs detailed ways that FDA's regulatory pathways could enable sponsors to expand access to epinephrine in the nonprescription setting via prescription-to-nonprescription switches or applications that include an ACNU.

A prescription-to-nonprescription switch requires strong evidence that consumers can understand when and how to use epinephrine based on information listed in the Drug Facts label. Presentations indicated that label comprehension studies, self-selection studies, actual use studies, and human factors studies may be necessary to support FDA decision-making. The recently finalized ACNU rule was also discussed. The rule supports new, innovative approaches such as digital tools or supplemental instructions to ensure safe and effective use of a nonprescription drug product.

All currently approved dosage forms of epinephrine (e.g., auto-injector, intranasal) are potential nonprescription candidates, though participants pointed to unique challenges presented by each dosage form. In regulatory decision-making for nonprescription products, FDA weighs a product's safety, misuse potential, and real-world feasibility of use. Throughout the workshop, clinicians, representatives from patient advocacy groups, and other participants generally agreed that epinephrine has a strong safety profile, and the risk of adverse events or misuse is low.

Priority Recommendations for Enhancing Access

Participants in the final panel emphasized several promising areas for enhancing access to epinephrine that merit further research. Participants highlighted the importance of gaining a deeper understanding of nonclinical factors affecting epinephrine access in community settings. These included exploring the economic implications of stock epinephrine in public settings and epinephrine affordability for individuals relying on public health plans. Additional research into patients' hesitancy to administer the drug and patterns of real-world use could also inform the development of mitigation strategies to address psychological barriers. Participants saw value in clinical research scoped to optimize dosage forms and routes of administration to improve efficacy, identify patients who fail to respond to epinephrine, better characterize phenotypes at higher risk for severe reactions, and evaluate emerging noninjectable epinephrine options. Refining allergy management approaches for older adults, who suffer from food and venom-induced reactions, was also noted as an opportunity for further investigation.

Participants also pointed to several policy avenues that could strengthen access. Improving pathways for writing prescriptions for stock epinephrine—particularly in school settings—was seen as a practical step forward. Louisiana was cited as a model for comprehensive legislation that supports both epinephrine and other emergency medications. Aligning state laws to account for all FDA approved dosage forms, ensuring epinephrine is readily available

Finally, participants noted that technological and educational advancements can play a significant role in improving anaphylaxis preparedness. Digital tools, such as health-based applications available via mobile phones, may help increase public education about treating anaphylaxis with epinephrine. In turn, digitally accessible public education tools may help reduce stigma around carrying and using epinephrine while reminding individuals not to depend solely on stock devices in public settings. Emerging technologies offer new opportunities to study real world anaphylaxis management, refine diagnostic tools, and monitor outcomes. The overarching goal of these emerging technologies, when combined with practical policy reforms, is creating long-term improvements in anaphylaxis diagnosis, treatment, and management for both patients and clinicians.

Conclusion

The Duke-Margolis Institute for Health Policy and the U.S. Food and Drug Administration thank the meeting participants and commenters on the associated public docket. The workshop successfully brought together diverse stakeholders to identify barriers, share solutions, and chart a path forward for improving anaphylaxis outcomes. Comments made during this meeting and within the public docket will inform FDA's efforts to improve access to epinephrine moving forward.