4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-2976]

Improving Anaphylaxis Outcomes: Approaches for Enhancing Access to Epinephrine; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled "Improving Anaphylaxis Outcomes: Approaches for Enhancing Access to Epinephrine." The purpose of the public workshop is to initiate a discussion on expanding epinephrine accessibility and use, including in community settings, to reduce anaphylaxis-related morbidity and mortality. This public workshop will be convened and supported by a cooperative agreement between FDA and the Duke-Margolis Institute for Health Policy.

DATES: The public workshop will be held virtually and in person on December 16, 2025, from 9 a.m. to 4:30 p.m. Eastern Time. Either electronic or written comments on this public workshop must be submitted by January 16, 2026. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held virtually using the Zoom Platform and in person at the Duke in DC Office, 1201 Pennsylvania Ave. NW, Suite 500, Washington, DC 20004 with limited seat availability. Parking is available through a number of area garages including one located at 1201 Pennsylvania Ave. with entrance off of E Street. Names of in-person attendees will be provided to building security. Upon entering the building, please walk toward the front desk. The security staff at the front desk will have a list of all confirmed in-

person attendees and will provide access to the elevators. Upon exiting the elevator on the 5th floor, turn right and you will find the entrance to the Duke offices.

You may submit comments as follows: Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 16, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2025-N-2976 for "Improving Anaphylaxis Outcomes: Approaches for Enhancing Access to Epinephrine." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law.

For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket, to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Phong Pham, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6122, Silver Spring, MD 20993-0002, 301-837-7656, Phong.Pham@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Anaphylaxis is a severe and rapidly progressive allergic reaction, with a lifetime prevalence in the United States of up to 5 percent (Ref. 1) and resulting in approximately 200 deaths annually (Ref. 2). This allergic reaction can occur within minutes of exposure to common allergens, including foods, medications, and insect stings; in some cases, anaphylaxis occurs with no identifiable trigger. The physiological cascade of anaphylaxis involves massive histamine release and vascular permeability changes that can lead to airway obstruction, cardiovascular collapse, and multi-organ failure within 15 to 30 minutes if left untreated. Unlike milder allergic reactions, anaphylaxis requires immediate intervention with epinephrine as the only effective first-line treatment (Refs. 3, 4).

Despite epinephrine's critical role in preventing anaphylactic deaths, potential barriers limit access to and use of this life-saving medication (Refs. 5, 6). For example, patients prescribed epinephrine may not have it available during anaphylaxis; may choose not to use it due to knowledge gaps, fear, stigma, misperceptions, or discomfort; or may use it incorrectly,

resulting in inadequate dosing (Ref. 7). Institutional barriers may also present access challenges in community settings, where anaphylactic emergencies commonly occur. Schools, workplaces, restaurants, sports facilities, transportation vehicles, and public venues may lack comprehensive policies for epinephrine storage, staff training, and emergency administration protocols. State laws vary significantly regarding Good Samaritan protections for lay administration of epinephrine, creating liability concerns that discourage institutions from maintaining emergency supplies. Additional potential barriers include economic obstacles due to the cost of epinephrine products that could potentially be administered in community settings (i.e., "community-use" epinephrine products), as well as geographic disparities, especially in rural communities where pharmacies may be spread out, emergency medical services can have longer response times, and healthcare infrastructure is limited. There are also potential procedural barriers with navigating the healthcare system such as obtaining healthcare provider authorization and maintaining a current prescription for epinephrine.

The purpose of the public workshop is to initiate a discussion on expanding epinephrine accessibility and use, including in community settings, to reduce anaphylaxis-related morbidity and mortality.

II. Topics for Discussion at the Public Workshop

For more information on the meeting topics, visit https://duke.is/EpiAccess. The Duke-Margolis Institute for Health Policy will publish a discussion guide outlining background information and current thinking on the topic areas to this website approximately 1 week before the meeting date. FDA will also post the agenda and other meeting materials to this website approximately 3 business days before the meeting.

The format of the public workshop will consist of a series of presentations, panel discussions, and open discussion.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: https://duke.is/EpiAccess. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number.

Registration is free. Persons interested in attending this public workshop must register and receive registration confirmation. Early registration is recommended. Registrants will receive confirmation when they have been accepted. If you need special accommodations due to a disability, please contact margolisevents@duke.edu no later than December 2, 2025, 11:59 p.m. Eastern Time.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session. All requests to make oral presentations must be received by November 21, 2025, 11:59 p.m. Eastern Time. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will select and notify participants by December 1, 2025, 11:59 p.m. Eastern Time. All requests to make oral presentations must be received by November 21, 2025, 11:59 p.m. Eastern Time. If selected for presentation, any presentation materials must be emailed to Brian Canter at brian.canter@duke.edu no later than December 11, 2025, 11:59 p.m. Eastern Time. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast via Zoom and the archived video footage will be available at the event website. The link for registration is the same as above: https://duke.is/EpiAccess. Registered webcast participants will be sent technical system requirements in advance of the event. It is recommended that you

review these technical system requirements before joining the streaming webcast of the public workshop.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at https://www.regulations.gov. It may be viewed at the Dockets Management Staff (see ADDRESSES). A link to the transcript will also be available on the internet at https://duke.is/EpiAccess.

Notice of this meeting is given pursuant to 21 CFR 10.65.

IV. References

The following references are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at https://www.regulations.gov as these references are copyright protected. Some may be available at the website address, if listed. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. Wood, RA, CA Camargo Jr., P Lieberman, HA Sampson, LB Schwartz, M Zitt, C Collins, M Tringale, M Wilkinson, J Boyle, and FER Simons, 2014, Anaphylaxis in America: The Prevalence and Characteristics of Anaphylaxis in the United States, J Allergy Clin Immunol, 133(2):461–467. Available at https://doi.org/10.1016/j.jaci.2013.08.016.

2. Ma, L, TM Danoff, and L Borish , 2014, Case Fatality and Population Mortality Associated With Anaphylaxis in the United States, J Allergy Clin Immunol, 133(4):1075–1083. Available at https://doi.org/10.1016/j.jaci.2013.10.029.

3. Golden, DBK, J Wang , S Waserman, C Akin, RL Campbell, AK Ellis, M Greenhawt, DM Lang, DK Ledford, J Lieberman, J Oppenheimer, MS Shaker, DV Wallace, EM Abrams, JA Bernstein, DK Chu, CC Horner, MA Rank, DR Stukus; Collaborators: AG Burrows, H Cruickshank; Workgroup Contributors: DBK Golden, J Wang, C Akin, RL Campbell, AK Ellis, M Greenhawt, DM Lang, DK Ledford, J Lieberman, J Oppenheimer, MS Shaker, DV Wallace, S

Waserman; Joint Task Force on Practice Parameters Reviewers: EM Abrams, JA Bernstein, DK Chu, AK Ellis, DBK Golden, M Greenhawt, CC Horner, DK Ledford, J Lieberman, MA Rank, MS Shaker, DR Stukus, and J Wang, 2024, Anaphylaxis: A 2023 Practice Parameter Update, Ann Allergy Asthma Immunol, 132(2):124–176. Available at https://doi.org/10.1016/j.anai.2023.09.015.

4. Dribin, TE, S Waserman, and PJ Turner, 2023, Who Needs Epinephrine? Anaphylaxis, Autoinjectors, and Parachutes, J Allergy Clin Immunol Pract, 11(4):1036–1046. Available at https://doi.org/10.1016/j.jaip.2023.02.002.

5. Prince, BT, I Mikhail, and DR Stukus, 2018, Underuse of Epinephrine for the Treatment of Anaphylaxis: Missed Opportunities, J Asthma Allergy, 11:143–151. Available at https://doi.org/10.2147/JAA.S159400.

6. Lieberman, JA and J Wang, 2020, Epinephrine in Anaphylaxis: Too Little, Too Late, Curr Opin Allergy Clin Immunol, 20(5):452–458. Available at https://doi.org/10.1097/ACI.0000000000000680.

7. Ridolo, E, M Montagni, L Bonzano, E Savi, S Peveri, MT Costantino, M Crivellaro, G Manzotti, C Lombardi, M Caminati, C Incorvaia, and G Senna, 2015, How Far From Correct Is the Use of Adrenaline Auto-Injectors? A Survey in Italian Patients, Intern Emerg Med, 10(8):937–941. Available at https://doi.org/10.1007/s11739-015-1255-z.

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