(TVAP) Data (OMB #0970–0467; expiration date February 28, 2026).

DATES: *Comments due* December 24, 2025.

ADDRESSES: The public may view and comment on this information collection request at: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202511-0970-005.* You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The Trafficking Victims Protection Act of 2000 (TVPA), as amended, authorizes the Secretary of HHS to expand benefits and services to victims of severe forms of trafficking in persons in the U.S. Through TVAP, grant recipients provide time-limited comprehensive case management services to confirmed and potential victims of a severe form of human trafficking, as defined by TVPA, as amended, who are seeking or have received HHS certification. Case management services must be provided to qualified persons directly by full-time case managers that are staffed by the prime recipient and may also be provided through a network of per capita service providers.

OTIP proposes to continue to collect information to measure grant project performance, provide technical assistance to grant recipients, assess program outcomes, inform program evaluation, respond to congressional inquiries and mandated reports, and inform policy and program development that is responsive to the needs of victims.

The information collection captures information on participant demographics (*e.g.,* age, sex, type of trafficking experienced, service location) and services provided, along with aggregate information on outreach activities conducted, subrecipients enrolled, and dollars spent per service. Minor nonsubstantive updates have been made to performance indicators under this collection to simplify response options or to bring the collection into alignment with OTIP's grant recipient reporting database, the Anti-Trafficking Information Management System (ATIMS).

Respondents: TVAP grant recipients and clients of those programs, specifically: TVAP and the Aspire: Child Trafficking Victim Assistance Demonstration Program funding recipients.

Annual Burden Estimates

Based on review of performance data received pertaining to the number of clients served through TVAP programs and funding levels, the total number of respondents for each form has been lowered. The time to complete each form remains the same.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Client Characteristics and Program Entry	5300	1	0.75	3975	1325
Client Case Closure	5300	1	0.167	885	295
Barriers to Service Delivery and Monitoring	120	4	0.167	80	27
Client Service Use and Delivery	5300	1	0.25	1325	442
Client Outreach	120	4	0.3	144	48
Subrecipient Enrollment	60	3	0.167	30	10
Client Service Costs	60	1	0.5	30	10

Estimated Total Annual Burden Hours: 2,157.

Authority: 22 U.S.C. 7105

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–20770 Filed 11–21–25; 8:45 am]

BILLING CODE 4184–73–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.*

Lowell M. Zeta,

Acting, Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–20658 Filed 11–21–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1109]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by December 24, 2025.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0607. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, Office of Operations,