www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or *https://www.regulations.gov.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–14158 Filed 7–13–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources & Services Administration

Request for Information, Training and Care Delivery Models for Safe Administration of Potential FDA-Approved Psychedelic Therapies in Ambulatory Clinical Settings

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice, request for information.

SUMMARY: On April 18, 2026, President Trump issued Executive Order (E.O.) 14401, ''Accelerating Medical Treatments for Serious Mental Illness'', acknowledging that individuals suffering from serious mental illness may not always respond to existing therapies. This request for information (RFI) solicits stakeholder feedback on training and care delivery models that could be used to ensure safe and effective delivery of potential future Food and Drug Administration (FDA)-approved psychedelic drugs, including drugs administered in ambulatory clinic settings, such as health centers and rural health clinics.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by August 13, 2026.

FOR FURTHER INFORMATION CONTACT: To request more information on this RFI, please contact Ashley Stultz and Ann Sheehy at *informationRFI@hrsa.gov.* When submitting comments or requesting information, please include the RFI title for reference.

ADDRESSES: In commenting, refer to the RFI title. Comments, including mass comment submissions, must be submitted in one of the following two ways (please choose only one of the ways listed):

1. *Electronically.* Starting July 14, 2026, you may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address: Health Resources and Services Administration, Department of Health and Human Services, 5600 Fishers Lane, Room 13N194, Rockville, MD 20857.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. All comments received before the close of the comment period will be posted on the following website as soon as possible after they have been received: *http://www.regulations.gov.* HRSA will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. HRSA continues to encourage individuals not to submit duplicative comments. HRSA will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments. HRSA encourages commenters to include supporting facts, research, and evidence in their comments. When doing so, commenters are encouraged to provide citations to the materials referenced, including active hyperlinks. Likewise, commenters who reference materials that have not been published are encouraged to upload relevant data collection instruments, data sets, and detailed findings as a part of their comment. Providing such citations and documentation will assist HRSA in analyzing the comments.

I. Background

On April 18, 2026, President Trump issued Executive Order (E.O.) 14401, ''Accelerating Medical Treatments for Serious Mental Illness'', acknowledging that individuals suffering from serious mental illness may not always respond to existing therapies, and emphasizing the importance of exploring psychedelic therapies as new treatment options. This RFI solicits stakeholder feedback on recommended training and care delivery models that could be used to ensure safe and effective delivery of any potential future FDA-approved psychedelic drugs. In particular, HRSA has interest in ensuring that patients in medically underserved communities have access to these therapies, if approved, and request stakeholder feedback on how psychedelics might be delivered in these settings, including ambulatory clinics such as health centers. HRSA also requests input on workforce training in psychedelic care delivery.

II. Solicitation of Public Comments

While HRSA accepts all relevant input, we are specifically inviting responses on the following topics, noting this RFI does not necessarily solicit comments on the full scope of topics related to psychedelic therapy. When responding, please provide clear explanations along with detailed responses, including protocols, publications, data and any other relevant materials that may assist HRSA in this RFI.

Workforce Training

HRSA recognizes that clinical delivery of psychedelic therapies in health care delivery sites must start with counseling and identification of appropriate patients for such therapies prior to administration of the drug. There also must be appropriate follow up in place following the administration of a psychedelic drug. Although these phases may not be mutually exclusive or entirely distinct, for the purposes of the RFI we are asking questions about training requirements in each of these three phases:

- *Pre-administration patient eligibility, screening and counseling:* What training should be required of providers counseling, screening, and identifying patients eligible for psychedelic therapy? Should a broad screening process and a more detailed diagnostic assessment be conducted as two separate activities (and if so, provided by different individuals) or combined into a single screening session? What competencies do providers need to achieve to serve patients in this phase of care? Should providers be required to have a professional degree (social work, psychologist, other)? Should providers be required to have a medical degree (physician, nurse practitioner, physician assistant, nurse, other), or not (peers or other trained non-professionals)? Is telehealth an appropriate means of screening and identifying patients for these therapies, and counseling patients on what to expect during psychedelic administration? How do multiple providers (*e.g.,* primary care and behavioral health providers) communicate plans for psychedelic therapies and/or collaborate to provide psychedelic therapies?
- *In-clinic day of drug administration:* What training should be

required of providers administering psychedelic therapies in an ambulatory clinic setting? What competencies do providers need to achieve to serve patients in this phase of care? Should providers be required to have a professional degree (social work, psychologist, other), or not (peers or other trained non-professionals)? Should providers be required to have a medical degree (physician, nurse practitioner, physician assistant, nurse, other)? Is there a need for a state licensing requirement for providers? Is telehealth and/or remote monitoring an acceptable means of caring for patients during drug administration and observation in clinic?

- *Post-administration follow up:* What training should be required of providers caring for patients in follow up of psychedelic administration in the days and weeks that follow? Should providers have specialized training in evidence-based psychotherapy keyed to the specific intervention administered? Should providers be required to have a professional degree (social work, psychologist, other), or not (peers or other trained non-professionals)? Should providers be required to have a medical degree (physician, nurse practitioner, physician assistant, nurse, other)? Is telehealth an appropriate means of conducting follow-up?
- *General training/supervision:* What training models would be most effective (*e.g.,* didactic, simulation-based, supervised practicum, apprenticeship, certification)? How should supervision requirements differ across provider types, if any?

Federally Qualified Health Centers, Certified Community Behavioral Health Clinics, Rural Health Clinics, and Other Ambulatory Clinic Settings

Patients living in medically underserved communities often have disparate access to new therapies, and improving access to future FDA-approved psychedelic therapies is an Administration priority. HRSA is exploring how HRSA can provide technical assistance and guidance to assist Federally Qualified Health Centers, Certified Community Behavioral Health Clinics, and Rural Health Clinics to be able to safely and effectively administer psychedelic therapies in order to reach medically underserved populations. To understand what may be needed in such settings, HRSA requests responses to the following:

- What should be the basic (essential) requirements for safe administration of psychedelic therapies in ambulatory clinic settings, like health centers?
- What are the ideal environmental and situational features desired in a clinic setting to optimize therapeutic outcomes? Which of these features are essential, and which are more ''nice to have''?
- Should a licensed medical provider (physician, nurse practitioner, physician assistant, etc.) medically evaluate a patient prior to drug administration? Should a medical provider be available on site during a psychedelic treatment session?
- How many trained providers should be physically present on-site per patient receiving psychedelic therapy?
- Is telehealth or remote (off-site) monitoring an acceptable model for psychedelic drug therapy, either alone or in combination with an on-site provider?
- Should health centers be required to achieve certification to deliver psychedelic drugs?
- Should requirements be different for different formulations?
- How might implementation of the care delivery model affect workforce productivity and clinic capacity?
- What facility, storage, security, and inventory-control requirements would be necessary for health centers to satisfy legal requirements and to safely receive, store, manage, and administer psychedelic medications, and what challenges would health centers face in meeting those requirements?
- How should clinic organization or operations be adapted to provide psychedelic therapies?

Technology-Enabled Scalability

The labor-intensive nature of psychedelic therapy poses a significant challenge to scaling these therapies in medically underserved communities, where workforce shortages are most acute. HRSA is interested in whether and how artificial intelligence (AI), digital health tools, and other technologies might safely expand access and capacity without compromising patient safety. HRSA seeks information related to the following:

- Could tools, including AI technology, support patient screening, eligibility determination, risk stratification, or detection of contraindications? What human oversight should be required, and what are the limits of automated screening for this population?
- Could AI-enabled monitoring (*e.g.,* automated detection of physiological or behavioral signs of distress) augment or partially substitute for continuous in-person observation during administration, and under what conditions? What safeguards would be essential, recognizing that patients may be acutely vulnerable and unable to self-advocate?
- Could AI-supported tools (*e.g.,* integration aids, symptom tracking, conversational support) extend clinician-led follow up and integration?
- Could AI and simulation-based tools (*e.g.,* virtual standardized patients, scenario-based training) accelerate or standardize workforce training, particularly in rural and medically underserved settings?
- Which technology-enabled models offer the greatest potential to expand access in health centers, Certified Community Behavioral Health Clinics, and Rural Health Clinics while maintaining safety, and could they widen or narrow existing disparities?

III. Collection of Information Requirements

Please note, this is an RFI only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

This RFI is issued solely for information and planning purposes; it does not constitute a request for proposals, applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, HRSA is not seeking proposals through this RFI and will not accept unsolicited proposals. Respondents are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. In addition, HRSA will not respond to questions related to policy issues raised in this RFI.

HRSA will actively consider all input as we develop future policy. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. In addition, HRSA

shall publicly post the public comments received in their entirety.

Ann M. Sheehy,

Principal Deputy Administrator.

[FR Doc. 2026–14146 Filed 7–13–26; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, Division of Injury Compensation Programs, 5600 Fishers Lane, Room 8W–25A, Rockville, Maryland 20857; 1–800–338–2382, or visit our website at: *https://www.hrsa.gov/vaccine-compensation.*

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.,* provides that those seeking compensation are to file a petition with the United States Court of Federal Claims and to serve a copy of the petition to the Secretary of HHS, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that ''[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**.'' Set forth below is a list of petitions received by HRSA on June 1, 2026, through June 30, 2026. This list provides the name of the petitioner, city, and state of vaccination (if unknown then the city and state of the person or attorney filing the claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master ''shall afford all interested persons an opportunity to submit relevant, written information'' relating to the following:

1. The existence of evidence ''that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,'' and

2. Any allegation in a petition that the petitioner either:

a. ''[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by'' one of the vaccines referred to in the Table, or

b. ''[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine'' referred to in the Table.

In accordance with Section 2112(b)(2), all interested persons may submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three copies of the information with the Clerk of the United States Court of Federal Claims at the address listed above (under the heading **FOR FURTHER INFORMATION CONTACT**), with a copy to HRSA addressed to Director, Division of Injury Compensation Programs, Health Systems Bureau, 5600 Fishers Lane, 8W–25A, Rockville, Maryland 20857. The Court's caption (*Petitioner's Name* v. *Secretary of HHS*) and the docket number assigned to the petition should be used as the caption for the written submission. Chapter 35 of Title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

Thomas J. Engels,

Administrator.

List of Petitions Filed

1. Kylie Vizzusi, Carson City, Nevada, Court of Federal Claims No: 26–0799V
2. Mary Scott, Mesquite, Texas, Court of Federal Claims No: 26–0800V
3. Sergio Tavarez, West Lawn, Pennsylvania, Court of Federal Claims No: 26–0801V
4. Amber Campbell, Woodridge, Illinois, Court of Federal Claims No: 26–0802V
5. Rachel Seeds, Alisa Viejo, California, Court of Federal Claims No: 26–0805V
6. Michael Degarmo, Mustang, Oklahoma, Court of Federal Claims No: 26–0806V
7. Latoya Kennedy, Bellingham, Washington, Court of Federal Claims No: 26–0807V
8. Annamarie Tesoro Porter, Solvang, California, Court of Federal Claims No: 26–0810V
9. Hazel Nicholson, Pensacola, Florida, Court of Federal Claims No: 26–0811V
10. Jael Narain Mendoza, Kaplan, Louisiana, Court of Federal Claims No: 26–0815V
11. Brenda Thompson, Menomonee, Wisconsin, Court of Federal Claims No: 26–0816V
12. Elmo Peyton, Boscobel, Wisconsin, Court of Federal Claims No: 26–0817V
13. Gayle Hermann, Philadelphia, Pennsylvania, Court of Federal Claims No: 26–0818V
14. Joan Cornish, Phoenix, Arizona, Court of Federal Claims No: 26–0819V
15. Jennifer Jangula, Woodridge, Illinois, Court of Federal Claims No: 26–0821V
16. Ivan Ekblom, Grants Pass, Oregon, Court of Federal Claims No: 26–0823V
17. Kelly Rothenberger, Washington, District of Columbia, Court of Federal Claims No: 26–0824V
18. Mai Takieng, Petaluma, California, Court of Federal Claims No: 26–0825V
19. Tanisha Williams, Woodridge, Illinois, Court of Federal Claims No: 26–0826V
20. Georgine Cwynar, Machesney Park, Illinois, Court of Federal Claims No: 26–0827V
21. Joseph Pires, Wareham, Massachusetts, Court of Federal Claims No: 26–0829V
22. Anna Severina, East Meadow, New Jersey, Court of Federal Claims No: 26–