Authority: Social Security Act, Section 409; 45 CFR 286,245–286.285.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2026–01855 Filed 1–29–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–0131]

FDA Rare Disease Innovation Hub Future Programming; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the following request for comments for a future public workshop series entitled ''Rare disease Innovation, Science, and Exploration (RISE) Workshop.'' The purpose of the public workshops is to focus on challenges that are common to multiple diseases or a class of diseases, and for which evolving science offers innovative solutions. The workshops will primarily focus on cross-cutting or common issues and will not be focused on any specific product under review by the Agency. The Agency further welcomes comments that highlight general rare disease-related issues of potential interest for the FDA Rare Disease Innovation Hub (Hub) to inform its future activities.

DATES: Submit either electronic or written comments by December 31, 2026. See the **SUPPLEMENTARY INFORMATION** section for comment deadlines corresponding to specific workshop sessions.

ADDRESSES: 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 December 31, 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–2026–N–0131 for ''FDA Rare Disease Innovation Hub Future Programming; Request for Comments.'' 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: Philipa Friedman, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–7911, *RDInnovationHub@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA is publishing this request for comments to obtain suggestions for topics for future RISE Workshops. The Hub supports the RISE Workshop series pursuant to its commitment to further advance regulatory science of rare disease therapies and the Agency's PDUFA VII commitments to enhance regulatory science and expedite drug development and rare disease product review under the Food, Drug, and Cosmetic Act.

The Hub-sponsored RISE workshop series focuses on challenges that are common to multiple diseases or a class of diseases, and for which evolving science offers innovative solutions. The workshops are open to the public and designed for interaction and discourse between the various rare disease community members and perspectives, including drug developers, patient and disease organizations, academics, FDA regulators and reviewers, and relevant staff from other federal agencies. All workshops include coordination of the relevant medical product Centers and

address the Centers' approaches to the relevant issues. The workshops also include a discussion of the role of patients and patient/disease organizations in the design and implementation of innovative solutions. The workshops primarily focus on cross-cutting or common issues and will not be focused on any specific product under review by the Agency. Preference will be given to submissions that are germane to multiple disease states and/or that are submitted jointly by two or more entities.

For consideration for the summer RISE Workshop, FDA requests comments by February 28, 2026. For consideration for the fall RISE Workshop, FDA requests comments by May 31, 2026. The Agency requests that submissions include:

- A description of the proposed topic;
- Suggested speakers and/or subject matter experts;
- A description of the impact of the topic on the development and regulatory science of rare disease therapies;
- The disease state(s) affected by the challenge highlighted in the submission;
- If relevant, related FDA guidances or existing programs addressing the challenge highlighted in the submission.

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

Lowell M. Zeta,

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

[FR Doc. 2026–01903 Filed 1–29–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: HRSA AIDS Drug Assistance Program Data Report, OMB No. 0915–0345—Extension

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than March 31, 2026.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 13N82, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: HRSA AIDS Drug Assistance Program (ADAP) Data Report, OMB No. 0915–0345 Extension

Abstract: HRSA's Ryan White HIV/AIDS Program (RWHAP) ADAP is authorized under Part B of the RWHAP statute, codified in sections 2611 to 2631 of the Public Health Service Act, which provides grants to U.S. states and territories. RWHAP ADAP is a state and territory administered program that provides Food and Drug Administration-approved medications to low-income people with HIV who have limited or no health coverage from private insurance, Medicaid, or Medicare. RWHAP ADAP funds may also be used to purchase health care coverage for eligible clients and for services that enhance access, adherence, and monitoring of drug treatments.

All 50 states, the District of Columbia, Puerto Rico, Guam, the U.S. Virgin Islands, and the five U.S. Pacific Territories or Associated Jurisdictions receive RWHAP Part B grant awards, including funds for RWHAP ADAP. RWHAP Part B requires the annual submission of an ADAP Data Report, which is composed of a Recipient Report and a Client Report. The Recipient Report is a collection of basic information about grant recipient characteristics and policies including program administration, purchasing mechanisms, funding, and expenditures. The Client Report is a collection of de-identified client-level records (one record for each client enrolled in RWHAP ADAP), which includes the client's encrypted unique identifier, basic demographic data, enrollment and certification information, details on medication and/or health care coverage assistance received (including associated costs), and HIV clinical information.

HRSA is not proposing any changes to the collection, and there are no anticipated changes in the reporting burden.

Need and Proposed Use of the Information: The RWHAP statute mandates the submission of a biennial report by the Secretary of HHS to the appropriate committees of Congress concerning the coordination of federal HIV programs across HHS (42 U.S.C. 300ff-81(b)). HRSA uses the ADAP Data Report to evaluate the national impact of RWHAP ADAP by providing deidentified client-level data on individuals being served, services being delivered, and costs associated with these services. The client-level data is used to assess the health outcomes of people with HIV receiving services through RWHAP ADAP, monitor the use of RWHAP ADAP funds in addressing the HIV epidemic and its impact on communities, and track progress toward achieving the goals identified in ending the HIV epidemic in the United States.

Likely Respondents: State ADAPs of RWHAP Part B recipients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and use technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.