## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2025–N–3623]**

### Advancing the Development of Pediatric Therapeutics (ADEPT) 10: Addressing Challenges in Neonatal Product Development—Leveraging Rare Disease Frameworks; Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the following public workshop entitled ''Advancing the Development of Pediatric Therapeutics (ADEPT) 10: Addressing Challenges in Neonatal Product Development—Leveraging Rare Disease Frameworks.'' The aim of the public workshop is to discuss common challenges in neonatal and rare disease product development and identify opportunities to leverage rare disease product development frameworks in the neonatal product development space.

**DATES:** The public workshop will be held on Wednesday, December 10, 2025, 1:00 p.m.—5:00 p.m. Eastern Time, and Thursday, December 11, 2025, from 8:30 a.m. until 4:00 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public workshop on December 10 and 11, 2025, will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Additionally, the meeting will be streamed online on both dates. Entrance for in-person registered public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/about-fda/visitor-information* and *https://www.fda.gov/about-fda/visitor-information/visitor-parking-and-campus-map.*

**FOR FURTHER INFORMATION CONTACT:** Marianne Noone, the Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–7495, *OPT@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

#### I. Background

Since 2014, FDA has hosted an annual public workshop focused on Advancing the Development of Pediatric Therapeutics (ADEPT). The ADEPT Workshops offer opportunities for stakeholders to meet to discuss challenging scientific issues related to pediatric product development and pediatric regulatory science. The primary aims of ADEPT Workshops are to:

- Discuss advancements in pediatric therapeutics development;
- Identify gaps in current knowledge and explore innovative approaches to address those gaps; and
- Provide a platform for open dialogue between regulators, industry, academia, and patient organizations.

#### II. Topics for Discussion at the Public Workshop

The specific topics for discussion at this workshop include, but are not limited to, the following:

- identifying common challenges in neonatal and rare disease product development;
- discussing ethical considerations relevant to neonatal and rare disease product development;
- identifying opportunities to leverage rare disease tools and strategies for neonatal conditions; and
- discussing the regulatory landscape of rare disease programs/resources and their application to neonatal conditions.

#### III. Participating in the Public Workshop

*Registration:* To register for the public workshop, please visit the following website: *https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/advancing-development-pediatric-therapeutics-adept-10-addressing-challenges-neonatal-product.* Please provide complete contact information for each attendee, including name, email address, and affiliation.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop in-person must register by December 9, 2025, at 12:00 p.m. Eastern Time; virtual attendees may register by December 10, 2025, at 12:00 p.m., Eastern Time. Early registration for in-person attendance is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the first day of the public workshop (December 10, 2025) will be provided beginning at 11:00 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact *OPT@fda.hhs.gov* no later than November 26, 2025.

If you have never attended a Zoom event before, test your connection at *https://zoom.us/test.* Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

*Transcripts:* Please be advised that as soon as a transcript of the public workshop is available, it will be accessible on the workshop website: *https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/advancing-development-pediatric-therapeutics-adept-10-addressing-challenges-neonatal-product.*

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

**Grace R. Graham,**

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

[FR Doc. 2025–18273 Filed 9–19–25; 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: Medicare Rural Hospital Flexibility Program Performance, OMB No. 0915–0363—Revision

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

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

**DATES:** Comments on this ICR should be received no later than October 22, 2025.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent

within 30 days of publication of this notice to: *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.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* Medicare Rural Hospital Flexibility Program Performance, OMB No. 0915–0363—Revision.

*Abstract:* The mission of the Federal Office of Rural Health Policy (FORHP) within HRSA is to sustain and improve access to quality health care services for rural communities. FORHP administers the Medicare Rural Hospital Flexibility Program (Flex Program) authorized by Section 1820(g) of the Social Security Act (42 U.S.C. 1395i–4(g)). The Flex Program enables state designated entities to support critical access hospitals in quality improvement, quality reporting, performance improvement, and benchmarking; to assist facilities seeking designation as critical access hospitals; and to create a program to establish or expand the provision of rural emergency medical services. HRSA currently collects information from grant recipients that participate in the Flex Program using an OMB-approved set of performance measures, the Medicare Rural Hospital Flexibility Program Performance Measures, and seeks to revise its approved information collection. HRSA is proposing significant changes to the method by which performance measures are collected, the organization of the measures, and the measures themselves. More detail is provided in the ''Need and Proposed Use of the Information'' section below.

A 60-day Notice was published in the **Federal Register** on November 6, 2024, vol. 89, No. 215; pp. 88053–55. A total of three comments were received. The comments and HRSA's responses are described below.

*Need and Proposed Use of the Information:* For this program, performance measures were developed to provide data useful to program administration, to benefit Flex Program recipients, and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Modernization Act of 2010. These measures cover principal topic areas of interest to FORHP, including: (a) quality reporting, (b) quality improvement interventions, (c) financial and operational improvement initiatives, (d) population health management, and (e) rural emergency medical services integration. In addition to informing HRSA's progress toward meeting the goals set in the Government Performance and Results Modernization Act, the information is important in identifying and understanding programmatic improvement across program areas, as well as guiding future activities and prioritizing areas of need and support.

Performance measures are collected electronically in the Performance Improvement and Measurement System (PIMS), which awardees currently access through the HRSA Electronic Handbooks, a data collection platform. As part of a broader change affecting all programs across FORHP, HRSA proposes to change the method of PIMS report submission from the Electronic Handbooks to a different electronic data collection platform. In addition, HRSA proposes to reduce the total number of forms submitted. The current collection involves eight forms, and HRSA proposes reducing this to six forms: one for recipients to select which program areas they are working in and one for each program area selected. One commenter noted the difficulty in reporting their annual spending. This feedback was incorporated into the new electronic data collection platform and that specific form will be removed and instead, the spending will be reported elsewhere without the specific problems of the coding background.

Performance measures in PIMS currently are organized by a series of checkboxes, where a state entity selects which hospitals are participating in a funded intervention and if that hospital has shown improvement after that intervention. HRSA proposes to change the organization of the measures to align with a format similar to a work plan submission, which is an existing requirement recipients must meet. Instead of the series of checkboxes used in the current collection, HRSA is proposing a series of dropdown menus where respondents can choose more specific information. One commenter noted that the change to dropdown menus to align more closely with the work plan would lead to a better reporting system. They noted that the current system of a series of checkboxes does not provide enough detail into what the program is currently doing and increases challenges in reporting, as errors are more likely to occur.

Finally, HRSA proposes revisions to performance measures in PIMS that include changes to align with current terminology used by HRSA, a broadening scope for some activities, and providing examples of more specific measures. Dropdown menus would contain lists of both common projects completed across the Flex Program and common outcome measures associated with each project. Respondents would not be required to collect all of the measures listed, rather they would be able to choose from a list of examples. One commenter noted that dropdown menus could be more effective if they were organized by program topic or funding area, rather than by hospital, and they should also include an option of ''other.'' HRSA's proposed changes to the data collection platform would organize the dropdown menus by program topic and would contain skip logic, meaning only an outcome measure related to the specific program topic would be allowed to be chosen, and all dropdowns would include an option for ''other.''

With these changes, HRSA estimates the burden on the recipients would decrease. Even though HRSA is proposing to include more specific performance measures in PIMS reporting, the additional measures reflect data the recipients are currently collecting in outside forms and spreadsheets. The current reporting system requires recipients to move between multiple forms and spreadsheets outside of the PIMS system and enter the information manually. The new system reduces duplication and manual data entry by allowing recipients to update their work plans, which are already in PIMS, with outcome data following the end of the year. One commenter noted that making the data collection directly reflective of the work plan could reduce the administrative burden of tracking measures that may not be related to their work plan. The same commenter also noted the preference to use the data collection platform to report their required work plan, which HRSA intends to do as part of this new collection.

*Likely Respondents:* Respondents are the Flex Program recipients. There are currently 45 states participating in the Flex Program.

*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 utilize 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.

Following comments received after the publication of the 60-day notice, HRSA decreased the average burden per response and total burden hours. Burden will be reduced by consolidating information into Salesforce, rather than entities needing to maintain data in multiple locations to report back to FORHP.

Total Estimated Annualized Burden Hours:

| Form name | Number of respondents | Number of responses per respondent | Total responses | Average burden per response (in hours) | Total burden hours |
|---|---|---|---|---|---|
| Performance Improvement Measurement System | 45 | 1 | 45 | 55 | 2,475 |
| Total | 45 | | 45 | | 2,475 |

**Maria G. Button,**

*Director, Executive Secretariat.*

[FR Doc. 2025–18266 Filed 9–19–25; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR–23–199: ClinGen Genomic Curation Expert Panels.

*Date:* November 3, 2025.

*Time:* 9:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Marcienne Wright, Ph.D., Scientific Review Officer, National Institutes of General Medical Sciences, Scientific Review Branch, 45 Center Drive, Bethesda, MD 20892, (301) 827–7635, *marci.wright@nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Vascular Biology and Diseases.

*Date:* November 4, 2025.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Cynthia D Anderson, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes Health, 6705 Rockledge Drive, Room 207–E, Bethesda, MD 20892, *cynthia.anderson@nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR Panel: Musculoskeletal, Skin and Oral Sciences Clinical Studies/Trials.

*Date:* November 4–5, 2025.

*Time:* 8:30 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Sushmita Purkayastha, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 451–1138, *sushmita.purkayastha@nih.gov.*

*Name of Committee:* Population Sciences and Epidemiology Integrated Review Group; Reproductive, Perinatal and Pediatric Health Study Section.

*Date:* November 4–5, 2025.

*Time:* 9:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Lisa Anne Deroo, MPH, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–4994, *lisa.deroo@nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Program Project: Cancer Research.

*Date:* November 4–5, 2025.

*Time:* 9:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Caterina Bianco, MD, Ph.D., Chief, Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W110, Bethesda, MD 20892, (240) 276–6459, *biancoc@mail.nih.gov.*

*Name of Committee:* Genes, Genomes, and Genetics Integrated Review Group; Therapeutic Approaches to Genetic Diseases Study Section.

*Date:* November 4–5, 2025.

*Time:* 9:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Maddalena Tilli Shiffert, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 710P, Bethesda, MD 20892, (301) 594–4257, *shiffertmt@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Hepatology and Toxicology.

*Date:* November 4–5, 2025.

*Time:* 9:30 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Stephanie Nicole Hicks, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–5710, *hickssn@mail.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Cardiovascular Sciences.

*Date:* November 4, 2025.

*Time:* 9:30 a.m. to 6:30 p.m.

*Agenda:* To review and evaluate grant applications.