validating assumptions, incorporating new information, and refining the program.

This draft guidance is being issued to fulfill the performance goals (available at *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027*) under the sixth reauthorization of the Prescription Drug User Fee Act (PDUFA VII). This REMS logic model guidance is the first in a series of planned guidances for industry and FDA staff to optimize REMS design and improve the way a REMS is assessed.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''REMS Logic Model: A Framework to Link Program Design With Assessment.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 for the submission of investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 for the submission of new drug applications and abbreviated new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 for the submission of biologics license applications have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 208 pertaining to Medication Guides for prescription drug and biological products have been approved under OMB control number 0910–0393. The collections of information in 21 CFR 201.56 and 201.57 for the content and format requirements for labeling of drugs and biologics have been approved under OMB control number 0910–0572. The collections of information in 21 CFR part 316 regarding orphan drug product development are approved under OMB control number 0910–0167. The collections of information pertaining to Prescription Drug User Fee Program have been approved under OMB control number 0910–0297.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: May 2, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–09928 Filed 5–6–24; 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: Rural Communities Opioid Response Program Performance Measures

**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 July 8, 2024.

**ADDRESSES:** Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 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 Joella Roland, 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:* Rural Communities Opioid Response Program (RCORP) Performance Measures, OMB No. 0906–0044—Revision

*Abstract:* HRSA administers RCORP, which is authorized by section 711(b)(5) of the Social Security Act (42 U.S.C. 912(b)(5)) and is a multi-initiative program that aims to: (1) support treatment for and prevention of substance use disorder (SUD), including opioid use disorder (OUD); and (2) reduce morbidity and mortality associated with SUD, including OUD, by improving access to and delivering prevention, treatment, and recovery support services to high-risk rural communities. To support this purpose, RCORP grant initiatives include:

- RCORP—Implementation grants fund established networks and consortia to deliver SUD/OUD prevention, treatment, and recovery activities in high-risk rural communities.
- RCORP—Psychostimulant Support grants aim to strengthen and expand access to prevention, treatment, and recovery services for individuals in rural areas who misuse psychostimulants, to enhance their ability to access treatment and move toward recovery.
- RCORP—Medication Assisted Treatment Access grants aim to establish new access points in rural facilities where none currently exist.
- RCORP—Behavioral Health Care support grants aim to expand access to and quality of behavioral health care services at the individual-, provider-, and community-levels.
- RCORP Overdose Response recipients address immediate needs in rural areas through improving access to, capacity for, and sustainability of prevention, treatment, and recovery services for SUD.
- RCORP Child and Adolescent Behavioral Health grants aim to establish and expand sustainable behavioral health care services for children and adolescents aged 5–17 years who live in rural communities.
- RCORP-Neonatal Abstinence Syndrome grants aim to reduce the incidence and impact of Neonatal Abstinence Syndrome in rural communities by improving systems of care, family supports, and social determinants of health.
- Note that additional grant initiatives may be added pending fiscal year 2025 and future fiscal year appropriations.

HRSA currently collects information about RCORP grants using approved

performance measures. HRSA developed separate performance measures for RCORP's new Overdose Response, Behavioral Health, and Neonatal Abstinence Syndrome grants and seeks OMB approval for the new performance measures.

*Need and Proposed Use of the Information:* Due to the growth in the number of grant initiatives included within RCORP, as well as emerging SUD and other behavioral health trends in rural communities, HRSA is submitting a revised ICR that includes measures for RCORP's new Overdose Response, Child and Adolescent Behavioral Health, and Neonatal Abstinence Syndrome grants.

For this program, performance measures were developed to provide data on each RCORP initiative and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act of 1993. These measures cover the principal topic areas of interest to HRSA's Federal Office of Rural Health Policy, including: (a) provision of, and referral to, rural behavioral health care services, including SUD prevention, treatment and recovery support services; (b) behavioral health care, including SUD prevention, treatment, and recovery, process and outcomes; (c) education of health care providers and community members; (d) emerging trends in rural behavioral health care needs and areas of concern; and (e) consortium strength and sustainability. All measures will speak to the progress on meeting the set goals of the Federal Office of Rural Health Policy.

*Likely Respondents:* The respondents will be the recipients of the RCORP grants.

*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.

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 |
|---|---|---|---|---|---|
| RCORP—Implementation | 290 | 2 | 580 | 1.24 | 719.20 |
| RCORP—Psychostimulant Support | 15 | 1 | 15 | 1.30 | 19.50 |
| RCORP—Medication Assisted Treatment Access | 11 | 1 | 11 | 1.95 | 21.45 |
| RCORP—Behavioral Health Care Support | 58 | 1 | 58 | 2.02 | 117.16 |
| Rural Communities Opioid Response—Overdose Response (NEW) | 47 | 3 | 141 | 0.56 | 78.96 |
| RCORP—Child and Adolescent Behavioral Health (NEW) | 9 | 2 | 18 | 0.48 | 8.64 |
| RCORP—Neonatal Abstinence Syndrome (NEW) | 41 | 4 | 164 | 2.31 | 378.84 |
| Total | 471 | | 987 | | 1,343.75 |

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Maria G. Button,**

*Director, Executive Secretariat.*

[FR Doc. 2024–09888 Filed 5–6–24; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Heart, Lung, and Blood Institute; Notice of Closed Meeting

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

The meeting 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:* Heart, Lung, and Blood Initial Review Group; NHLBI Mentored Clinical and Basic Science Study Section.

*Date:* June 27–28, 2024.

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

*Agenda:* To review and evaluate grant applications.

*Place:* The Bethesdan Hotel, Tapestry Collection by Hilton, 8120 Wisconsin Ave, Bethesda, MD 20814 (Hybrid Meeting).

*Contact Person:* Manoj Kumar Valiyaveettil, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208–R, Bethesda, MD 20817, (301) 402–1616, *manoj.valiyaveettil@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 1, 2024.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2024–09896 Filed 5–6–24; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Dental and Craniofacial Research; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute of Dental and Craniofacial Research.