III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,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.*

Dated: December 1, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26454 Filed 12–7–21; 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; Environmental Information and Documentation, OMB No. 0915–0324, 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 February 7, 2022.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or by mail to the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 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 acting HRSA Information Collection Clearance Officer at (301) 443–9094.

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

Information Collection Request Title: Environmental Information and Documentation (EID), OMB No. 0915–0324, Extension.

Abstract: HRSA is requesting approval of an extension for the EID checklist which consists of information that the agency is required to obtain to comply with the National Environmental Policy Act of 1969 (NEPA). NEPA establishes the federal government's national policy for protection of the environment. HRSA has developed the EID for applicants of funding that would potentially impact the environment and to ensure that their decision-making processes are consistent with NEPA.

Need and Proposed Use of the Information: Applicants must provide information and assurance of compliance with NEPA on the EID checklist. This information is reviewed in the Pre-Award stage (and/or prior to the implementation of the project). The information is reviewed in the Post-Award stage for project changes and the information is reviewed before the implementation of the project changes.

Likely Respondents: HRSA applicants applying for federal loan guarantees, federal construction grants, and cooperative agreements.

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
NEPA EID Checklist	1,500	1	1,500	1	1,500
Total	1,500		1,500		1,500

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. 2021–26560 Filed 12–7–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Rural Communities Opioid Response Program Performance Measures, OMB No. 0906–0044, Revision

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 February 7, 2022.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 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 acting HRSA Information Collection Clearance Officer at (301) 443–9094.

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

Information Collection Request Title: Rural Communities Opioid Response Program (RCORP) Performance Measures, OMB No. 0906–0044, Revised.

Abstract: RCORP 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, to include 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 to fund established networks and consortia to deliver SUD/OUD prevention, treatment, and recovery activities in high-risk rural communities;
- RCORP-Medication Assisted Treatment Expansion grants to enhance access to medication-assisted treatment within eligible hospitals, health clinics, or tribal organizations in high-risk rural communities;
- RCORP-Neonatal Abstinence Syndrome grants 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;
- RCORP-Psychostimulant Support grants to strengthen and expand prevention, treatment, and recovery services for individuals in rural areas who misuse psychostimulants; to enhance their ability to access treatment and move towards recovery; and
- Note that additional grant programs may be added pending Fiscal Year 2022 and future Fiscal Year appropriations.

Additionally, all RCORP grant award recipients are supported by eight cooperative agreements: RCORP-Technical Assistance, which provides extensive technical assistance to award recipients; RCORP-Evaluation, which evaluates the impact of the RCORP initiative on rural communities; three RCORP-Behavioral Health Care Workforce Centers, which provide workforce training and education initiatives in the region served by the Northern Border Regional Commission; and three RCORP-Centers of Excellence, which disseminate best practices related to the treatment for and prevention of substance use disorders within rural communities.

Need and Proposed Use of the Information: Due to the growth in the number of grant programs included in the RCORP initiative, as well as emerging SUD and other behavioral health trends in rural communities, HRSA is submitting a revised package that includes changes to existing RCORP performance measures as well as new performance measures that better demonstrate the impact of the initiative on rural communities and reduce burden on the grant recipients.

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 the 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 Federal Office of Rural Health Policy's progress toward meeting the goals set.

Likely Respondents: The respondents will be the grant award recipients of the RCORP initiatives.

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. Please note that since RCORP-Psychostimulant Support includes substantially different measures than the other RCORP grant programs, HRSA calculated that program's burden hours separately.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent (annually)	Total responses	Average burden per response (in hours)	Total burden hours
Rural Communities Opioid Response Program—Implementation/Neonatal Abstinence Syndrome/MAT Expansion	290	2	580	1.24	719.20
Rural Communities Opioid Response Program—Psychostimulant Support	15	1	15	1.30	19.50
Total	305	.....	595	.....	738.70

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. 2021–26559 Filed 12–7–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; COVID–19 Provider Relief Programs Application and Attestation Portal, and Claims Reimbursement Submission Activities, OMB No. 0906–XXXX—NEW

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has 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 January 7, 2022.

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 acting HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: COVID–19 Provider Relief Programs Application and Attestation Portal, and Claims Reimbursement Submission Activities, OMB No. 0906–XXXX—NEW.

Abstract: HRSA administers the Provider Relief Programs (which includes the Provider Relief Fund (PRF), the American Rescue Plan Act Rural (ARP–R) payments, the COVID–19 Coverage Assistance Fund (CAF), and the COVID–19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment, and Vaccine Administration for the Uninsured (Uninsured Program or UIP)). The Provider Relief Programs disbursed, and are continuing to disburse funds to eligible healthcare providers through two pathways: (1) Direct provider payments via the PRF and ARP–R payments, and (2) claims reimbursement via the CAF and the UIP. This information collection includes four components: (1) The PRF and ARP–R application portal; (2) the PRF and ARP–R attestation portal; (3) the CAF application portal; and (4) the UIP application portal. To date, information for these programs has been collected under a Paperwork Reduction Act waiver executed pursuant to public health emergency authorities. HRSA is seeking comments regarding the CAF and the UIP for the first time. These information collections support administration of the Provider Relief Programs including the PRF, the Uninsured Program, and the CAF (funds for these three programs were appropriated under the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136), Paycheck Protection Program and Health Care Enhancement Act (Pub. L. 116–139), Coronavirus Response and Relief Supplemental Appropriations Act (Division M of Pub. L. 116–260)), and the ARP–R payments (funds were appropriated under the American Rescue Plan Act of 2021, Pub. L. 117–2, as well as funds for the Uninsured Program).

A 60-day notice was published in the **Federal Register**, 86 FR 47119 (August 23, 2021). There were no public comments.

Need and Proposed Use of the Information: Providers who apply for Provider Relief Programs (*i.e.,* PRF, ARP–R, CAF, and UIP payments) must apply for direct provider payments or claims reimbursement and attest to a set of Terms and Conditions to enable HRSA's appropriate disbursement and oversight of recipients' use of funds. Information collected will allow for (1) assessing if recipients have met statutory and programmatic requirements; (2) conducting audits; (3) gathering data required to calculate, disburse, and report on PRF, ARP–R, CAF, and UIP payments; and (4) program evaluation. HRSA staff may also use information collected to identify and report on trends in the effect of the COVID–19 pandemic on health care providers and uninsured or underinsured patients throughout the United States. HHS makes publicly available the names of payment recipients and the aggregate amounts received, for all providers who attest to receipt of a payment and acceptance of the Terms and Conditions or who retain payments for more than 90 days and are deemed to have accepted the Terms and Conditions. By accepting funds, the recipient consents to HHS publicly disclosing the payments that recipient has received.

Likely Respondents: Health care providers that apply to receive, or have applied to receive, PRF, ARP–R, CAF, or UIP payments, and attested to the associated Terms and Conditions.

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.