

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Persons with access to the internet may obtain the draft guidance at either 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.

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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.

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