

RMPs depends on the stakeholder type (primary, secondary, or other stakeholder) and its operation.

We anticipate that stakeholders will be able to leverage information across products, but we understand that the actual burden for a given stakeholder will depend on the portfolio of covered products and the complexity of their operations. Our estimate reflects what we believe is the average burden among all respondents.

This draft guidance also refers to previously approved FDA collections of information found in FDA regulations. The collections of information found in 21 CFR 310.306, 314.81(b)(3)(iii), and 600.82 on notifying FDA of a permanent discontinuance or an interruption in manufacturing of certain drugs or biological products, and 21 CFR part 314 new drug and abbreviated new drug applications, and 21 CFR part 600 biologics license applications have been approved under OMB control numbers 0910-0001 and 0910-0338, respectively; the collections of information in 21 CFR parts 210 and 211 on current good manufacturing practice have been approved under OMB control number 0910-0139.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at 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>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: May 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request 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 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 June 21, 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 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: When submitting comments or requesting information, please include the information collection request title for reference.

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

Abstract: This information collection comment request is for continued approval of the Medicare Rural Hospital Flexibility Program Performance Measures. HRSA is proposing to continue this data collection with minor changes to the organization of the data. The current performance measures are collected electronically in the Performance Improvement and Measurement System which awardees access securely through the HRSA Electronic Handbooks.

The Medicare Rural Hospital Flexibility Program (Flex Program) is authorized by Section 1820 of the Social Security Act (42 U.S.C. 1395i-4), as amended. The purpose of the Flex Program is to enable 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.

A 60-day notice published in the **Federal Register**, Vol. 87, No. 46, FR 13300-13301 (March 9, 2022). There were no public comments.

Need and Proposed Use of the Information: For this program, performance measures were developed to provide data useful to the Flex program 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 the Federal Office of Rural Health Policy, including: (a) Quality reporting, (b) quality improvement interventions, (c) financial and operational improvement initiatives, (d) population health management, (e) rural emergency medical services integration and (f) innovative care models. In addition to informing the Office's progress toward meeting the goals set in Government Performance and Results Modernization Act of 2010, the information is important in identifying and understanding programmatic improvement across program areas, as well as guiding future iterations of the Flex Program and prioritizing areas of need and support.

This submission includes the addition of minor revisions in the organization of the measures to align with the changes to the organization of the program areas within the Flex Program. The revisions include changes to align with current language and a broadening of scope for some activities. The measures will remain unchanged. For example, population health improvement activities were previously combined with rural emergency medical services integration, and these measures will be separated into two distinct program areas. The burden remains unchanged with these changes.

Likely Respondents: Respondents are the Flex Program coordinators for the states participating in the Flex Program. 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.

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 (within the Electronic Handbooks system	45	1	45	70	3,150
	45	45	3,150

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. 2022–10808 Filed 5–19–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0275–60D]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the information collection request (ICR) must be received on or before July 19, 2022.

ADDRESSES: Submit your comments to Sherrette.Funn@hhs.gov or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or

requesting information, please include the document identifier OS–0990–0275–60D and project title for reference. Submit requests to Sherrette A. Funn, the Reports Clearance Officer, at Sherrette.Funn@hhs.gov or call (202) 795–7714.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (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.

Information Collection Request Title: Performance Data System (PDS).

Type of Collection: Renewal.

OMB No.: 0990–0275.

Abstract: This request for clearance is to extend data collection activities for a currently approved collection using the OMB approved Performance Data System (PDS) (OMB No. 0990–0275), the tool used by the Office of Minority Health (OMH) to collect program management and performance data for all OMH-funded projects. The revised data collection instrument keeps all the same data elements, but includes additional formatting to clarify data elements. Additionally, a few columns were reordered in order to make the form more intuitive. Grantee data collection via the UDS (original data collection system) was first approved by

OMB on June 7, 2004 (OMB No. 0990–275).

Need and Proposed Use of the Information: The clearance is needed to continue data collection using the PDS, a system that enables OMH to comply with Federal reporting requirements and monitor and evaluate performance by enabling the efficient collection of performance-oriented data tied to OMH-wide performance reporting needs. The ability to monitor and evaluate performance in this manner, and to work towards continuous program improvement are basic functions that OMH must be able to accomplish to carry out its mandate with the most effective and appropriate use of resources.

Likely Respondents: Respondents for this data collection include the project directors for OMH-funded projects and/or the data entry persons for each OMH-funded project. Affected public includes non-profit institutions, State, Local, or Tribal Governments.

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.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Project Directors	100	4	45/60	300