

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
HDE Records—814.126(b)(2)	62	1	62	2	124

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Notification of emergency use—814.124(a)	22	1	22	1	22

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of respondents in tables 1, 2, and 3 are an average based on data for the previous 3 years, *i.e.*, fiscal years 2017 through 2019. The number of respondents has been adjusted to reflect updated respondent data. This has resulted in an overall increase of 5,803 hours to the total estimated burden. The number of annual reports submitted under § 814.126(b)(1) in table 1 reflects 50 respondents with approved HUD applications. Based on further review, the estimated number of recordkeepers has been adjusted from 65 respondents to 62 respondents in table 2 to reflect the most current data available. Therefore, under § 814.126(b)(2) in table 2, the estimated number of recordkeepers is 62.

We have also updated the burden estimate consistent with new provisions in § 814.104(b)(4)(i) regarding “Human Subject Protection; Acceptance of Data from Clinical Investigations for Medical Devices” (83 FR 7366; February 21, 2018) (approved under OMB control number 0910–0741). Section 814.104 is being amended to address submission of data from clinical investigations in an HDE. To the extent the applicant includes data from clinical investigations, the applicant will be required to include the information and statements as described in § 814.104(b)(4)(i). Consistent with our estimate in OMB control number 0910–0741, this revision increases our burden estimate for an HDE by 8 hours per submission.

Dated: February 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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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; Information Collection Request Title: Rural Health Clinic COVID–19 Testing Program Data Collection, OMB No. 0906–0056—Extension

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 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 March 26, 2021.

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 Lisa Wright-Solomon, the HRSA Information

Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Rural Health Clinic COVID–19 Testing Program Data Collection, OMB No. 0906–0056—Extension.

Abstract: This ICR is for continued approval of the Rural Health Clinic (RHC) COVID–19 Testing Program Data Collection. HRSA is proposing to continue this data collection with no changes. The current performance measures are collected electronically in the RHC COVID–19 Testing Report (CTR), which funded providers access via rhccovidreporting.com. RHC COVID–19 Testing Program Data Collection supports the HRSA requirement to monitor and report on funds distributed under the Paycheck Protection Program and Health Care Enhancement Act. Signed into law on April 24, 2020, the Paycheck Protection Program and Health Care Enhancement Act appropriated \$225 million to RHCs to support COVID–19 testing efforts, expand access to testing in rural communities, and other related expenses. On May 20, 2020, HRSA issued funding as one-time payments to 2,406 RHC organizations based on the number of certified clinic sites they operate, providing \$49,461.42 per clinic site (4,549 RHC clinic sites total across the country).

The RHC CTR collects monthly, aggregate data from funded organizations. Funded organizations provide basic identifying information, report on the number of and location of testing sites, indicate how they used the funds, and report the total number of patients tested and the number of tests with a positive result.

Funded organizations must report the number of patients tested and the number of positive tests on a monthly

basis for the duration of the reporting period. HRSA will use this information to evaluate the effectiveness of COVID-19 Testing Program at an aggregate level, assist HRSA in understanding how RHC COVID-19 Testing Program funding is being used to support RHC organizations and patients, and ensure that HRSA is compliant with federal reporting requirements.

A 60-day notice published in the **Federal Register** on December 10, 2020, vol. 85, No. 238; p. 79492. There were no public comments.

Need and Proposed Use of the Information: The RHC CTR is designed to collect information from funded providers who use RHC COVID-19 Testing Program funding to support COVID-19 testing efforts, expand access

to testing in rural communities, and other related expenses. These data are critical to meet HRSA requirements to monitor and report on how federal funding is being used and to measure the effectiveness of RHC CTR. Specifically, these data will be used to assess the following:

- Whether program funds are being spent for their intended purposes;
- Where COVID-19 testing supported by these funds is occurring;
- Number of patients tested for COVID-19; and
- Results of provided COVID-19 tests.

Likely Respondents: Respondents are RHC organizations who received funding for COVID-19 testing and related expenses.

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
RHC COVID-19 Testing Report	2,406	12	28,872	.25	7,218

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 Information Collection Request Title: Small Health Care Provider Quality Improvement Program, OMB No. 0915-0387—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 the proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA 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 April 26, 2021.

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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443-1984.

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

Information Collection Request Title: Small Health Care Provider Quality Improvement Program, OMB No. 0915-0387—Extension.

Abstract: This program is authorized by Title III, Public Health Service Act,

Section 330A(g) (42 U.S.C. 254c(g)), as amended. This authority authorizes HRSA's Federal Office of Rural Health Policy to issue grants that expand access to, coordinate, contain the cost of, and improve the quality of essential health care services, including preventive and emergency services, through the development of health care networks in rural and frontier areas and regions. Across these various programs, the authority allows HRSA to provide funds to rural communities to support the direct delivery of health care and related services, expand existing services, or enhance health service delivery through education, promotion, and prevention programs.

The purpose of the Small Health Care Provider Quality Improvement Grant (Rural Quality) Program is to provide support to rural primary care providers for implementation of quality improvement activities. The goal of the program is to promote the development of an evidence-based culture and delivery of coordinated care in the primary care setting. Additional objectives of the program include improved health outcomes for patients, enhanced chronic disease management, and better engagement of patients and their caregivers. Organizations participating in the program are required to use an evidence-based quality improvement model, perform tests of change focused on improvement, and use health