

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 606.121 and parts 610 and 630 have been approved under OMB control number 0910–0116; and the collections of information for consignee notification have been approved under OMB control number 0910–0681.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <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 9, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–10252 Filed 5–11–23; 8:45 am]

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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; Enhancing HIV Care of Women, Infants, Children and Youth Building Capacity Through Communities of Practice

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 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 June 12, 2023.

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, Samantha Miller, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 594–4394.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Enhancing HIV Care of Women, Infants, Children and Youth Building Capacity through Communities of Practice, OMB No. 0915–xxxx—New.

Abstract: HRSA aims to increase delivery of evidence-based interventions that enhance client outcomes, increase the skill level of the HIV workforce providing care and treatment to Women, Infants, Children and Youth, and involve partnerships for dissemination of best practices to Ryan White HIV/AIDS Program (RWHAP) Part D participants. To that end, HRSA seeks to implement a Communities of Practice (CoP) platform for RWHAP Part D recipients. A CoP engages recipient teams in improvement learning sessions using subject matter experts along with application experts who help recipient teams select, test, and implement changes on the front line of care. Through organizational self-assessments, didactic learning on specific care topics, goals setting, and work plan development, each team can strategically benefit their organization. CoPs afford participants the opportunity to work in a group to solve a recognized challenge related to a CoP domain and support dialogue among participants and the consultant/subject matter experts. Recipient teams commit to working over a period of 12 months, alternating between Learning Sessions in which teams come together to learn about the chosen topic and to plan changes, and Action Periods in which the teams return to their respective organizations and test those changes in their clinic settings. The domains for the proposed CoPs are trauma informed care, pre-conception counseling, and

youth transitioning into adult HIV care services.

A 60-day notice published in the **Federal Register** on February 27, 2023, vol. 88, No. 38; pp. 12386–12387. The one comment received was outside the scope of the ICR, and therefore no changes to the information collection were made as a result of this comment.

Need and Proposed Use of the Information: Process and outcome evaluations are a critical part of ensuring that CoP initiatives were implemented as planned and met their intended outcome. Evaluation of technical assistance (TA) depends on establishing clear goals and plans from the beginning of the process. This includes specifying the intended impact of the TA with concrete, measurable objectives. To judge performance against goals, HRSA will administer TA evaluation surveys following TA and training, webinars, teleconferences, and meetings. Findings will drive quality improvement activities and reports.

The evaluation plan focuses on process and impact evaluation of all CoP Teams (Pre-Conception Counseling and Sexual Health, Trauma-Informed Care, and Transitioning Adolescents to Adult Care) over the duration of the 4-year period of performance. The evaluation plan components will be operationalized to include TA satisfaction measures (reaction), change in knowledge after the TA (learning), and change in behavior or practice after the introduction of evidence-based interventions (behavior). More specifically, the evaluation plan includes (1) post TA satisfaction measures, (2) pre-post measures of CoP staff knowledge about effective practices, (3) retrospective measures to gather measures of CoP staff knowledge for the first community of practice only, and (4) measures of TA usefulness and impact on CoP performance.

Likely Respondents: Up to 90 RWHAP Part D Women, Infants, Children and Youth recipients will participate in the CoPs. Each recipient may have up to six staff members who may complete the survey.

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
Pre-conception Counseling Community of Practice Retrospective Pretest-Post Assessment	90	1	90	.4733	42.6
Community of Practice Pre-Assessment	180	1	180	.2900	52.2
Community of Practice Post-Assessment	180	1	180	.3767	67.8
Community of Practice Session Assessment	270	6	1,620	.0767	124.3
Targeted and Intensive TA Assessment	120	1	120	.0833	10.0
Foundational TA Assessment	150	1	150	.0616	9.2
Total	990	2,340	306.1

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: Submission to OMB for Review and Approval; Public Comment Request; Delta States Rural Development Network Grant Program, OMB No. 0915–0386—Revision

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 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 June 12, 2023.

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 HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 594–4394.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Delta States Rural Development Network Grant Program—OMB No. 0915–0386—Revision.

Abstract: The Delta States Rural Development Network Grant (Delta Program) is authorized by the Public Health Service Act, section 330A(f) (42 U.S.C. 254c(f)). The Delta Program supports projects that demonstrate evidence based and/or promising approaches around cardiovascular disease, diabetes, acute ischemic stroke, or obesity in order to improve health status in rural communities throughout the Delta Region. Key features of Delta Program-supported projects are collaboration, adoption of an evidence-based approach, demonstration of health outcomes, program replicability, and sustainability. HRSA collects information from Delta Program award recipients using an OMB-approved set of performance measures and seeks to extend that approved information collection.

A 60-day notice published in the **Federal Register** on February 02, 2023, vol. 88, No. 22; pp. 7095–96. There were no public comments. Since the publication of the 60-day notice, HRSA

has updated the estimated average burden per response from 1.66 hours to 2 hours, with a corresponding increase in the estimated total annual burden for this ICR.

Need and Proposed Use of the Information: For this program, performance measures were drafted to provide data useful to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act of 1993 (Pub. L. 103–62). These measures cover the principal topic areas of interest to HRSA including the following: (a) access to care, (b) population demographics, (c) staffing, (d) sustainability, (e) project specific domains, and (f) health related clinical measures. These measures encompass HRSA’s progress toward meeting the goals set.

Likely Respondents: Grant recipients of the Delta 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.