

**II. Electronic Access**

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This draft guidance document is also available at <https://www.regulations.gov>, <https://www.fda.gov/regulatory-information/>

*search-fda-guidance-documents*. Persons unable to download an electronic copy of “Content of Human Factors Information in Medical Device Marketing Submissions” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 1500052 and complete title to identify the guidance you are requesting.

**III. Paperwork Reduction Act of 1995**

While this guidance contains no new 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 the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E .....	Premarket notification .....	0910–0120
814, subparts A through E .....	Premarket approval .....	0910–0231
814, subpart H .....	Humanitarian Device Exemption .....	0910–0332
860, subpart D .....	De Novo classification process .....	0910–0844
800, 801, and 809 .....	Medical Device Labeling Regulations .....	0910–0485
820 .....	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation .....	0910–0073

Dated: December 5, 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: Submission to OMB for Review and Approval; Public Comment Request; Ending the HIV Epidemic Initiative Triannual Report, OMB No. 0915–0051—Extension**

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

**ACTION:** Notice.

**SUMMARY:** In compliance with of 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 9, 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](http://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](mailto:paperwork@hrsa.gov) or call (301) 594–4394.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* Ending the HIV Epidemic (EHE) Initiative Triannual Report OMB No. 0915–0051—Extension.

*Abstract:* HRSA’s Ryan White HIV/AIDS Program (RWHAP) funds and coordinates with cities, states, and local clinics/community-based organizations to deliver efficient and effective HIV care, treatment, and support services to low-income people with HIV. Since 1990, the RWHAP has developed a comprehensive system of safety net providers who deliver high quality direct health care and support services to over half a million people with HIV—more than 50 percent of all people with diagnosed HIV in the United States. Nearly two-thirds of clients (patients) live at or below 100 percent of the Federal poverty level and approximately

three-quarters of RWHAP clients are racial/ethnic minorities.<sup>1</sup>

The Federal Ending the HIV Epidemic in the U.S. (EHE) initiative focuses on reducing the number of new HIV infections in the United States by at least 90 percent by 2030, which would be fewer than 3,000 per year.<sup>2</sup> Authorized by section 311(c) and title XXVI of the Public Health Service Act, this 10-year initiative beginning in fiscal year (FY) 2020 focuses on 48 counties; Washington, DC; San Juan, Puerto Rico; and seven states that have a substantial rural HIV burden. EHE initiative efforts focus on the following four key strategies that together can end the HIV epidemic in the United States:

1. Diagnose all people with HIV as early as possible.
2. Treat people with HIV rapidly and effectively to reach sustained viral suppression.
3. Prevent new HIV transmissions by using proven interventions, including pre-exposure prophylaxis and syringe services programs.
4. Respond quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.

The EHE initiative is a collaborative effort among key Department of Health and Human Services agencies, primarily HRSA, the Centers for Disease Control and Prevention, the National Institutes of Health, the Indian Health Service,

<sup>1</sup> HRSA. Ryan White HIV/AIDS Program Data Report, 2020.

<sup>2</sup> HRSA. Ending the HIV Epidemic in the U.S. <https://www.hrsa.gov/ending-hiv-epidemic>. Accessed July 12, 2022.

and the Substance Abuse and Mental Health Services Administration. Through HRSA’s RWHAP and Health Center Program, the agency has a leading role in helping diagnose, treat, prevent, and respond to end the HIV epidemic in the United States.

In June 2022, HRSA awarded nearly \$115 million to RWHAP recipients to help implement the EHE initiative to support innovative strategies that help people with HIV access care, support, and treatment services to live longer, healthier lives. EHE initiative funding was awarded to 39 metropolitan areas (RWHAP part A) and eight states (RWHAP part B) to implement strategies and interventions for the provision of core medical and supportive services to reduce new HIV infections.<sup>3</sup>

In September 2022, HRSA published a Notice seeking public comment on this ICR in the **Federal Register**, 87 FR 59443–44 (September 30, 2022). There were no public comments.

*Need and Proposed Use of the Information:* To support Federal requirements to monitor and report on funds distributed through the EHE Initiative, HRSA created a reporting module, the EHE Triannual Report, an

aggregate data report submitted three times a year by EHE recipients and providers of services. EHE-funded providers report aggregate information on the number of clients receiving specific services and the number of clients who were prescribed antiretroviral medications in the 4-month reporting period. This module will provide HRSA with frequent and timely data on EHE Initiative progress by providing information on the number of clients who are reached through the EHE Initiative. In addition, HRSA can calculate the number of clients who did not receive services in the previous year by subtracting the number of clients who received services in the previous year and the number of new clients from the total number of clients. This will provide valuable information on the scope of outreach to new clients and clients who have had a lapse in service, which could be an indication of reengagement in care. This module will support project officer monitoring and HRSA’s understanding of service provision. Finally, the information collected in the EHE Triannual Report will complement the annual

information collected through the RWHAP Services Report and other reporting mechanisms and support HRSA in its ability to monitor EHE initiative activities and assess progress toward meeting national goals for ending the HIV epidemic.

*Likely Respondents:* RWHAP part A and part B recipients and subrecipients funded by the EHE initiative.

*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
EHE Module .....	47	3	141	2	282
	47	.....	141	.....	282

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: The Rural Health Network Development Planning Performance Improvement and Measurement System Database, OMB No. 0915–0384—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, 2023.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 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](mailto:paperwork@hrsa.gov) or call Samantha Miller, the HRSA Information Collection Clearance Officer at (301) 594–4394.

<sup>3</sup> FY 2022 EHE Awards. <https://ryanwhite.hrsa.gov/about/parts-and-initiatives/fy->

*2022-ending-hiv-epidemic-awards*. Accessed August 19, 2022.