

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs> or <https://www.regulations.gov>.

Dated: August 12, 2019.

Lowell J. Schiller,
Principal Associate Commissioner for Policy.

[FR Doc. 2019-17513 Filed 8-14-19; 8:45 am]

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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: Ryan White HIV/AIDS Program Core Medical Services Waiver Application Requirements, OMB No. 0915-0307—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, included below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than October 15, 2019.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA

Information Collection Clearance Officer, Room 14N136B, 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 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: Ryan White HIV/AIDS Program (RWHAP) Core Medical Services Waiver Application Requirements, OMB No. 0915-0307—Extension

Abstract: Title XXVI of the Public Health Service (PHS) Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (RWHAP), requires that grant recipients expend funds on core medical services including antiretroviral drugs for individuals with HIV who are eligible under the legislation. In addition, no less than 75 percent of the remainder of the total award amount after reserving statutory permissible amounts for administrative and clinical quality management costs are to be expended on core medical services.¹ For a grant recipient under the RWHAP Parts A, B, or C to be exempted from this requirement, a waiver must be requested from HRSA and submitted to the agency for review and approval in accordance with statute.

On October 25, 2013, HRSA published revised standards for core medical services waiver requests in the **Federal Register** (78 FR 63990). These revised standards allow grant recipients flexibility to adjust resource allocation based on the current situation in their local environments. These standards ensure that grant recipients receiving

waivers demonstrate the availability of core medical services, including antiretroviral drugs, for persons with HIV served under the HRSA RWHAP. The core medical services waiver request process applies to RWHAP grant applicants and recipients under Parts A, B, and C of Title XXVI of the PHS Act. Core medical services waivers are effective for a 1-year period. Grant applicants may submit a waiver request before, or with the annual grant application, and grant recipients can submit up to four months after the grant award has been made.

Need and Proposed Use of the Information: HRSA uses the documentation submitted in core medical services waiver requests to determine if the grant applicant or recipient meets the statutory requirements for waiver eligibility including: (1) No waiting lists for AIDS Drug Assistance Program services; and (2) evidence of core medical services availability within the grant recipient's jurisdiction, state, or service area to all persons with HIV identified and eligible under Title XXVI of the PHS Act.²

Likely Respondents: RWHAP Parts A, B, and C grant applicants and recipients.

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 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
Waiver Request	20	1	20	5.5	110
Total	20	20	110

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

¹ Sections 2604(c)(1), 2612(b)(1), and 2651(c)(1) of the PHS Act.

² Sections 2604(c)(2), 2612(b)(2), and 2651(c)(2) of the PHS Act.

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, Division of the Executive Secretariat

[FR Doc. 2019-17509 Filed 8-14-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Minority Health; Correction

AGENCY: Office of Minority Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice; correction.

SUMMARY: The Office of the Assistant Secretary for Health published a document in the **Federal Register** of August 8, 2019, announcing the Advisory Committee on Minority Health's public meeting. The document includes supplementary information on the topic of the meeting that is now incorrect due to the more specific focus on strategies to address HIV-related health disparities among racial and ethnic minority populations to inform efforts related to the federal Ending the HIV Epidemic Initiative.

FOR FURTHER INFORMATION CONTACT:

Violet Woo, Designated Federal Officer, Advisory Committee on Minority Health, Office of Minority Health, Department of Health and Human Services, Tower Building, 1101 Wootton Parkway, Suite 600, Rockville, Maryland 20852. Phone: 240-453-2882; fax: 240-453-2883; email *OMH-ACMH@hhs.gov*.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of August 8, 2019, in FR Doc. 2019-16969, on page 38999, in the second column, replace the second paragraph under

SUPPLEMENTARY INFORMATION to read: The topics to be discussed during this meeting will include strategies to address HIV-related health disparities among racial and ethnic minority populations. The recommendations will be given to the Deputy Assistant Secretary for Minority Health to inform efforts related to the federal Ending the HIV Epidemic Initiative.

Dated: August 8, 2019.

Violet Woo,

Designated Federal Officer, Advisory Committee on Minority Health.

[FR Doc. 2019-17560 Filed 8-14-19; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651-0111]

Agency Information Collection Activities: Arrival and Departure Record (Forms I-94, I-94W) and Electronic System for Travel and Authorization (ESTA)

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security (DHS).

ACTION: 60-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies. Comments are encouraged and must be submitted (no later than October 15, 2019) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice must include the OMB Control Number 1651-0111 in the subject line and the agency name. To avoid duplicate submissions, please use only one of the following methods to submit comments:

(1) **Email.** Submit comments to: *CBP_PRA@cbp.dhs.gov*.

(2) **Mail.** Submit written comments to CBP Paperwork Reduction Act Officer, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, Economic Impact Analysis Branch, 90 K Street NE, 10th Floor, Washington, DC 20229-1177.

FOR FURTHER INFORMATION CONTACT:

Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229-1177. Telephone number 202-325-0056 or via email *CBP_PRA@cbp.dhs.gov*. Please

note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877-227-5511, (TTY) 1-800-877-8339, or CBP website at <https://www.cbp.gov/>.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Arrival and Departure Record, Nonimmigrant Visa Waiver Arrival/Departure, Electronic System for Travel Authorization (ESTA).

OMB Number: 1651-0111.

Form Numbers: CBP Forms I-94 and I-94W.

Current Actions: This submission is being made to extend the expiration date of this information collection with no changes to the burden hours or to the information collected.

Type of Review: Extension (with no change).

Affected Public: Individuals.

Abstract: Forms I-94 (Arrival/Departure Record) and I-94W (Nonimmigrant Visa Waiver Arrival/Departure Record) are used to document a traveler's admission into the United States. These forms are filled out by