

**DATES:** Authority for the Nonprescription Drugs Advisory Committee will expire on August 27, 2021, unless the Commissioner formally determines that renewal is in the public interest.

**FOR FURTHER INFORMATION CONTACT:** Moon Hee V. Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, email: [NDAC@fda.hhs.gov](mailto:NDAC@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pursuant to 41 CFR 102-3, FDA is announcing the renewal of the Nonprescription Drugs Advisory Committee (the Committee). The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner.

The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad spectrum of human symptoms and diseases and advises the Commissioner either on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded or on the approval of new drug applications for such drugs. The Committee serves as a forum for the exchange of views regarding the prescription and nonprescription status, including switches from one status to another, of these various drug products and combinations thereof. The Committee may also conduct peer review of agency sponsored intramural and extramural scientific biomedical programs in support of FDA's mission and regulatory responsibilities.

Pursuant to its charter, the Committee consists of a core of 10 voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of internal medicine, family practice, clinical toxicology, clinical pharmacology, pharmacy, dentistry, and related specialties. Members are invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified

member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/advisory-committees/nonprescription-drugs-advisory-committee/nonprescription-drugs-advisory-committee-charter> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please check <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: November 12, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## 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; Ryan White HIV/AIDS Program Parts A and B Unobligated Balances and Rebate Addendum Tables, OMB No. 0906-xxxx-NEW

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

**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.

**DATES:** Comments on this ICR should be received no later than December 18, 2019.

**ADDRESSES:** Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or by fax to (202) 395-5806.

**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](mailto:paperwork@hrsa.gov) or call (301) 443-1984.

#### SUPPLEMENTARY INFORMATION:

*Information Collection Request Title:* Ryan White HIV/AIDS Program Parts A and B Unobligated Balances and Rebate Addendum Tables, OMB No. 0906-xxxx-NEW.

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

Grant recipients funded under Parts A, B, C, and D of the RWHAP (codified under Title XXVI of the Public Health Service Act) are required to report financial data to HRSA at the beginning (Allocations Report) and at the end of each grant budget period (Expenditures Report) using the HRSA Electronic Handbooks (EHBs).<sup>1</sup> HRSA RWHAP Parts A and B collect unobligated balances (UOB) of federal funds and rebate addendum information by subprogram from their grant recipients. Parts A and B use the UOB and rebate addendum financial information to determine formula funding as directed by the RWHAP statute. These data were collected when grant recipients submitted their annual Federal Financial Report (FFR SF-425) in hard copy only, and were submitted to the individual HHS Operating Divisions. HRSA added UOB and rebate addendum tables after the FFR SF-425, using a suggested format through the HRSA EHBs. This financial information is collected in the same location to

<sup>1</sup> The Allocations Report and the Expenditures Report were approved by OMB under the 0915-0318 control number.

streamline the process for the grant recipients. The UOB and rebate addendum data tables will be collected in the HRSA EHBs below the FFR SF-425 control number and the Paperwork Burden Statement.

A 60-day notice was published in the **Federal Register** on July 19, 2019, vol. 84, No. 139; pp. 34903-04. There were no public comments.

*Need and Proposed Use of the Information:* RWHAP Part A and Part B recipients currently complete the UOB and rebate addendum tables in a non-electronic form and upload them as attachments as a part of their FFR SF-425 submission. This new process will decrease administrative burden,

increase transparency, and improve the quality of data submitted to HRSA. These UOB and rebate addendum tables are essential for allowing HRSA to ensure that RWHAP recipients are meeting the goal of accountability to Congress, clients, advocacy groups, and the general public. Information provided in the UOB and rebate addendum tables is critical for HRSA, states and territories, local clinics, and individual providers to evaluate the effectiveness of these programs.

*Likely Respondents:* HRSA RWHAP Parts A and B 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. 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
Part A UOB Table .....	52	1	52	0.5	26.0
Part B UOB Table .....	59	1	59	0.5	29.5
	111	.....	111	.....	55.5

**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; Chart Abstraction of Ryan White HIV/AIDS Program Recipient Data, OMB No. 0906-xxxx—New**

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

**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.

**DATES:** Comments on this ICR should be received no later than December 18, 2019.

**ADDRESSES:** Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA\_submission@omb.eop.gov* or by fax to (202) 395-5806.

**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:* Chart Abstraction of Ryan White HIV/AIDS Program Recipient Data, OMB No. 0906-xxxx—New.

*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 to low-income people with HIV. 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 and ethnic minorities. Since 1990, the RWHAP has developed a comprehensive system of HIV service 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.

HRSA is required to assess the quality of care provided by RWHAP grant

recipients. HHS guidelines (*e.g.*, Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV; Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents; and Sexually Transmitted Diseases Treatment Guidelines, 2015) and U.S. Preventative Services Task Force (USPSTF) guidelines serve as the basis for assessing the quality of care within the RWHAP. The purpose of the *Chart Abstraction of RWHAP Data* study is to assess the extent to which the care provided with funding from the RWHAP is meeting the HHS and USPSTF guidelines. The study will collect data from RWHAP service providers via a provider screening phone interview, a provider pre-site visit interview, and medical records data abstraction. The data will reflect the full range of HIV outpatient ambulatory health services, primary care, and screening and treatment for hepatitis, sexually transmitted infections (STIs), and opioid use disorder provided by service providers and allow HRSA to assess the extent to which care provided by RWHAP service providers meets the HHS and USPSTF guidelines.

A 60-day notice was published in the **Federal Register** on May 10, 2019, vol. 84, No. 91; pp. 20638-20639. There were no public comments.