



Billing Code: 4165-15-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; AIDS Drug Assistance Program Data Report ADR, OMB No. 0915-0345 – Revision

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.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

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 30-day 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 AIDS Drug Assistance Program Data Report (ADAP) OMB No. 0915-0345 – Revisions*

Abstract: HRSA's Ryan White HIV/AIDS Program AIDS Drug Assistance Program (RWHAP ADAP) is authorized under Part B of the RWHAP legislation, codified in sections 2611 et seq. of the Public Health Service Act, which provides grants to U.S. states and territories. HRSA's RWHAP ADAP is a state and territory-administered program that provides Food and Drug Administration-approved medications to low-income people with HIV who have limited or no health coverage from private insurance, Medicaid, or Medicare. HRSA's RWHAP ADAP funds may also be used to purchase health insurance for eligible clients and for services that enhance access, adherence, and monitoring of drug treatments.

All 50 states, the District of Columbia, Puerto Rico, Guam, the U.S. Virgin Islands, and the five U.S. Pacific Territories or Associated Jurisdictions receive RWHAP Part B grant awards

including funds for RWHAP ADAP. RWHAP Part B reporting requirements include the annual submission of an ADAP Data Report (ADR), including a Recipient Report and a Client Report. The Recipient Report is a collection of basic information about grant recipient characteristics and policies including program administration, purchasing mechanisms, funding, and expenditures. The Client Report is a collection of client-level records (one record for each client enrolled in the RWHAP ADAP), which includes the client's encrypted unique identifier, basic demographic data, enrollment information, services received and clinical data.

HRSA is proposing several changes to the ADR Recipient and Client Reports to improve question clarity, delete obsolete data elements, combine related data elements, add new data elements, and improve response options to reflect program practices and support HRSA's analysis and understanding of program impact. In addition, a new initiative, *Ending the HIV Epidemic: A Plan for America* (EHE), began in Fiscal Year 2020 and some of its data collection requirements will be incorporated in existing annual data collections, including the ADR, in order to limit recipient burden. Specifically, the Recipient Report includes the following proposed changes:

- addition of two new “Yes/No” questions
- addition of one new follow-up question that requests the number of new clients enrolled
- addition of one question on funding to monitor the use of funds provided to ADAPs for the EHE initiative
- clarification on two existing questions

- revision to one existing question that requests program income and manufacturer rebates reinvested in ADAP, and
- deletion of six obsolete data elements.

The Client Report includes the following proposed changes:

- revision to reporting of RWHAP ADAP-funded medications to include all medications rather than a subset of medications;
- revision to one existing question that requests reporting of all RWHAP ADAP-funded medications using the National Drug Code from the Drug Identification Code (d-codes);
- revision to reporting of clinical data for clients to include all clients rather than a subset of clients; and
- deletion of three data elements that were combined with other existing data elements.

New and revised data elements require reporting of information that should already be collected by recipients to meet legislative or programmatic requirements for the proper oversight and administration of the program.

A 60-day notice was published in the Federal Register on December 3, 2019, vol. 84, No. 232; pp. 66202-03. There were two public comments. Both comments were requests to clarify the data reporting changes, which included requests for a copy of the ADR instrument.

Need and Proposed Use of the Information: HRSA's RWHAP requires the submission

of annual reports by the Secretary of Department of Health and Human Services to the appropriate committees of Congress. HRSA uses the ADR to evaluate the national impact of the HRSA RWHAP ADAP by providing client-level data on individuals being served, services being delivered, and costs associated with these services. The client-level data is used to monitor health outcomes of people with HIV receiving care and treatment through the HRSA RWHAP ADAP, to monitor the use of HRSA RWHAP ADAP funds in addressing the HIV epidemic and its impact on vulnerable communities, and to track progress toward achieving the goals identified in the National HIV/AIDS Strategy.

Likely Respondents: State ADAPs of RWHAP Part 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
Recipient Report	54	1	54	6	324
Client-Level Report	54	1	54	81	4,374
Total	*54		54		4,698

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