Supporting Statement A

HRSA AIDS Drug Assistance Program Data Report

OMB Control No. 0915-0345 – Extension

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Health Resources and Services Administration's (HRSA's) Ryan White HIV/AIDS Program (RWHAP) AIDS Drug Assistance Program (ADAP) is authorized under Part B of the RWHAP statute, codified in sections 2611 to 2631 of the Public Health Service Act (42 USC 300ff-11 et seq), which provides grants to U.S. states and territories. RWHAP ADAP is a state and territory-administered program that provides Food and Drug Administration-approved medications to low-income people with HIV. RWHAP ADAP funds may also be used to purchase health care coverage 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 and confirmation information, details on medication and/or health care coverage assistance received (including associated costs), and HIV clinical information.

2. Purpose and Use of Information Collection

The purpose of collecting these data will be to compile and analyze client-level data to address performance measures and HRSA core clinical performance measures.

RWHAP ADAPs will report data on allowable services and selected clinical data associated with those services. This will enable HRSA to obtain accurate counts of the number of clients served by the **HRSA RWHAP Part B ADAP**. In addition, HRSA HAB will use the data to monitor the outcomes achieved on behalf of HIV clients receiving care and treatment through HRSA RWHAP grant recipients and/or subrecipients; monitor the use of HRSA RWHAP funds for the appropriate use to address the HIV epidemic in the United States, and address the needs and concerns of the U.S. Congress and the HHS Secretary concerning the HIV epidemic and the HRSA RWHAP.

HRSA designed the ADR variables are designed to fulfill its responsibilities in the administration of grant funds in addition to maintaining accurate records of the recipients receiving RWHAP funding, services provided, and clients served. Client-level data enables HRSA to monitor the ability of the ADAPs to reach populations impacted by the HIV epidemic while ensuring that programmatic objectives such as addressing HIV disparities are met.

Grant recipients will collect information on the ADR and submit the data annually. HRSA will generate descriptive reports on the uses of funds and the types of recipients receiving them and will conduct detailed analyses of national and regional information about clients and services.

3. Use of Improved Information Technology and Burden Reduction

To report client-level data, grant recipients will need access to the Internet. The Recipient Report will be completed online through a secure web-based grants administration system, the online portal managed by HRSA. Many of the items on the Recipient Report will be pre-populated based on information already contained in the system. The client-level data will be uploaded to the system in the required Extensible Markup Language (XML) format.

HRSA has several options available to grant recipients collecting the necessary data variables for the submission of the ADR. HRSA has developed an optional data collection application, CAREWare, which exports the client-level data into the required XML format for grant recipients to submit the data to a secure web-based grants administration system. CAREWare is available at no cost to all HRSA RWHAP recipients. In addition to CAREWare, HRSA continues to work with several vendors of proprietary HIV care database systems to ensure that the systems are compatible with the ADR data reporting. HRSA also provides a free online tool, TRAX, which allows grant recipients who use other types of data collection systems, such as electronic health records, to convert data to the required submission format.

4. Efforts to Identify Duplication and Use of Similar Information

The data required to evaluate or monitor the HRSA RWHAP Part B are not available elsewhere. There are no known studies of people with HIV or sample studies of people in defined demographic groups that provide comprehensive, overall program information specifically about grant recipients and clients of the HRSA RWHAP. The

ADR is the only comprehensive source of ADAP clients and services information that sufficiently addresses and meets HRSA HAB’s data collection needs and objectives.

5. Impact on Small Businesses or Other Small Entities

This information collection includes small entities; however, this activity does not impose a significant impact on such entities. The information collection system will be designed so that small organizations providing fewer HRSA RWHAP services will be able to skip some of the requested information compared to larger organizations that provide more services.

6. Consequences of Collecting the Information Less Frequently

The ADR is submitted annually. If the information were reported less frequently, HRSA would not be able to carry out its responsibility to oversee compliance with the intent of Congressional appropriations in a timely manner. Annual reporting of the characteristics of ADAP clients is necessary to understand who the program is serving as well as the extent that the ADAP program is addressing national priorities. If the information were not collected, HRSA would not know, and would not be able to report:

- Whether program funds are being spent for their intended purposes;
- How many and what demographic characteristics of individuals are receiving services, and how different services are distributed across various groups;
- How the distribution of program funds, the distribution of services, and the characteristics of individual beneficiaries are changing from one year to the next; and
- To what extent the ADAP program is improving HIV health outcomes.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The data will be collected in a manner fully consistent with the guidelines in 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice/Outside Consultation

Section 8A:

A 60-day notice published in the **Federal Register** on January 30, 2026, vol. 91, 20; pp. 4085-86. There were no public comments.

Section 8B:

A February 2026 pilot was conducted with six ADAP grant recipients following the 60-Day Federal Register Notice found that respondents reported no issues with submitting ADR data. Recipients indicated strong familiarity with client-level reporting and noted improved support from reporting manuals and guidance. There are no changes to the estimated burden.

9. Explanation of any Payment/Gift to Respondents

The proposed collection of information does not involve any remuneration to respondents.

10. Assurance of Confidentiality Provided to Respondents

The ADR does not require any information that could identify individual clients or retreive information about individual clients using a personal identifier. Individual-level data on clients who received services are collected, but client names or other personally identifiable information are not collected. Data will be kept private to the extent allowed by law.

11. Justification for Sensitive Questions

The U.S. Congress mandated that client-level data be collected under the RWHAP, including demographic information on clients served, services provided, and their clinical data. These data are needed to show the distribution of ADAP funds used to serve eligible people with HIV, identify the costs associated with medication assistance and health coverage premium support for services that enhance access, adherence, and monitoring of drug treatments. Clinical data also enables HRSA to monitor clinical outcomes achieved by clients served by RWHAP. These data provide information to the U.S. Congress on the role of the HRSA RWHAP in addressing the HIV epidemic.

12. Estimates of Annualized Hour and Cost Burden

The estimated average annualized burden is **4,698 hours**. Burden estimates are detailed by recipient respondents in Table 1, which presents the annualized burden hours for each data collection instrument: the Recipient Report and the Client Report. Estimates are based on prior experience in collecting, maintaining, and reporting. There is no change in the burden estimate for this ICR. Respondents did not report any issues with submitting ADR data.

12A. 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 Report	54	1	54	81	4,374
Total	54		54		4,698

12B.

The annualized burden costs for recipients are based on the May 2024 National Occupational Employment and Wage Statistics Query System, https://www.bls.gov/oes/current/oes_nat.htm. The respondents, Healthcare Support Workers (occupational code 31-9099), take 87 hours (4,698 hours in total for all respondents) annually to complete the ADR data collection at a labor rate of $22.14 per hour, which is doubled to account for overhead. The estimated net total hour cost

Table 2: Estimated Annualized Burden Costs

Form Name	Total Burden Hours	Hourly Wage Rate (x2)	Total Respondents Costs
Recipient Report	324	$44.28	$14,346.72
Client Report	4,374	44.28	$193,680.72
Total	**4,698**		**208,027.44**

Planned frequency of information collection:

The ADR submission occurs once a year while data collection is an ongoing process throughout the year. The secure web-based grants administration platform which houses the ADR will be open to recipients in April and the submission deadline is in June.

13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

There are no direct costs to respondents other than their time in participating in the data collection and quality assurance**.**

14. Annualized Cost to Federal Government

HRSA maintains a contract to provide technical assistance, the distribution of OMB-approved forms, data entry and analysis for RWHAP data collection support activities. While not a separate budget line item, the contract cost to support the AIDS Drug Assistance Program data collection is estimated to be approximately 12.5%. The estimated average annual cost is $912,143.78 x 12.5% = $114,018.

Contract year	Task 2 (Expenditures)	A&E estimated

	cost	cost (12.5%)
Base year (2022-23)	$1,767,253.26	$220,906.66
Option year 1 (2023-24)	$1,791,354.67	$223,919.33
Option year 2 (2024-25)	$1,835,418.84	$229,427.36
Option year 3 (2025-26)	$1,903,123.41	$237,890.43
Total cost		$912,143.78

In addition, HRSA requires 15 percent of one (1) FTE (including overhead) at a GS-14, step 6 at a total cost of $37,778 to review and prepare award notices. The average annual total cost of the project is $151,796 and the total cost of the four-year project is $607,184.

15. Explanation for Program Changes or Adjustments

HRSA is not proposing any changes to the collection.

16. Plans for Tabulation, Publication, and Project Time Schedule

The ADR includes two reporting periods: the Recipient Report aligns with the grant year, and the Client Report aligns with the calendar year. The ADR is submitted in June. HRSA compiles ADAP data to prepare an annual report for the Secretary of HHS and Congress. These reports are also published on the HRSA HAB resource websites.

After OMB approval, ADR forms and instructions will be available on the HRSA HAB resource website. This will enable grant recipients sufficient time to update their data collection systems for the revised report.

16. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB number and Expiration date will be displayed on every page of every form/instrument.

17. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.