

**Health Resources and Services Administration
Supporting Statement
ADAP Data Report**

OMB Control No. 0915-0345

Revision

Terms of Clearance: None

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Health Resources and Services Administration (HRSA) is requesting continued approval from the Office of Management and Budget (OMB) for a revision of the client-level data reporting system, the Ryan White Program’s HIV/AIDS Program (RWHAP) Part B AIDS Drug Assistance Program (ADAP) Data Report (ADR). The current ADR Information Collection Request (ICR), which expires on December 31, 2020, is currently used to collect information from grant recipients funded under Part B of the Ryan White HIV/AIDS Treatment Extension Act of 2009. The RWHAP, authorized under Title XXVI of the Public Health Service Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009, 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. See Attachment A for a copy of the 2009 legislation. The Department of Health and Human Services (HHS) HRSA administers funds for the RWHAP.

The RWHAP supports a comprehensive system of direct health care and support services for over half a million people with HIV. The HRSA RWHAP makes financial assistance available for the development, organization, coordination, and operation of more effective and cost-efficient systems for the delivery of essential core medical and support services to persons with HIV. Funding priorities are determined by stakeholders at local and state levels, resulting in uniquely structured programs that address their jurisdictions’ critical gaps and needs. HRSA also works in partnership with RWHAP recipients at state and local levels to use innovative approaches for community engagement, needs assessment, planning processes, policy development, service delivery, clinical quality improvement, and workforce development activities that are needed to support a robust system of HIV care, support and treatment.

Part B of the Ryan White HIV/AIDS Treatment Extension Act of 2009 funds States and U.S. Territories to improve the quality, availability, and organization of HIV/AIDS health care and support services. The ADAP is authorized in section 2623 of the Ryan White HIV/AIDS Treatment Extension Act of 2009. This section authorizes a portion of Part B funds to be “earmarked” for ADAP, a program that provides medications for the treatment of HIV. Program funds may also be used to purchase health insurance for eligible clients and for services that enhance access to, adherence to, and monitoring of drug treatments. Grants are awarded to all 50 States, the District of Columbia, Puerto Rico, Guam, the U.S. Virgin Islands, and several US Territories.

The information to be collected in the ADR includes an online Recipient Report and submission of client-level data by electronic upload. The data and information collected using the ADR are designed to be complementary to (but not duplicative of) the Ryan White Services Report (RSR)¹, a three-part data collection system already approved by the Office of Management and Budget. The variables contained in both the RSR and the ADR are designed to enable HRSA to fulfill its responsibilities in the administration of grant funds. Accurate records of the grantees receiving Ryan White HIV/AIDS Program funding, services provided, and clients served continue to be critical to the implementation of the legislation and thus are necessary for HRSA to fulfill its responsibilities. Client-level data enables HRSA to monitor the ability of the ADAP program to reach populations impacted by the HIV/AIDS epidemic, while ensuring that programmatic objectives such as addressing HIV/AIDS disparities are met.

In addition, a new initiative, *Ending the HIV Epidemic: A Plan for America* (EHE), began in FY 2020 and some of the data element requirements will be incorporated in existing annual data collections, including the ADR, in order to limit recipient burden.

2. Purpose and Use of Information Collection

The RWHAP requires the submission of annual reports by the Secretary of DHHS to the appropriate committees of Congress. The collection of the Recipient Report and Client-level data enables HRSA to more effectively respond to requests from the Secretary of DHHS. Recipient-level data is needed to support the implementation and monitoring of the Ending the HIV Epidemic (EHE) initiative. Client-level information is needed by HRSA in order to respond to the request for reviews of program performance and information for strategic planning. Client-level data is also needed to support the implementation and monitoring of the National HIV/AIDS Strategy (NHAS).

In selecting the variables to include in the ADR, HRSA's goal was to collect only the data necessary to respond to inquiries from Congress and other stakeholders and to fully reflect the program. The ADR is submitted annually in June. The ADR consists of two components – the Recipient Report and Client Report. The Recipient Report consists of 11 items divided into two sections:

- (1) Grantee Contact Information – This includes the name of the grantee as well as grant number, DUNS number, Recipient address, and contact information of the person completing the report;
- (2) Programmatic Summary Submission – This includes program administration such as ADAP program limits and federal poverty level eligibility requirements, as well as funding, expenditures, and medications on the ADAP formulary and cost saving strategies.

Grant recipients report data on ADAP clients in the Client Report. A client is a patient who is determined to be eligible and enrolled in the ADAP. Unlike the Recipient Report which reports data based on the grant year, the Client Report reports client data based on the calendar year. Some data is required for all clients (i.e., demographic and enrollment information); additional data is required for clients who received a particular service (i.e., type of service, number of months, and cost information). The Client Report consists of 31 items divided into five sections:

- (1) Client Demographics – This includes race, ethnicity, gender, and year of birth, HIV/AIDS status, poverty status, and health insurance coverage;

¹ The Ryan White Services Report ICR (OMB No. 0915-0323, revised in CY2018 under OMB No. 0922-0039)

- (2) Enrollment and Certification – For new clients, ADAPs are required to report application date, approval date and date of first service. For all clients (both new and existing), the dates that clients were determined to be eligible to continue to receive ADAP services, client’s enrollment status as of the end of the reporting period and reason(s) for disenrollment (if applicable) are required to be reported;
- (3) ADAP Health Insurance Services – For clients receiving ADAP-funded insurance services, type of ADAP-funded insurance assistance, total insurance premium paid and number of months this payment covered, and total deductible and copays, are required to be reported in this section;
- (4) Medication Assistance Services – The national drug code and costs are reported for all clients for whom an ADAP-funded medication was dispensed during the reporting period.
- (5) Clinical Information – This includes the most recent CD4 and viral load counts, including the dates on which the blood tests were completed;

The client-level data requested in the ADR enable HRSA to effectively respond to requests from the Secretary of DHHS, Congress and other stakeholders as well as monitor performance measures and NHAS implementation. The ADR Client Report variables are consistent with the variables in its other client-level data reporting system, the RSR. Ensuring that these data collections are complementary enables HRSA to comprehensively fulfill its responsibilities in the administration of grant funds, the allocation of funds, the evaluation of programs for the population served, and the improvement of the quantity and quality of care². Each year, HRSA generates descriptive reports about the uses of funds and conduct detailed analyses of national and regional information about clients and services. Grant recipients may also generate descriptive reports and conduct analyses for internal use or for use by local planning groups. HRSA has several resources in place to help grant recipients use data to improve program performance.

As previously noted, client-level data is necessary to ensure that HRSA can respond to requests from Congress and other stakeholders. HRSA also requires data to demonstrate the need for funding requests; monitor use of HRSA funds; ensure adherence to grant requirements; assess the impact of services funded by the RWHAP; and appraise the performance of funded programs, including the RWHAP and EHE Initiative.

3. Use of Improved Information Technology and Burden Reduction

The ADAP Module is housed in the Electronic Handbooks (EHBs), an existing web system for recipients to enter other data required for RWHAP- and EHE-funded agencies, such as the Ryan White Services Report (RSR). Users must obtain or learn this technology for other RWHAP purposes beyond the use of the ADAP Module. The EHBs system also allows for some information to pre-populate, particularly organization details, while other data are stored and saved for the next data collection so that users can easily update or change their data.

4. Efforts to Avoid Duplication and Use of Similar Information

² See attachment: *The Health Resources and Services Administration’s HIV/AIDS Bureau Grant Recipients and Subrecipients Data Reporting Overview*.

Data of the type required to evaluate or monitor the HRSA RWHAP Part B is not available elsewhere. No known studies of people with HIV or sample studies of people in defined demographic or risk groups provide comprehensive, overall program information specifically about grant recipients, subrecipients, and clients of the HRSA RWHAP. The ADR is the only comprehensive source of ADAP clients and services information that adequately addresses and meets HRSA HAB's data collection needs and objectives.

5. **Impact of Small Entities or Other Small Entities**

No small businesses will be involved in this information collection.

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 the NHAS priorities, including addressing disparities among different populations. If the information were not collected at all, 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 types 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 reducing HIV/AIDS disparities.

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

The request fully complies with the regulation.

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

Section 8A:

A 60-day Federal Register Notice was published in the *Federal Register* on December 3, 2019 (Vol. 84, No. 232, pp. 66202–66203). See attached for public comments.

Section 8B:

In July 2019, four ADAP grant recipients were consulted to obtain their views on the revisions to the ADR data collection. All four recipients stated that the changes would not result in a burden increase.

However, two Part B recipients expressed that some burden would be in the preparation as they would need to update their data system and retrain their staff. While one of these recipients didn't have an estimate of these costs, the other thought it would be about \$1,000. One ADAP grantee said they will probably need to make changes to their Pharmacy Benefits Management contract and that there may be an increase in cost. Another recipient stated that the new updates – the change in the use of medication codes and the requirement for clinical data for all clients would actually reduce the time it takes to complete the report.

HRSA RWHAP ADAP Respondents

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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 Report does not require any information that could identify individual clients. Aggregate data on the number of clients who received services are be collected, but client names or other personally identifiable information are not collected.

11. Justification for Sensitive Nature

There are no questions of a sensitive nature.

12. Estimates of Annualized Hour Burden and Cost Burden

The estimated average annualized hour burden is 4,698 hours per year. Burden estimates are broken out

by recipient respondents as seen in Table 1: Estimates of Annualized Burden Hour by each data collection instrument: Recipient Report and Client-level Report. Estimates from grant recipients are based on prior experience in collecting, maintaining, and reporting data using the data systems.

12A. Table 1: Estimated Annualized Burden Hours

The estimated annual time and cost burdens to respondents are presented in the tables below:

ADR Data Collection	Number of Respondents	Number of Responses per Respondent	Total Responses	Average burden per response (in hours)	Total Burden Hours
Grantee Report	54	1	54	6	324
Client-level Report	54	1	54	81	4,374
Total	54		54		4,698

12B. Estimated Annualized Burden Costs

The annualized burden costs for recipients is based on the May 2019 National Occupational Employment and Wage Estimates by the Bureau of Labor, https://www.bls.gov/oes/current/oes_nat.htm. The respondent, a healthcare support worker (occupational code 31-9099), takes 87 hours (4,698 hours in total for all respondents) annually to complete the ADR data collection at a labor rate of \$18.80 per hour. The net total hour cost, \$88,322.4, is double to account for employer overhead and fringe benefits, yielding a total hour cost of \$176,644.80.

Table 2: Estimated Annualized Burden Costs

Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondents Costs
Grantee Report	324	\$18.80	\$6,091.2
Client-level Report	4,374	\$18.80	\$82,231.2
Total	4,698		88,322.4 x 2 (overhead/fringe) = \$176,644.8

Planned frequency of information collection:

The ADR Report submission occurs once a year while data collection is an-going process throughout the year. The EHB which houses the ADR Report will be open to recipients in April and the submission deadline is in June.

13. Estimates of Annualized Cost Burden to Respondents

Grant recipients are responsible for maintaining their own data system and already have access to the EHBs. Only one of the four grant recipients contacted could provide an estimate of the upfront costs for training staff and making necessary IT changes to the data system and estimated the cost would be \$1,000.

14. Estimates of Annualized Cost to the Government

The contract task that supported the initial system setup and supports system maintenance and data collection efforts each year is \$120,000. In addition, there will be the cost for a GS 13 (Step 5) at 12% (approximately \$12,500) and a GS 14 (Step 5) at 6% (approximately \$7,400) time to monitor the project. The estimated total cost is \$139,900.

15. Explanation for Program Changes or Adjustments

The 4,698 burden estimate of this information collection request is the same as the currently approved burden inventory.

The Recipient Report does include a few changes. Specifically, there were revisions made to reporting medications, medications services and clinical data. To monitor the use of funds provided to ADAPs for the EHE initiative, one question on funding was also added to the Recipient Report. Recipients already collect this data element.

In the Client-level Report, three data elements that were combined with other data elements were deleted. Furthermore, revisions were made to twelve data elements so that they can align with the RSR report. Specifically, clinical data will now be collected for all clients rather than only those who received medication assistance. This revision will not be an added burden since most ADAPs already collected clinical data for all of their clients. In fact, this change will decrease the level of effort, since ADAPs will no longer need to filter out clients who only received healthcare coverage assistance. Also, the change in reporting valid National Drug Codes (NDC) rather than the Drug Identification Code (d-codes) for medication will save time as ADAPs initially collect NDC codes and then convert them to D-Codes. The Recipient Report includes two new data elements regarding client enrollment. Also, there was a revision made to an existing question that requests program income and manufacturer rebated reinvested in ADAP. Furthermore, six obsolete data elements were deleted from the Recipient Report.

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

There are two different reporting periods for the ADR. The Recipient Report is based on the grant year reporting period and the Client Report is based on the calendar year reporting period. The ADR is submitted in June. HRSA compiles the data received from the ADAPs and produces an annual report for the Secretary of HHS and Congress. In addition, beginning in June 2019, HRSA staff produced its inaugural ADAP Annual Client-Level Data Report. This report includes national summaries for all clients receiving ADAP services during the calendar years 2014 through 2017. These summaries are distributed to constituency and advocacy groups and are uploaded to the HRSA HAB Web site. The next report will be released in June 2020. The next report that would reflect the revisions proposed in this

collection of information request would be released in 2021.

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

No exemption is being requested. The expiration date will be displayed appropriately.

18. **Exceptions to Certifications for Paperwork Reduction Act Submissions**

This information collection activity will comply with the requirements in 5 CFR 1320.9.