Health Resources and Services Administration Supporting Statement ADAP Data Report

OMB Control No. 0915-0345

Revision

Terms of Clearance: None

A. Justification

1. <u>Circumstances Making the Collection of Information Necessary</u>

The Health Resources and Services Administration (HRSA) is requesting 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 June 30, 2023, is currently used to collect information from grant recipients funded under Part B of the RWHAP legislation. The RWHAP, authorized under Title XXVI of the Public Health Service Act 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 RWHAP legislation. The Department of Health and Human Services (HHS) HRSA administers funds for the RWHAP.

The HRSA RWHAP supports a comprehensive system of direct health care and support services for over half a million people diagnosed 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 RWHAP funds States and U.S. Territories to improve the quality, availability, and organization of HIV/AIDS health care and support services. A portion of the RWHAP Part B appropriation supports ADAP, which supports the provision of HIV medications and related

¹ Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2016. http://hab.hrsa.gov/data/data-reports. Published November 2017. Accessed July 20, 2018.

services, including health insurance premium and cost-sharing assistance. Grants are awarded to all 50 States, the District of Columbia, Puerto Rico, Guam, the U.S. Virgin Islands, and five US Territories.

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.

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

The ADR variables are designed to enable HRSA 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 once annually. HRSA will generate descriptive reports about 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

In order 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 HRSA Electronic Handbooks (EHBs), developed by HRSA. Many of the items on the Recipient Report will be pre-populated based on information already existing 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 to gather 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 the HRSA EHBs. CAREWare is available at no cost to all HRSA RWHAP recipients. In addition to CAREWare, HRSA continues to work with a number of 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 Avoid Duplication and Use of Similar Information

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 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**

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 that provide fewer HRSA RWHAP services will skip more of the requested information than 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 the National HIV/AIDS Strategy 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 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 reducing HIV disparities.

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 Federal Register Notice was published in the *Federal Register* on November 9, 2022 (Vol. 87, No. 216, pp. 67702–03). No comments were received. A 30-day Federal Register Notice was published in the *Federal Register* on January 31, 2023 (Vol. 88, No. 20, pp. 6286-6287).

Section 8B:

In October 2022, seven ADAP grant recipients were consulted to obtain their views on the revisions to the ADR data collection. The seven recipients stated that the changes would not result in a burden increase or they were unsure of any anticipated challenges.

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. Individual-level data on clients who received services are collected, but client names or other personally identifiable information are not collected.

11. Justification for Sensitive Nature

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 diverse and vulnerable populations, identify the costs associated with medication assistance and health insurance premium for services that enhance access, adherence, and monitoring of drug treatments. Clinical data also allows 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 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 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
Recipient Report	54	1	54	6	324
Client Report	54	1	54	81	4,374
Total	54		54		4,698

12B. Estimated Annualized Burden Costs

The annualized burden costs for recipients are based on the May 2021 National Occupational Employment and Wage Estimates by the Bureau of Labor,

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 \$19.56 per hour. The net total hour cost, \$91,892.88, is doubled to account for the employer's overhead and fringe benefits, yielding a total cost of \$183,758.76.

Table 2: Estimated Annualized Burden Costs

Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondents Costs
Recipient Report	324	\$19.56	\$6,337.44
Client Report	4,374	\$19.56	\$85,555.44
			\$91,892.88 x 2
Total	4,698		(overhead/fringe) =
			\$183,785.76

Planned frequency of information collection:

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

13. Estimates of Annualized Cost Burden to Respondents

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

14. Estimates of Annualized Cost to the Government

HRSA has maintained a contract to provide technical assistance, distribute the OMB-approved

HRSA RWHAP ADR, and perform data entry and analysis. For FY 2023, this contract is \$1,767,253.26. In addition, government personnel requires 10% time of 1 FTE at a GS-13 level (\$112,015) to review and prepare award notices (approximately \$11,201.50). The total estimated cost is \$1,778,454.76.

15. Explanation for Program Changes or Adjustments

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

The submitted ADR FRN includes three proposed revisions:

- Replacement of the Recertification Date variable with the Last Date of Eligibility
 Confirmation will remove the previous 6-month recertification requirement, which is no
 longer required by policy, see <u>Policy Clarification Notice 21-02</u>, and allows Recipients to
 report the latest eligibility confirmation date for existing clients;
- Reinstate a question that was inadvertently removed from the 2021 ADR that is needed to assess the quality of medication data; and
- Change the DUNS number variable to Unique Entity Identifier (UEI). On April 4, 2022, the Federal Government stopped using DUNs numbers, making it less burdensome for entities to do business with the federal government. As a result, Recipients no longer have to report the DUNs number in the ADR.

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.

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.