

**Supporting Statement**  
**AIDS Drug Assistance Program (ADAP) Data Report**  
**OMB Control No. 0915-0345**

**Terms of Clearance:** None

**A. Justification**

1. Circumstances Making the Collection of Information Necessary

The Health Resources and Services Administration (HRSA) is requesting approval from the Office of Management and Budget (OMB) for an extension of the client-level data reporting system, the Ryan White HIV/AIDS Program Part B AIDS Drug Assistance Program (ADAP) Data Report (ADR). The ADR, which expires December 31, 2017, is currently used to collect information from grantees funded under Part B of the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Ryan White HIV/AIDS Program; see Tab A for a copy of the 2009 legislation), as codified under Title XXVI of the Public Health Service Act. The HIV/AIDS Bureau within HRSA of the United States Department of Health and Human Services (HHS) administers funds for the Ryan White HIV/AIDS Program. The program is authorized by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111–87) through 2013. The legislation was first enacted in 1990 as the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act and was amended and reauthorized in 1996, 2000, and 2006.

The Ryan White HIV/AIDS Program funds HIV-related medical care and essential support services as well as technical assistance (TA), clinical training, and research on innovative models of care. The program funds grantees through “Parts” to deliver care to meet the needs of different communities and individuals infected and affected by HIV/AIDS. These Parts, which range from Part A through F, target funds to specific State and local entities and together create a comprehensive funding structure. The Ryan White HIV/AIDS program reaches more than half a million people annually who have insufficient health care coverage or financial resources to meet their HIV clinical and supportive needs, filling gaps in care not covered by other sources.

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. 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 disease. 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. The following states, territories, and

Pacific Island jurisdictions are eligible to apply for RWHAP ADAP funding: All 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, the Federated States of Micronesia, and the Republic of the Marshall Islands.

While there are core requirements for all grantees, they are given some program flexibility to most effectively respond to the local needs of their clients. For example, while all grantees are required to implement an ADAP recertification process every six months to ensure that clients receiving services continue to be eligible for the program, each grantee establishes its own financial eligibility criteria while ensuring that Ryan White Program funds are the payer of last resort. In addition, current legislation requires that grantees must cover all classes of approved HIV antiretroviral medications in their ADAP formulary; however, each grantee decides which specific medications within each class will be included in its formulary and how those medications will be distributed.

The information to be collected in the ADR includes an online grantee-level report (Tab B) and submission of client-level data by electronic upload (see Tab C for the data elements of the ADR client-level data upload). For more information about the ADR, see Tab D for the 2016 ADR Instruction Manual. The data and information collected using the ADR are designed to be complementary to (but not duplicative of) the Ryan White Services Report (RSR), a three-part data collection system already approved by the OMB (OMB No. 0915-0323). 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.

This extension package will contain minor revisions to data elements within the Client-level variables. Specifically, changes to variable IDs 6 (“Gender”) and 7 (“Transgender”) will include the following changes: the deletion of variable ID 7, “Transgender”; the addition of “Transgender Male to Female”, “Transgender Female to Male”, and “Transgender Other” as response options for variable ID 6, “Gender”; and the deletion of “Unknown” as a response option for variable ID 6, “Gender”. These modifications will allow HRSA to align its data collection efforts across all of its reports.

## 2. Purpose and Use of Information Collection

The Ryan White HIV/AIDS Program requires the submission of annual reports by the Secretary of HHS to the appropriate committees of Congress. The collection of grantee-level and client-level data enables HRSA to more effectively respond to requests from the Secretary of HHS. In

addition, 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 will be submitted annually in June. The ADR consists of two components – the grantee-level variables (Grantee Report) and client-level variables (Client Report). The Grantee 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, 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.

Grantees will 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 Grantee Report which reports data based on the grant year, the Client Report will report client data based on the calendar year. Some data will be required for all clients (i.e., demographic and enrollment information); additional data will be required for clients who received a service (i.e., service, clinical and cost information). The Client Report consists of 34 items divided into five sections:

- (1) Client Demographics – This includes race, ethnicity, gender, and year of birth as well as poverty status, and health insurance coverage;
- (2) Clinical Information – This includes the most recent CD4 and viral load counts, including the dates on which the blood tests were completed;
- (3) Enrollment and Certification – For new clients, ADAPs will be 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) will be required to be reported;
- (4) ADAP Services Received – 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, will be required to be reported in this section;
- (5) Drugs and Drug Expenditures – The five-digit drug code, start date, days' supply and cost will need to be reported for all clients for whom an ADAP-funded medication was

dispensed during the reporting period. If ADAP programs collect dispensing fees separately, that information will need to be reported as well.

The client-level data requested in the ADR enable HRSA to effectively respond to requests from the Secretary of HHS, 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 Ryan White Services Report. Ensuring these systems 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 care.

Each year, HRSA will generate descriptive reports about the uses of funds and conduct detailed analyses of national and regional information about clients and services. Grantees 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 grantees 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 Ryan White HIV/AIDS Program; and appraise the performance of funded programs.

### 3. Use of Improved Information Technology and Burden Reduction

This submission of data to HRSA is fully electronic. In order to submit the ADR, grantees will need access to the Internet. The Grantee report will be completed online through a secure Web-based application accessed through HRSA's Electronic Handbooks (EHBs). Some of the items on the Grantee Report will be pre-populated based on information already existing in the system. This is expected to save grantees time. Additional items in the Grantee Report will be manually entered using a Web form. The Client Report will be completed using data collected by the grantee using their own data collection system and uploaded to HRSA's secure server via the Web application. Client level data (contained in the Client Report) will need to be in the required Extensible Markup Language (XML) format, with one record for each ADAP client. The Web application will allow multiple XML uploads to accommodate grantees that maintain data in multiple systems. When a grantee uploads multiple data files, data for the same client will be merged according to pre-determined rules.

Several canned reports will be built into the Web application to allow grantees to review their data prior to submission to HRSA. In addition, data validation checks will be programmed into the application to automatically check the validity of data in the Grantee and Client reports. This automatic process is designed to improve the quality of the data submitted to HRSA.

Use of information technology varies greatly among grantees. Some grantees have established data systems that are capable of producing the required reports with minimal effort, while other grantees will need technical assistance to establish effective systems. To comply with the proposed information collection, all grantees will need to either establish or modify, and maintain, a data system that is capable of collecting and reporting the required client-level data elements for clients enrolled in the ADAP. HRSA anticipates that grantees receiving ADAP funds have data systems that fall into three general categories: Grantees may use CAREWare, another proprietary vendor system, or a custom system to collect and maintain data on ADAP clients.

HRSA has developed its own database system, CAREWare, available at no cost to all Ryan White HIV/AIDS Program grantees as an option for grantees to consider in meeting their reporting needs. CAREWare includes a module specific to ADAP which will be updated to collect all data required for the ADR and to submit the data in the required XML format. In addition, as with the RSR, HRSA will offer to work with vendors of proprietary, HIV-care database systems to help them ensure that their systems are compatible with the proposed ADR reporting requirements.

Users of proprietary vendor systems will need to ensure that the system is capable of producing the ADR in the required format. Although HRSA has not yet identified any ADR-ready vendors, as noted above HRSA anticipates collaborating with vendors in the future to make their systems ADR-ready, to ensure a smooth transition for grantees, and support the reporting of accurate data. For the RSR, this collaboration has included facilitating Web conferences with users of specific vendors, providing the XML schema to vendors, and offering technical assistance as the vendors work to develop and implement the ADR variables and reporting schema into their systems. Grantees that use a custom-built system will need to use the XML schema provided by HRSA to write a program that will extract data from the system and create the XML file. Technical support will be available to assist these grantees in devising a method of extracting and converting their data into the required format.

Information Technology Assessment technical assistance will be available to all grantees as they prepare their systems and practices for the ADR. The goal of this technical assistance will be to understand what the grantees are currently doing, what their plans are, and what types of assistance they need.

To further support grantees in completing the ADR, several webinars will be held that will cover the content and the mechanics of submitting the ADR. Grantees will also be introduced to the technical assistance resources available to support them in meeting the ADR reporting requirements.

#### 4. Efforts to Identify Duplication and Use of Similar Information

The ADR is the only data collection system where data on ADAP clients and services are collected.

5. Impact on Small Businesses or Other Small Entities

No small entities will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

The ADR will be submitted annually. If the information was 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 was 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

This information collection fully complies with 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 April 24, 2017 (Vol. 82, No. 77 pp. 18918 - 18919). See Tab E for a copy of the notice. There were no public comments.

**Section 8B:**

In 2017, ADAP grant recipients were consulted to obtain their views on the ADR data collection, even though the data collected is the same as in the previous year. Input was provided by the following five ADAP representatives outside of the agency. One ADAP reported the ADR to be burdensome because they had not yet fully adopted a data system capable of producing the ADR. In addition, in recent years, the demand for ADAP services have increased in their state. They

are now in the process of testing CAREWare but will not be ready for its full implementation until next year. Overall, respondents thought the process was getting easier every year, in particular with that data elements being the same. In addition, ADAPs thought the materials, webinars, and technical assistance available to complete the ADR were adequate and satisfactory.

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## 9. Explanation of any Payment/Gif to Respondents

The proposed collection of information does not involve any remuneration of respondents beyond the contracted agreement to collect data.

## 10. Assurance of Confidentiality Provided to Respondents

Measures have been incorporated into the ADR to fully protect the confidentiality of clients receiving services. These are:

- All ADAP clients are assigned a Unique Client Identifier (UCI), which is encrypted through a hashing algorithm embedded within the data management system at the grantee site before the data are submitted to HRSA.

- Grantees do not provide HRSA with any information that could identify individual clients. The data submitted cannot be used alone or in combination by HRSA to identify specific ADAP clients.

11. Justification for Sensitive Questions

All clients reported in the ADR are HIV-positive. The ADR provides client-level information on the characteristics of clients served, the types of services provided, and the current health status of clients, based on core clinical performance measures established by HRSA; grantee-level data are also provided. Data are drawn from client-level databases and reports collected by grantees.

12. Estimates of Annualized Hour and Cost Burden

12A. Estimated Annualized Burden Hours

Burden estimates were requested from five agencies representing a variety of ADAP models. These burden estimates are presented in the table below.

**Estimated Annualized Burden Hours**

<b>Instrument</b>	<b>Number of Respondents</b>	<b>Number of Responses per Respondent</b>	<b>Total Responses</b>	<b>Average Burden per Response (in hours)</b>	<b>Total Burden Hours</b>
Grantee Report	54	1	54	6	324
Client Report	54	1	54	81	4,374
Total :	54*		54		4,698

\*The same respondents complete the Grantee Report and the Client-level Report.

12B. Estimated Annualized Burden Costs

Grantees are responsible for maintaining their own data systems or using the ADR module of CAREWare, the system provided without cost by HRSA to collect ADR data, to comply with grant requirements. There are no direct costs to respondents other than their time in participating in the data collection and quality assurance. The updated annualized burden costs for recipients is based on the *May 2016 National Occupational Employment and Wage Estimates* for Miscellaneous Community and Social Service Specialists from the Bureau of Labor Statistics Occupational Employment Statistics, [https://www.bls.gov/oes/2016/may/oes\\_nat.htm#00-0000](https://www.bls.gov/oes/2016/may/oes_nat.htm#00-0000).



<b>Instrument</b>	<b>Total Burden Hours</b>	<b>Hourly Wage Rate</b>	<b>Total Burden Hours</b>
Grantee Report	324	\$19.84	\$6,428.16
Client Report	4,374	\$19.84	\$86,780.16
Total	4,698		\$93,208.32

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

Grantees are responsible for maintaining their own data systems or using the ADR module of CAREWare, the system provided without cost by HRSA to collect ADR data, to comply with grant requirements. 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<sup>i</sup>

<b>Analysis and Reporting of ADR Data by Staff from the HAB Division of Science and Policy</b>	
160 hours by Supervisory Public Health Analyst (GS-14) at \$ 112,021/year (\$53.68/hour)	\$8,588.80
160 hours by Health Statistician (GS-14) at \$ 130,692/year (\$62.62/hour)	\$10,019.20
<b>Maintenance of CAREWare Software to Conform with ADR</b>	
160 hours by Supervisory Public Health Analyst (GS-14) at \$141,555/year (\$69.78/hour)	\$11,164.80
<b>Uploading Software, Reports, and Instructions to HRSA Web Site</b>	
100 hours by Program Analyst (GS-12) at \$79,720/year (\$45.42/hour)	\$4,542.00
<b>Data and Reporting System Support, Training, and Technical Assistance</b>	
Data Support Contractor	
Materials Development and Webinars	71,051.20
Data Support Helpline	106,576.80
<b>Total Estimated Annual Cost</b>	<b>\$211,942.80</b>

15. Explanation for Program Changes and Adjustments

The burden for this extension has not changed from the burden shown in the current inventory. However, this package will contain minor revisions to data elements within the Client-level variables. Specifically, changes to variable IDs 6 (“Gender”) and 7 (“Transgender”) will include the following changes: the deletion of variable ID 7, “Transgender”; the addition of “Transgender Male to Female”, “Transgender Female to Male”, and “Transgender Other” as response options for variable ID 6, “Gender”; and the deletion of “Unknown” as a response option for variable ID 6, “Gender”. These modifications will allow HRSA to align its data collection efforts across all of its reports.

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

There are two different reporting periods for the ADR. The Grantee 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.

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

The expiration date will be displayed appropriately.

18. Exceptions to Certifications for Paperwork Reduction Act Submissions

This information collection fully complies with the guidelines in 5 CFR 1320.9. The necessary certifications are included in the package

<sup>i</sup> Based on 2017 OPM Pay Schedule for Washington D.C. Metro area, <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2017/DCB.pdf>.