

Supporting Statement

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 with revisions 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, 2014, 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 (DHHS) 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. 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. Grants are awarded to all 50 States, the District of Columbia, Puerto Rico, Guam, the U.S. Virgin Islands, and several US Territories.

Since 2005, grantees have supplied aggregate ADAP data and information to HRSA using the ADAP Quarterly Report (AQR; OMB No. 0915–0294). In 2013, ADAPs began submitting the client-level data via the ADR. As of April 30, 2014, HAB retired the AQR and now only requires the submission of the ADR by ADAPs. The information to be collected in the ADR includes an online grantee-level report (similar to the AQR) and submission of client-level data by electronic upload. For more information about the ADR, see Tabs B and C for screenshots and full content of the ADR Grantee Report and Tab D for the data elements of the ADR client-level data upload. The data and information collected using the ADR is 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 Office of Management and Budget (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.

On April 11, 2012, a memo from the Secretary of the Department of Health and Human Services (HHS) directed the Health Resources and Services Administration (HRSA) along with other Health and Human Services Operating Divisions (Op Divs) to work together to: 1) identify seven common Core HIV/AIDS indicators; 2) develop implementation plans to deploy these indicators; and 3) streamline data collection; and reduce reporting by at least 20 – 25 percent. In November 2012, the HIV/AIDS Indicators Implementation Group (HAIIG), comprised of representatives from HHS Op Divs, the Department of Housing and Urban Development, the Veterans' Health Administration and community partners, successfully identified the required common Core HIV/AIDS indicators.

Revisions to the ADR are required to support implementation of the core indicators, streamlining data collection, and reducing reporting burden. Eleven data elements will be deleted from the ADR and several variables were modified to reduce reporting burden. *Sex at Birth*, defined to be the biological sex assigned to the client at birth, will be added to align with variables collected by other HHS Op Divs. *Type of ADAP-funded insurance assistance received* will also be added to track ADAP's payment of full or partial premium and co-pays and deductibles.

In addition to the new data elements noted above, other new variables will be added to the RSR to address provisions set forth in Section 4302 of the Affordable Care Act (ACA). The ACA includes several provisions aimed at eliminating health disparities in America. Section 4302 (Understanding health disparities: data collection and analysis) of the ACA focuses on the standardization, collection, analysis, and reporting of health disparities data. Section 4302 requires the Secretary of DHHS to establish data collection standards for race, ethnicity, and sex. The race/ethnicity data elements include reporting of Hispanic, Asian, and Native Hawaiian/Pacific Islander subgroups. The categories for HHS data standards for race and ethnicity are based on the disaggregation of the OMB standard used in the American Community Survey (ACS) and the 2000 and 2010 Decennial Census. The subgroup categories can be rolled-up to the OMB standard. These new data elements will be used in data analysis intended to identify and understand health disparities.

2. Purpose and Use of Information Collection

The Ryan White HIV/AIDS Program requires the submission of annual reports by the Secretary of DHHS 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 DHHS. 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 and will report data based on the grant year reporting period. 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, 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, federal poverty level eligibility requirements, 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 – ADAPs will be required to report application date, approval date and date of first service. 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.

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.

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 available in 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.

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

As previously noted, the AQR, aggregate quarterly reports regarding ADAP clients and services was retired in April 2014. The ADR is now 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 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

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 June 18, 2014 (Vol. 79, No. 117 pp. 34764-34765). There were no public comments.

Section 8B:

In 2014, input on the burden and the impact on the new changes in the ADR on the burden was provided by the following five ADAP representatives outside of the agency.

California ADAP

- Celia Banda-Brown, ADAP Section Chief
 - o celia.banda-brown@cdph.ca.gov, (916) 449-5943

Georgia ADAP

- Libby Brown, ADAP Manager
 - o lsbrown@dhr.state.ga.us, (404) 657-3127

Kansas ADAP

- Jeni Mulqueen, ADAP Director
 - o jmulqueen@kdheks.gov, (785) 368-8218

North Carolina ADAP

- John S. Furnari, ADAP Director
 - o john.furnari@dhhs.nc.gov , (919) 733-9576

Virginia ADAP

- Carrie Rhode, ADAP Coordinator
 - o carrie.rhodes@vdh.virginia.gov, (804) 864-7914

9. Explanation of any Payment/Gif to Respondents

Respondents will not receive any payments or gifts.

10. Assurance of Confidentiality Provided to Respondents

Measures have been incorporated into the ADR to 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. The data submitted cannot be used alone or in combination by HRSA to identify specific ADAP clients.

The project does not require IRB.

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

Instrument	Number of Respondents	Responses per Respondent	Total Responses	Hours per Response	Total Burden Hours
Grantee Report	54	1	54	6	324
Client Report	54	1	54	81	4,374
Total :	54	1	54	87	4,698

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 Department of Labor website was used to determine appropriate wage rates for respondents (http://www.bls.gov/oes/current/oes_nat.htm#13-0000).

Instrument	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Grantee Report	324	30.67	9,937.08
Client Report	4,374	30.67	134,150.58
Total	4,698	30.67	144,087.66

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

Analysis and Reporting of ADR Data by Staff from the HAB Division of Science and Policy	
160 hours by Supervisory Health Scientist (GS-15, Step 1) at \$124,995/year (\$59.89/hour)	\$9,582.40
160 hours by Health Statistician (GS-14, Step 5) at \$120,429/year (\$57.70/hour)	\$9,232.00
Maintenance of CAREWare Software to Conform with ADR	
160 hours by Supervisory Public Health Analyst (GS-14, Step 1) at \$106,263/year (\$50.92/hour)	\$8,147.20
Uploading Software, Reports, and Instructions to HRSA Web Site	
100 hours by Program Analyst (GS-13, Step 5) at \$101,914/year (\$48.83/hour)	\$4,883.00
Data and Reporting System Support, Training, and Technical Assistance	
Data Support Contractor	
Materials Development and Webinars	\$71,051.20
Data Support Helpline	\$106,576.80
Reporting System Contractor	\$650,000.00
Total Estimated Annual Cost	\$859,472.60

15. Explanation for Program Changes and Adjustments

In the previous OMB, the burden estimate in the first year of ADR collection included the development or adjustment of ADAPs' data collection systems to include the collection of client level data elements for the first time. In the following second and third year, the new burden estimate was dramatically decreased from 52,404.66 hours to 4,161 hours with the assumption that ADAP data collection systems would be in place. In this current inventory for the ADR the burden estimate is for 4,698 burden hours, an increase of 537 hours from the currently approved burden of 4,161 hours per year. ADAPs may now have a more accurate sense of how long the ADR does take to complete. For example, ADAPs now report that the Grantee Report takes an average of 6 hours, whereas previously ADAPs reported that it took them 12 hours. This is due to familiarity of the data elements and data collection systems in place. The Client-level Report, which may require ADAPs to pull data from various data systems has proven to take longer than previously estimated by ADAPs. Before, ADAPs estimated it take them 24 hours, but now ADAPs are reporting that it takes them an average of 81 hours. This increase may also largely reflect HAB's push to improve data collection through submitting complete and accurate data. ADAPs can now monitor their data using the Completeness Report and Confirmation Report to check the quality of their data. The increase in burden estimates is also likely attributable to asking questions in this latest sample of ADAPs that cover more of the scope of their data collection and reporting activities (e.g. improving data quality and monitoring data collection year-round) and with greater specificity than for estimating burden when grantees were sampled

previously.

Despite the change from a bi-annual to an annual submission, this did not decrease the amount of effort it takes to prepare the ADR. Finally, all grantees who responded with burden estimates expressed that the current data elements changes in the Client Report described above would have little to no affect in their current burden estimates.

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 (April 1 – March 31) and the Client Report is based on the calendar year reporting period (Jan 1 – Dec 31). The ADR is submitted in June. HRSA compiles the data received from the ADAPs and produces an annual report for the Secretary of DHHS and Congress. In addition, HRSA staff produces national summaries that are distributed to constituency and advocacy groups and are uploaded to the HIV/AIDS Bureau Web site. Summaries consist of aggregate-level data only.

17. 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.

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