

Supporting Statement

ADAP Data Report

A. Justification

1. Circumstances of Information Collection

The Health Resources and Services Administration (HRSA) is requesting approval from the Office of Management and Budget (OMB) for a new data collection system for the Ryan White HIV/AIDS Program Part B AIDS Drug Assistance Program (ADAP) – the ADAP Data Report (ADR). The ADR will be 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.

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

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.

Since 2005, grantees have supplied ADAP data and information to HRSA using the ADAP Quarterly Report (AQR; OMB No. 0915-0294). Grantees submit the AQR every three months as part of funding requirements. The AQR is a grantee-based data collection instrument in which grantees report in the aggregate on the number and characteristics of clients served. The AQR includes information on: patients served; pharmaceuticals prescribed; medication pricing; other sources of financial support for AIDS medications; eligibility requirements; service costs; and coordination with Medicaid.

The aggregate data reported in the AQR have some inherent limitations. Aggregate data lack the precision to adequately evaluate grantees and clients in a systematic manner, particularly given the flexibility in the programs previously noted. In addition, the aggregate data reported for ADAP clients does not permit an unduplicated count of clients receiving ADAP-funded services, nor permit more detailed information by population subgroup or service type.

Therefore, OMB approval is being requested for the enhanced collection of ADAP program data from grantees. The ADR is designed to replace the historic AQR which will be gradually retired using a system transition plan (outlined below). The information to be collected in the ADR includes an online grantee-level report (similar to the current AQR) and submission of client-level data by electronic upload and will be known as the ADAP Data Report. 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.

HRSA has developed a transition plan of phasing out the historic AQR and moving to relying solely upon the ADR for collecting client level ADAP data from grantees. This transition is modeled after the successfully implemented transition plan in the Ryan White Data Report (RDR), a system that has transitioned to the Ryan White Services Report (RSR). Specifically, grantees will continue to report using the ADAP Quarterly Report (AQR) as they become accustomed to collecting and reporting data in the ADR. The AQR will provide aggregate data, including services provided and clients served, which will be critical to ensure that HRSA can continue to respond to requests from the Secretary of DHHS, Congress and other stakeholders during the implementation of the ADR. HRSA will assess the quality of the information provided through the new data system and identify any technical assistance (TA) needed.

Once grantees become accustomed to the new reporting system, the AQR will be retired; HRSA anticipates this will occur in 2014. HRSA expects the ADR to better support clinical quality management, performance measurement, service delivery, and client monitoring at both the grantee and client levels, enhancing the quality and utility of the reported data.

The collection and submission of data for the Ryan White HIV/AIDS Program is a public health activity and is consistent with provisions of the Ryan White HIV/AIDS Treatment Extension Act of 2009 and enabling directives, rules, and guidelines governing the use of Federal funds. The Ryan White HIV/AIDS Program requires the submission of annual reports by the DHHS Secretary to Congress. Therefore, unduplicated client-level data are necessary to effectively answer the overarching questions about the ADAP program.

2. Purpose and Use of Information

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 consists of two components – the grantee-level variables (Grantee Report) and client-level variables (Client Report). The Grantee Report will be similar to the current AQR; the one substantive change is that, unlike the AQR, the ADR Grantee Report requires the dates that new medications are added to the formulary. The Grantee Report consists of 18 items divided into three sections:

- (1) Grantee Contact Information – This includes the name of the grantee as well as grant number, ADAP number, DUNS number, address, contact information and the reporting period;
- (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;
- (3) Annual Submission – This includes program administration such as frequency of recertification, cost saving strategies and sources of ADAP funding.

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. 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 39 items divided into five sections:

- (1) Client Demographics – This includes race, ethnicity, gender, pregnancy status and year of birth as well as poverty status, health insurance coverage and whether or not the client is in a high risk insurance pool;

- (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 well as the reason(s) for disenrollment (if applicable) will be required to be reported;
- (4) ADAP Services Received, - For clients receiving ADAP-funded insurance services, total insurance premium paid and number of months this payment covered, total deductible and copays, and total amount of Medicare Part D co-insurance, copayment or TrOOP expenses 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 is consistent with what grantees are currently required to report in aggregate form in the AQR, i.e., demographics, enrollment information, clinical information, and drug expenditures. Additional variables were added that HRSA does not currently collect, but as previously noted 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. HRSA also made an effort to make the ADR Client Report variables as consistent as possible with the variables in its other client-level data reporting system, the Ryan White Services Report, only modifying elements to conform to ADAP standards when necessary. 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.

There will be two six-month reporting periods annually based on the ADAP fiscal year. For example, in year 1, the first reporting period will be April 1 2012 – September 30, 2012, and the first submission will be due December 15, 2012. The second reporting period will be October 1, 2012 – March 31 , 2013, and the second submission will be due June 15, 2013. A portion of the Grantee Report containing program administration information such as frequency of recertification, cost saving strategies and sources of ADAP funding is not expected to change more often than once a year and therefore will only be submitted annually.

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

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. Additionally, HRSA has made funding available to grantees to enhance their Health Information Technology capacity to collect and report client-level data for recipients of ADAP services. This funding was distributed through Special Projects of National Significance competitive grants ranging from \$50,000 - \$100,000 per ADAP beginning September 1, 2011.

To further support grantees in the transition to new ADR data reporting, HRSA is planning annual regional training sessions. Grantees will be asked to send at least one representative to the training. The training 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

As previously noted, grantees currently submit aggregate quarterly reports regarding ADAP clients and services. However, aggregate data lack the precision to adequately monitor grantees receiving the ADAP program in a systematic manner and effectively respond to requests from the DHHS Secretary, Congress and other stakeholders. Grantees will continue to report aggregate data using the AQR for a finite period as the ADR is implemented, to ensure they have an opportunity to make a smooth transition to the new system without compromising the ability of HRSA to collect data and report to Congress each year.

5. Involvement of Small Entities

No small entities will be involved in this information collection.

6. Consequences If Information Collected Less Frequently

The ADR will be submitted twice per year. Semi-annual data reporting will allow HRSA to respond to any issues that arise, such as unexpected increases in medication costs or waiting lists. 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. Regular 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. Consistency With the Guidelines in 5 CFR 1320.6

This information collection fully complies with 5 CFR 1320.6.

8. Consultation Outside the Agency

The notice required in 5 CFR 1320.8(d) was published in the Federal Register on July 22, 2011 (76, 141, 44018-44019); see Tab E. One comment was received.

HRSA has been exploring a client-level data system for ADAP for several years. In 2007, the Research Triangle Institute (RTI) investigated the feasibility of ADAP client-level data collection, including assessing the readiness of grantees to report ADAP client-level data and potential challenges they may face in reporting client-level data. In August 2010, the National Association of State and Territorial AIDS Directors (NASTAD) requested information from grantees about their information systems and structures and determined how specific client demographic, enrollment, and expenditure information is currently captured. In August 2010 at the biannual Ryan White HIV/AIDS Program All-Grantee Meeting, grantees were invited to a HRSA - facilitated workshop during which HRSA formally introduced the initial draft of the ADR. HRSA considered the feedback received from grantees and proposed a set of ADR variables in January 2011.

HRSA hosted two ADR vetting Webinars in January 2011. The Client Report was vetted on January 13 and the Grantee Report was vetted on January 27. With the assistance of HRSA Project Officers, all grantees were invited to participate and were provided with the presentation slides, advanced copies of the data elements, and worksheets to use to organize their feedback. Additionally, the proposed variables were posted on the HRSA and TARGET Center Websites. The TARGET Website is designed to serve as a technical assistance resource for Ryan White HIV/AIDS Program grantees, planning bodies, and HAB staff. Through the website, individuals and organizations can receive information and referrals related to the Ryan White HIV/AIDS Program and the range of technical assistance supported by HAB. Grantees were asked to review the proposed variables and to seek input from their programs and contractors prior to each Webinar in order to inform the discussion. Grantees were asked to submit written feedback to NASTAD within the two-week period following each Webinar.

The purpose of the vetting Webinars was to share HRSA's thinking on the ADR, including the proposed data items, timelines, and available resources. In addition, HRSA sought grantees' feedback and

thoughts on the proposed ADR variables, and encouraged grantees to share their concerns and potential solutions with HRSA and each other.

Of the 57 grantees, 47 (82%) were represented in the client-level variables Webinar; 39 (68%) were represented in the grantee-level variables Webinar. Of those who participated, 16 grantees provided verbal feedback during the Webinars – 13 in response to the client-level variables, and five in response to the grantee-level variables. In addition, 18 grantees submitted written feedback in the two-week period following each vetting Webinar – 17 in response to the client-level variables, and four in response to the grantee-level variables.

HRSA considered the feedback received from grantees during the vetting and, where feasible, revised the variables to reflect actual ADAP practice and preferences. For example, definitions were clarified, response categories were added, and variables were eliminated or limited to be reported for only certain types of services.

Considering feedback received both during the two Webinars and during the follow-periods after the Webinars, 28 grantees (49%) did not provide any feedback to the proposed variables and are assumed to be in agreement with the variables as proposed.

In addition, specific input on the availability of data, frequency of collection, clarity of instructions, reporting format, and reporting burden was provided by nine grantee representatives. These consultations show that the data collection instruments are written using plain, coherent, and unambiguous terminology and are understandable to potential respondents.

9. Remuneration of Respondents

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

10. Assurance of Confidentiality

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 In addition, gclients. The data submitted cannot be used alone or in combination by HRSA to identify specific ADAP clients.

11. Questions of a Sensitive Nature

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 Burden

Discussions were held with nine volunteer grantee agencies representing a variety of ADAP models as a basis for the burden estimates for the ADR that follow. These burden estimates are presented in two tables. Table 1 (Estimated Annual ADR Burden for the First Year of the Information Collection) represents the estimated burden for the first year, including the estimated time to adjust existing or develop new data collection systems to collect the elements that HRSA is requesting. HRSA does not require grantees to use a specific data collection system. Rather, grantees are expected to modify existing or develop new data collection systems to collect and report the required data elements for both the Grantee and Client Reports in the specified formats. These data systems are maintained locally and HRSA does not have any access to these systems. Modifications to these data systems are necessary to initially meet the new requirements and as such, are only represented in the year one burden. This is a one-time burden for grantees and will not be a factor after the first year. Table 2 (Estimated Annual ADR Burden for the Second and Subsequent Years of the Information Collection) represents the estimated burden for subsequent years. Burden estimates are further broken out by burden to complete the Grantee Report and burden to complete the Client Report.

The annual estimate of burden for the first year of the information collection is as follows:

TABLE 1.

Estimated Annual ADR Burden for the First Year of the Information Collection

Instrument	Number of Respondents	Responses per Respondent	Total Responses	Hours per Response	Total Burden Hours
Grantee Report	57	2	114	12.50	1,425.00
Client Report	57	2	114	34.19	3,897.66
Data Collection System	57	1	57	826.00	47,082.00
Total:					52,404.66

The annual estimate of burden for subsequent years is as follows:

TABLE 2.

Estimated Annual ADR Burden Subsequent Years of the Information Collection

Instrument	Number of Respondents	Responses per Respondent	Total Responses	Hours per Response	Total Burden Hours
Grantee Report	57	2	114	12.50	1,425.00
Client Report	57	2	114	24.00	2,736.00
Total :					4,161.00

12B. Estimates of Annualized Cost Burden to Respondents

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.

13. Estimates of Annualized Cost to the Government

TABLE 3

Analysis and Reporting of ADR Data by Staff from the HAB Division of Science and Policy	
160 hours by Supervisory Health Scientist (GS-15) at \$123,758/year (\$59.49/hour)	\$9,518.40
160 hours by Health Statistician (GS-14) at \$119,238/year (\$57.32/hour)	\$9,171.20
Maintenance of CAREWare Software to Conform with ADR	
160 hours by Supervisory Public Health Analyst (GS-14) at \$105,211/year (\$50.58/hour)	\$8,092.80
Uploading Software, Reports, and Instructions to HRSA Web Site	
100 hours by Program Analyst (GS-13) at \$103,872/year (\$49.93/hour)	\$4,993
Data and Reporting System Support, Training, and Technical Assistance	
Data Support Contractor	\$177,628.00
Reporting System Contractor	\$300,000.00
Total Estimated Annual Cost	\$509,403.40

Estimated Annual Cost to the Federal Government

14. Changes in Burden

This is a new collection of information.

15. Time Schedule, Publication and Analysis Plan

The reporting periods are the first half and the second half of the ADAP fiscal year, i.e., April 1 – September 30 and October 1 – March 31. Semiannual reports from the grantees will be submitted to HRSA approximately 2.5 months following the end of each reporting period. HRSA will verify, clean, and compile the data received from the grantees and produce an annual report for the Secretary of DHHS and Congress. In addition, HRSA staff will produce national summaries that will be distributed to constituency and advocacy groups and will be uploaded to the HRSA Web site. Summaries will consist of aggregated data only.

Upon approval by OMB, the final ADR data elements and instructions will be made available to grantees to allow them as much time as possible to modify their data collection systems and processes to conform to the new report.

16. Exemption for Display of Expiration Date

No exemption is requested.

17. Exceptions to Certification for PRA Submissions

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