

Supporting Statement

Health Resources and Services Administration AIDS Drug Assistance Program Quarterly Report

OMB Control No. 0915-0294

Terms of Clearance: None

A. Justification

1. Circumstances Making the Collection of Information Necessary

This is a request for extension of the current OMB approval for the ADAP Quarterly Report (AQR) used by the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau to monitor the AIDS Drug Assistance Program (ADAP) grants under OMB No. 0915–0294. The current expiration date is March 14, 2014. The ADAP grantees will submit a final AQR on data from January 1 – March 31, 2014 with a submission deadline of April 30, 2014. The AQR will then no longer be a data collection requirement for ADAPs. The AQR will be replaced by a new data collection, the ADAP Data Report (ADR).

ADAP is funded through 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. The Ryan White HIV/AIDS Program provides emergency assistance to localities that are disproportionately affected by the human immunodeficiency virus (HIV) epidemic and makes financial assistance available for the development, organization, coordination, and operation of more effective and cost-efficient systems for the delivery of essential services to persons with HIV disease. ADAP falls under Part B of the Ryan White HIV/AIDS Program and provides medications for the treatment of HIV disease. Program funds may also be used to purchase health insurance for eligible clients or for services that enhance access, adherence, and monitoring of drug treatments.

The HIV/AIDS Bureau (HAB) within the Health Resources and Services Administration (HRSA) of the Public Health Service (PHS) administers funds for the Ryan White HIV/AIDS

Program. All 50 States, the District of Columbia and several Territories receive ADAP grants. Each grantee chooses how to distribute the pharmaceuticals and how to provide other ADAP-eligible services. ADAPs are encouraged to conserve resources by coordinating with State Medicaid programs and other relevant programs. States also provide funding to ADAP through the State budgets.

The AQR is a provider-based data collection instrument in which service organizations report on the number and characteristics of clients served in the aggregate. The AQR includes information on: patients served; pharmaceuticals prescribed; medication pricing; other sources of financial support for AIDS medications; eligibility requirements; cost data; and coordination with Medicaid. As part of the funding requirements, ADAP grantees submit the AQR once every three months. However, in 2014 the last AQR submission will be on April 30, 2014 and the AQR will be replaced by a new data collection. See Tab B for a copy of the AQR instrument and Tab C for a copy of the instructions.

The AQR provides HRSA with information needed to respond to inquiries from Congress and the public and to assess performance goals set through the Government Performance and Results Act (GPRA) and the Program Assessment and Ratings Tool (PART).

2. Purpose and Use of Information Collection

The primary purpose of the AQR is to enable HRSA to respond to inquiries about ADAP clients and services. HRSA also uses data collected from ADAPs to understand how medications are best distributed and how well resources are being used.

The AQR consists of two sections that request data on eight topics and a cover page. The cover page contains identifying information and is generated automatically by the online data entry system. The eight topics are as follows:

1. Client Utilization – demographic information for clients who receive services
2. Funding and Expenditures – sources and uses of program funding from the State, HRSA, and other sources
3. Formulary – the list of medications offered through the ADAP

4. Financial Eligibility Criteria – income restrictions for participation and types of co-payments
5. Medical Eligibility Criteria – clinical criteria (e.g., HIV positive, threshold CD4 or viral load counts)
6. Cost Saving Strategies – methods for obtaining pharmaceuticals at the best possible price
7. Drug Pricing Data – actual costs paid for each drug
8. Medicaid Coordination – methods for reducing duplication of services

The two sections of the report are divided into items completed quarterly (section 1) and items completed annually (section 2). Items in section 2 are unlikely to change more than once each year and are submitted with the first quarterly report of the year. The remaining quarterly reports provide data on services provided during the reporting quarter.

Each ADAP grantee completes the quarterly reports online. See Tab D for screenshots of the AQR online data entry system.

3. Use of Improved Information Technology and Burden Reduction

Grantees have been encouraged to complete their data reports via the Internet. At present, all grantees use the online data system to submit reports. However, if grantees have any problems with local networks or Internet access, the grantees may submit paper copies of the reports. The online data system, accessible through HRSA's Electronic Handbooks (EHBs), calculates totals and pre-populates selected information (e.g., contact information), which saves the ADAP grantees time. The ADAP grantees have been submitting the AQR electronically through the online data system with rare problems.

4. Efforts to Identify Duplication and Use of Similar Information

The AQR is the only data on clients receiving ADAP services that the ADAP grantees routinely provide to HRSA. There is no other source of information available to characterize the services provided by ADAPs.

5. Impact on Small Businesses or Other Small Entities

No small businesses are involved in this data collection. Grantees who report data are State and Territorial governments.

6. Consequences of Collecting the Information Less Frequently

The reports from the ADAPs are required quarterly which allows HRSA to respond to any issues that arise, such as unexpected increases in medication costs. This also provides prompt notification when programs expend all of their funds.

7. Special Circumstances Relating to the Guidelines in 5 CFR 1320.5

The data will be collected in a manner fully consistent with the guidelines in 5 CFR 1320.6.

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

Section 8A:

The notice required in 5 CFR 1320.8(d) was published in the *Federal Register* on December 17, 2013, Volume 78, Number 242, pages 76309-76310. See Tab E for a copy of the Federal Register Notice. No comments were received.

Section 8B:

Additionally, two ADAP representatives familiar with the AQR were contacted in 2014 and asked for burden estimates. The representatives indicated that completing the AQR is straightforward and that the current burden estimates are accurate. See Tab F for a list of these ADAP representatives.

9. Explanation of any Payment/Gift to Respondents

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

10. Assurance of Confidentiality Provided to Respondents

The ADAPs only report program data and aggregate client data. It is not possible to identify any individuals from the client utilization data.

11. Justifications for Sensitive Questions

This data collection includes no questions of a sensitive nature.

12. Estimates of Annualized Hour Burden and Cost Burden

12A. Estimated Annualized Burden

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
ADAP	ADAP Quarterly Report (Only Section 1 required for 4 th quarterly report)	57	1	17	969

12B. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
ADAP	ADAP Quarterly Report (Only Section 1 required for 4 th quarterly report)	969	\$30.05	\$29,118

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

There are no additional costs for this activity.

14. Annualized Cost to the Government

The contract that supports data collection efforts and provides technical assistance to grantees for this program was awarded on September 15, 2010 for an estimated \$502,365. The contractor is

responsible for distributing the forms to ADAPs, maintaining the online data system, and offering any telephone or email consultation needed to report data.

15. Explanation for Program Changes or Adjustments

This is a request for an extension of an approved information collection. Two ADAPs were asked for burden estimates and the increase for one organization was due to new staff. The submission of the AQR will no longer be required for ADAPs after the submission deadline on April 30, 2014.

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

ADAPs will submit their last AQR on April 30, 2014 for the reporting period, January 1 - March 31, 2013. Thereafter, the AQR will no longer be a requirement for ADAPs to complete.

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

The expiration date will be displayed.

18. Exceptions to Certification for Paper Reduction Act Submissions

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

List of Attachments

Tab A: Authorizing Legislation

Tab B: ADAP Quarterly Report

Tab C: Instructions for Completing the ADAP Quarterly Report

Tab D: ADAP Quarterly Report Web System Screenshots

Tab E: 60-Day Federal Register Notice

Tab F: Grantee Feedback on the ADAP Quarterly Report

