AIDS Drug Assistance Program Quarterly Report

Supporting Statement for Paperwork Reduction Act Submission

HIV/AIDS Bureau Office of Science and Policy Health Resources and Services Administration 5600 Fishers Lane, Room 7-90 Rockville, MD 20857

Supporting Statement Health Resources and Services Administration AIDS Drug Assistance Program Quarterly Report

A. Justification

1. Circumstances of Information Collection

This is a request for extension of the current OMB approval for a quarterly report 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 February 28, 2011.

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.

As part of the fund requirements, ADAP grantees submit the ADAP Quarterly Report (AQR) once every three months. 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

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pricing; other sources of financial support for AIDS medications; eligibility requirements; cost data; and coordination with Medicaid. Information that only changes annually (e.g., State funding levels) is submitted once each year with the first quarterly report due July of each year. The remaining three quarterly reports provide updates on patients served, types of pharmaceuticals prescribed, and prices paid to provide medication. 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 GPRA and PART.

2. Purpose and Use of Information

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
- 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)
- 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

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

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. Involvement of Small Entities

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

6. Consequences If Information Collected 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. Consistency With the Guidelines in 5 CFR 1320.5(d)(2)

The data will be collected in a manner fully consistent with the guidelines in 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 September 20, 2010, Volume 75, Number 181, pages 57277-57278. See Tab E for a copy of the Federal Register Notice. No comments were received.

Additionally, three ADAP grantee representatives familiar with the AQR were contacted between October 28 and November 2, 2010 and asked explicitly about the clarity of the reporting requirements, accuracy of the burden estimates, and aspects of the data report that affected burden. The representatives indicated that completing the AQR is straightforward and that the current burden estimates are accurate. The most time-consuming aspect of the AQR is entering the cost of medications.

The following three ADAP grantee representatives were contacted:

Kathleen Rogers (608) 267-6875 <u>Kathleen.Rogers@dhs.wisconsin.gov</u>

Jeni Mulqueen Part B ADAP Director (785) 368-8218 jmulqueen@kdheks.gov

Chris Cullinan ADAP Administrator (603) 271-4480 <u>Ccullinan@dhhs.state.nh.us</u>

9. Remuneration of Respondents

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

10. Assurance of Confidentiality

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

<u>11. Questions of a Sensitive Nature</u>

This data collection includes no questions of a sensitive nature.

<u>12. Estimates of Annualized Hour Burden</u>

The estimated annual burden to ADAPs is as follows:

Form	Number of Respondent s	Responses per Respondent	Total Responses	Hours per Response	Total Burden Hours	Hourl y Wage Rate	Total Costs
First quarterly report	57	1	57	3.0	171	\$26.68	\$4562
Second, third, and fourth quarterly reports	57	3	171	1.5	256.5	\$26.68	\$6843
Total	57	4	228	7.5	427.5		\$11405

13. Estimates of Annualized Cost Burden to Respondents

There is no additional capital or start up cost for this activity.

14. Estimates of 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.

<u>15. Changes in Burden</u>

This is a request for an extension of an approved information collection. No changes in burden are expected.

16. Time Schedule, Publication and Analysis Plan

The ADAPs report data using the fiscal year April 1-March 31.

The timeline of activities for this project is as follows:

April 1	First quarter begins		
June 30	First quarter ends		
July 31	First quarterly report due with quarterly service information and annual items		
October 31	Second quarterly report due		
January 31	Third quarterly report due		
April 30	Fourth quarterly report due		

<u>17. Exemption for Display of Expiration Date</u>

No exemption is requested.

<u>18. Exceptions to Certification for PRA Submissions</u>

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