

# **Supporting Statement for the AIDS Drug Assistance Program Health Resources and Services Administration**

## **A. Justification**

### **1. Circumstances of Information Collection**

This is a request for an extension without change of OMB approval for a quarterly report used by the Health Resources and Services Administration's (HRSA's) HIV/AIDS Bureau to monitor the AIDS Drug Assistance Program Grants. The ADAP report is currently approved under OMB No. 0915-0294 and has an expiration date of January 31, 2008. The AIDS Drug Assistance Program (ADAP) is funded through Part B of Title XXVI of the Public Health Service Act, the Ryan White HIV/AIDS program, which provides grants to States and Territories.

The Ryan White HIV/AIDS Treatment Modernization Act was originally passed in 1990 (as the Ryan White CARE Act), and was amended in 1996, 2000, and 2006 (codified under Title XXVI of the Public Health Service Act). The purpose of this legislation is to provide emergency assistance to localities that are disproportionately affected by the human immunodeficiency virus (HIV) epidemic and to make 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. It also provides grants to States for the delivery of services to HIV positive individuals and their families. The HIV/AIDS Bureau (HAB) within the Health Resources and Services Administration (HRSA) of the Public Health Service (PHS) administers funds for all Parts of the Act.

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 is a program under Part B of Title XXVI 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.

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 funding requirements, ADAP grantees submit quarterly reports that include information on: patients served, pharmaceuticals prescribed, medication 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, type of pharmaceuticals prescribed, and prices paid to provide medication.

The quarterly report provides HRSA with the type of information needed to respond to inquiries from Congress and the public and to assess performance goals set through GPRA and PART. The ADAP quarterly report enables HRSA to respond to inquiries quickly and accurately.

## **2. Purpose and Use of Information**

The primary purpose of this quarterly report is for HRSA to be able to respond to inquiries about the ADAP services and clients served. HRSA also uses data collected from ADAPs to understand how medications are best distributed and how well resources are being used. This report provides HRSA with precise information and has minimal burden to grantees submitting data.

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

1. Client Utilization – the numbers and types of clients who receive services

2. Funding – sources of 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 that are only completed once each year as this information is unlikely to change (section 2). The annual section is completed 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. At present, all ADAPs are submitting monthly progress reports through the Internet.

### **3. Use of Improved Information Technology**

Grantees complete their data reports via the Internet. At present, all grantees use the online data system to submit reports at <https://grants.hrsa.gov/webexternal> which is the Grantee/Applicant Electronic Handbook for grantees to submit information electronically. The online system now calculates totals and pre-populates selected information (e.g., contact information and annual responses), which reduces burden and minimizes error.

#### **4. Efforts to Identify Duplication**

This quarterly report is the only data the ADAPs routinely provide to HRSA. The report provides focused information to meet HRSA's information needs as well as reduce burden to grantees. 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 are collected in a manner consistent with the guidelines in 5 CFR 1320.6.

The focus of the program is to provide medical, health and social support services to underserved and vulnerable populations living with HIV/AIDS. To measure the success of programs in reaching and serving these populations, it is important that we be able to report on the proportion of minorities served by program funds. The ADAP quarterly report is a provider-based data collection instrument in which service organizations report on the number and characteristics of clients served in the *aggregate*.

#### **8. Consultation Outside the Agency**

The notice required in 5 CFR 1320.8(d) was published in the *Federal Register* on October 4, 2007, Volume 72, Number 192 (pages 56773-56774). One email comment was received from the Indiana State Department of Health. An HIV Medical Services Program Manager sent an email with a technical question about the changes to the electronic reporting system, which has been upgraded. The new system pre-populates certain fields, and the commenter had a technical question regarding this function, as well as a comment stating that ethnicity and race should not have to be reported separately.

The commenter also states that the upgraded system is a good one. The comment and response are attached.

In addition to the required FR notice, a copy of the report was posted on the HRSA web site and an email sent to all ADAP administrators notifying them that the form was available for review and comment.

### **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 aggregate data on the total number of clients served. It is not possible to identify any individuals from the client utilization data. The remaining questions ask about program services and policies.

### **11. Questions of a Sensitive Nature**

This data collection includes no questions of a sensitive nature.

### **12. Estimates of Annualized Hour Burden**

The annual burden was based on feedback from several grantees experience with the current reporting requirements.

The estimated annual burden to ADAPs is as follows:

Form	Number of Respondents	Responses per Respondent	Total Responses	Hours per Response	Total Burden Hours
First quarterly report	57	1	57	3.0	171
Second, third, and fourth quarterly	57	3	171	1.5	256.5

reports					
Total	57	4	228	7.5	427.5

### **13. Estimates of Annualized Cost Burden to Respondents**

The ADAP grantees have the responsibility of maintaining their own data system to comply with grant requirements. The costs to fulfill recordkeeping requirements are estimated as 427.5 hours at \$26.68 per hour for a total of \$11,405.70.

### **14. Estimates of Annualized Cost to the Government**

The contract that supports data collection efforts and provides technical assistance to grantees for this program is scheduled to be awarded on September 15, 2004 for an estimated \$548,844.53. The contractor will be responsible for sending the forms to ADAPs, providing direction about this effort, and offering any telephone consultation needed to begin data collection efforts.

### **15. Changes in Burden**

There are no changes in the burden for this activity. The ADAP currently has 428 burden hours approved by OMB, and this extension has no change to the total hours or number of respondents.

### **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
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**17. Exemption for Display of Expiration Date**

No exemption is requested.

**18. 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 package.