Supporting Statement for the

Ryan White HIV/AIDS Program Annual Data Report Form

A. Justification

1. Circumstances of Information Collection

This is a request by the Health Resources and Services Administration (HRSA) for an extension of OMB approval to continue using the Ryan White HIV/AIDS Program Data Report (Ryan White Data Report) for the collection of service and client data under OMB No. 0915-0253. The current expiration date is February 28, 2011. The Ryan White Data Report (RDR) was initially implemented as the CARE Act Data Report (CADR) in 1999 by HRSA's HIV/AIDS Bureau (HAB). It underwent revisions to incorporate the legislative changes and language that occurred in 2006.

Title XXVI of the Public Health Services (PHS) Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Ryan White HIV/AIDS Program) was originally passed in 1990, and amended in 1996, 2000, and 2006 (codified under Title XXVI of the PHS Act). The 2009 legislation continues the Ryan White HIV/AIDS Program through fiscal year 2013.

The purpose of the Ryan White HIV/AIDS Program is to provide assistance to localities that are disproportionately affected by the HIV/AIDS 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 living with HIV/AIDS. The HIV/AIDS Bureau (HAB) within HRSA administers funds for all Parts of the Ryan White HIV/AIDS Program. Each Part is authorized by the PHS Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009, in the following sections: Part A in Section 2610, Part B in section 2623, Part C in Section 2655, and Part D in section 2671. See Tab A for a copy of the 2009 legislation.

Part A of the Ryan White HIV/AIDS Program provides for two types of awards: formula grants and supplemental grants. These grants provide direct financial assistance to designated Eligible Metropolitan Areas (EMAs) and Transitional Grant Areas (TGAs) that have been the most severely affected by the HIV/AIDS epidemic. The purpose of these funds is to deliver or enhance HIV-related core medical and support services to people living with HIV/AIDS and their affected partners and family members.

Part B of the Ryan White HIV/AIDS Program authorizes the distribution of Federal funds to States and Territories to improve the quality, availability, and delivery of core medical and support services for individuals living with HIV/AIDS, and their affected partners and family members. The Ryan White HIV/AIDS Program emphasizes that such care and support is part of a coordinated continuum of care designed to improve medical outcomes.

Part C of the Ryan White HIV/AIDS Program provides support for early intervention services, including preventive, diagnostic, and therapeutic services for people living with HIV/AIDS and their affected partners and family members. This support includes a comprehensive continuum of outpatient HIV primary care services including: HIV counseling, testing, and referral; medical evaluation and clinical care; other primary care services; and referrals to other health services.

Part D of the Ryan White HIV/AIDS Program supports coordinated family-centered outpatient care for women, infants, children, and youth with HIV/AIDS and their affected partners and family members. The Adolescent Initiative is a separate initiative under the Part D program that is aimed at identifying adolescents who are HIV-positive and enrolling and retaining them in care.

All Parts of the Ryan White HIV/AIDS Program specify HRSA's 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. Accurate records of the providers receiving Ryan White HIV/AIDS Program funding, the services provided, and the clients served continue to be critical to the implementation of the legislation and thus are necessary for HRSA to fulfill its responsibilities. Ryan White HIV/AIDS Program grantees are required to report aggregate data to HRSA annually. The Ryan White Data Report form (OMB # 0915-0253) is completed by grantees and their subcontracted service providers. The report has seven different sections requesting (1) characteristics of the service providers; (2) demographic information about the clients served; (3) information about the type of core and support services provided and the number of clients served; (4) information about HIV counseling and testing services; (5) clinical information about the clients who receive medical care; (6) demographic tables for Parts C and D; and (7) information about the Health Insurance Program. In addition, the RDR includes pre-populated information on grantees' disbursement of funds and collects data on the cost of providing services. See Tab B for a copy of the RDR instrument and Tab C for a copy of the instructions.

OMB approval is being requested for extension of the RDR form used to collect aggregate-level data from Parts A- D grantees and their service providers. The current approval, OMB No. 0915-0253, expires February 28, 2011. An extension will enable HAB to continue data collection and reporting for calendar year 2011.

2. Purpose and Use of Information

The primary purposes of the RDR are to: (1) Characterize the organizations where clients receive services; (2) provide information on the number and characteristics of clients who receive services; and (3) enable HRSA to describe the type and number of services a client receives. This information supports the goal of accountability to the Congress, clients, advocacy groups, and the general public. The information collected on the RDR is critical for HRSA, State and local grantees, and individual providers to assess the status of existing HIV-related service delivery systems and the need for service expansion. The partnership among HRSA, grantees, providers, and clients provides a unique opportunity to ensure that all parties share in the benefits of accurate and timely information. These data help to support improved care for people living

with HIV/AIDS, their affected partners and family members. The collective responsibility ensures that service dollars reach targeted populations, appropriate HIV services are provided, and adequate funding is available to meet future HIV-related service needs.

The descriptive elements in the RDR that address these issues include:

- 1. General provider and program characteristics that describe the types of organizations providing services, such as ownership status, sources of revenue, expenditures, paid and volunteer staff, and eligibility criteria;
- 2. Unduplicated aggregate counts of clients served by each service provider, in total and for different demographic groups; and
- 3. Utilization data about medical and support services and health insurance coverage that can be used to estimate the number of clients receiving each type of service and/or program.

Annually, HRSA generates descriptive reports and conducts detailed analyses about the clients served and the range of core medical and support services provided. HRSA will continue to use these data to demonstrate in annual data reports, reports to Congress, and state profiles the progress being made by grantees in serving populations disproportionately affected by HIV/AIDS.

3. Use of Improved Information Technology

Data may be submitted by all agencies through direct data entry, RWCAREWare upload—a free application designed specifically to assist agencies in collecting and reporting the required data —or XML uploads. Grantees access their RDR deliverables and complete data entry and submission through HRSA's Electronic Handbooks (EHBs). They also access, review, and approve their providers' RDRs through the EHBs. Providers enter their data through a Web interface (https://performance.hrsa.gov/hab) and, if necessary, correct and resubmit data reports at the request of their grantee(s)-of-record. This system has resulted in approximately 99 percent accuracy in initial data submissions. There are a few grantees with unreliable or no Internet connection that submit by paper. These data are entered by a third party directly through the RDR Web site (https://performance.hrsa.gov/hab).

4. Efforts to Eliminate Duplication in Client Counts

Because the RDR does not collect client-level data with unique identifying information, clients who receive services from more than one provider are counted more than once when HAB aggregates provider data at the national level. To eliminate duplicate counting, HAB is currently implementing a client-level data collection and reporting system designed to replace the RDR after all service providers have integrated the new system and successfully collected and reported high quality client data to HAB. Ryan White HIV/AIDS Program grantees are now required to submit client-level data using the Ryan White HIV/AIDS Program Services Report (RSR; OMB No. 0915-0323). The first annual RSR submission included data on services provided in calendar year 2009. Only the sub-set of service providers who provided outpatient/ambulatory medical care, medical case management, and case management services were required to submit

client-level data the first year. This sub-set represents approximately 72% of all funded providers of direct services. Completeness rates for key data elements ranged from 0 - 99% in the first annual RSR submission.

Because client-level data reporting requirements are relatively new for the Ryan White HIV/AIDS Program grantees, the grantees are still required to report aggregate data in the Ryan White Data Report to HRSA annually. The more mature aggregate reporting requirements provide accurate records of the providers receiving Ryan White HIV/AIDS Program funding, the services provided, and the clients served, which continue to be critical to the implementation of the legislation and necessary for HRSA to fulfill its responsibilities.

Aside from the RDR and the RSR, data required to evaluate or monitor each of the Ryan White HIV/AIDS Programs are not available. Research studies conducted on people living with HIV/AIDS and sample studies of people in defined demographic areas or risk groups cannot provide comprehensive, overall program information about grantees, providers, and beneficiaries of the Ryan White HIV/AIDS Program. No other federal agency collects these comprehensive data in one report.

5. Involvement of Small Entities

This data collection effort does not significantly affect small businesses or other small entities.

6. Consequences If Information Collected Less Frequently

Grantees routinely subcontract to service providers on an annual basis. Service providers are accountable to grantees and they, in turn, are responsible to HRSA for the quality and accuracy of the reported information. Without annual data reports that document how grant funds are expended, HRSA would be unable to fulfill its responsibility to oversee compliance with the intent of the legislation and Congressional appropriations in a timely manner. In addition, annual reports documenting the characteristics of the program's beneficiaries confirm whether the administration of the funds is responsive to the changing epidemiology of HIV/AIDS.

7. Consistency With the Guidelines in 5 CFR 1320.5(d)(2)

The data will be collected in a manner 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 24, 2010 (Volume 75, Number 185, Pages 58392-58393). See Tab D for a copy of the Federal Register Notice. No comments were received.

In addition, grantee representatives familiar with the RDR were contacted on October 28, 2010 for comments on 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 RDR is straightforward and has become routine for them and their funded service providers. The grantees have established schedules and processes to complete the annual RDR. The most challenging aspects of the RDR relate to reporting financial information and coordinating with other grantees on the submission of reports for providers that are multiply funded. Grantees

further indicated that certain aspects of the RDR system, e.g., the availability of the CAREWare database that automatically produces the report, the ability to manually edit data in the Web system, and the staggered reporting deadlines, make the reporting process more efficient. See Tab E for contact information for the grantee representatives and a summary of the conversations.

9. Remuneration of Respondents

Respondents will not be remunerated.

10. Assurance of Confidentiality

The RDR does not require any information that could identify individual clients. It is an aggregate data report; therefore, names and personal identifiers are not included. All reports and tabulated data that are released to the general public are summaries of information across providers, which protect individual providers from being identified.

Respondents will be assured of the confidentiality of their identities and information to the maximum extent allowable by law. Data collection will fully comply with all aspects of the Privacy Act. The grantee or provider will maintain all client-identifying information. Respondents will be assured that their participation in HRSA programs will not be affected by their responses to any of the questions.

For grantees that use CAREWare, several measures have been incorporated to fully protect the confidentiality of people receiving services. These precautions include an algorithm for the creation of unique, *encrypted* client numbers to protect client-level information stored in the local system and the submission of aggregate level data (rather than client-level data) to HRSA by service providers and grantees.

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

All the clients described in the RDR are either living with HIV/AIDS or are affected partners and family members of people living with HIV/AIDS. The purpose of the data collection is to describe the demographics of these clients, their health status, and the quality and provision of services being provided to them by Ryan White HIV/AIDS Program providers. However, the RDR does not contain patient- or client-level data. Data will be drawn from client-level databases and records collected by providers, but the data sent to HRSA will not include any client-level data or any client identifying information. All service providers are well aware of the sensitive nature of the data collected and the need to protect the privacy of their clients. However, they need the client-level data to provide appropriate services.

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

The estimated average annualized hour burden is shown in Table 1. The estimates for grantees and service providers are based on prior experience collecting, maintaining, and reporting data using the current report forms. The estimates include the estimated time to collect, review, and prepare electronic files for submission to HRSA. The estimated number of hours for Part A and B grantees is a function of the number of service providers from which they receive data (mean of 30 providers for Part A and 24 for Part B). Part C and D grantees are themselves direct service

providers, although they may also subcontract to additional service providers. Part A and Part B grantees typically maintain data in a central location and require less time to assemble annual reports. The estimated response burden for a service provider is based on the estimated time required to submit its annual data.

Program under which grantee is funded	Number of grantee respondents	Responses per grantee	Hours to coordinate receipt of data	Total hour burden	Hourly wage rate	Total hour cost
Part A	56	1	40	2,240	\$24.00	53,760
Part B	59	1	40	2,360	24.00	56,640
Part C	354	1	20	7,080	24.00	169,920
Part D	98	1	20	1,960	24.00	47,040
Subtotal	567			13,640	24.00	\$327,360

Table 1: Annual Response Burden for Ryan White HIV/AIDS Program Grantees and Service Providers

Program under which provider is funded	Number of provider respondents	Responses per provider	Hours per response	Total hour burden	Hourly wage rate	Total hour cost
Part A only	685	1	26	17,810	\$18.00	320,580
Part B only	558	1	26	14,508	18.00	261,144
Part C only	95	1	44	4,180	18.00	75,240
Part D only	59	1	42	2,478	18.00	44,604
Multiply funded	683	1	50	34,150	18.00	614,700
Subtotal	2080			73,126	18.00	\$1,316,268
	Number of			Total hour		Total hour
	Respondents			burden		cost
Total for Both						
Grantees &	2,647			86,766		\$1,643,628

<u>13. Estimates of Annualized Cost Burden to Respondents</u>

Providers

Grantees are responsible for maintaining their own data system or using the RDR module of RWCAREWare. There are no direct costs to respondents other than their time in participating in the data collection.

14. Estimates of Annualized Cost to the Government

HRSA has maintained a contract to provide technical assistance, to distribute OMB-approved RDR requirements to all Ryan White HIV/AIDS Program grantees, and to enter data from paper

forms. A contract for data collection is currently in place through September 2011. The estimated annual cost for the data reporting is \$175,000.

Table 2: HAB's Costs to Analyze and Report the Data

800 hours by Health Statistician (GS-13) at \$43.26/hour	34,608.00
160 hours by Clerk Typist at (GS-3) at \$13.18/hour	2,108.80
Analysis and Reporting of Data Total	\$36,716.80
Maintenance of RW CAREWare to Conform with RDR:	
160 hours by Supervisory Public Health Analyst at \$52.62/hour	8,419.20
Upload of Reports, Forms, Instructions and CAREWare:	
40 hours by Program Analyst (GS-9) at \$25.09/hour	1,003.60
Total	\$46,139.46

15. Changes in Burden

The current inventory for the RDR is for 86,766 burden hours, a decrease of 7,476 hours from the previous estimate of 94,242 hours. This adjustment is due to the decreasing numbers of service providers.

16. Time Schedule, Publication and Analysis Plan

The following timetable shows the schedule of events for the RDR:

January – December	Ryan White HIV/AIDS Program grantees provide services and collect data on services
January – March	HAB and data contractor staff conduct Web- based training on RDR for new Ryan White HIV/AIDS Program grantees
January – March 15	Agencies report data for prior calendar year
April 1 – May 31	Data verification by HAB and data contractor staff, if necessary
Fall	Annual report published

In addition to an annual report for the Secretary of the Department of Health and Human Services and Congress, HRSA uses the RDR to derive the information needed for some of its GPRA and PART measures. As needed, national summaries across programs as well as by each Part are produced by HAB analysts and distributed to constituency and advocacy groups and placed on the HAB Web site for use at local sites.

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

The expiration date will be displayed.

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 ICR package.

List of Attachments

Tab A: Authorizing Legislation

Tab B: Ryan White Data Report

Tab C: Instructions for Completing the Ryan White Data Report

Tab D: 60-Day Federal Register Notice

Tab E: Grantee Feedback on the Ryan White Data Report