

**SUPPORTING STATEMENT
HEALTH RESOURCES AND SERVICES ADMINISTRATION
CLIENT-LEVEL DATA REPORTING SYSTEM**

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 revised client-level data reporting system, the Ryan White HIV/AIDS Program Services Report (Ryan White Services Report). The Ryan White Services Report (RSR; OMB No. 0915-0323), which expires 3/31/2011, is currently used to collect information from grantees and their subcontracted service providers funded under Parts A, B, C, D, and F 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. Signed into law in October 2009 (Public Law 111-87), the Ryan White HIV/AIDS Program reauthorizes the Ryan White Comprehensive AIDS Resources Emergency Act (CARE Act) through 2013. The CARE Act was enacted in 1990 and, in addition to 2009, was reauthorized in 1996, 2000, and 2006.

The purpose of the Ryan White HIV/AIDS Program is to provide emergency assistance to localities that are disproportionately affected by the human immunodeficiency virus (HIV) epidemic. It makes financial assistance available for the development, organization, coordination, and operation of more effective and cost-efficient systems for the delivery of essential core medical and support services to persons with HIV disease. The Ryan White HIV/AIDS Treatment Extension Act of 2009 provides Federal HIV/AIDS programs the flexibility to respond effectively to the changing epidemic.

The HIV/AIDS Bureau (HAB) within the Health Resources and Services Administration (HRSA) of the United States Department of Health and Human Services (DHHS) administers funds for all Parts of the Ryan White HIV/AIDS Program. Each Program Part is authorized by the Public Health Service Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009, in the following sections: Part A under Section 2610; Part B under section 2623; Part C, Early Intervention Services, under Section 2655; Part D under section 2671; and Part F under section 2693.

OMB approval is being requested for the collection of client-level data from grantees and their service providers funded under Parts A, B, C, D, and F of the Ryan White HIV/AIDS Program. These data collection activities utilize online grantee- and provider-level reports, and client-level data by electronic upload. See Tab B for screenshots of the Grantee Report; Tab C for screenshots of the Provider Report; Tab D for the client-level data elements; and Tab E for the RSR Instruction Manual.

The U.S. Congress mandated that client-level data be collected under the Ryan White HIV/AIDS

Treatment Modernization Act of 2006. These data provide HRSA with information about the allocation of funds by grantees of record, the unduplicated number of clients served and services provided, demographic information about clients served, and the cost of providing services.

The different Parts of the Ryan White HIV/AIDS Program awards grants to cities, States and territories, and community-based organizations. Seventy-five percent of Part A, B, and C funds must be used to fund core medical services, which include:

- Outpatient and ambulatory health services;
- HIV/AIDS medications;
- Oral health care;
- Early intervention services;
- Health insurance premium and cost sharing assistance;
- Home health care;
- Medical nutrition therapy;
- Hospice care;
- Community-based health services;
- Mental health services;
- Substance abuse outpatient care; and
- Medical case management, including treatment adherence services.

The remaining 25 percent may fund support services that are needed for individuals with HIV/AIDS to achieve their medical outcomes, such as: respite care for individuals with HIV/AIDS; outreach services; medical transportation; linguistic services; and referrals for health care and support services.

Part A of the Ryan White HIV/AIDS Program provides for two types of awards—grants to Eligible Metropolitan Areas (EMAs) and grants to Transitional Grant Areas (TGAs). Grants are awarded based on counts of people living with HIV/AIDS in the 5 most recent calendar years:

- Metropolitan areas with a cumulative total of more than 2,000 cases of HIV/AIDS during the most recent 5-year period and a population of 50,000 or more are eligible for funding as EMAs.
- Metropolitan areas with a cumulative total of at least 1,000, but not more than 1,999, cases of HIV/AIDS during the most recent 5-year period and a population of 50,000 or more are eligible for funding as TGAs.

The method for determining eligibility for Part A funds gives priority to urban areas with the highest number of people living with HIV/AIDS, while also helping midsize cities and areas with emerging needs. Including the count of HIV-positive people to the formula for determining funding distributions allows medical care and support services to be provided in a way that reflects the spread of the virus in urban areas. By linking the current count of people who are HIV-positive to funding levels, the law encourages outreach and testing, which will get people into treatment earlier, for the purpose of saving more lives.

Part B of the Ryan White HIV/AIDS Program provides grants to States and territories to improve

the quality, availability, and organization of HIV/AIDS health care and support services. Base Part B grants are awarded using a formula that is based on living cases of HIV/AIDS. Additional Part B funds are “earmarked” for the AIDS Drug Assistance Program (ADAP), which primarily provides medications and health insurance to eligible clients. Part B providers may include public or nonprofit entities. For-profit entities are eligible only if they are the sole available providers of quality HIV care in the area. Some States provide some services directly, while others work through subcontracts with Part B HIV Care Consortia or with fiscal intermediary agencies. A consortium is an association of public and nonprofit health care and support service providers and community-based organizations that plans, develops, and delivers services for people living with HIV disease. A fiscal intermediary is an agency that the grantee contracts with to award service contracts and monitor funding use.

Part C of the Ryan White HIV/AIDS Program provides grants directly to service providers (e.g. ambulatory medical clinics) to support outpatient HIV early intervention services and ambulatory care. Specifically, the law assures that public and nonprofit organizations receiving Part C funds provide core medical and early intervention services, including HIV counseling and testing.

Part D of the Ryan White HIV/AIDS Program provides comprehensive, community-based, and family-centered services to children, youth, and women living with HIV and their families. Grantees are expected to provide care, treatment, and support services or to create a network of medical and social service providers who collaborate to supply services. Part D also funds a Youth Initiative, which supports youth-specific programs across the nation.

The Part F Minority AIDS Initiative (MAI) of the Ryan White HIV/AIDS Program is a national initiative that provides special resources to reduce the spread of HIV/AIDS and improve health outcomes for people living with HIV disease within communities of color. Enacted to address the disproportionate impact of the disease in such communities, Part F MAI seeks to strengthen organizational capacity and expand HIV-related services in minority communities. Part F is also known as Part A MAI and Part B MAI.

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.

Valid and complete information about the characteristics of clients and the services provided to them is needed from all grantees to document the equitable distribution of funds used to serve diverse population groups in need of care, identify gaps in service delivery, and to ensure coordination and quality of care. Since 1999, RWHAP grantees have supplied this information to HRSA using the Ryan White HIV/AIDS Program Annual Data Report (RDR; OMB No. 0915-0253). The RDR includes aggregate client and service data.

Because client-level data reporting requirements are relatively new for the Ryan White HIV/AIDS Program grantees, the grantees will continue to report using the RDR through 2011.

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. However, once grantees become accustomed to the client-level reporting system, HRSA expects the RSR to better support clinical quality management, performance measurement, service delivery, and client monitoring at both the system and client levels, enhancing the quality and usefulness of the reported data.

The collection and submission of data for the Ryan White HIV/AIDS Program (RWHAP) is a public health activity and is consistent with provisions of the Ryan White HIV/AIDS Program (Public Law 111-87) and enabling directives, rules, and guidelines governing the use of Federal monies.

The RWHAP requires the submission of Annual Reports by the Secretary of Health and Human Services to the appropriate committees of Congress. Client-level data is one requirement for the Secretarial submission.

The submission of client-level data from recipients of the Ryan White HIV/AIDS program funds meets OMB's request for collection of race and ethnicity data at the grantee-level. In addition, client-level information is needed by HRSA in order to respond to OMB's Performance and Assessment Rating Tool (PART) reviews. OMB uses PART reviews to assess program performance and for strategic planning. The information that is needed for PART reviews is client-level.

2. Purpose and Use of Information

The purpose of collecting these data is to compile and analyze client-level data to address performance measures including the Government Performance Results Act (GPRA), Program Assessment Rating Tool (PART), and HRSA core clinical performance measures (see attachments for the client-level data elements and rationale for inclusion of each element in the RSR).

In the RSR, agencies only report data on funded services and selected clinical data associated with those services. This allows HRSA to obtain accurate counts of the number of clients served by the Ryan White HIV/AIDS Program. In addition, the data submitted to HRSA/HAB are used for monitoring the outcomes achieved on behalf of HIV/AIDS clients and their impacted families receiving care and treatment through RWHAP grantees and/or providers; monitoring the use of RWHAP funds for the appropriate use to address the HIV/AIDS epidemic in the United States; and addressing the needs and concerns of U.S. Congress and the DHHS Secretary concerning the HIV/AIDS epidemic and the RWHAP.

Grantees and service providers collect information on the RSR and submit the data once annually, for review by their respective Part A, B, C, and/or D grantee(s). The various responsibilities are distributed as follows (see attachments for the RSR instruction manual):

- Provider organizations collect information about their clients, the services provided to

- their clients, and information about their organization;
- Providers upload this information to HRSA's secure server;
- Providers may, if they wish, generate descriptive reports and conduct analyses for their internal use;
- Grantees enter information about their organization and the contracts in place with their services providers under each grant (including contract dates, amounts, and authorized services)
- Grantees review the information about the provider organization, and an aggregate report of the client-level data;
- Grantees approve the data and submit them to HRSA;
- Grantees may generate descriptive reports and conduct analyses for internal use or for use by their providers, consortia, or planning councils;
- Grantees may distribute analyses and reports to their providers, and may assist providers in preparing analyses for their internal use; and
- HRSA generates descriptive reports about the uses of funds and the types of providers receiving them, and conducts detailed analyses of national and regional information about clients and services.

3. Use of Improved Information Technology

This collection of information is fully electronic. Use of information technology varies greatly among grantees, though most grantees have now established data systems that are capable of producing the required reports with minimal effort. Grantees can improve data quality, reporting efficiency, and responsiveness to the public by having their providers use an automated system that determines the number of clients served, the services provided to them, and the health status of these clients.

In order to report client-level data, grantees and providers will need access to the Internet. The Grantee and Service Provider Reports are completed online through a secure Web-based data entry system developed by HRSA. Many of the items on the Grantee Report and Service Provider Report are pre-populated based on information already existing in the system. The client-level data set is uploaded to the system in the required Extensible Markup Language (XML) format.

HRSA has made several options available to grantees to complete the RSR. HRSA has developed its own database system, CAREWare, available at no cost to all Ryan White HIV/AIDS Programs. For smaller agencies that do not utilize an electronic client data system, HRSA also developed a "light" version of CAREWare. This "light" version of CAREWare allows users to enter only the variables required for the Client Report. Both the regular and "light" versions of CAREWare export the data in the required format, which grantees and providers then upload to the Web-based data entry system. In addition to CAREWare, HRSA continues to work with a number of vendors of proprietary, HIV-care database systems to ensure that the systems are compatible with the proposed RSR.

Agencies 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. HRSA developed a tool, Tool for RSR Export (T-REX), and user guides to help grantees convert their client-level data into the required format. Technical support is also available to assist grantees in this effort.

4. Efforts to Identify Duplication

Data of the type required to evaluate or monitor each of the Ryan White HIV/AIDS Program Parts are not available elsewhere. No known studies of people living with HIV or sample studies of people in defined demographic or risk groups provide comprehensive, overall program information specifically about grantees, providers, and beneficiaries of the RWHAP. The RSR is the only comprehensive source of grantee, provider, and client-level information that will adequately address and meet HAB's data collection needs and objectives.

5. Involvement of Small Entities

This information collection includes small entities; however, this activity does not impose a significant impact on such entities. The information being requested or required has been held to the minimum required for the intended use. The information collection system is designed so that small organizations that provide fewer Ryan White HIV/AIDS Program services will skip more of the requested information than larger organizations that provide more services.

6. Consequences If Information Collected Less Frequently

Without annual reporting on the use of grant funds, HRSA would not be able to carry out its responsibility to oversee compliance with the intent of congressional appropriations in a timely manner. Because the epidemiology of HIV/AIDS is changing constantly, annual reporting of the characteristics of individual beneficiaries of the Ryan White HIV/AIDS Program grants is necessary to determine whether the administration of funds is responding to changes in the affected population.

If the information is not collected at all, HRSA will not know, and will not be able to report:

- Whether program funds are being spent for their intended purposes;
- How program funds are being distributed among several discretionary categories by State and local grantees;
- How many and what types of individuals are receiving services, and how various services are distributed across various types of individuals;
- How rearrangement of the Part A program to more effectively direct funds to areas hardest hit by the epidemic is affecting the number and characteristics of individual service recipients; and
- How the distribution of program funds, the distribution of services, and the characteristics of individual beneficiaries are changing from one year to the next.

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 (Vol. 75, No. 181, pp. 57278-57279). See Tab F for a copy of the notice. No comments were received.

Input on the availability of data, frequency of collection, clarity of instructions, reporting format and reporting burden was provided by the following grantee representatives outside of the agency:

Arthur Okrent
North Carolina Department of Health and Human Services
Part B grantee, 28 providers
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Jeananne Capetta
Cuyahoga County Board of Commissioners
Part A grantee, 12 providers
(516) 449-5943
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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 RSR to fully protect the confidentiality of clients receiving services. The following precautions have been instituted in the collection and analysis of data:

- All RWHAP clients are assigned a Unique Client ID (UCI), which is encoded through a hashing algorithm embedded within the data management system at the service provider site before the data set is submitted to HRSA;
- Grantees do not provide HRSA with any information that could identify individual clients. The data submitted cannot be used alone or in combination to identify specific Ryan White clients;

- All RSR reports and tabulated data that are released to the general public will be summarized across providers to eliminate confidentiality threats posed by cells containing data from providers that see a small number of clients.

11. Questions of a Sensitive Nature

All clients described in the RSR are HIV-positive or members of the HIV-affected population. The purpose of the data collection is to describe the demographics of these clients and their health status, as well as the quality of services being provided to them by Ryan White HIV/AIDS Program-funded providers. Data are drawn from client-level databases and reports collected by providers. The reports provide 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.

12. Estimates of Annualized Hour Burden

The estimated average annualized hour burden is 17,975 hours per year. Burden estimates are broken out by burden to grantee respondents and burden to service provider respondents, as seen in Table 1 (Estimates of Average Annualized Hour Burden to Respondents). Estimates for grantees and service providers are further divided by RSR component. Estimates for grantees and providers are based on prior experience in collecting, maintaining, and reporting data using the RSR and interviews with volunteers from grantee agencies.

Grantee Report

The Grantee Report will have 567 respondents, representing the 567 grants allocated by HRSA. Each grantee will submit one Grantee Report for each of its grants per reporting period. Based on discussions with grantees representing each Program Part, we averaged the response time associated with completing the Grantee Report for each Part, multiplied the average response time by the total number of grants for each Part, and summed across all Parts. The total annual hour burden associated with the Grantee Report is 408 hours.

Service Provider Report

The Service Provider Report will have 2,080 respondents. Each provider agency will submit one Provider Report per reporting period. This includes agencies that provide services directly to clients as well as providers of administrative support services. Based on discussions with grantee representatives, many of whom are also direct service providers, we determined that it will take each provider agency an average of 2.3 hours to complete the Service Provider Report, for a total hour burden of 4,784.

Client Report

The Client Report will have 1,878 respondents. Each provider agency will submit one Client Report per reporting period. This includes agencies that provide services directly to clients. The amount of time the service provider takes to collect and process a Client Report takes into

consideration the amount of time to enter client-level data into data collection systems (accounting for the fact that it will take longer to enter a new client record than to update a continuing client’s record); to compile and report the data; and to correct any errors. The estimated amount of time for the Client Report differs for providers who do not have electronic data systems. We have estimated that each year, three percent of all direct service providers do not have electronic data systems and may each take 106.25 hours to collect and process a Client Report; an increase from the 3.75 hours for providers that do have electronic data systems. We estimate 12,783 burden hours per year to complete the Client Report.

**TABLE 1.
Estimates of Average Annualized Hour Burden to Respondents**

The response burden for grantees is estimated as:

Component	Source of funding	Number of respondents	Responses per grantee	Hours per response	Total hour burden
Grantee Report	Part A	56	1	2.04	114
	Part B	59	1	2.52	149
	Part C	354	1	0.32	113
	Part D	98	1	0.33	32
	Subtotal	567			408

The response burden for service providers is estimated as:

Component	Number of respondents	Responses per provider	Total Responses	Hours per response	Total hour burden
Service Provider Report	2,080*	1	2,080*	2.30	4,784

Component	Electronic Data System	Number of respondents	Responses per provider	Total responses	Hours per response	Total hour burden
Client Report	No	56	1	56	106.25	5,950
	Yes	1,822	1	1,822	3.75	6,832.5
	Subtotal	1,878**		1,878**		12,783

*All providers, including providers of administrative support services and direct client services.

**Providers of direct client services only.

Total Burden.....17,975

13. Estimates of Annualized Cost Burden to Respondents

Grantees are responsible for maintaining their own data system or using the RSR module of CAREWare, the system provided without cost by HRSA to collect RSR data. There are no direct costs to respondents other than their time in participating in the data collection and quality assurance.

14. Estimate of Annualized Cost to the Federal Government

Table 3 shows the estimated annual cost to the Federal government.

The annual cost to HRSA for a contractor to provide data support, training, and technical assistance for the RSR is approximately \$350,000. The annual cost to HRSA for Web data collection support and technical assistance is approximately \$370,000.

**TABLE 3.
Estimated Annual Cost to the Federal Government**

Analysis and Reporting of RSR Data by Staff from the Division of Science and Policy	
160 hours by Supervisory Health Scientist (GS-15) at \$123,758/year (\$59.29/hour)	\$9,486.40
1,040 hours by Health Statistician (GS-13) at \$89,033/year (\$42.66/hour)	\$44,366.40
160 hours by Clerk Typist (GS-3) at \$27,130/year (\$12.99/hour)	\$2,078.40
Total	\$55,931.20
Maintenance of CAREWare Software to Conform with RSR	
160 hours by Supervisory Public Health Analyst (GS-14) at \$105,211/year (\$50.41/hour)	\$8,065.60
Uploading Software, Reports, and Instructions to HAB Web Site and Importing Client-Level Data	
160 hours by Program Analyst (GS-9) at \$51,630/year (\$24.74/hour)	\$3,958.40
Data and Reporting System Support, Training, and Technical Assistance	
Data Support Contractor	\$350,000.00
Reporting System Contractor	\$370,000.00
Total	\$720,000.00

15. Changes in Burden

The current inventory for the RSR is for 17,975 burden hours, a decrease of 70,216 hours from

the currently approved burden of 88,191 hours per year, averaged across the first three years of the data collection. This change in burden involves both adjustments and program changes.

First, an adjustment is due to the decreased numbers of service provider respondents. We estimate that 2,080 providers will complete the Service Provider Report and 1,878 will complete the Client Report, a decrease from 2,253 and 2,112 providers respectively. This amounts to an average savings of 2,000 burden hours per year.

Second, there is a decrease in burden because the Client Level Data Collection System is no longer included as a component in the burden table. In the first three years of data collection, there was a one-time burden associated with the amount of time to develop or adjust Client-Level Data Collection Systems to collect the data elements requested in the Client Report. Because most grantees and providers have submitted the RSR previously, they should already have Data Collection Systems in place. The one-time burden amounted to 190,147 hours total in Year 1 and Year 2, or an average of 63,400 hours per year averaged across the first three years of the information collection.

Third, a Program decrease in reporting frequency from twice per year in Year 1 of the information collection to annually contributes to the change in burden. This decrease in reporting frequency results in a burden decrease of about 13,500 total hours, or 4,600 hours per year averaged across the first three years of the information collection.

16. Time Schedule, Publication, and Analysis Plans

The reporting period is the calendar year, i.e., January 1 – December 30. Annual reports from the grantees should be submitted to HRSA approximately 2 months following the end of each reporting period. HRSA compiles the data received from the grantees and produces an annual report for the Secretary of DHHS and Congress. In addition, HRSA staff produces national summaries that are distributed to constituency and advocacy groups and are uploaded to the HIV/AIDS Bureau Web site. Summaries consist of aggregate-level data only.

Upon approval by OMB, the RSR forms and instructions will be made available to grantees to allow them as much time as possible to modify their data collection systems to conform to the revised report.

17. Exemption for Display of Expiration Date

No exemption is requested.

18. Exceptions to Certifications for PRA 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: RSR Grantee Report Screenshots

Tab C: RSR Provider Report Screenshots

Tab D: RSR Client-level Data Elements

Tab E: RSR Instruction Manual

Tab F: 60-day Federal Register Notice