

Supporting Statement

Health Resources and Services Administration Client-Level Data Reporting System

OMB Control No. 0915-0323

Terms of Clearance: None

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Health Resources and Services Administration (HRSA) is requesting approval from the Office of Management and Budget (OMB) for an extension with revisions of the client-level data reporting system, the Ryan White HIV/AIDS Program Services Report (RSR). The RSR, which expires May 31, 2014, 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 Program (RWHAP). The RWHAP is authorized under Title XXVI of the Public Health Service Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009. See Tab A for a copy of the 2009 legislation. 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.

RWHAP provides 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 RWHAP provides Federal HIV/AIDS programs the flexibility to respond effectively to the changing epidemic. The different Parts of the RWHAP 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 and 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.

The U.S. Congress mandated that client-level data be collected under the Ryan White HIV/AIDS Treatment Modernization Act of 2006 and requires the submission of Annual Reports by the Secretary of Health and Human Services to the appropriate committees of Congress. These data provide information about the allocation of funds by grantees, the number of clients served, services provided, client demographics, clinical data of clients served and costs of providing

services. These data collection utilize the online Grantee Report, the Service Provider Report, and electronic upload of the Client Report. 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 Draft RSR Instruction Manual. The Draft RSR Instruction Manual is currently being reviewed by RSR contractors and HAB and is scheduled for release in June 2014.

On April 11, 2012, a memo from the Secretary of the Department of Health and Human Services (HHS) directed the Health Resources and Services Administration (HRSA) along with other Health and Human Services Operating Divisions (Op Divs) to work together to: 1) identify seven common Core HIV/AIDS indicators; 2) develop implementation plans to deploy these indicators; and 3) streamline data collection; and reduce reporting by at least 20 – 25 percent. In November 2012, the HIV/AIDS Indicators Implementation Group (HAIIG), comprised of representatives from HHS Op Divs, the Department of Housing and Urban Development, the Veterans' Health Administration and community partners, successfully identified the required common Core HIV/AIDS indicators.

Revisions to the Ryan White Services Report (RSR) are required to support implementation of the core indicators, streamlining data collection, and reducing reporting burden. Nine data elements will be deleted from the RSR and 22 variables will be modified to reduce reporting burden. Two new data elements will be added to the RSR: 1) *Date of client's confidential confirmatory HIV test with a positive result in the reporting period*; and 2) *Date of client's first outpatient ambulatory medical care visit after positive HIV test*. These data elements are required to deploy the *Linkage to HIV Medical Care* core indicator. Another data element, *Sex at Birth*, defined to the biological sex assigned to the client at birth, will be added to align with variables collected by other HHS Op Divs.

In addition to the new data elements noted above, other new variables will be added to the RSR to address provisions set forth in Section 4302 of the Affordable Care Act (ACA). The ACA includes several provisions aimed at eliminating health disparities in America. Section 4302 (Understanding health disparities: data collection and analysis) of the ACA focuses on the standardization, collection, analysis, and reporting of health disparities data. Section 4302 requires the Secretary of DHHS to establish data collection standards for race, ethnicity, and sex. The race/ethnicity data elements include reporting of Hispanic, Asian, and Native Hawaiian/Pacific Islander subgroups. The categories for HHS data standards for race and ethnicity are based on the disaggregation of the OMB standard used in the American Community Survey (ACS) and the 2000 and 2010 Decennial Census. The subgroup categories can be rolled-up to the OMB standard. These new data elements will be used in data analysis intended to identify and understand health disparities.

2. Purpose and Use of Information Collection

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. 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 and Burden Reduction

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 RSR data collection.

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 and Use of Similar Information

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. Impact on Small Businesses or Other 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 of Collecting the Information 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; 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. 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 1320.5.

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

Section 8A:

A 60-day Federal Register Notice was published in the *Federal Register* on January 3, 2014 (Vol. 79, No. 2, pp. 401-402). See Tab F for a copy of the notice. There were no public comments.

Section 8B:

In 2014, input on the burden and the impact on the new changes in the Client Report on the burden was provided by the following seven grantee representatives outside of the agency. There were two grantees representing Parts A and B and three grantees representing Part C. We were unable to obtain burden estimates from Part D grantees.

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6. Stuart Fisk, CRNP – Part C
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9. Explanation of any Payment/Gift to Respondents

The proposed collection of information does not involve any remuneration to respondents.

10. Assurance of Confidentiality Provided to Respondents

Measures have been incorporated into the RSR to 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.
- 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. Justification for Sensitive Questions

The U.S. Congress mandated that client-level data be collected under the Ryan White HIV/AIDS Treatment Modernization Act of 2006, including demographic information on clients served, services provided, and their clinical data. These data are needed to show the distribution of funds used to serve diverse population groups, identify gaps in service delivery and ensure quality care. Clinical data also allows HRSA to monitor clinical outcomes achieved by clients served by RWHAP. These data provides information to the U.S. Congress on the role of the RWHAP in addressing the HIV/AIDS epidemic.

12. Estimates of Annualized Hour and Cost Burden

The estimated average annualized hour burden is 122,550 hours per year. Burden estimates are broken out by burden to grantee respondents and burden to service provider respondents, as seen in Table 12A. 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. Also see Table 12B for estimated annual burden costs. Wage sources came from the

Bureau of Labor and Statistics, http://www.bls.gov/oes/current/oes_nat.htm.

12A. Estimated Annualized Burden Hours

Grantee Report

The Grantee Report will have 595 respondents, representing the 567 grants allocated by HRSA. Each grantee will submit one Grantee Report for each of its grants per reporting period. We multiplied the average response time by the total number of grants. The total annual hour burden to gather, maintain, and complete the Grantee Report is 4,165 hours with an average of seven hours.

Service Provider Report

The Service Provider Report will have 1,793 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 17 hours to gather and maintain data and complete the Service Provider Report, for a total hour burden of 30,481.

Client Report

The Client Report will have 1,312 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. We estimate 87,904 hours total burden hours per year with an average of 67 hours per provider agency to complete the Client Report.

12A. Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. Responses per Respondents	Average Burden per Response (in hours)	Total Burden Hours
Parts A, B, C Grantees	Grantee Report	595	1	7	4,165
	Provider Report	1793	1	17	30,481
	Client Report	1312	1	67	87,904
Total		3,700		91	122,550

12B. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondents Costs
Parts A, B, C Grantees	Grantee Report	4,165	30.67	127,740.55
	Provider Report	30,481	30.67	934,852.27
	Client Report	87,904	30.67	2,696,015.68
Total		122,550		3,758,608.50

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

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. Annualized Cost to the Federal Government

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

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

Analysis and Reporting of RSR Data by Staff from the Division of Policy and Data	
160 hours by Supervisory Health Scientist (GS-15) at \$123,758/year (\$59.30/hour)	\$9,488.00
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 (\$13.00/hour)	\$2,080.00
Total	\$55,934.40
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, Training, and Technical assistance Contractors	\$585,000.00
Reporting System Contractor	1,400,000.00
Total	1,985,000.00

15. Explanation for Program Changes or Adjustments

The current inventory for the RSR is for 122,550 burden hours, an increase of 104,575 hours from the currently approved burden of 17,975 hours per year. This change in burden largely reflects HAB’s push to improve grantee data collection, completeness and quality. One grantee

stated that providers are now required to review Completeness Reports throughout the year to identify, locate and complete missing data. Other reasons for the increase in burden as stated by grantees include:

- Training of providers in completing the Provider and Client Report due to increased staff turnover
- Provision of technical assistance to providers year round
- Some grantees have invested more time to improve the automation of their data collection
- Increased availability of electronic or paper records to retrieve client data means spending more time to improve the quality of the data (e.g. not leaving data missing)
- Staff skill sets may be inadequate

The increase in burden estimates is also likely attributable to asking questions in this latest sample of grantee that cover more of the scope of their data collection and reporting activities (e.g. improving data quality and monitoring data collection year-round) and with greater specificity than for estimating burden when grantees were sampled for previous renewals.

Finally, all grantees who responded with burden estimates expressed that the current data elements changes in the Client Report described above would have little to no affect in burden estimates.

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

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

The expiration date will be displayed appropriately.

18. Exceptions to Certifications for Paperwork 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: 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