Supporting Statement A

Health Resources and Services Administration

Client-Level Data Reporting System

OMB Control No. 0906 - 0039 - Extension

Terms of Clearance: None

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Health Resources and Services Administration (HRSA) is requesting continued approval from the Office of Management and Budget (OMB) for an extension of the client-level data reporting system, the Ryan White HIV/AIDS Program Services Report (RSR). The current RSR Information Collection Request (ICR), which expires December 31, 2021, is currently used to collect information from grant recipients and subcontracted providers, funded under Parts A, B, C, and D of the Ryan White HIV/AIDS Program (RWHAP) legislation. The RWHAP, authorized under Title XXVI of the Public Health Service Act, is administered by HRSA's HIV/AIDS Bureau (HAB). HRSA HAB awards funding to recipients in areas of the greatest need to respond effectively to the changing HIV epidemic, with an emphasis on providing life-saving and life-extending medical care, treatment, and support services for people living with HIV in the United States. See Tab A for a copy of the 2009 legislation.

The RWHAP supports a comprehensive system of direct health care and support services for over half a million people living with HIV[1]. The RWHAP 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 living with HIV. Funding priorities are determined by stakeholders at local and state levels, resulting in uniquely structured programs that address their jurisdictions' critical gaps and needs. HRSA HAB also works in partnership with RWHAP recipients at state and local levels to use innovative approaches for community engagement, needs assessment, planning processes, policy development, service delivery, clinical quality improvement, and workforce development activities that are needed to support a robust system of HIV care, support and treatment.

The RWHAP requires Part's A, B, and C must allocate 75 percent of funds for core medical services (e.g., outpatient ambulatory health services, antiretroviral treatment, substance use, etc.) and 25 percent may fund support services (e.g., case management, outreach, medical transportation, housing, etc.).

---

[1] Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2016. http://hab.hrsa.gov/data/data-reports. Published November 2017. Accessed July 20, 2018.

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. Funded service providers are permitted to collect client level information and report de-identified data to HRSA HAB, as a public health authority, pursuant to 45 CFR 164.512(b). HRSA HAB is authorized by law to receive such information for the purpose of preventing or controlling disease, and the conduct of public health interventions. These data provide information about the allocation of funds by grant recipients, the number of clients served, services provided, client demographics, clinical data of clients served and costs of providing services. These data are collected in a Recipient Report, Service Provider Report, and as well as the Client Report, which is a data file containing the client-level data elements. See Tab B for the draft 2021 RSR Instruction Manual.

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

Grant recipients 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 recipients receiving them, and conducts detailed analyses of national and regional information about clients and services.

The benefits to recipients of collecting these data are substantial. Recipients will have access to information on the full scope of services provided through RWHAP-related expenditures. This information provides a clear picture of service utilization and client outcomes in HRSA RWHAP eligible clients. It increases recipients’ ability to conduct required monitoring of all funded subrecipients. In addition, collecting this data will support recipients in showing the impact of the HRSA RWHAP within their states/jurisdictions/service areas. The information collected through this data collection will allow the HRSA RWHAP to understand the full scope and impact of the program’s investment in HRSA RWHAP services at the state and local levels. It provides necessary data to understand service utilization and client outcomes for all HRSA RWHAP eligible clients.

3. Use of Improved Information Technology and Burden Reduction

This collection of information is fully electronic and grant recipients have established data systems that are capable of producing the required reports with minimal effort. Grant recipients can improve data quality, reporting efficiency, and responsiveness to the public by having their subrecipients 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, grant recipients and subrecipients will need access to the Internet. The Recipient and Service Provider Reports are completed online through a secure Web-based data entry system developed by HRSA. Many of the items on the Recipient 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 grant recipients to complete the RSR. HRSA has developed an optional data collection application, CAREWare, which is available at no cost to all HRSA RWHAP recipients and subrecipients. 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 reporting. HRSA also provides a free online tool, TRAX, which allows subrecipients who use other types of data collection systems, such as electronic health records, to convert data to the required submission format.

4. Efforts to Identify Duplication and Use of Similar Information

Data required to evaluate or monitor each of the HRSA RWHAP Parts are not available elsewhere. No known studies of people with HIV or sample studies of people in defined demographic or risk groups provide comprehensive, overall program information specifically about grant recipients, subrecipients, and clients of the HRSA RWHAP. The RSR is the only comprehensive source of recipient, subrecipient, and client-level information that will adequately address and meet HRSA 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 HRSA RWHAP 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 is changing constantly, annual reporting of the characteristics of individual beneficiaries of the HRSA RWHAP grants is necessary to determine whether the administration of funds is responding to changes in the populations impacted by HIV.

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 grant recipients;
- 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.
- The impact of the care and treatment on HIV health outcomes of people with HIV receiving medical services with RWHAP funds.

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,* 86 Fed. Reg. 44376 (August 12, 2021). See Tab C for a copy of the notice. There were no public comments.

Section 8B:

From May to June 2021, eight RWHAP grant recipients – two recipients for each RWHAP Part (A, B, C, and D) – provided input on their process of submitting the RSR. The names, titles, organizations, telephone numbers, and e-mail addresses of those consulted are provided below:

RWHAP Part A

Ana Nieto
Contracts Officer
County of Miami-Dade
Tel: (305) 375-4477
Email: Ana.Nieto@miamidade.gov

James William

Research Analyst III
County of Orange
Tel: (714) 834-8031
Email: jwilliams@ochca.com

RWHAP Part B

Gloria Sims
Ryan White HIV/AIDS Part B Core and Support Services Manager
Alabama Department of Health
Tel: (334) 206-2094
Email: gloria.sims@adph.state.al.us

Michael Ostapoff
Health Program Associate
Connecticut Department of Health
Tel: (860) 509-8093
Email: Michael.Ostapoff@ct.gov

RWHAP Part C

Amanda Hodges
Ryan White Program Coordinator
Community Health Net
Tel: (814) 454-4530 ext. 477
Email: ahodges@community-healthnet.com

Wanda Henderson
Program Manager
Warren-Vance Community Health Center
Tel: (252) 572-2610
Email: mwandahenderson@gmail.com

RWHAP Part D

Cora Giddens
Program Director
University of Texas South Western Medical Center
Tel: (469) 291-2868
Email: cora.giddens@utsouthwestern.edu

Melissa Beaupierre
Project Director
Grady Memorial Hospital Corporation
Tel: (404) 616-6230

Email: mbeaupierre@gmh.edu

The recipients were asked to provide feedback on the clarity of RSR instructions, challenges experienced in submitting the RSR, and the burden estimate for submitting the RSR. Six of the eight respondents noted that the instruction for collecting and submitting the RSR is clear. Two respondents specifically referred to the RSR instruction manual as clear and helpful in submitting the RSR. Two respondents indicated that the RSR instructions are unclear, particularly instructions regarding the HRSA EHBs. They suggested providing more instructions for recipients to understand their subrecipient's view in the HRSA EHBs and making the instructions simpler for newer staff. This feedback was relayed to the Ryan White Data Support team that updates the RSR manual every year and will be addressed in the next version.

All eight respondents specified that they experienced some challenges while collecting data and submitting the RSR. Five respondents mentioned the great amount of time it takes to ensure quality data. Four respondents expressed frustration with missing data. This feedback was relayed to the Data Integration, Systems and Quality (DISQ) cooperative agreement recipient, i.e., the technical assistance team that helps RWHAP recipients and providers with submitting quality data.

Below are some comments from the respondents:

"The annual RSR Instruction Manual that's produced has very concise, detailed, and helpful instructions. Applause, applause."

"Providing recipients with screenshots of the process through the provider portal would allow recipients to help the providers get through the process more easily."

"The challenge is in data integrity – maintaining the accuracy, completeness, and reliability of our client-level data when this data comes from multiple automated systems"

"We are continually collecting data throughout the year to make the months prior to the due date as smooth as possible."

"I spend several weeks of time reviewing and helping providers vet and complete their data sets and help them to submit their RSR."

"Submitting the RSR data may take about 30 minutes if there are no errors or if only minor updates are required. It's addressing missing data issues that tends to be a significant factor that takes several hours over several days to address depending on the volume of missing data."

9. <u>Explanation of any Payment/Gift to Respondents</u>

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 HRSA RWHAP clients are assigned a Unique Client ID (UCI), which is encoded through a hashing algorithm embedded within the data management system at the subrecipient site before the data set is submitted to HRSA.
- Grant recipients 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 contain cell suppression 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 HRSA RWHAP in addressing the HIV epidemic.

12. Estimates of Annualized Hour and Cost Burden

The estimated average annualized hour burden is 206,480 hours per year, a slight decrease from the previous burden estimate in 2019. With no changes to the reporting requirements, recipients estimated similar burden estimates from 2019. Recipients' burden estimates are broken out by burden to recipient respondents and burden to subrecipient respondents, as seen in Table 1 (Estimates of Average Annualized Hour Burden to Respondents). Estimates for grant recipients and service providers are further divided by RSR component. Estimates for grant recipients and providers are based on prior experience in collecting, maintaining, and reporting data using the RSR and interviews with volunteers from recipient agencies.

12A. Estimated Annualized Burden Hours

Recipient Report

The Recipient Report will have 595 respondents, an increase from 475 in 2019. Each recipient will submit one Recipient 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 Recipient Report is 6,545 hours with an average of 11 hours.

Provider Report

The Provider Report will have 2,063 respondents, a slight decrease from 2,079 in 2019. 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 recipient representatives, many of whom are also direct service providers, we determined that it will take each provider agency an average of 13 hours to gather and maintain data and complete the Provider Report, for a total hour burden of 26,819.

Client Report

The Client Report will have 1,532 respondents, down from 1,607 in 2019. 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 173,116 hours total burden hours per year with an average of 113 hours per subrecipient agency to complete the Client Report.

12A. Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
RWHAP Parts A, B, C, and D recipients	Recipient Report	595	1	595	11	6,545
	Provider Report	2,063	1	2,063	13	26,819
	Client-level Data Report	1,532	1	1,532	113	173,116
	Total	4,190		4,190		206,480

12B. Estimated Annualized Burden Costs

The annualized burden cost for recipients is based on the May 2020 National Occupational Employment and Wage Estimates by the Bureau of Labor, https://www.bls.gov/oes/current/oes_nat.htm. The respondent, a healthcare support worker (occupational code 31-9099), takes 206,480 hours per response in total for all respondents annually to complete the RSR data collection at a labor rate of $19.92 per hour. The total hour cost is $4,113,081.60.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondents Costs
RWHAP Parts A, B, C, and D recipients	Recipient Report	6,545	$19.92	$130,376.40
	Provider Report	26,819	$19.92	$534,234.48
	Client-level Data Report	173,116	$19.92	$3,448,470.72
	Total	206,480		$4,113,081.60

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

Grant recipients are responsible for maintaining their own data system or using the RSR module of CAREWare, the system provided without cost by HRSA to report 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

HRSA has maintained a contract to provide technical assistance, the distribution of OMB-approved Ryan White HIV/AIDS Services Report forms, data entry and analysis. For 2021, this contract will be $1,700,000.00. In addition, government personnel require 10% time of 1 FTE at a GS-13 level ($103,690) to review and prepare award notices.

15. Explanation for Program Changes or Adjustments

There are no program changes or adjustments under this request.

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 grant recipients should be submitted to HRSA approximately two (2) months following the end of each reporting period. HRSA compiles the data received from the grant recipients and produces an annual report for the Secretary of HHS and Congress. In addition, HRSA staff produce national summaries that are distributed to constituency and advocacy groups and are uploaded to the HRSA HIV/AIDS Bureau website. Summaries consist of aggregate-level data only.

Upon approval by OMB, the RSR forms and instructions will be made available to grant recipients 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 Instruction Manual

Tab C: 60-day Federal Register Notice