Supporting Statement A

Ryan White HIV/AIDS Program Client-Level Data Reporting System

OMB Control No. 0906-0039 - Revision

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) of the revised Ryan White HIV/AIDS Program Services Report (RSR). HRSA is proposing two substantive changes to the RSR: 1) an additional response option for the Client Health Coverage data element, 2) modification to a data elements question due to the expiration of the Drug Addiction Treatment Act of 2000 Waiver requirement. In addition, there is a nonsubstantive change to modify the race and ethnicity data collection element due to revisions to OMB's Statistical Policy Directive No.15: Standard for Maintaining, Collecting, and Presenting Data on Race and Ethnicity. The current RSR Information Collection Request (ICR), which expires December 31, 2024, is used to collect information from grant recipients, as well as their subrecipients funded under Parts A, B, C, and D of the Ryan White HIV/AIDS Program (RWHAP). The RWHAP, authorized under Title XXVI of the Public Health Service Act, is administered by HRSA's HIV/ AIDS Bureau (HAB). HRSA awards funding to recipients in areas of the greatest need to respond effectively to the changing HIV epidemic, with an emphasis on providing lifesaving and life-extending medical care, treatment, and support services for people living with HIV in the United States.

The HRSA RWHAP supports a comprehensive system of direct health care and support services for more than half a million people with HIV.[1] The HRSA 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 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 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 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,

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[1] Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2022. http://hab.hrsa.gov/data/data-reports. Published November 2023.

housing, etc.).

The U.S. Congress mandated that client-level data be collected under the Ryan White HIV/AIDS Treatment Modernization Act of 2006, which 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, a public health authority, pursuant to 45 CFR 164.512(b). HRSA HAB is authorized by law to receive such information to prevent or control disease and conduct 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 the Client Report, which is a data file containing the client-level data elements.

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 clients and their 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 the 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 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 information collection is fully electronic, and grant recipients have established data systems 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 their health status.

Grant recipients and subrecipients will need access to the Internet to report client-level data. The Recipient and Service Provider Reports are completed online through a secure Web-based data entry system, ensuring the safety and confidentiality of their data. Many of the items on the Recipient Report and Service Provider Report are pre-populated based on information already 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 multiple 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. All forms and software are 508-compliant.

4. Efforts to Identify Duplication and Use of Similar Information

Data of the type required to evaluate or monitor each HRSA RWHAP Parts are unavailable elsewhere. No known studies of people with HIV or sample studies of people in defined demographic or risk behavior categories 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 ensure 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.
- 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 clients served by the RWHAP.

7. Special Circumstances Relating to the Guidelines of 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 notice published in the Federal Register on April 24, 2024, vol. 89, No. 79; pp. 30384-85. There were no public comments. A 30-day notice published in the Federal Register on July 16, vol. 89, No. 136; pp. 57913-14.

Section 8B:

From March - April 2024, nine RWHAP grant recipients were contacted for their input on their process of submitting the RSR. Specifically, the nine recipients were contacted for feedback on the clarity of RSR instructions, challenges experienced in submitting the RSR, and the burden estimate for submitting the RSR. Four grant recipients responded, representing RWHAP Parts A, B, C, and D.

The four respondents noted clear instructions for collecting and submitting the RSR. One respondent expressly referred to the RSR instruction manual as clear, detailed, and helpful in submitting the RSR. Another respondent stated that they have relied on the instructions for over 20 years, and the last respondent recommended that the instructions be published earlier in the year.

All four respondents shared their experiences, noting that they encountered minimal challenges while collecting data and submitting the RSR. Two respondents mentioned their organization's internal data cleaning issues, highlighting the need for improved internal data management. The other two respondents faced issues with the Electronic Handbook being down or the multiple updates to the CAREWare builds, indicating the importance of system stability and consistency.

9. Explanation of any Payment/Gift to Respondents

Respondents will not receive any payments or gifts.

10. Assurance of Confidentiality Provided to Respondents

Measures have been incorporated into the RSR to protect the confidentiality of clients receiving services. Data will be kept private to the extent allowed by law. 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 data received by HRSA HAB is de-identified, HRSA does not receive any PII from our recipients and providers.
- All RSR reports and tabulated data that are released to the 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, race and ethnicity, 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 provide 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. With two minor modifications to the reporting requirements, recipients estimated similar burden estimates from 2021. 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 the 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

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Recipient Report	595	1	595	11	6,545
Provider Report	2,063	1	2,063	13	26,819
Client Report	1,532	1	1,532	113	173,116
Total	4,190		4,190		206,480

Recipient Report

The Recipient Report will have 595 respondents. Each grant recipient will submit one Recipient Report for each grant 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, with an average of 11 hours. This is based off the pilot study conducted in April 2024, described in Section 8B.

Service Provider Report

The Service Provider Report will have 2,063 respondents. Each provider agency will submit one Service 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 would take each provider agency an average of 13 hours to gather and maintain data and complete the Service Provider Report, for a total hour burden of 26,819.

Client Report

The Client Report will have 1,532 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 individual 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 total burden hours per year with an average of 113 hours per subrecipient agency to complete the Client Report. This is based off the pilot study conducted in April 2024, described in Section 8B.

12B. Estimated Annualized Burden Costs

The annualized burden cost for recipients is based on the May 2023 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 for all respondents annually to complete the RSR data collection at a labor rate of $21.39 per hour. The total hour cost is $8,833,214.4.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate (X2)	Total Respondents Costs
RWHAP Parts A, B, C, and D recipients	Grantee Report	6,545	$42.78	$279,995.1

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate (X2)	Total Respondents Costs
	Service Provider Report	26,819	$42.78	$1,147,316.82
	Client Report	173,116	$42.78	$7,405,902.48
	Total	206,480		$8,833,214.4

Hourly Wage Rate based on the United States Department of Labor, Bureau of Labor Statistics, https://www.bls.gov/oes/current/oes319099.htm. Hourly wage of $21.39 doubled to account for benefits.

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

Other than their time, there is no cost to respondents.

14. Annualized Cost to Federal Government

HRSA has maintained a contract to provide technical assistance, distribute OMB-approved RSR forms, and perform data entry and analysis. For 2024, this contract will be $1,775,858.26. In addition, government personnel require a 10% time of 1 FTE at a GS-14, Step 6 level ($24,394.35) to review and prepare award notices. The wage has been multiplied by 1.5 to account for overhead costs. The total annual cost is $ 1,800,252.61 (rounded up to 1,800,253).

15. Explanation for Program Changes or Adjustments

HRSA HAB requests a revision of the current RSR with three proposed Program Changes. The proposal includes an additional response option for the Client Health Coverage data element, modification to a data elements question due to the expiration of the Drug Addiction Treatment Act of 2000 Waiver requirement, and modification to the race and ethnicity data collection element due to revisions to OMB’s Statistical Policy Directive No.15: Standard for Maintaining, Collecting, and Presenting Data on Race and Ethnicity.

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

The reporting period is the calendar year, i.e., January 1 – December 31. Annual reports from the grant recipients should be submitted to HRSA approximately three (3) 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. The annual report is made available to the public on December 1st of every year, and is distributed via email and various websites (e.g., HRSA and TargetHIV). In addition, HRSA staff produces national summaries that are distributed to constituency and advocacy groups and uploaded to the HRSA HAB 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 OMB number and Expiration date will be displayed on every page of every form/instrument.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.