

Supporting Statement

Health Resources and Services Administration Client-Level Data Reporting System

OMB Control No. 0906 - xxxx - NEW

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 a new information collection request (ICR) - "Client-Level Data Reporting System." The Ryan White HIV/AIDS Program (RWHAP), authorized under Title XXVI of the Public Health Service Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009, funds and coordinates with cities, states, and local clinics/community-based organizations to deliver efficient and effective HIV care, treatment, and support to low-income people living with HIV (PLWH). See attached for a copy of the 2009 legislation. The Department of Health and Human Services (HHS) HRSA administers funds for the RWHAP.

The HRSA RWHAP supports a comprehensive system of direct health care and support services for over half a million people living with HIV (PLWH)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 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 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.).

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

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.

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 an as well as the Client Report, which is a data file containing the client-level data elements. See Tab B for screenshots of the Recipient Report; Tab C for screenshots of the Provider Report; Tab D for the Client Report with the client-level data elements; and Tab E for the RSR Instruction Manual.

This new ICR is being developed to replace an existing ICR (OMB control number 0915-0323), for which HRSA has collected Ryan White Services Report (RSR) data since 2009. HRSA will continue to collect and report the client-level data elements supplied by the existing 0915-0323 ICR through 2019. In 2019, HRSA will discontinue use of the existing 0915-0323 ICR and will collect and report on the data elements defined in the new ICR. While there will be no overlap in the data collected and reported between the existing and new ICR, HRSA is submitting this new ICR in tandem with the existing ICR to allow recipients the ability to make modifications to their RSR systems between the two reporting periods. This will allow recipients to continue collecting and reporting on both the old and new variables without interruption.

2. Purpose and Use of Information Collection

The purpose of collecting these data will be 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).

Agencies will report on data on allowable services and selected clinical data associated with those services. This will allow HRSA to obtain accurate counts of the number of clients served by the HRSA RWHAP. In addition, the data submitted to HRSA HAB will be 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 will collect information on the RSR and submit the data once annually. HRSA will generate descriptive reports about the uses of funds and the types of recipients receiving them, and will conduct detailed analyses of national and regional information about clients and services.

3. Use of Improved Information Technology and Burden Reduction

This collection of information will be fully electronic as grant recipients have established data systems that are capable of producing the required reports with minimal effort. Grant recipients will be able to 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 will be 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 will be pre-populated based on information already existing in the system. The client-level data set will be uploaded to the system in the required Extensible Markup Language (XML) format.

HRSA will make 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 of the type required to evaluate or monitor each of the HRSA RWHAP 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 grant recipients, subrecipients, and clients of the HRSA RWHAP.

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 collection system will be 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 PLWH served by the RWHAP.

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 November 27, 2017 (Vol. 82, No. 226, pp. 56039–56040). No comments were received.

Section 8B:

Feedback on the Client Report was provided by the following recipient representatives outside of the agency. There were four grant recipients representing RWHAP Parts A, three grant recipients representing RWHAP Part B and two grant recipients representing RWHAP Part C.

HRSA RWHAP Part A Respondents

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HRSA RWHAP Part B

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HRSA RWHAP Part C

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Six of the 9 respondents noted that there would be minimal to no burden increases in their data collection and reporting efforts in response to HRSA HAB's proposed changes. Specifically, the RWHAP Part A Detroit Department of Public Health, RWHAP Part A Maryland Department of Public Health and RWHAP Part B State of Hawaii Department of Public Health have reported that they are already collecting data in this manner. Others reported needing additional clarification in order to provide more accurate reporting burden estimates.

Below is the feedback from each of the respondents:

General comments: All respondents reported that they already collected these data. However, one did report that they currently do not have access to the system that collects zip code data. Besides updating data collection processes and reports, respondents would also need to clean and review these data to ensure accuracy. Respondents asked for clarification on the number that needed to be reported for each zip code. We clarified that they would be reporting the number of clients who received services eligible for RWHAP funding regardless of the actual funding used to pay for those services (eligible scope).

RWHAP Part A recipient: "We feel that the request aligns with what we are currently doing in the Detroit EMA [Eligible Metropolitan Area] to meet the eligible scope requirements. Additionally, based on the low level of program income our sub-recipients receive, we do not feel this will increase the reporting burden."

RWHAP Part A recipient: "We don't generate program income." The recipient also noted that, in the next 18-24 months, they are transitioning to an integrated system with RWHAP Part B partners.

RWHAP Part A recipient: The RWHAP Part A noted that it currently has 4 full time staff and an award of 5.7 million. They are still awaiting final award. If there is a reduction in funding, they will be reducing staff even further (3.5 FTE). The respondent sees a need to train providers on the reporting requirement changes and how to report on the RSR. The respondent estimated that they would need at least .5 FTE to full FTE required for this change.

RWHAP Part B recipient: The recipient noted that they have determined that the impact on operations should be minimal. They currently collect the information on all clients, so the greatest impact would have been on the reporting function. The operator of their electronic data collection system has said the impact will be minor.

RWHAP Part B recipient: The recipient indicated that they have preempted this request and have been collecting client level data for HRSA RWHAP services funded with pharmacy rebates since calendar year 2017. However, they estimate that with this increased number of services it would require an additional 960 hours during the RSR submission cycle to ensure completeness of all data elements for the state and all sub-recipients

RWHAP Part C recipient: “I imagine any changes to the RSR will be no more difficult as I expect it will take me quite some time to put together my first one. I can provide a rough estimate. We serve over 1800 patients, with a large majority of these patients would receive the services described previously. The data needed for the RSR would have to be hand entered. The additional time added would be a minimum of 250 hours over the course of the year. (15 minutes per patient at 1,000 patients).”

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 will be taken to protect the confidentiality of clients receiving services. See below for a list of precautions in the areas of collection and analysis of data:

- All HRSA RWHAP clients will be 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 213,843 hours per year. 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 475 respondents, representing the 567 grants allocated by HRSA. 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 5,255 hours with an average of eleven hours.

Service Provider Report

The Service Provider Report will have 2,079 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 will 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 27,027.

Client Report

The Client Report will have 1,607 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 181,591 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 | Total Responses | Average Burden per | Total Burden Hours |
|---------------------|-----------|--------------------|------------------|-----------------|--------------------|--------------------|
|---------------------|-----------|--------------------|------------------|-----------------|--------------------|--------------------|

| | | | per Respondent | | Response (in hours) | |
|--------------------------------------|-------------------------|-------|----------------|-------|---------------------|---------|
| RWHAP Parts A, B, C Grant recipients | Grantee Report | 475 | 1 | 475 | 11 | 5,225 |
| | Service Provider Report | 2,079 | 1 | 2,079 | 13 | 27,027 |
| | Client Report | 1,607 | 1 | 1,607 | 113 | 181,591 |
| | Total | 4,161 | | 4,161 | | 213,843 |

12B. Estimated Annualized Burden Costs

| Type of Respondent | Form Name | Total Burden Hours | Hourly Wage Rate | Total Respondents Costs |
|---|-------------------------|--------------------|----------------------|-------------------------|
| RWHAP Parts A, B, C, and D Grant recipients | Grantee Report | 5,225 | \$16.73 ² | \$87,414.25 |
| | Service Provider Report | 27,027 | \$16.73 | \$335,051.71 |
| | Client Report | 181,591 | \$16.73 | \$3,038,017.43 |
| | Total | 213,843 | | \$3,460,483.39 |

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

² Mean hourly wage for Data Entry and Information Processing Workers. Occupation Code: 43-9020. https://www.bls.gov/oes/current/oes_nat.htm.

Grant recipients will be 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 2018, this contract will be \$1,250,000.00. In addition, government personnel require 10% time of 1 FTE at a GS-13 level (\$96,970) to review and prepare award notices.

15. Explanation for Program Changes or Adjustments

No applicable as this is a new information collection request.

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

The reporting period will be the calendar year, i.e., January 1 – December 30. Annual reports from the grant recipients should be submitted to HRSA approximately 2 months following the end of each reporting period. HRSA will compile the data received from the grant recipients and produces an annual report for the Secretary of HHS and Congress. In addition, HRSA staff will produce national summaries that are distributed to constituency and advocacy groups and are uploaded to the HRSA 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 grant recipients to allow them as much time as possible to modify their data collection systems

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.