Supporting Statement A

Chart Abstraction of Ryan White HIV/AIDS Program Recipient Data
OMB Control No. 0906-XXXX - New

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 titled "Chart Abstraction of Ryan White HIV/AIDS Program (RWHAP) Recipient Data" HRSA will annually collect clinical information from a combination of 50 RWHAP recipients and subrecipients. The 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 with HIV. See Tab A 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 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 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 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 grant recipients' organization and staffing, the number of clients served, services provided, client demographics, clinical data of clients served and costs of providing services.

HRSA has sought OMB approval for the Ryan White HIV/AIDS Program Services Report (RSR) (OMB#: 0906-0039, Expiration 12/31/2021). The RSR has attempted in the past to

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 December 2018. Accessed September 9, 2019.

collect client level clinical information. Much of the clinical information contained in the RSR was incomplete or inaccurate because the information was not stored as structured data, clinical event occurred prior to the period of data collection, clinical information required interpretation by recipient data management staff, or the variables were not reflective of clinical practice guidelines. HRSA proposed removing most clinical information from the RSR and collecting the clinical information by contractor with trained staff. As a result, HRSA would have relevant, complete, and accurate clinical information while maintaining minimal burden to a small subset of RWHAP recipients and subrecipients. See attachment for comparison of RSR and chart abstraction project variables.

The clinical information will allow HRSA to meet the annual report submission to Congress and to understand changes in the clinical needs of people with HIV. This information will provide a more accurate understanding of the clinical needs of people with HIV (segmented by demographics), clinical service provided through the RWHAP, and clinical staffing supported by the RWHAP. Additionally, HRSA will have access to clinical information related to emerging and pressing clinical issues such as substance use trends and treatment, sexually transmitted infection testing and treatment, hepatitis testing and curing, and age specific care for a subset of recipients and subrecipients.

2. Purpose and Use of Information Collection

HRSA is required to assess the quality of care provided by RWHAP recipients. U.S. Department of Health and Human Services (HHS) care and treatment guidelines (e.g., Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV; Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV- Infected Adults and Adolescents; and Sexually Transmitted Diseases Treatment Guidelines, 2015) and U.S. Preventative Services Task Force (USPSTF) guidelines serve as the basis for assessing the quality of care within the RWHAP. The purpose of the Chart Abstraction of Ryan White HIV/AIDS Program (RWHAP) information collection is to assess the extent to which the care provided with funding from the RWHAP is meeting the HHS and USPSTF guidelines. The clinical information collected from RWHAP recipients and subrecipients via a provider screening phone interview, a provider pre-site visit interview, and medical records data abstraction. The data will reflect the full range of HIV outpatient ambulatory health services, primary care, and screening and treatment for hepatitis, sexually transmitted infections, and substance use disorder provided by RWHAP service providers.

Information will be collected from a combination of 50 RWHAP recipients and subrecipients once a year by a contractor. The same 50 RWHAP recipients and subrecipients will participate each year with a different sample of patients' medical records abstracted each year. The sample of RWHAP recipients and subrecipients will be representative of the 920 RWHAP recipients and subrecipients funded to provide outpatient ambulatory health services and the patients receiving those services. The contractor will provide HRSA with the unanalyzed data. HRSA will analyze the data.

HRSA will generate descriptive reports regarding the patients and organizations demographics; laboratory screenings; comorbidities; mental health screening and referrals, substance use

screening, treatment status, and referrals; pregnancy status; women's care; age specific care; hepatitis screening, testing, and treatment; and sexually transmitted infection testing and treatment.

3. Use of Improved Information Technology and Burden Reduction

This information collection is achieved through a combination of electronic and non-electronic methods. The information gathered via provider screening phone interview and provider pre-site visit interview is not documented in a pre-existing electronic format and requires contact with a recipient or subrecipient staff person to collect the information. Contract staff will speak with a recipient or subrecipient staff person via phone for one hour or less to gather the information in the provider screening phone interview. This information is used to determine of the recipient or subrecipient is eligible to participate in the chart abstraction. Next, contracted staff will speak with a recipient or subrecipient staff person via phone for 30 minutes or less to gather information in the provider pre-site visit interview. This information is used to gather information about the care team members and organization demographics.

The information collected from the patients' electronic health record requires onsite contact with a recipient or subrecipient staff person. Once the contractor is onsite at the recipient or subrecipient's office, the contract staff will spend up to two hours receiving an orientation to the electronic health record including how to log into the system and location of data to be collected. The recipient or subrecipient staff are not involved in the information collection after the orientation. The contractor identifies the needed patients' information from the electronic health record and directly enters the information collected into a secure web portal. The use of a contractor to collect the patient information increases the quality of information collected and decreases the burden of collection on the recipients and subrecipients.

4. Efforts to Identify Duplication and Use of Similar Information

A limited amount of information required to evaluate and monitor the RWHAP ambulatory outpatient health services is available in the RSR. The RSR previously contained more information, but was removed due to recipient data quality issues and HRSA's inability to distinguish between the clients' need for care vs. receipt of care. No known studies or database with comprehensive, high quality data of people with HIV receiving RWHAP outpatient ambulatory health services that is representative of the RWHAP exists. Because no data collection, federal or otherwise, contains comprehensive, high quality data representative of the RWHAP program, HRSA proposes the current information collection. This information collection will be the only comprehensive source of client-level information that will adequately address and meet HRSA'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 has been held to the minimum required for the intended use. The majority of the information is collected by a

contractor and will minimally involve small entities.

6. Consequences of Collecting the Information Less Frequently

The information will be collected on an annual basis. Without annual information collection, HRSA would not be able to carry out its responsibility to assess and report the quality of outpatient ambulatory health services provided by RWHAP recipients and subrecipients in a timely manner. Because the epidemiology of HIV is changing constantly and clinical care and treatment continues to advance, annual collection of clinical information is necessary to assess the quality of outpatient ambulatory health services provided, consistency with HHS and USPSTF guidelines, and that outpatient ambulatory health services are 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:

- The quality of RWHAP care and services;
- Assess the extent to which HHS and USPSTF guidelines are met;
- How many and what types of patients are receiving outpatient ambulatory health services, and how outpatient ambulatory health services are distributed across various types of patient; and
- The impact of the outpatient ambulatory health services on HIV, primary care, and age related health outcomes of people with HIV served by the RWHAP recipients and subrecipients.

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 Federal Register Notice was published in the *Federal Register* on May 10, 2019 (Vol. 84, No. 91. Pages 20638 – 20639). There were no public comments.

Section 8B:
HRSA contractor consulted with Jonathan Colasanti, MD, MSPH (Assistant Professor of Medicine at Emory University and Associate Medical Director of the Ponce de Leon Center, Infectious Diseases Program of the Grady Health System) to determine applicability of health outcomes data regarding HIV and other medical conditions of interest.

9. Explanation of any Payment/Gift to Respondents

Because RWHAP grants' administration is capped at 10%, RWHAP recipients and subrecipients that are deemed eligible and agree to participate in the study will be reimbursed for expenses incurred as a result of participating in the study that are not covered through their grant funding. The reimbursement will be up to $1200 annually.

10. Assurance of Confidentiality Provided to Respondents

HRSA will review the design and procedures prepared by the contractor to ensure they meet industry standards. This review will also ensure compliance with the spirit and the letter of regulations from the HHS governing such projects. Systems and procedures for collecting and processing data are designed to help ensure the protection of the data provided. The contractor will ensure this project has a data security plan with adequate provisions to protect the privacy of subjects and the confidentiality of their information in all methods of data collection. The data collection tool will adhere to Federal Information Security Management Act (FISMA) Moderate security standards to ensure high standards of information security. In addition, all data will be transmitted securely via the file transfer protocol (FTP) and will be maintained on secure servers. Data will be obtained from various individuals involved in implementing the program, including the RWHAP Administrator/Director, via interviews. RWHAP Administrator/Director will be provided with the purpose of the study and what taking part in the survey will involve. If the provider chooses to participate, he/she will be asked to provide verbal consent stating that he/she understands the purpose of the study, is willing to participate but can change his/her mind at any time, and that all information gathered will be stored securely and used only for the purposes of this information collection. As with the health record abstraction data, no direct identifiers will be collected or associated with the interview or survey data collected from clients. Verbal consent is preferable as the signed consent form would create the only identifier indicating client participation in providing data about potentially sensitive topics.

Data across projects will be kept confidential to the extent allowed by law. Questions on the recipient or subrecipients policies, practices and experiences are part of their regular business knowledge, and there are no questions of a personal nature or the personal choices or behaviors of respondents. 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.

This information collection's privacy impact assessment has been approved by HHS (Tab G Privacy Impact Assessment).

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 information also allows HRSA to monitor clinical outcomes achieved by clients served by RWHAP recipients and subrecipients. 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 total burden for the individual for information collection participation is estimated at 120

minutes for medical records sample selection guides (i.e., RWHAP Administrator/Director), 30 minutes for the site screening interviews, and 60 minutes for the pre site visit interview. Time estimates are based on experience with similar instruments in other studies of comparable organizations.

12A. Estimated Annualized Burden Hours

Exhibit 12A below offers an estimate of the reporting burden for a sample of 50 respondents to the medical records sample selection guide, 100 site screening interviews of and 50 pre site visit provider interviews. For all instruments, it is estimated that the total burden will be 1,510 hours.

- The medical chart/records abstraction will collect information from 3,200 – 4,000 records [Total number of sites =50, Number of records per site = 64-80, Number of staff helping to identify sampled cases per site =1] and will take an average of 2.5 hours for the RWHAP Administrator/Director to help to identify sampled cases for medical chart/records abstraction. HRSA contractor staff will conduct the actual medical chart/records abstraction after receiving guidance from the Administrator/Director.
- The site screening interview will have 100 respondents [Number of sites =100, Number of respondents per site=1 and will take an average of 30 minutes for each interview. The RWHAP Administrator/Director will participate in the site screening interview.
- The pre-site visit interview will have 50 respondents [Number of sites =50, Number of respondents per site=1 and will take an average of 60 minutes for each interview. The RWHAP Administrator/Director will participate in the site screening interview.

12A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
RWHAP Site Administrators (Private Sector)	Medical Record Data Abstraction	50	1	50	2.5	125
RWHAP Director or Senior Clinician (Private Sector)	Site Screening Interview	100	1	100	.5	50
RWHAP Director or Senior Clinician (Private	Pre-Site Visit Interview	50	1	50	1	50

Sector)						
	Total	200		200		225

12B. Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
RWHAP Site Administrators (Private Sector)	125	$52.58	$6,572.50
RWHAP Director or Senior Clinician (Private Sector)	100	$97.04	$9,704.00
Total	**200**		**$16,276.50**

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

The total cost of the contract that supports this three-year information collection is $3,611,268, annualized to $1,203,756. This includes the labor costs to create the sampling methodology, develop the data collection instruments, interview the sites, medical chart/records abstraction, and prepare the data files. In addition, government personnel require 20% time of 1 FTE at a GS-13 level ($96,970, unloaded) to prepare the description reports of the information collected and 10% of 1 FTE GS-14 ($128,911, unloaded) to guide the development of the descriptive reports.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

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

Information will be collected between March – December each year and will be submitted to HRSA annually in January 2021, January 2022, and January 2023. HRSA will compile the data received from the contractor and produce an annual report. In addition, HRSA will staff produces national summaries that are distributed to constituency and advocacy groups and are uploaded to the HRSA HIV/AIDS Bureau Web site. Summaries will consist of aggregate-level data only.

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

The expiration date will be displayed appropriately.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

List of Attachments

Tab A. Legislation

Tab B. Medical Record Data Abstraction Screenshots

Tab C. Data Dictionary

Tab D. Provider Site Screening Interview Form

Tab E. Provider Pre-Site Visit Interview Form

Tab F. IRB Approval Letter

Tab G. Privacy Impact Assessment

Tab H. Comparison of RSR and Chart Abstraction Project Variables