



Billing Code 4165-15

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Proposed Collection: Public Comment Request**

**Information Collection Request Title: Assessing Client Factors Associated with Detectable HIV Viral Loads and Models of Care and the Ryan White HIV/AIDS Program**

**OMB No. 0906 – xxxx – New**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR should be received no later than **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

*Information Collection Request Title:* Assessing Client Factors Associated with Detectable HIV Viral Loads and Models of Care and the Ryan White HIV/AIDS Program  
OMB No. 0906 – xxxx – New

*Abstract:* The Ryan White HIV/AIDS Program (RWHAP), first authorized by the U.S. Congress in 1990, is administered by HRSA’s HIV/AIDS Bureau (HAB). In 2015, 533,036 clients received services from RWHAP-funded providers; 97.0 percent were living with HIV. This information collection request covers two distinct evaluation studies with RWHAP provider sites that will share some data collection instruments. The sharing of data collection instruments will minimize the burden on RWHAP provider sites related to data collection, increase the sample size that could be used for data analysis resulting in greater generalizability of results,

and provide richer and more robust data that may offer additional depth to the findings of each study.

The first evaluation study, *Assessing Client Factors Associated with Detectable HIV Viral Loads*, will explore clinical activities and barriers to achieving and sustaining viral suppression. Early and effective treatment for HIV has been shown to greatly reduce associated morbidity and mortality. In spite of the known benefit of treatment, many individuals remain out of care or access care only intermittently; the CDC estimated that, in 2013, approximately 45 percent of people living with HIV (PLWH) in the United States were not virally suppressed, indicating a significant gap in the percentage of PLWH who are being successfully engaged and retained in care. In spite of the increased attention on retention in care and the overarching goal of viral suppression, little data exist regarding the specific individual factors that are associated with sub-optimal viral suppression. Such information would be valuable in targeting programs to reach populations that are currently not achieving viral suppression.

The second evaluation study, *Models of Care and the Ryan White HIV/AIDS Program*, seeks to answer the critical questions of what individual and system-wide factors, including the models of care employed among RWHAP provider sites, contribute to better health outcomes for PLWH. While advances in treatment have improved survival in patients with HIV, longer lives are associated with increased prevalence of adverse effects of HIV infection and therapeutic complications, concurrent with medical conditions related to aging processes that would occur in the absence of HIV. These long-term complications amplify chronic disease management as a major issue for the HIV population and a challenge for the delivery of effective health care.

These studies will inform HAB about how the method of health services delivery (the “model of care”) contributes to better health outcomes, including HIV-related outcomes. Understanding the most effective models of care will be important for HIV specialists, primary care physicians, and other clinicians who care for PLWH as they design and coordinate a full array of primary care and support services for their HIV patients. These primary care and support services have a direct impact on viral suppression, which, in turn, improves life expectancy and quality of life, and prevents HIV transmission.

The two studies inform each other in that the degree to which clients are virally suppressed may be attributed partly to the model of care practiced at their clinic. Likewise, the degree to which its clients have achieved viral suppression may drive a clinic to practice a particular model of care. The two studies will collect several identical data elements through their individual collection instruments, allowing data to be aggregated across the two studies. The aggregation of data across the two studies will minimize the burden on RWHAP provider sites related to data collection, increase the sample size that could be used for data analysis resulting in greater generalizability of results, and provide richer and more robust data that may offer additional depth to the findings of each study.

*Need and Proposed Use of the Information:* The *Assessing Client Factors Associated with Detectable HIV Viral Loads* study will identify characteristics of RWHAP clients and health facilities that are associated with the ability to achieve and sustain an undetectable viral load as compared to the characteristics that are associated with sub-optimal viral suppression. This study will enable the development of better targeted services for improved viral suppression

rates. The *Models of Care and the Ryan White HIV/AIDS Program* study will compare HIV and primary health outcomes across various models of care to determine which are most effective in responding to HIV to improve health outcomes for people living with HIV and to prevent HIV transmissions. The results from this study will enable improvements or redesigns of effective delivery of HIV care among Ryan White providers, which will, in turn, improve HIV clinical outcomes such as viral suppression.

In both studies, an analysis of the perceptions of providers and clients will further support the understanding of the impact of individual and system-wide factors on achieving health outcomes. The two studies will share data to inform both studies' objectives, allow for a larger sample size from which to generalize conclusions, and reduce the overall burden of response on RWHAP providers and clients. The objectives of both studies will be achieved through collection of the following data:

- RWHAP provider interviews – Site staff interviewees (in person);
- RWHAP client surveys – Clients with detectable and undetectable viral load at each clinic;
- RWHAP client records abstraction – Medical chart and administrative records (e.g., service utilization and health outcomes data);
- RWHAP site survey data – Site Director responses; and  
RWHAP client semi-structured interviews – Clients with detectable and undetectable viral load.

These studies will build upon and complement HAB's study focusing on RWHAP outcomes within the context of the changing health care landscape; and will use the RWHAP site survey and chart abstraction instruments that were submitted as part of that study. The data will be

collected by a contractor selected by HRSA.

*Likely Respondents:* RWHAP Administrators, RWHAP Care Providers, and RWHAP Clients.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below. Both research studies are included in the table, with burden proportional to the number of RWHAP provider sites from which each study will collect data: 25 distinct facilities for *Assessing Client Factors Associated with Detectable HIV Viral Loads* and 50 distinct facilities for *Models of Care and the Ryan White HIV/AIDS Program*. The table below provides the level of burden inclusive of both studies.

Total Estimated Annualized Burden – Hours

<b>Form Name</b>	<b>Number of Respondents</b>	<b>Number of Responses per Respondent</b>	<b>Total Responses</b>	<b>Average Burden per Response (in hours)</b>	<b>Total Burden Hours</b>
Site Survey*	75	1	75	0.5	37.5
Medical Records Sample Selection Guide*	75	1	75	1	75
Provider Interview Guide	375	1	375	2	750
Focus Groups Guide	400	1	400	1.5	600
Client Survey	500	1	500	1	500
Client semi-structured interview	150	1	150	1	150
<b>Total</b>	<b>1,575</b>		<b>1,575</b>		<b>2112.5</b>

\* The site survey and medical records sample selection instruments were submitted in March 2017 for OMB review as part of the Ryan White HIV/AIDS Program Outcomes and Expanded Insurance Coverage Information Collection Request.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency’s functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

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