



Billing Code: 4165-15

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Assessing Client Factors Associated with Detectable HIV Viral Loads; and Models of Care and the Ryan White HIV/AIDS Program

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to 202-395-5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443-1984.

SUPPLEMENTARY INFORMATION: *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). The RWHAP provides medical services, treatment, and/or support services to 533,036 clients in 2015; 97.0 percent of these clients were living with HIV. This information collection request covers two distinct evaluation studies with RWHAP provider sites that will share components of data collection instruments through shared variables. Sharing data collection instruments will minimize burden for RWHAP provider sites collecting this data and will increase the sample size for data analysis thus resulting in more robust data and greater generalizability of results.

The first evaluation study, *Assessing Client Factors Associated with Detectable HIV Viral Loads*, will explore individuals' specific facilitators and barriers to achieving and sustaining viral suppression. Early and effective treatment for HIV has been shown to greatly reduce associated morbidity and mortality, and prevents transmission of HIV. 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 is valuable for targeting programs to reach populations that are

currently not achieving HIV 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. Yet little is known about how the method of health services delivery (the “model of care”) contributes to better health outcomes, including HIV-related outcomes. For example, does it make a difference if a patient receives HIV care from a primary care provider, a specialist, or from a care team that includes both? Understanding the most effective models of care is 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 patients. These primary care and support services have a direct impact on HIV 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 achieve and sustain viral suppression 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 burden for RWHAP provider sites

collecting this data and will increase the sample size for data analysis thus resulting in more robust data and greater generalizability of results.

A 60-day Federal Register Notice was published in the *Federal Register* on May 18, 2017 (Volume 82, page 22838) which solicited comments on this data collection. Four comments were received that focused on how facilities will be selected for participation and the importance of adequate nutrition for PLWH.

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 HIV/AIDS Program 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 client records abstraction – Medical chart and administrative records (e.g., service utilization and health outcomes data);
- RWHAP provider interviews – Site staff interviewees (in person);
- RWHAP client focus groups (Models of Care study sites only) – Clients at selected clinics that represent a given model of care;
- RWHAP client surveys (HIV Viral Suppression study sites only) – Clients with detectable and undetectable viral load at each clinic; and
- RWHAP client semi-structured interviews (HIV Viral Suppression study sites only) – 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 HRSA contractor.

Likely Respondents: RWHAP Administrators, RWHAP Service 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

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 Records Sample Selection Guide*	75	1	75	1	75
RWHAP Service Providers (Private Sector)	Provider Interview Guide (HIV Viral Suppression)	125	1	125	2	250
RWHAP Service Providers (Private Sector)	Provider Interview Guide (Models of Care)	250	1	250	2	500
RWHAP Clients (Individual/ Household)	Focus Groups Guide	240	1	240	1.5	360
RWHAP Clients (Individual/ Household)	Client Survey	500	1	500	0.5	250
RWHAP Clients (Individual/ Household)	Client Semi-Structured Interview	150	1	150	0.5	75
	Total	1,340		1,340		1,510

* The medical records sample selection instrument has been previously submitted as part of the RWHAP Outcomes Study proposed data collection project.

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.

Amy McNulty,

Acting Director,

Division of the Executive Secretariat.

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