

**Health Resources and Services Administration**  
**SUPPORTING STATEMENT**  
**HIV Quality Measures (HIVQM) Module**

**OMB Control No. 0906-0022**

**Revision**

**A. Justification**

**1. Circumstances Making the Collection of Information Necessary**

The Health Resources and Services Administration (HRSA) is requesting continued OMB approval to collect information for the Ryan White Program's HIV Quality Measures (HIVQM) Module. The current information collection request will expire on December 31, 2019. The HIVQM Module is a voluntary data system that recipients funded under all Parts of the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Ryan White HIV/AIDS Program (RWHAP)) and their funded service providers can use to monitor their performance to providing quality HIV services. 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 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 with HIV.<sup>1</sup> 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 and their service providers 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.

Under the Ryan White HIV/AIDS Treatment Modernization Act of 2006 (Public Law 109-415), all RWHAP recipients are required to establish clinical quality management programs to:

- Assess the extent to which HIV health services are consistent with the most recent Public Health Service guidelines for the treatment of HIV disease and related opportunistic infections, and
- Develop strategies for ensuring that such services are consistent with the guidelines for improvement in the access to and quality of HIV services.

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<sup>1</sup> 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.

In 2013 the HIV/AIDS Bureau (HAB) further restructured its HIV Performance Measures with the goals of:

- Identifying core performance measures that are most critical to the care and treatment of people living with HIV;
- Combining measures to address people of all ages living with HIV;
- Aligning measures with U.S. Department of Health and Human Services priorities, guidelines, and initiatives;
- Promoting relevant performance measures used in other federal programs;
- Archiving performance measures; and
- Monitoring progress toward achieving the goals identified in the National HIV/AIDS Strategy (NHAS).

The HAB performance measures include several priority performance measures categories: 1) core, 2) all ages, 3) adolescent/adult, 4) HIV infected children, 5) HIV exposed children, 6) medical case management, 7) oral health, 8) AIDS Drug Assistance Program (ADAP-RWHAP's drug assistance program) and 9) system level.

As per HAB's Policy Clarification Notice 15-02: Clinical Quality Management, RWHAP recipients are required to select performance measures for funded service categories that meet a client utilization threshold and calculate the performance measures on a quarterly basis. RWHAP recipients have been creating their own data collection and procedures to meet the performance measurement requirement. For example, 50% of recipients use CAREWare, a free software created and maintained by HAB to help recipients in collecting, managing and submitting RWHAP data. CAREWare had a performance measure module that comes stocked with HAB performance measures. Recipients are also able to build custom performance measures in the CAREWare performance measure module. The CAREWare performance measure module calculates the numerator, denominator, and percentage for any measure in the module based on any period of performance. The CAREWare performance measure module has an export function by which recipients and provider can upload the export to the HIVQM Module.

In 2016, HAB introduced the HIVQM Module as an online tool that recipients and service providers can use to enter HAB performance measures on a quarterly basis and meet the clinical quality management requirement. In addition, the HIVQM Module allows recipients to generate monitoring reports and benchmark their performance with other recipients and service providers nationally. The use of the HIVQM Module is voluntary for RWHAP recipients and service providers, but strongly encouraged. Since the HIVQM Module's launch, a little less than half of RWHAP recipients (out of 600 recipients) have entered data into the HIVQM Module across all the reporting period. An average of about 10% of recipients and service providers enter data each quarter. We anticipate higher use of the HIVQM Module with the implementation of the data stratifications as the data stratifications were developed in response to recipient requests.

## **2. Purpose and Use of Information Collection**

Recipients can enter data in the HIVQM Module on the above-mentioned performance measures and

then generate reports to assess their performance and also compare their performance regionally and nationally against other recipients. The HIVQM Module provides recipients an easy-to-use and structured platform to voluntarily continually monitor their performance in serving their clients particularly in access to care and the provision of quality HIV services. The main purpose for the module is to help recipients set goals and monitor performance measures and their quality improvement projects. HRSA expects the HIVQM Module to better support clinical quality management, performance measurement, service delivery, and client monitoring at both the recipient and client levels.

The module will also provide HRSA a better assessment of the quality of the services provided by the RWHAP and to monitor improvements in the HAB performance measures over time.

*HAB proposes to make three modifications to the HIVQM Module:*

- *Allow recipients to import performance measures data from a CSV format file, rather than entering individual data into the module.*
- *Provide an option to enter data for specific populations for a subset of performance measures based on age, gender, race/ethnicity, and specific risk factors.*
- *Produce summary reports that will also allow recipients to compare their performance measures by Ryan White Program Part (i.e. by Part A, B, C and D), thus providing another perspective to analyze and look at their performance measures.*

These modifications are a reflection of recipient requests to enhance the HIVQM Module and better meet the needs of their performance measurement requirement. We have received feedback from RWHAP recipients and providers about the need to compare performance measure data for subpopulations using the data stratifications. In response to the requests, we incorporated functionality into the HIVQM Module for recipients and providers to enter subpopulation or strata data for each performance measure. Recipients and providers will be able to enter as many strata as they are tracking in their own program and want to compare at the state, regional, and national levels.

Furthermore, HAB believes that these modifications will not increase burden but rather decrease burden for those who will use the import feature. The additional data on age, gender, race/ethnicity and specific risk factors are also data that should be already collected and should just be matter of data entry or import.

### **3. Use of Improved Information Technology and Burden Reduction**

The HIVQM Module is housed in the Electronic Handbooks (EHBs), an existing website for recipients to enter other data required for RWHAP-funded agencies such as the Ryan White Services Report (RSR) and the AIDS Drug Assistance Program (ADR). The integration of the HIVQM Module into the existing EHBs streamlines users' access and technology knowledge. In addition, some information, particularly the provider information, will be pre-populated using data from the organization's RSR. Data entered will also be saved for the next data collection so that users can easily update or change their data.

The new feature allows for import of performance measures data rather than manually entering data. The data import will reduce burden. CAREWare performance measure module has an export feature, which recipients and providers can use to upload performance measure data into the HIVQM Module. The combination of the CAREWare export and HIVQM Module import functions will reduce data entry burden for recipients and providers.

See attached for the HIVQM Module Draft Manual.

#### **4. Efforts to Avoid Duplication and Use of Similar Information**

In 2007, HAB first released performance measures for recipients to use as a guide for their clinical quality management program. Recipients report on some clinical data elements electronically through the required Ryan White Services Report (RSR), OMB control #0906-0039, and the AIDS Drugs Assistance Program Data Report (ADR), OMB control #0915-0345, on an annual basis; however, this information gives recipients and HAB only a snapshot of the quality of HIV services provided.

Per the requirement to establish clinical quality management programs, recipients may also be already collecting this data for this purpose. The HIVQM Module is an optional tool that recipients may choose to enter their performance measure data into the module and generate reports to assess their individual performance and compare across other recipients and service providers nationally.

#### **5. Impact of Small Businesses and Other Small Entities**

No small businesses will be involved in this data collection. To minimize the burden of other small entities, entering performance measure data and using the HIVQM Module is entirely voluntary and the information being requested has been held to the absolute minimum required for the intended use of the data.

#### **6. Consequences if Information Collected Less Frequently**

HRSA RWHAP recipients can enter their data in the HIVQM Module up to four times a year. There are no legal obstacles to reduce the burden; however, in order for organizations to appropriately assess their performance measures, HAB recommends that they collect their data quarterly at a minimum.

#### **7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

The request fully complies with the regulation.

#### **8. Comments in Response to the Federal Register Notice/Outside Consultation**

The 60-day FRN notice required in 5 CFR 1320.8(d) was published in the *Federal Register* on March 14, 2019, (Vol. 84, No. 50; pp. 9362-9363). Five public comments were received. Three public comments were related to CAREWare, and concern that the data collected in the HIVQM Module were similar to data collected in CAREWare. HAB responded by explaining how CAREWare and the HIVQM Module differ, and that CAREWare produces and exports performance measurement data in a format that is easy for the HIVQM Module to accept, while avoiding duplication. HAB also confirmed that the HIVQM Module aligns with some, but not all of the performance measures, in CAREWare and that not all recipients utilize CAREWare. In addition, CAREWare only allows recipients to look at their own performance measures while the HIVQM Module allows recipients to compare their performance measures at state, regional and national levels. Furthermore, HAB is working on allowing data to be extracted from CAREWare and uploaded to the HIVQM Module. The fourth comment centered on the additional new data elements and where these data can be entered into the HIVQM Module. The addition of these new data elements into the existing data system has not yet been incorporated and is scheduled to

be completed in 2020. The final comment asked if there was a formal agreement between HAB and the Centers for Medicare & Medicaid that would allow recipients who participated in the HIVQM Module to qualify and comply with requirements to receive incentives from these programs. HAB does not have this formal agreement.

#### **9. Explanation of any Payment/Gift to Respondents**

Respondents will not receive any payments or gifts.

#### **10. Assurance of Confidentiality Provided to Respondents**

The HIVQM Module does not require any information that could identify individual clients. Aggregate data on the number of clients who received services will be collected, but client names or other personally identifiable information will not be collected.

#### **11. Justification for Sensitive Questions**

There are no questions of a sensitive nature.

#### **12. Estimates of Annualized Hour and Cost Burden**

*Respondents:*

Respondents for the HIVQM Module are recipients and service providers of the HRSA Ryan White HIV/AIDS Program. The HIVQM Module is a voluntary data collection and is open to all RWHAP recipients and service providers four times a year. Over the past four reporting periods, for example, 61 agencies used the Module only one time, 19 agencies used the Module twice, 27 used the Module three times and 15 used the Module four times. These numbers are increasing as HAB continues to advertise and improve the functionality of the Module. The HIVQM Module was piloted for this revision request in June 2019. Eight recipients or service providers who had submitted data for more than two reporting periods in the last year and represented the use of various data systems were invited to provide feedback and a burden estimate. Positive feedback included: 1) the addition of the data elements which some recipients are already collecting data for; 2) the data upload function which will make uploading data easier and 3) the ability to compare their performance measures with other providers. Other feedback included the following: 1) consideration for the age range response options under data element, Age, to be flexible since various reports require different age ranges and 2) the number of states or other groupings that are being compared should be included in the reports. The main challenge in entering data to the HIVQM Module is finding resources for IT to develop coding for the upload feature. However, RWHAP recipients and providers understand that this will be a one-time expense and will make data uploading easier and decrease error. It is important to note, however, that CAREWare users do not incur this expense, as HAB provides the CAREWare platform free-of-charge to its users, maintains the platform and manages all of its enhancements; and HAB provides dedicated technical assistance to CAREWare users throughout the year. Some respondents added that they are waiting to get additional HAB funding to improve their non-CAREWare Electronic Health Record technology overall and that the upload feature for the HIVQM Module would be part of that improvement.

#### **12A. Estimated Annualize Burden Estimates:**

The annual burden estimates varied as patient load and use of technology varied. The average came to six hours with a range of 2 to 10 hours. This estimate also reflects recipients hand entering performance measures which will be reduced in the future reporting periods when recipients will have the ability to import data. The annualized burden costs for recipients is based on the May 2018 National Occupational Employment and Wage Estimates by the Bureau of Labor. [https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm). The respondent, a healthcare support worker (occupational code 31-9099), takes 6 hours per response for 4 responses at a labor rate of \$18.80 per hour or \$37.60 to include employer overhead and fringe benefits. The total hour cost is \$2,089,958.

The estimated annual time and cost burdens to respondents are presented in the tables below. Please note that this number is an overestimation as this estimation assumes that ALL recipient and service providers will use the HIVQM and will enter all four times a year. Currently, a fraction of the total number of recipients and service providers use this HIVQM, and not all of them report data during each reporting period.

Type of Collection	Number of Respondents	Responses per Respondent	Total Responses	Hours per Respondent	Total Burden Hours	Wage Rate	Total Hour Cost
HIVQM Module Report	2,316	4	9,264	6	<b>55,584</b>	\$37.60	\$2,089,958
Total	2,316		9,264		<b>55,584</b>		\$2,089,958

The HIVQM is open to recipients and service providers four times a year in March, June, September and December. Recipients and service providers are encouraged to monitor performance measures at least four times a year.

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

Other than their time, there is no other annual cost burden to respondents. There is a one-time cost for coding for the upload feature for recipients who wish to use this feature. Depending on the recipient’s use and resources in technology (i.e.EHRs, IT staff, etc) these costs vary from minimal to no costs.

**14. Annualized Cost to the Federal Government**

The contract task that supports the initial system setup and supports system maintenance and data collection efforts each year is \$120,000. In addition, there will be the cost for a GS 13 (Step 3) at 12% (approximately \$12,800) and a GS 14 (Step 5) at 6% (approximately \$8,000) time to monitor the project. The estimated total cost is \$140,800.

**15. Explanation for Program Changes or Adjustments**

HAB proposes to make three modifications to the HIVQM Module as described above to respond to recipient and service provider needs. HAB believes that these modifications will not increase burden and hope that the import feature will ease the burden instead. The data used for the stratifications (e.g age, gender, etc.) are required variables for the RSR and ADR.

There is a five-hour increase (from one hour to six hours) per response from the last total burden estimate of 6,948 hours. The previous burden estimate was calculated when the respondents had no actual experience in using the HIVQM Module. Current pilot participants who now have at least 2 years of experience with entering data estimate an additional 5 hours for the generation, cleaning and verification of data. This increase in burden is not due to the changes or addition of new data elements as proposed, but rather due to an underestimation of burden from pilot participants who had not yet used the HIVQM Module. We anticipate that with the upload feature in place, this burden will decrease in the future.

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

The information collected will not be published, tabulated or manipulated by HAB or any other entity. The purpose of this data collection is to give RWHAP recipients and service providers the ability to calculate their performance measures by entering a denominator that represents the number of patients who should receive a specific care or service and a numerator that represents that number of patients who actually received the care or service during a 12-month period. Recipients and service providers can then create their own reports for the purposes of evaluating their program and/or comparing their data with other organizations regionally and nationally.

The HIVQM Module will be available to RWHAP recipients and service providers to enter annual data four times a year. Below is the schedule specifying the annual period.

<b>HIVQM Module Opens</b>	<b>HIVQM Module Closes</b>	<b>Measurement Year/ Period</b>
March 1 <sup>st</sup>	March 31 <sup>st</sup>	January 1 <sup>st</sup> – December 31 <sup>st</sup>
June 1 <sup>st</sup>	June 30 <sup>th</sup>	April 1 <sup>st</sup> – Mar 31 <sup>st</sup>
September 1 <sup>st</sup>	September 30 <sup>th</sup>	July 1 <sup>st</sup> – June 30 <sup>th</sup>
December 1 <sup>st</sup>	December 31 <sup>st</sup>	Oct 1 <sup>st</sup> – Sept 30 <sup>th</sup>

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

No exemption is being requested. The expiration date will be displayed.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

This information collection activity will comply with the requirements in 5 CFR 1320.9.