

Supporting Statement A

HIV Quality Measures Module

OMB Control No. 0915-XXXX

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 data system for the Ryan White Program's HIV Quality Measures (HIVQM) Module. 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)) can use to monitor their performance to providing quality HIV services. See Attachment A for a copy of the 2009 legislation as codified under Title XXVI of the Public Health Service Act. The HIV/AIDS Bureau within HRSA of the United States Department of Health and Human Services (DHHS) administers funds for the RWHAP. The program is authorized by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87), first enacted in 1990 as the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act and was amended and reauthorized in 1996, 2000, and 2006.

The RWHAP provides entities funded by the program with flexibility to respond effectively to the changing HIV epidemic, with an emphasis on providing life-saving and life-extending services for people living with HIV. There are also legislative requirements that all RWHAP recipients must follow such as the establishment of clinical quality management programs to assess their HIV services according to the most recent Public Health Service guidelines and to develop strategies to improve access to quality HIV services.¹ In 2013 the HIV/AIDS Bureau (HAB) 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;

¹ See Sections 2604(h)(5), 2618(b)(3)(E), 2664(g)(5), and 2671(f)(2) of the PHS Act.

- 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) ADAP (RWHAP's drug assistance program) and 9) system level. The HIVQM Module was created by the HAB to be the online tool to facilitate recipients in meeting the clinical quality management program requirement. The use of the module is voluntary for RWHAP recipients and subrecipients, but strongly encouraged.

2. Purpose and Use of Information Collection

Recipients can enter data in the 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 will provide 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 RWHAP and to monitor improvements in the HAB performance measures over time.

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). Users must obtain or learn this technology for other RWHAP purposes beyond the use of the HIVQM Module. 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. See Attachment B for the HIVQM Module Draft Manual.

4. Efforts to Identify 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 #0915-0323, 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 performance.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study. 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 of Collecting the Information Less Frequently

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

Section 8A:

A 60-day Federal Register Notice was published in the *Federal Register* on November 25, 2015, vol. 80, No. 227; pp. 73776-73778. See Attachment C for the 60-Day Notice. There were no public comments.

Section 8B:

The HIVQM Module was piloted in March 2016 among RWHAP recipients who had previously participated in User Acceptance Testing of the module in the EHB. They were provided screenshots of the module and asked how long it would take them to complete the module. Many of the recipients said they would be able to pull the data from another source and then manually enter the data into the module. One recipient said that this data collection may duplicate their existing data collection activities, however, others shared that reports generated from the module could be helpful in assessing their performance measures. Most of the recipients who responded with a burden estimate said that the data entry would take an hour or less. Below is the list of recipients who responded with an estimate burden:

Marcia King
Unconditional Love, Incorporated.
Tel: (321) 253-0846
Email: mking@chcfl.net

Don Calhoun
University of Virginia
Email: cal482250@yahoo.com

Julia Cohen
New York City Department of Health and Mental Hygiene
Tel: (347) 396-7455
Email: jcohen8@health.nyc.gov

Tara Radke
El Rio Santa Cruz Neighborhood Health
Tel: (520) 629-2888
Email: tarar@elrio.org

Jeffrey Vollman
North Georgia Health District
Tel: (706) 281-2360
Email: Jeffrey.vollman@dph.ga.gov

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.

This data collection does not require IRB approval.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

12. Estimates of Annualized Hour and Cost Burden

The annual burden estimates displayed below are based on consultations with recipients who had previously tested the system functionalities of the HIVQM Module. The estimated annual time and cost burdens to respondents are presented in the tables below:

12A. Estimated Annualized Burden Hours

| Type of Respondent | Form Name | No. of Respondents | No. Responses per Respondent | Total Responses | Average Burden per Response (in hours) | Total Burden Hours |
|--------------------|--------------|--------------------|------------------------------|-----------------|--|--------------------|
| RWHAP Recipient | HIVQM Module | 2,316 | 4 | 9,264 | 1 | 9,264 |
| Total | | 2,316 | 4 | 9,264 | 1 | 9,264 |

The annualized burden costs for recipients is based on the 2010 Bureau of Labor Statistics annual earnings table of full-time state and local government workers,
<http://www.bls.gov/ncs/ocs/sp/nctb1514.txt>. A respondent takes 1 hour per response for 3 responses and is paid \$17.38 per hour. The total costs per respondent annually is \$52.14.

12B. Estimated Annualized Burden Costs

| Type of Respondent | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|-------------------------------|--------------------|------------------|------------------------|
| Health Information Technician | 4 | \$17.38 | \$69.52 |
| Total | 4 | | \$69.52 |

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 contract task that supported 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 5) at 12%

(approximately \$12,500) and a GS 14 (Step 5) at 6% (approximately \$7,400) time to monitor the project. The estimated total cost is \$139,900.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

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 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 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 to enter annual data three times a year. Below is the schedule specifying the annual period.

| HIVQM Module Opens | HIVQM Module Closes | Measurement Year/ Period |
|---------------------------|----------------------------|-------------------------------------|
| November 1, 2016 | November 30, 2016 | September 1, 2015 – August 31, 2016 |
| March 1, 2017 | March 31, 2017 | January 1, 2017 - December 31, 2017 |
| July 1, 2017 | July 31, 2017 | May 1, 2016 - April 30, 2017 |

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

The OMB number and Expiration date will be displayed on every page of the instrument.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.