Supporting Statement A

Special Study—Emerging Issues Related to Affordable Care Act Implementation: The Future of Ryan White HIV/AIDS Services: A Snapshot of Outpatient Ambulatory Medical Care

Terms of Clearance: None.

Justification

1. Circumstances Making the Collection of Information Necessary

The Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) is requesting approval from the Office of Management and Budget (OMB) to conduct site visits for the *Special Study-Emerging Issues Related to ACA Implementation: The Future of the Ryan White Services: A Snapshot of Outpatient Ambulatory Medical Care* project. This is a new project request targeting the collection of programmatic level data (e.g., core medical and support services provision, gaps in services) through one-on-one and group interviews with Ryan White HIV/AIDS Program (RWHAP) grantee personnel. Data collected through interviews will occur early and later in the first year of the Affordable Care Act (ACA) implementation. For the purposes of this request, the Early Implementation Site Visit Interview Guide (Attachment A), Later Implementation Site Visit Interview Guide (Attachment B), and List of Site HIV Outpatient Ambulatory Medical Care Visit Activities/Services (Attachment C) has been included for review.

The Ryan White HIV/AIDS Program (RWHAP) provides HIV-related services in the United States for those who do not have sufficient health care coverage or financial resources for coping with HIV disease. Starting January 1, 2014, the ACA will begin making health care coverage available to many HIV-positive individuals who did not previously have access to such coverage. This ACA expansion of health coverage will impact a significant portion of Ryan White HIV/AIDS Program's (RWHAP) traditional clients who will be moving into third party reimbursement care. The transition will require increased support and coordination to ensure that clients do not experience gaps in coverage or gaps in care. The purpose of this evaluation study is to assess the status of Ryan White services during the early and later stages of ACA implementation and to collect information on service provision, quality of care, barriers, gaps, and challenges related to ACA implementation. Interviews conducted with RWHAP grantee providers during site visits are an integral part of efforts to evaluate: (1) how and to what extent RWHAP providers are adapting their service models to serve their clients in the new ACA health care coverage environment; 2) the changes in the types of services they receive; and 3) provider's perceptions of care coordination and quality.

Immediately following the early stage of ACA implementation (defined as January – June 2014), HRSA will conduct in-person site visits to 30 RWHAP grantee provider sites to interview two-to-four provider staff at each site about their facility's implementation of the RWHAP under ACA implementation. Follow-up interviews will occur with each of these sites immediately following later stage implementation (defined as July-December 2014). Up to 15 of sites will receive a second site visit as part of the follow-up, the remainder will be conducted by telephone. Participation in the interview process will be voluntary and not a condition of the grantee's funding. The site visit protocol was designed to collect information about models of care, the essential package of services needed for a RWHAP client, specific package of services received by clients during RWHAP-funded outpatient ambulatory medical care visits, gaps in services, challenges in receiving services, and how providers are addressing budgeting, staffing and service provisions both early and later in ACA implementation.

This program is authorized under Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment D).

2. Purpose and Use of Information Collection

The ACA will offer new options for obtaining health care services for many individuals with HIV. Due to these changes, additional information concerning staffing, continuity and coordination of care, and utilization of RWHAP funds to provide essential services are necessary. Data from this evaluation study will be used to assess the status of Ryan White services during the early and later stages of ACA implementation and how well the RWHAP is positioned to improve clinical outcomes, including viral suppression, retention to care, and linkage to care services.

The following questions provide a sample of the program-level questions that HRSA plans to ask during the site visits:

- What are the different care models/approaches to care used by various grantee providers?
- What is the essential package of services needed for a RWHAP client? What is the specific package of services received by a client during a RWHAP-funded outpatient ambulatory medical care visit?
- What challenges do HIV/AIDS clients face in receiving core medical and support services?
- From a health systems perspective, how is a RWHAP provider site addressing budgeting, staffing, services provisions, during early and later ACA implementation?
- How are RWHAP grantee providers preparing for changes in billing, cost, and other financial considerations as a result of ACA implementation?

HRSA will use the information obtained through the site visits to:

- Describe each site's service model and how the model differs for clients at different stages of their care ;
- Identify the essential package of services needed for RWHAP clients and what services clients engaged in an outpatient ambulatory care visit receive;
- Inform an analysis of gaps in services and untended interruptions in continuity of care;
- Describe the changes made by provider sites in terms of staffing, budgeting, and services related to ACA implementation.
- Provide each of the above both at early and later implementation of the ACA to monitor trends over time.

3. Use of Improved Information Technology and Burden Reduction

We anticipate collecting all site visit data via in person and telephone interviews and therefore will not utilize electronic data collection because lengthy written responses to open-ended interview questions are typically more burdensome than verbal responses to these same questions. To further minimize burden, we have designed questionnaire tools and interview guides that ensure that the discussion is limited and the questions are well-organized, flow well together, and are easy to understand and answer. Interviews will be scheduled at a date and time that is convenient for the interviewee. Only the minimum information necessary will be collected for this project.

4. Efforts to Identify Duplication and Use of Similar Information

The overall evaluation strategy of this project utilizes two sources of data: (1) Ryan White HIV/AIDS Services Report (RSR) and (2) site visit materials. Of these two sources, only the site visit interview guide materials will be addressed within this request for OMB approval, as the RSR was previously submitted and approved by OMB separately. RSR provides client-level information concerning treatment and service utilization numbers and will provide data to support the site visit data. Site visits, however, focus on qualitative program-level data that will contextualize the information obtained through the RSR and provide data that is not captured through these mechanisms.

The site visits are necessary because there is no source of current, complete information on the status of ACA implementation in RWHAP grantee facilities. This data collection is project-specific.

5. Impact on Small Business or Other Small Entities

No small businesses will be involved in this study.

6. Consequences of Collecting the Information Less Frequently

The information provided through the data collection will be vital to understanding of the impact of ACA implementation on RWHAP-funded facilities. Data collection will be

conducted twice throughout the duration of the contract period – once during the early implementation period of ACA and again later in ACA implementation period. Without collecting this data twice, HRSA will not be able to identify progress in the implementation and the longer term outcomes of the ACA on RWHAP-funded programs.

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines in 5 CFR 1320.5

The collection of information fully complies with the guidelines in 5 CFR 1320.5(d)(2).

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 January 3, 2014, Vol. 79, No. 2, pp. 398-399) which solicited comments on this data collection (See Attachment D). There were no public comments.

Section 8B: The RWHAP is a unique program established by HRSA and the most significant aspects of ACA implementation began recently on January 1, 2014. Because ACA implementation is relatively new, no data collection has been conducted by HRSA or other agencies to determine its associated impacts on RWHAP service provision and resource capacity. Therefore, there is no similar or duplicate information that will suffice for the information collected for this project.

In February 2014, HRSA's contractor pretested the interview guide with study staff to refine wording, increase efficiency, and assist with burden estimates. Comments provided were incorporated into revised versions of the interview guide and data collection tools.

In April 2014, HRSA's contractor will conduct a site visit with representatives of one of the selected facilities in order to pilot test the interview guide and services list. The overarching goals of the pilot test will be to assess, field test, and refine the interview guide and services list.

9. Explanation of any Payment/Gift to Respondents

No payments or gifts will be provided to respondents for participating in the data collection.

10. Assurance of Confidentiality Provided to Respondents

Data will be obtained from various individuals involved in implementing the program, including the: Program Administrator, Clinic Director and direct service staff (e.g. clinician, case manager, outreach worker). Data will be kept confidential to the extent allowed by law.

HRSA will likely be able to associate particular service models and Medicaid expansion status with specific facilities in their reports. Therefore, the identities of the respondents will be easily recognized. However, the questions on facility's policies and practices and the information from respondents is part of their regular business knowledge and there are no questions of a personal nature or the personal choices or behaviors of respondents. Thus, Abt's IRB has deemed the proposed activities eligible for exemption as non-sensitive data collection with professional stakeholders (see Attachment E for IRB Waiver Letter)

11. Justification for Sensitive Questions

There are no questions of a sensitive nature in the assessment form.

12. Estimates of Annualized Hour and Cost Burden

The total burden for the individual for data collection participation is estimated at 180 minutes for HIV Providers and 210 minutes for Administrators. Time estimates are based on experience with similar instruments in other studies of comparable organizations. In addition, the interview guide and tools were pretested (see Section A.8).

12A: Number of Respondents, Frequency of Response, and Annual Hour Burden

This assessment focuses on changes in the type and amount RWHAP-funded services provided to clients. In our experience we have found that most individual RWHAP clients are unaware of which services that they receive are funded by RWHAP, or some other funding mechanism. For this reason we will only being interviewing staff and will not interview individual RWHAP clients.

Exhibit 1 shows the number of respondents, frequency of response, and annual hour burden for the proposed project. The Early Implementation Site Staff Interview Guide will have 90 respondents [Number of sites = 30, Number of respondents per site = 3] and will take an average of two hours (120 minutes) for each of the three respondents to complete. The Later Implementation Site Staff Interview Guide will have 90 respondents [Number of sites =30, Number of respondents per site = 3] and will take an average of 1 hour (60 minutes) for each of the three respondents to complete. The List of Site HIV Outpatient Ambulatory Medical Care Visit Activities/Services will have 30 respondents [Number of sites=30, Number of respondents per site=1] and will take an average of 30 minutes to complete. For all of these instruments, it is estimated that the total burden will be 285 hours. The early implementation interviews and list of site HIV outpatient ambulatory medical care visits activities/services will be conducted after six months of the ACA implementation and later implementation interviews will be conducted after 12 months of ACA implementation. Different sections of the interview guides will be utilized with different types of respondents.

Exhibit 1. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
HIV Providers	Early Implementation Site Staff Interview Guide	60	1	2	120
Administrators	Early Implementation Site Staff Interview Guide	30	1	2	60
HIV Providers	Later Implementation Site Staff Interview Guide	60	1	1	60
Administrators	Later Implementation Site Staff Interview Guide	30	1	1	30
HIV Providers	List of Site HIV Outpatient Ambulatory Medical Care Visit Activities/Services	30	1	30/60	15
Total					285

12B: Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/ Capital Costs

Exhibit 2 offers an estimate of reporting burden for a sample of 60 HIV Providers to complete a 120-minute Early Implementation Site Staff Interview Guide and 60-minute Later Implementation Site Staff Interview Guide for a total of 180 hours (Attachment A and B). The exhibit also offers an estimate of reporting burden for a sample of 30 Administrators to complete a 120-minute Early Implementation Site Staff Interview Guide, a 60-minute Later Implementation Site Staff Interview Guide, and a 30-minute List of Site HIV Outpatient Ambulatory Medical Care Visit Activities/Services for a total of 105 hours (Attachment A, B, and C).. Based on U.S. Government Bureau of Labor Statistics data published for May 2012 (posted at http://www.bls.gov/oes/current/oes_nat.htm), we estimate an hourly wage of $44.18 for HIV Providers and an hourly wage of $47.34 for Administrators. Other than their time to complete the interview, there are no direct monetary costs to respondents.

Exhibit 2. Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
HIV Providers	180	$44.18	$7,952.40
Administrators	105	$47.34	$4,970.70
Total			$12,922.10

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

There is no capital/startup or operation and maintenance cost to respondents involved in collecting the information.

A.14. Annualized Cost to Federal Government

The project will span 24 months and begin in late 2013 and end in late 2015. The total estimated cost to the Federal Government for the *Special Study—Emerging Issues Related to Affordable Care Act Implementation: The Future of Ryan White HIV/AIDS Services: A Snapshot of Outpatient Ambulatory Medical Care* data collection activity is $995,322. This includes the contractor labor cost of creating the sampling plan, developing the interview guide, conducting the site visits, and analyzing the interview responses ($855,382) and the contractor travel costs to conduct 30 site visits at early implementation and an additional 30 site visits at later implementation ($115,940) plus 10% of a GS-14 HRSA employee's (project officer's) time at $120,000 annual salary ($12,000).

Exhibit 3. Annualized Costs to the Government

Year	Contractor	HRSA	Total
2013	$121,415.25	$3,000.00	$124,415.25
2014	$485,661.00	$12,000.00	$497,661.00
2015	$364,245.75	$9,000.00	$373,245.75
Total			$995,322.00

A.15. Explanation for Program Changes or Adjustments

This is a new data collection.

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

Under the guidance and direction of HRSA, the contractor will conduct quantitative and qualitative analyses of the interview responses. An interim report will be prepared following

the early implementation site visits in the first year. A final report will be prepared following the collection of additional data and more extensive analyses. Although the final report will be structured similarly to the interim report, it will present additional analyses that are possible once all data are collected. The project schedule is as follows.

Activity/Deliverable	***Target Date***
Begin early implementation data collection	2 weeks after OMB approval
Interim report to HRSA	16 weeks after OMB approval
Begin later implementation data collection	24 weeks after OMB approval
Draft final report to HRSA	50 weeks after OMB approval
HRSA review of report	54 weeks after OMB approval
Final report and recommendations to HRSA	63weeks after OMB approval

Interview notes, field notes, and any secondary data obtained will be saved in an NVivo 10.0 Database designed for this study. Data coding will occur concurrently with data collection and the data will be integrated as codes in outcome analysis. The codes will aid in the identification of patterns of effective implementation of ACA in RWHAP-funded HIV provider sites.

HRSA will use the information collected to expand their understanding of the HIV provider site's progress with ACA implementation. Assessments from site visits will be documented in internal reports and used to inform annual reporting. Over time, the data collected through site visits will provide HRSA, the HIV provider sites, and other stakeholders with a clearer understanding of the impact of ACA implementation at RWHA-funded facilities; gaps in services; and successes and challenges.

A.17. Reasons Display of OMB Expiration Date is Inappropriate

The expiration date will be displayed.

A.18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.

B. Collections of Information Employing Statistical Methods

Statistical methods will not be used in this data collection.

1. Respondent Universe and Sampling Methods

The respondent universe will be HIV Provider and Administrator staff across RWHAP-funded sites. Thirty Ryan White HIV/AIDS Program sites were selected from 15 States using a purposive sampling strategy to include 1) Medicaid expansion and non-expansion States; 2) areas with high and low prevalence of HIV/AIDS; 3) adequate distribution across various geographic locations (i.e., metropolitan, micropolitan, and rural); 4) sites that reflect the varied types of services provided by the RWHAP; 5) sites with a broad range of the number of clients being served; 6) sites that were funded and delivered Outpatient Ambulatory Medical Care (OAMC), versus only non-OAMC services; and 6) sites that receive a mix of Ryan White Parts A, B, C, and/or D funding.

2. Procedures for the Collection of Information

HRSA's contractor will interview staff at selected RWHAP-funded program sites. Appropriate persons will be identified through consultations with HRSA and RWHAP leadership at each site to include two HIV Providers and one Administrator per site. The interview process will include an interviewer, note-taker, and interviewee(s). Detailed notes will be taken during the course of the interviews, to be reviewed, coded, and analyzed following the interview. Interviews will be recorded if respondents permit.

This project will utilize purposive sampling and is not intended to be representative or generalizable to all RWHAP-funded program sites. Furthermore, no weights will be calculated for analyzing and reporting the site visit results. The final products, including internal reports for HRSA, will contain the descriptive results of the site visits. The reports will provide findings using frequencies and other descriptive statistics.

3. Methods to Maximize Response Rates and Deal with Nonresponse

HRSA's contractor will be conducting the site visits with staff using updated contact information, and therefore expects limited, if any, non-response due to an inability to locate sample members. The interview guides and data collection tools were developed with consideration to length and comprehension level so it is appropriate for staff to complete. HRSA anticipates achieving a 90 percent interview response rate to minimize non-response bias and include a broad range of the provider sites.

4. Tests of Procedures or Methods to be Undertaken

HRSA's contractor pretested the data collection tools, including the interview guides, with study staff to assess the questions that will be asked at site visits. One of the overarching goals of the pretest was to review, field test, and refine the site visit questions. HRSA learned important details about terminology and potential probes informed the questions asked in the interview guide. Additionally, the interviews were helpful in determining the amount of time needed to conduct an interview.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

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List of Attachments

Attachment A:	Early Implementation Site Visit Interview Guide
Attachment B:	Later Implementation Site Visit Interview Guide
Attachment C:	List of Site HIV Outpatient Ambulatory Medical Care Visit Activities/Services Table
Attachment D:	Public Law 111-87-Oct 30, 2009 (123 STAT. 2885)
Attachment E:	60-day Federal Register Notice
Attachment F:	IRB Waiver