Supporting Statement A

Ryan White HIV/AIDS Program Outcomes and Expanded Insurance Coverage

Terms of Clearance: None.

A. Justification

A.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) for data collection activities to evaluate **Ryan White HIV/AIDS Program (RWHAP) Outcomes in a Changing Healthcare Landscape**. The data to be collected focus on the effect of different types of healthcare coverage has on RWHAP client outcomes. These data include types of the healthcare coverage that clients obtained, their access to and use of RWHAP core medical, pharmaceutical and support services, as well as their HIV and other primary healthcare outcomes. Data collection will occur through medical chart/ records abstraction, site staff interviews via phone and limited site visits, client focus groups, and web-based surveys of site administrators. For the purposes of this request, the following documents have been included for review: Medical Chart/ Records Abstraction Tool, Site Interview Guide, Focus Group Guide, and Site Survey.

HRSA/HAB implements the RWHAP to provide HIV-related services in the United States for individuals who do not have sufficient healthcare coverage or financial resources for managing their HIV disease. The expansion of healthcare coverage now offers new options of obtaining healthcare services for many individuals with HIV. Many are now eligible to receive third party reimbursement care through the expansion of healthcare coverage options. These changes have required that RWHAP service providers and clients adapt in order to; coordinate RWHAP-funded services with new third party healthcare coverage to avoid fragmentation of care and fill gaps in services experienced by clients across the varying healthcare coverage options.

The purpose of this evaluation study is to determine the effect that healthcare coverage has had on overall health outcomes, service utilization, and gaps in care for people living with HIV who receive services within RWHAP. (The scope of the evaluation study is limited to only clients receiving services and sites funding through the RWHAP.) This evaluation seeks to understand how Ryan White HIV/AIDS Program provider sites meet the needs of clients under the variety of healthcare coverage options clients are encountering with the healthcare coverage across the country.

The following table describes the evaluations questions (primary and supporting) and corresponding data source and analysis this evaluation study.

Table 1: Evaluation Questions by Data Source and AnalysisOverall Outcomes			
Evaluation Question	**Supporting Evaluation Questions**	**Data Source**	**Analysis**
1. What is the effect on all client health outcomes (e.g. viral suppression, retention prescription of antiretroviral therapy, recipient of clinical screenings, etc.) for RWHAP clients who have received healthcare coverage after January 2014?	• Do client outcomes differ stratified by type of coverage: Medicaid, private insurance, no insurance? • Do rates of access and utilization of RWHAP core medical and support services differ stratified by type of coverage: Medicaid, private insurance, no insurance? • Do health insurance-related factors (e.g. cost-sharing, type of healthcare coverage cost of premium, or others) affect RWHAP client's healthcare outcomes? • Do challenges accessing and utilizing core medical or support care services differ stratified by type of coverage: Medicaid, private insurance, no insurance? • What are specific gaps in the client's healthcare coverage that the RWHAP helps to fill stratified by type of coverage: Medicaid, private insurance, no insurance? • What challenges or barriers limit covered RWHAP clients' utilization of healthcare coverage?	• Charts /Records Abstraction • RSR Client Data • Site Survey • Site Interview	• Qualitative and quantitative: Assess differences in use patterns across healthcare coverage options. • Qualitative and quantitative: Assess differences in key primary healthcare outcomes for RHWAP clients by type of healthcare coverage. • Qualitative and quantitative: Determine changes in healthcare outcomes for RHWAP clients before and after January 2014. • Qualitative and quantitative: Investigate baseline client characteristics and health outcomes. • Qualitative: Examine the different barriers to care and limits in RWHAP core medical and support services that exist across health care coverage options. • Qualitative and quantitative: Analyze RWHAP core medical and support services use patterns among clients before and after January 2014.

2. Which RWHAP services contribute most to a client's retention in care and viral suppression?	• Do the types of core medical or support services associated with client retention and viral suppression differ stratified by type of coverage: Medicaid, private insurance, no insurance? • Does access to HIV pharmaceuticals differ stratified by type of coverage: Medicaid, private insurance, no insurance? • To what degree are clients changing healthcare cover for pharmaceuticals (e.g. ADAP provided, Medicaid, private insurance)? • Does the frequency of switching pharmaceutical coverage effect retention in care and viral suppression? • Are there differences in client characteristics or service utilization patterns associated with clients who have high rates of service utilization and poor retention in care and viral suppression? • What effects would it have on clients if the RWHAP support services were not available?	• Charts /Records Abstraction • RSR Client Data • Site Survey • Site Interview	• Qualitative and quantitative: Analyze associations between retention in care and viral suppression and varying healthcare coverage factors such as type of coverage, cost-sharing, and access to services (including pharmaceuticals). • Qualitative and quantitative: Determine RWHAP core medical service use patterns most associated with successful retention and suppression • Qualitative and quantitative: Determine varying types, levels, and sufficiency of pharmaceutical coverage across all healthcare coverage options. • Qualitative: Gather service provider and client perspectives on the role of RWHAP support services in maintaining retention and viral suppression. • Qualitative: Examine the anticipated direct and indirect effects on retention in care and viral suppression among clients not accessing RWHAP support services. • Quantitative: Investigate the level of RWHAP clients switching between insurance-based pharmaceutical coverage and support. • Quantitative: Assess the effect switching healthcare coverage has on retention in care and viral suppression.

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

A.2. Purpose and Use of Information Collection

The changing healthcare landscape offers new options of obtaining healthcare services for many individuals with HIV. Due to these changes, additional information concerning overall client health outcomes, pharmaceutical and core medical processes and outcomes, and client service utilization is needed. Data from this evaluation study will be used to provide HRSA/HAB with the necessary information to understand the changes in primary healthcare outcomes of RWHAP clients, before and after January 2014. This understanding will inform how the RWHAP can best serve clients in the changing healthcare landscape.

Medical chart/records abstraction, site interviews, focus groups, and site surveys will provide the data necessary to conduct the evaluation. The following presents a description of the data to be collected:

Medical Chart/ Records Abstraction – On-site: Medical chart/ records abstraction will be conducted for up to 15 clients at each of 25 purposively-selected sites, for a total of 375 clients in all. Instrumentation for data abstraction will include a record abstraction protocol and a web-based abstraction form. Medical records data abstraction will include demographics, medical visit frequency, prescribed antiretroviral therapy, HIV clinical data (including ICD 9/10 codes), laboratory results, comorbidity data, substance use and/or mental health data, preventive screening and counseling, vaccinations, hospitalizations, and any gaps in care (e.g., lost or no longer in follow up). If available, we will also collect data regarding Emergency Department visits, as well as substance use and mental health treatment facility stays. Additional billing and health coverage sections will focus on healthcare coverage sources (e.g., Medicaid, QHP, supplemental, no coverage) and on identifying gaps in coverage. The data will be HIPAA de-identified and individual client consent will not be required[1], unless a clinic chooses to add such an additional requirement.

Site Interviews – Telephone and Face-to-Face: Using structured interview protocols, we will conduct site interviews with up to 25 purposively-selected sites via phone (up to six will be conducted in person to coincide with the on-site client focus groups). Each interview will be conducted jointly with a RWHAP site administrator and senior service provider. Interviews will focus on the provider site's perception of the changing healthcare landscape effect on client health outcomes and service utilization, as well as facilitators and barriers to overcoming gaps in services. The information gathered will be used to inform our understanding of how different types of healthcare coverage facilitate or challenge clients' ability to obtain a full array of needed services. We will include questions about the kinds of support services that are available or unavailable to clients through health care coverage

[1] http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/research/index.html

options. We will also explore the level of coverage offered for such support services compared to RWHAP-funded services. Finally, we will gather information which support services would potentially become unavailable (or significantly reduced) for clients if RWHAP funding was not available. The interviews will also explore client access to pharmaceuticals after January 2014, including the extent to which clients are changing medication coverage, including Medicaid, QHP and ADAP coverage and how changes affect comprehensive and continuous coverage. The site interviews allow for greater context and follow-up discussions regarding the "how" and "why" behind the answers to questions. This information is extremely useful in better understanding nuances not captured in close-ended survey responses and medical chart/record abstraction..

Focus Groups – Face-to-Face: On-site client focus groups will be conducted by the study team at up to six study sites. We will ask sites to gather a convenience sample of up to 10 clients with differing types of healthcare coverage, including no healthcare coverage. The focus groups will employ a guide to query participants regarding issues such as their experiences before and after January 2014, how healthcare coverage affects access to care including pharmaceuticals, experiences with enrolling, disenrolling and other changes in ADAP, Medicaid and QHP pharmaceutical coverage. Respondents will also be queried about the services they receive that help them best manage their HIV and other health conditions. Client perspective is particularly important to test and validate provider perceptions of the client experience.

Site Surveys – Online: We will survey all providers that offer outpatient ambulatory care (OAMC) services to clients (some providers only provide non-clinical support services); we expect to receive responses from at least 305 providers. This survey will inform efforts to better understand potential health insurance utilization and its effect on healthcare access. The survey will address barriers to health insurance utilization, including client cost sharing requirements, adequacy of provider networks, and utilization controls. To understand how providers are leveraging the RWHAP in the changing healthcare landscape, we will include questions on the role the program can play in reducing these barriers. The survey will also address provider perceptions of which core medical and support services are most essential for retention in care and viral load suppression, as well as the effect of insurance coverage on clients' ability to access these essential services. The survey is designed to begin to inform understanding of clients' experiences and outcomes by type of healthcare coverage (e.g., Medicaid expansion, QHP and uninsured). Finally, the survey will address client access to pharmaceuticals after January 2014, including extent to which clients are changing medication coverage, including Medicaid, QHP and ADAP coverage and how changes affect comprehensive and continuous coverage.

We estimate that this evaluation study will encounter unavoidable limitations due to the types of data collection instruments, which may result in over or understatement of the conclusions. The site interviews, focus groups, and site surveys will gather self-report qualitative data. Self-reported data are at risk of threats to reliability and validity. For

example, the participants may not understand the questions, provide a desired answer, or provide inaccurate or misleading information. To address the limitation, we are taking a number of steps. We constructed the tools to ask open-ended questions and trained the interviews on the evaluation study purpose and objectives. Additionally, we will use the qualitative information collected to contextualize the quantitative information.

A.3. Use of Improved Information Technology and Burden Reduction

We anticipate collecting data in-person, via telephone, and via an online data collection system.

Medical Chart/Records Abstraction—On-Site: All Medical Chart/Records Abstraction will be completed on-site at 25 sites for up to 15 clients. Site staff will be involved for approximately one hour to identify and provide access to the records that will be abstracted. To minimize burden, the Abt Team will conduct all chart/records abstraction without the assistance of site staff. All data will be entered into a data entry application being developed by Abt. The laptops used for data collection will employ full disk encryption. The application is designed to erase the source file upon confirmation of automatic upload to Abt's secure servers. Each file will only be identified by an encrypted unique client identifier (eUCI) created using a hashing algorithm that prevents recovery of the source data used to create it. The system will automatically generate the eUCI using information from: the first and third letters of the client's first name, the first and third letters of the client's last name, the full date of birth (DOB) and gender. Once entered, this information will automatically be converted to the eUCI - and the DOB will be transformed to age. The data entry program will simultaneously delete the name and DOB. Therefore, no personally identifying information will be transferred or saved in this upload (e.g., initials of client and date of birth). These pieces of information will only be used to create the unique client ID and then will be deleted before upload. In addition, any other data that could be a HIPAA identifier will be converted at the time of entry (e.g., service event will be recorded as month and year only).

Site Interviews—Telephone and Face-to-Face: Interviews will be conducted by primarily by telephone. Detailed notes will be taken in Word. Face-to-face interviews will be conducted only at sites in which in-person focus groups are planned (up to six sites). The interviews will be an average of two hours in length. Site interviews will not utilize electronic data collection, beyond electronic notetaking in Word for both. To further minimize burden, we have designed 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.

Focus Groups—Face-to-Face: All focus groups will be conducted face-to-face with clients. The decision to conduct face-to-face focus groups is based on the need to develop and maintain rapport between the focus group facilitator and participants. During the face-to-face focus groups, evaluation staff will have the ability to probe and provide clarification on complex questions. Focus groups will not utilize electronic data collection, beyond electronic notetaking in Word. To further minimize burden, we have designed the focus group protocol to 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 client participants. Only the minimum information necessary will be collected for this project.

Site Surveys—Online: Site surveys will be conducted using FluidSurveys, an online data collection platform. Technology will be used to manage, secure, and store the data to ensure data management control. Using protected electronic data is the most secure form of data management because it eliminates the possibility of paper documents being lost by the survey staff or data being lost in transit or delivered to an incorrect location. Additionally, an online survey will reduce the burden on the site administrators completing the survey, since they will have the flexibility to complete the survey at their convenience. Data reflected in these surveys will be aggregated and will not contain any personally identifiable information that can or could be mapped back to an individual site.

A.4. Efforts to Identify Duplication and Use of Similar Information

The overall evaluation strategy of this project utilizes five sources of data: (1) Ryan White HIV/AIDS Services Report (RSR, OMB control number 0915-0323)/ ADAP Data Report Data (ADR; OMB control number 0915-0345) both already collected by HAB; (2) Site Surveys; (3) Site Interviews; (4) Focus Groups; and (5) Medical Chart/ Records Abstraction. Of these five sources, only the medical chart/records abstraction, site interviews, focus groups, and site surveys will be addressed within this request for OMB approval, as the RSR/ADR was previously submitted and approved by OMB separately. RSR/ADR provides client-level RWHAP service utilization and HIV outcomes, but is limited in scope and does not contain other primary care service utilization and outcomes data, nor does it allow for observing changes in healthcare coverage through the year. However, it does provide some level of service utilization and health outcomes data for the entire RWHAP client population that will be useful for comparison and estimation.

Site survey data will provide quantitative information regarding the changing healthcare landscape. Site interviews and focus groups focus on qualitative program-level data that will contextualize the information obtained through the RSR and the survey and provide data that is not captured through these mechanisms. Medical Chart/ Records will provide client-level data that cannot be captured in the interviews, focus groups, surveys, or RSR/ADR data. The

Medical Chart/ Records Abstraction data provides the key health outcome and service utilization data, as well as the healthcare coverage data.

Given the complexity inherent changing healthcare landscape and its effect on RWHAP clients, healthcare providers, and services, no extant or single data source can provide sufficient information to answer the key evaluation questions of this study. Triangulating across the qualitative and quantitative data sources described above will enable the answering of critical project-specific questions.

A.5. Impact on Small Business or Other Small Entities

Information collection will not have a significant effect on small entities.

A.6. Consequences of Collecting the Information Less Frequently

During this evaluation, the frequency of data collection from the sites and the clients they serve is held to the minimum necessary to meet the evaluation objectives. Data collection of each type will only be conducted once.

A.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).

A.8. Consultation Outside the Agency

A Federal Register Notice was published on June 24, 2016 (Volume 81, No. 122, page 41313-41214) which solicited comments on this data collection. Comments were received from two organizations: Academy of Nutrition and Dietetics and God's Love We Deliver. Both sets of comments focused recognizing the importance of food and nutritional services in RWHAP services and client's overall health outcomes. The current study design focuses on all aspects of RWHAP services, including food and nutritional services supportive services and their effects on overall client health. This was already an intended part of the study focus; therefore, no changes are required.

The Abt Team consulted with five RWHAP sites similar in size and scope to those that will be involved in the study to determine the appropriateness and level of burden regarding the data collection instruments and approach.

A.9. Explanation of any Payment/Gift to Respondents

Gift cards with a value of no more than $20 from major stores (e.g., Walmart, TARGET) will be used as an incentive for clients to participate in the focus groups, as well as to reimburse

them for their time and contribution to the study. Although participation in the focus groups is voluntary, respondents are likely to perceive a time cost and burden associated with their participation. Survey research literature suggests monetary incentives increase response rate, with no known adverse effect on reality (Dillman, 1978, 2000).

A.10. Assurance of Confidentiality Provided to Respondents

HRSA will review the evaluation design and procedures to ensure they meet industry standards to protect participants. This review will also ensure compliance with the spirit and the letter of regulations from the Department of Health and Human Services (DHHS) governing such projects. Systems and procedures for collecting and processing data are designed to help ensure the protection of participants and the data they provide. Abt will ensure this project has a data security plan that is compliant with applicable Department of Health and Human Services policies on information security, including HHS-OCID Policy for Information Systems Security and Privacy. All data will be transmitted securely via FTP and will be maintained on secure servers.

Data will be obtained from various individuals involved in implementing the program, including Site Administrators and Healthcare Providers (e.g., senior clinician). Data will also be collected from clients who have received program services via focus group discussions. Focus group participation is voluntary. Clients will be provided with the purpose of the study and what taking part in the focus group will involve. If the client chooses to participate, he/she will be asked to provide verbal consent stating that he/she understands the purpose of the study, is willing to participate but can change his/her mind at any time, and that all information gathered will be stored securely (as evidenced by compliance with Department of Health and Human Services policies on information security, including HHS-OCID Policy for Information Systems Security and Privacy) and used only for the purposes of this study. Verbal consent is preferable as the signed consent form would create the only identifier indicating client participation in providing data about potentially sensitive topics.

All 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 the study reports. Therefore, the identities of the respondents may be recognized by HRSA staff. However, questions on the site's policies, practices and experiences with changing healthcare landscape are part of their regular business knowledge and there are no questions of a personal nature or the personal choices or behaviors of respondents.

HRSA and DHHS reviewed and approved the privacy impact assessment for this project in March 2017.

A.11. Justification for Sensitive Questions

The focus group will include questions about HIV care and treatment. It will also include questions regarding participation in Medicaid coverage (indirectly asks about income) and receipt of HIV medical services. It is necessary to ask questions about client participation in Medicaid and HIV services received to assess availability of services based on coverage type. As part of consent procedures, respondents will be explicitly informed that they have the right to refuse to answer any question they may deem sensitive. All participants of the focus group are RWHAP clients, meaning all participants will be among peers also receiving HIV care; hopefully reducing some of the stigma attached with certain sensitive questions. In addition, the focus will be facilitated by and Abt team member with many years' experience working with and conducting studies involving RWHAP clients.

A.12. Estimates of Annualized Hour and Cost Burden

A.12.1. Number of Respondents, Frequency of Response, and Annual Hour Burden

The Abt Team consulted with five RWHAP sites similar in size and scope to those that will be involved in the study to determine the appropriateness and level of burden regarding the data collection instruments and approach. The input provided was used to develop the estimates presented in Exhibit 1. Exhibit 1 offers an estimate of the reporting burden for a sample of 440 respondents to site surveys, medical records sample selection guide, site interviews, and focus groups. For all four instruments, it is estimated that the total burden will be 417.5 hours.

- The medical chart/ records abstraction will collect information from up to 15 records per site; [Number of sites =25, Number of staff helping to identify sampled cases per site =1] and will take an average of 1 hour (60 minutes) for the Site Administrator to help to identify sampled cases for medical chart/records abstraction. Abt Project Staff will conduct the actual medical chart/records abstraction after receiving guidance from the Site Administrator.
- The site administrators will also be asked to identify and recruit focus group participants; estimated time – 1 hour per site.
- The site interviews will have 50 respondents [Number of sites =25, Number of respondents per site = 2] and will take an average of 2 hours (120 minutes) for each respondent to complete. Site Administrators and Healthcare Providers will participate in the site interviews.
- The focus groups will have 60 respondents [Number of sites=6, Number of respondents per site=10] and will take an average of 1.5 hours (90 minutes) for each respondent to complete. Clients, adults over the age of 18, will participate in the focus groups.

- The site surveys will have 305 respondents [Number of sites = 305, Number of respondents per site = 1] and will take an average of one hour (30 minutes) for each respondent to complete. Site Administrators will participate in the site surveys.
- The total burden for the individual for data collection participation is estimated at 60 minutes for medical records sample selection guides (i.e., Site Administrators), 120 minutes for Site Interviews (i.e., Site Administrators and Healthcare Providers), 90 minutes for focus groups (i.e., clients), and 30 minutes for site surveys (i.e., Site Administrators). Time estimates are based on experience with similar instruments in other studies of comparable organizations.

Exhibit 1: Total Estimated Annualized Burden - Hours

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Site Survey	305	1	305	0.5	152.5
Medical Chart/Record Abstraction	25*	1	25	2	50
Focus Group (recruit participants)	25*	1	25	1	25
Site Interview Guide	50	1	50	2	100
Focus Groups Guide	60	1	60	1.5	90
Total	440*		440*		417.5

*The same respondents will complete the medical chart/record abstraction and recruit participants for the focus group.

A.12.2.Estimates of other Total Annual Cost Burden to Respondents or Record-keepers/ Capital Costs for the Hour Burdens

Exhibit 2 offers an estimate of the cost burden to respondents, by occupation. The following estimates are based on U.S. Government Bureau of Labor Statistics data published in May 2015 (posted at http://www.bls.gov/oes/current/oes_nat.htm).

- The hourly wage for Site Administrators is estimated at $50.99 (average hourly wage for Medical Health Services Managers, as published by the Bureau of Labor Statistics, May 2015). The estimated cost burden for Site Administrators is $20,964.43 [Hours = 277.5, Hourly Wage= $50.99].
- The hourly wage for Healthcare Providers is estimated at $94.48 (average hourly wage for Internists, as published by the Bureau of Labor Statistics, May 2015). The

estimated cost burden for Healthcare Providers is $4,724.00 [Hours = 50, Hourly Wage= $94.48].

- The hourly wage for Clients is estimated at $23.23 (average hourly wage for employees in all occupations in the United States, as published by the Bureau of Labor Statistics, May 2015). The estimated cost burden for clients is $2,090.70 [Hours = 90, Hourly Wage= $23.23].

For all three instruments, it is estimated that the total burden will be 417.5 hours.

Exhibit 2. Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Site Administrators	277.5	$50.99	$14,149.73
Healthcare Providers	50	$94.48	$4,724.00
Clients	90	$23.23	$2,090.70
Total	417.5		$20,964.43

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. Other than the time to participate in medical chart/ records abstraction, site interviews, focus groups, and site surveys there are no direct monetary costs to respondents.

A.14. Annualized Cost to Federal Government

The project will span 24 months from September 22, 2015- September 21, 2017. The total estimated cost to the Federal Government for the *Ryan White HIV/AIDS Program Outcomes in a Changing Healthcare Landscape* data collection activity is $648,218.00. This includes the labor costs to create the sampling methodology, developing the data collection instruments, conducting data collection, and analyzing the survey, interview, medical chart/records abstraction, and focus group responses ($638,218.00) plus 5% of a GS-13 HRSA employee's (project officer's) time at $100,000 annual salary ($5,000).

Exhibit 3. Annualized Costs to the Government

Year	Contractor	HRSA	Total
2016	$120,312.00	$5,000.00	$125,312.00
2017	$517,906.00	$5,000.00	$522,906.00
Total	$638,218.00	10,000.00	$648,218.00

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 collected data. A final report will be prepared following data collection and analyses. The project schedule is as follows.

Activity/Deliverable	*Target Date*
Begin data collection	TBD (once receive OMB approval)
Draft final report to HRSA	TBD (once receive OMB approval)
HRSA review of report	TBD (once receive OMB approval)
Final report to HRSA	TBD (once receive 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.

Medical chart/records abstractions will be conducted using a secure electronic web-based abstraction tool on laptops with full disk encryption and uploaded using Abt's secure servers in a format appropriate for import into SAS.

HRSA will use the information collected to expand their understanding of the RWHAP provider site's progress within the changing healthcare landscape. Over time, the data collected for this project will provide HRSA, the provider sites, and other stakeholders with a clearer understanding of the effect of changing healthcare landscape on healthcare coverage options and client health outcomes, gaps in healthcare, and facilitators and barriers related to utilizing healthcare services.

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

This submission describing data collection requests no exceptions to the Certificate for Paperwork Reduction Act (5 cfr 1320.9).