

Supporting Statement

Understanding and Monitoring Funding Streams in Ryan White Clinics

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), HIV/AIDS Bureau (HAB) administers the Ryan White HIV/AIDS Program (RWHAP) authorized under Title XXVI of the Public Health Service Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009.¹ The RWHAP is a federally funded program that provides grants to states and U.S. territories, eligible metropolitan areas (EMAs), and clinics. The goal of the RWHAP is to improve the quality, availability, and provision of HIV-related medical care and treatment and support services for uninsured or underinsured individuals and families affected by the disease. Since its establishment in 1990, the RWHAP has been providing care and services to more than half a million people with, and affected by, the HIV disease each year.

The RWHAP consists of several “Parts,” corresponding to sections of the authorizing statute. Part A provides emergency relief for areas with substantial need for HIV/AIDS care and support services that are most severely affected by the HIV/AIDS epidemic, including eligible metropolitan areas (EMAs) and transitional grant areas (TGAs). Part B provides grants to States and U.S. Territories to improve the quality, availability, and organization of HIV/AIDS health care and support services. Part B grants include a base grant; the AIDS Drug Assistance Program (ADAP) award; ADAP Supplemental Drug Treatment Program funds; and supplemental grants to States with “emerging communities,” defined as jurisdictions reporting between 500 and 999 cumulative AIDS cases over the most recent 5 years. Part C provides support for the Early Intervention Services (EIS) component of the Ryan White HIV/AIDS Program, including preventive, diagnostic, and therapeutic services for people living with HIV/AIDS (PLWHA) and their affected partners and family members. This support includes a comprehensive continuum of outpatient HIV primary care services including HIV counseling, testing, and referral; medical evaluation and clinical care; other primary care services; and referrals to other health services. Part D grantees provide coordinated family-centered outpatient care for women, infants,

¹ Ryan White HIV/AIDS Treatment Extension Act of 2009, Public Law 111-87 (October 30, 2009). Available from <http://www.gpo.gov/fdsys/pkg/PLAW-111publ87/html/PLAW-111publ87.htm>.

children, and youth infected with HIV/AIDS and their affected partners and family members. The RWHAP is the largest federal program designed exclusively for PLWHA, who have no health insurance (public or private), have insufficient health care coverage, or lack financial resources to get the care they need for their HIV disease. As such, the RWHAP fills gaps in care not covered by other funding sources.

In 2010, the Patient Protection and Affordable Care Act (ACA) was enacted into law. The ACA is expansive and includes a number of reforms that will likely impact the RWHAP. Some of the reforms have already been implemented, including the creation of Pre-Existing Insurance Plans and the barring of insurance carriers from denying coverage to children with pre-existing conditions such as HIV/AIDS, cancelling coverage for adults with health conditions because of unintentional mistakes on the application, or imposing lifetime dollar caps on essential health benefits. On October 1, 2013, insurance marketplaces (exchanges) from which individuals can purchase health insurance opened. Coverage under these plans may begin as early as January 1, 2014. Individuals with incomes from up to 400% of the federal poverty level (FPL) may be eligible for tax credits to reduce premium costs. Individuals with lower incomes may also be eligible for reductions in cost-sharing. Effective January 2014, states will have the option to expand Medicaid to individuals younger than 65 years of age with incomes up to 133% FPL.

The RWHAP program is currently at an important crossroad with the implementation of the ACA. The environment in which the RWHAP operates has changed considerably and policymakers are weighing changes that could influence the RWHAP funding levels, characteristics, and focus of services. The implementation of the ACA and its impact on PLWHA may result in changes being considered for the RWHAP. Part C and Part D currently have a significant role in providing core medical services to PLWHA. Direct medical services and medical case management make up the majority of Part C grant and Part D budgets. RWHAP funds also are used to cover the provision of critical support services to help PLWHA achieve positive medical outcomes. The ACA may impact the RWHAP client population, the requirements regarding the allocation of funds for particular services, and how services are coordinated by Part C and Part D grantees. It may also require a process for better integrating HIV care expertise previously provided through the RWHAP into the mainstream healthcare system. The magnitude of these effects will vary by state, by type of provider, and by whether or not the provider also serves Medicaid, Medicare, or privately insured clients.

HRSA requests OMB approval for a study to gain a better understanding of how RWHAP Part C and Part D grantees currently provide primary outpatient health care and essential support services to uninsured and underinsured clients. It will identify what types of core medical services and subservices, and support services are currently not covered or not fully covered by Medicaid, Medicare, and private insurance, yet are needed to provide high-quality HIV/AIDS care. The study also will provide information on how grantees monitor client healthcare coverage (e.g., payer source, type of insurance) and the cost of care. Together, this information will help HRSA understand the abilities of Part C and Part D grantees to support and track changing and expanded health insurance enrollment for their clients and to adapt to the changing funding landscape.

Lastly, the study will gather information regarding Part C and Part D grantees' level of participation in state-sponsored initiatives for the development of health homes, their relationship with managed care organizations (MCOs), and their status regarding recognition as a Patient Centered Medical Home (PCMH). This information will provide some basic information regarding grantees' ability to continue to serve PLWHA as the ACA is implemented differently among the states.

2. Purpose and Use of Information Collection

The purpose of this data collection is to help inform the development of sound policies to ensure the continuation of quality HIV/AIDS core medical and support services for PLWHA and their families. Since a large share of RWHAP clients are uninsured, the expansion of health coverage under the ACA is likely to change the focus of services needed for care completion. The information collected in this survey will serve two goals. First, it will help HRSA better understand how Part C and Part D grantees are positioned for the ACA given their current use of RWHAP funds in combination with reimbursements from Medicaid, Medicare and private insurance. Second, it will guide development of a technical assistance tool for grantees to track the changing role of RWHAP and other funding streams on their own clients and services.

Existing data collection by HAB documents the number of clients served using RWHAP funds, their characteristics and the services they receive. However, it does not provide information on other PLWHA served by these grantee providers. This survey will gather information on the total number of PLWHA served and non-RWHAP funding sources that also support care for PLWHA. It also asks how RWHAP funds are used to pay salaries for HIV/AIDS specialists or other care providers.

More importantly, the survey will gather information on how Part C and D grantee providers use RWHAP funds not only to care for uninsured clients, but also to support care completion for underinsured clients. In particular, it gathers data on what aspects of care completion for PLWHA are not currently covered or covered only with limitations for clients with Medicaid, Medicare and private insurance. It will also provide insight on how grantee providers are positioning themselves to take advantage of the opportunities for care completion under the ACA. To achieve this, the survey collects information on grantees' tracking of clients' health coverage and eligibility for Medicaid, Medicare or other coverage. It also asks about their agencies' participation in initiatives for the development of health home, recognition as a Patient-Centered Medical Home, and ability to participate in managed care, including knowing their cost of care for PLWHA.

In addition to providing information on the care environment, the survey will inform the development of a technical assistance tool that HAB is creating for Part C and D grantee providers. This "tracker" tool will help grantees use their own data to monitor changes in insurance coverage, service mix, and funding sources as the ACA is fully implemented. The types and level of specificity of internal data available to grantees will determine how many of the features of the tool will be usable by grantees. Therefore, the survey also collects information on the grantees' data systems and practices on capturing costs, reimbursements, services and subservices.

A web-based survey was designed and developed to collect information from a representative sample of Part C and Part D grantees. Grantees that receive Part C, Part D, and both Part C and D funding will be included. In addition, the sample will be drawn from the different types of grantees. These types include publicly-funded community health centers, hospital and university-based clinics, other community-based service organizations, and health departments.

The survey contains 31 items with a mix of multiple choice and open-ended questions (See Attachment A. Survey Instrument). It will be administered online to program directors. The instrument will focus on the following four areas:

1. funding sources used to provide services for PLWHA
2. grantees' ability to track client health coverage and health insurance status change
3. grantees' ability to estimate the cost of HIV/AIDS care by funding source and service category
4. grantees' level of participation in state-sponsored initiatives

Respondents will also have an opportunity to expand on their responses by providing additional feedback in the open-ended text boxes. Respondents will be asked to complete the survey only one time. The data provided will not contain individual or personally identifiable information.

During the recruitment, grantees will receive an introductory e-mail from HRSA introducing the study and informing them they may be contacted about participating. This will be followed by an invitation e-mail from the study team explaining the purpose of the survey and requesting their voluntary participation in the study. They will also receive a participant information sheet that will provide additional information about the purpose of the study. The participant information sheet will inform each respondent that participation is voluntary and the information will be reported in the aggregate. Finally, the e-mail will request a RSVP before an e-mail with instructions for completing the study and a link to the web-based survey is sent. The instructions e-mail will include a printable survey instrument and a glossary of terms attached (see Attachment B. Survey Implementation Materials).

Reminder calls and emails will be sent to grantees to remind them to complete the survey and answer any questions. The study team will monitor the completion of surveys and will focus follow-up efforts to achieve an overall response rate of 80 percent. We will also focus recruitment efforts to ensure appropriate sufficient response rates by all categories of grantee-provider characteristics.

3. Use of Improved Information Technology and Burden Reduction

Respondents will be completing a web-based survey instrument that will be administered via Survey Monkey. This collection method was selected in order to reduce any excess time burden during data entry. Online surveys have many advantages to mail surveys, computer assisted telephone surveys, or paper surveys completed in person/with assistance. Web-based surveys are highly efficient both in completion time for the respondent and in eliminating the need for data entry. The web-based survey will feature skip patterns and will require a response before moving

to the next question in order to reduce the amount of missing data and error in respondents completing the survey without assistance. In addition, the web-based survey will eliminate any other costs incurred by the need for postage, paper, and any other resources that other survey methods may require. The web-survey will be best suited to our sample population who are professionals with regular access to the Internet and are computer literate. Our study population will be able to receive the survey invitations via e-mail and be able to access the survey posted on the Internet.

4. Efforts to Identify Duplication and Use of Similar Information

There have been no previous studies conducted on the interrelationships among common payor sources, or funding streams, in RWHAP-funded Part C and Part D clinical settings. In addition, there is no information available on the ability of Part C and Part D grantees to track expanded health insurance enrollment for their clients to support the provision of RWHAP services to clients.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

6. Consequences of Collecting Information Less Frequently

Respondents will respond to the data collection one time only.

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

This information collection fully complies with 5CFR 1320.5.

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 October 3, 2013, vol. 78, No. 192; pp. 61367-61368 (see Attachment C. 60-Day FRN). Two public comments were received. The first comment requested copies of the study's data collection plan and draft instruments. These requested copies were provided to the respondents. The second comment requested information on sampling methods and suggested to expand the study to address issues related to contracting with and billing marketplace insurers and Medicaid managed care plans. The respondents also expressed concern regarding the time required to complete the study survey.

A response was prepared and sent to the commenting organization. A description of the study's stratified random sample with replacement approach was provided. The response also noted that although the study does not specifically address issues related to contracting with and billing marketplace insurers and Medicaid managed care plans, the study survey does include questions regarding clinics' relationships with private and Medicaid Managed Care Organizations (MCOs).

With regard to the length of time required to complete the survey, we explained that the estimate of 4.7 hours was derived by calculating the average time required by all grantees participating in the pilot test of the survey. One participating site estimated that it took 11 hours to complete the survey; a result that was much higher than those reported by other pilot sites. Omitting this estimate and recalculating the burden estimate would result in an average of about 3 hours to complete the survey with a median and mode of 2 hours.

Section 8B:

The team sought the views and advice of two outside study consultants on the project design and development and piloting of the survey instrument. Consultations took place regularly from the fall of 2012 through the summer of 2013, via conference calls and e-mail.

The following subject-matter experts were directly consulted:

1. **Eli Camhi**, Executive Director, SelectHealth/Special Populations, VSNYCHOICE, (917) 434-7372, ecamhi@generes.com
2. **Jennifer Kunkel**, Ryan White Grants Manager/HIV Services CQI Coordinator, ARTAS Project Director, Total Health Care, Inc., (301) 537-5774, jkunkel@verizon.net
3. **James Raper**, Director & Nurse Practitioner, 1917 HIV Outpatient, Research and Dental Clinics, Professor of Medicine, Division of Infectious Diseases, and Senior Scientist, Center for AIDS Research, University of Alabama at Birmingham (205) 975-7732. jimraper@uab.edu
4. **J. Kevin Carmichael MD**, FIDSA, Chief of Service, El Rio Community Health Center, Special Immunology Associates, (520) 628-8287, kevinc@elrio.org

9. Explanation of any Payment/Gift to Respondents

Respondents will not be remunerated.

10. Assurance of Confidentiality Provided to Respondents

The study survey instrument does not require any information that could identify individual clients. Names and personal identifiers will not be collected in the survey.

Grantee-provider contact information (i.e., names, titles, e-mail addresses, and telephone numbers) will be collected for survey recruitment purposes only. Respondents will be assured that their identities and information will be kept private to the maximum extent allowable by law. Participants' responses will be kept confidential, and no reported data will be attributed to any individual respondent.

The WRMA Institutional Review Board (IRB) has determined that the study is exempt from full IRB review, since it is a study that does not involve human subjects. No individual level data will be collected for the study (see Attachment E. IRB Exemption Memo).

11. Justification for Sensitive Questions

There are no questions of a sensitive nature collected in the survey. No patient or client-level identifying data will be collected for the study.

12. Estimates of Annualized Hour Burden

The burden estimate below is based on the average time per response indicated by the Part C and Part D grantee respondents who participated in the pilot of the survey instrument. Five of six grantees who participated in the pilot provided burden estimates ranging from 2 to 11 hours. The grantees were a mix of provider type that included health departments, publicly funded community health centers, community-based service organizations and large hospital systems located throughout the country. A total of three grantees estimated it took two hours to complete the survey while the other two estimated 6.5 and 11 hours. In addition, 4 out of the 6 grantees completed the entire survey while 2 grantees did not answer question 15 which asks about limits placed on reimbursements of outpatient ambulatory care subservices of clients covered by Medicaid, Medicare or private insurance. We also received feedback from 4 of the grantees via a feedback questionnaire. Clearer language and additional instructions were added as recommended by grantees. In addition, more response options were added, specifically, “Other” for some questions.

The average estimated burden is 4.7 hours, including the compilation of information in advance of completing the survey. It is important to note that omitting the burden estimate of 11 hours, a much higher estimate than those reported by the other grantees, would recalculate the burden estimate to about three hours.. Overall, the median and mode for completing the survey was two hours. There will be a total of 120 respondents completing the survey at one time.

The estimated annual time and cost burden to Part C and Part D grantees are presented in the tables below:

12A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Part C & D Grantee Staff	Survey	120	1	4.7	564

12B. Estimated Annualized Burden Costs

An estimated hourly wage of \$35.59 for the grantee employees required for gathering the information for the survey and completing the survey online was used. This estimate was developed by averaging the hourly wage of management and business and financial occupations in the healthcare field from the Bureau of Labor Statistics.² Completion of the survey is estimated to cost each of the 120 grantees \$167.23. The total cost for all 120 grantee respondents to complete the survey, including pre-survey compilation of information, equals \$20, 072.76.

The annual burden is based upon the average hourly salary of grantee program director, and business and finance managers.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Part C & D Grantee Staff	564	\$35.59	\$20, 072.76

The total annual burden for this activity is 564 hours.

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

There are no direct costs to respondents other than their time in participating in the survey.

14. Annualized Cost to the Federal Government

The estimated contract costs to the government for all data collection activities under Contract No. HSH250200646016I is \$683,870 annually. These costs include study design, preparation of the OMB clearance submission, design and development of the survey instrument, study recruitment, and all other aspects of data collection, analysis, and reporting. In addition, we estimate 200 hours of federal staff involved in oversight over the same time period. The cost is broken out into 120 hours of federal staff time at an average hourly wage of \$74.51 (GS-15), for a total of \$8, 941.20, and 80 hours of federal staff time at an average hourly wage of \$65.53 (GS-14), for a total of \$5,242.40. The total annualized cost to the government of data collection for the project is estimated at \$698,053.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation, Publication, and Time Schedule

Data collection via the web-based survey will be conducted during a 6-week period from March 4, 2014 to April 15, 2014. After the completion of the data collection, the information will be imported into MS Excel and processed for analysis. The objectives of the data analysis is to gain

² Bureau of Labor Statistics. Available from http://www.bls.gov/oes/current/naics2_62.htm#11-0000.

a better understanding of Part C and D grantees' role in providing quality care to PLWHA and to look at their practices in tracking the various funding streams that support the provision of this care. In addition, we will look at how grantees are positioned to adapt to health care changes under ACA. The analysis plan focuses on description, explanation and prediction and will use both quantitative and qualitative methods. The quantitative analysis will help describe the grantee's role in providing services to PLWHA and how they track the various funding streams to fund these services. The qualitative analyses will be used to elaborate on grantees' challenges and limitations on their tracking processes and readiness for ACA. See Exhibit 16A. *Evaluation Questions, Indicators and Analysis Techniques*.

Exhibit 16A. Evaluation Questions, Indicators and Analysis Techniques

Evaluation Questions	Indicators	Data Analysis
How are the services provided to PLWHA funded by Ryan White Part C and D grantees?	<ul style="list-style-type: none"> • Services provided • Number of PLWHA served in 2012 • Revenue received from each Ryan White Part in 2012 • Reimbursements received from Medicaid, Medicare and private insurance • Revenue from other sources • Part C and D funding used for FTE salaries • Services provided by RW funded FTE • Number of primary care providers for PLWHA • Limits on reimbursements of subservices for Outpatient Ambulatory Medicare Care under Medicaid, Medicare or private insurance • Limits on reimbursements of additional medical and support services under Medicaid, Medicare or private insurance • Number of weeks between billing and receiving reimbursements from Medicaid, Medicare and private insurance 	Univariate/Multivariate Analysis Qualitative thematic analysis
How do grantees track the funding sources used to provide HIV/AIDS care?	<ul style="list-style-type: none"> • Frequency of confirmation of health insurance status • Frequency of eligibility assessment for Medicaid, Medicare and private insurance • System used for tracking health insurance coverage • Means of maintaining and reporting changing client health insurance 	Univariate/Multivariate Analysis Qualitative thematic analysis

Evaluation Questions	Indicators	Data Analysis
	<ul style="list-style-type: none"> • Ability to calculate total revenue received for each individual service and attribute to different funding sources? • Records per service per client dollar amounts for individual services • Captures all services for all clients in one system • Collects information on reimbursements received for client • Routinely calculates average costs of care per client for planning and budgeting • Interest in Ryan White Tracker 	
<p>What are grantees' current <i>health provider status</i> and how does it position them to take advantage of health care reform?</p>	<ul style="list-style-type: none"> • Agency location • Services provided • Status as a Patient Centered Medical Home • Status as a Medicaid Health Home • Number of primary care providers for PLWHA • Relationship with private Managed Care Organizations • How program is reimbursed under Managed Care Organizations 	<p>Univariate/Multivariate Analysis</p> <p>Qualitative thematic analysis</p>

The research team will submit to HAB a final summary report on June 10, 2014 that will include a summary of findings, recommendations, and the study's limitations. A formal presentation will also take place with HAB staff on July 11, 2014. See Exhibit 16A below for the full schedule of the study.

Exhibit 16B: Time Schedule

Task	Dates
Recruitment to Study	March 2014
Data Collection	March–Mid-April 2014
Complete Analysis of Survey Data	Mid-May 2014
Final Report	June 2014
Presentation of Findings	July 2014

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

There are no exceptions to the certification.