Supporting Statement Part A

Providing Primary Care and Preventive Medical Services in Ryan White – Funded Medical Care Settings

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 (Ryan White Program) 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 Ryan White Program is a federally funded program that provides grants to states and U.S. territories, eligible metropolitan areas (EMAs), and clinics with the goal 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.

Many Ryan White-funded clinics have long promoted the medical home model, which involves the provision of comprehensive and coordinated care services, including prevention and other non-medical care services to promote access and adherence to HIV treatment. Through the years, this provision of care has evolved as the disease, population and treatment has also evolved. Today, people living with HIV (PLWH) are living longer and normal lives with effective antiretroviral treatment and in recent years, clinics are also seeing their patients develop other common chronic diseases such as diabetes, heart disease, and hypertension associated with normal and aging populations. Guidelines[2] on primary care for PLWH have recently been released to help providers navigate the integration of primary and preventative care into HIV care. In addition, the Affordable Care Act (ACA) will allow most PLWH to obtain more affordable health insurance and improve their access to primary and preventative care services. However, with already limited budgets, staffing and other resources, Ryan White-funded clinics may struggle to provide primary and preventative care services in-house or have insufficient referral systems.

The Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB) is requesting approval from the Office of Management and Budget (OMB) for a study that will

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[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.

[2] JA Aberg, JE Gallant, KG Ghanem, P Emmanuel, BS Zingman and MA Horberg. *Primary Care Guidelines for the Management of Persons Infected with HIV: 2013 Update by the HIV Medicine Association of the Infectious Disease Society of America;* CID 201_58 (January 1, 2014).

New York State Department of Health AIDS Institute, Office of the Medical Director. *Primary Care Approach to the HIV-Infected Patient;* http://www.hivguidelines.org/clinical-guidelines/adults/primary-care-approach-to-the-hiv-infected-patient/ (Updated November 2014)

examine how Ryan White-funded clinics are managing the provision of primary and preventative care services to people living with HIV (PLWH), specifically the protocols and strategies used to ensure comprehensive and coordinated care services. We will also look for facilitators and barriers that clinics experience when providing these services.

2. Purpose and Use of Information Collection

The purpose of this data collection is to obtain critical information that is currently not available on the provision of primary and preventative care for PLWH. Ryan White Programs are again seeing changes in their patient service needs and more research is needed to examine whether they are meeting these new service needs. The proposed study will provide HAB and policymakers with a better understanding of how the RWHAP currently provides primary and preventative care to PLWH. These data will provide the background to make informed policies and changes to the Ryan White Program in this new era when the well-being of PLWH demands a more complex and long-term HIV/AIDS care model.

There are four data collection instruments in this study: 1) the Clinic Director survey, 2) the clinician survey, 3) data extraction, and 4) telephone interview with the clinic medical director. The instruments will specifically gather information from each respondent to help HAB answer the following questions:

- What primary and preventative care services are being provided to PLWHA?
- How are these primary and preventative services provided and by whom?
- How are these primary and preventative care services coordinated?

The first online survey will be targeted to clinic directors from a sample of about 160 Ryan White-funded clinics and will collect data on care models used; primary care services, including preventive services; and coordination of care. Data collected from this survey will provide us with a general overview of the various HIV care models used as well as insight to possible facilitators and barriers to providing primary and preventative care services. See Attachment A for the online Clinic Director survey.

More in-depth data collection will be conducted with a smaller number of 30 clinics representing clinic type (publicly funded community health organization, other community-based organization, health department, and hospital or university-based) and size. The clinician survey will provide a more in-depth look at the clinic protocols and strategies and how they are being used and implemented by the clinicians. Specifically, the surveys will gather information regarding what entails a comprehensive physical exam during each patient visit, what primary care services are provided, and how comorbidities are managed between providers and clinics. The data will also serve to assist in identifying additional gaps in service provision, tracking of referrals, and reviewing coordination of care practices. See Attachment B for the online Clinician survey.

The data extraction will provide quantitative information on the provision of select primary and preventative care services within a certain time period. With these data, the study team can assess the accuracy of information provided in the online surveys on the provision of care. The data extraction requires clinics to report whether clients within a small subsample received a service. For each client selected, providers will review EHR data to answer whether the client received a given service and related follow up care (if necessary). The data collection will only

collect services provided to a client and will not request identified personal health information (PHI), such as name, full date of birth, or service dates. See Attachment C for the Data Extraction instrument.

Lastly, the interviews with the medical director will allow the study team to follow-up on the results of the survey and data extraction and collect qualitative data and more in-depth details on the provision of primary and preventative care services, specifically any facilitators and barriers. See Attachment D for the Medical Director Interview Guide.

3. Use of Improved Information Technology and Burden Reduction

The Clinic Director and clinician respondents will be completing a web-based survey instrument that will be administered via SNAP software. 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 surveys 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 surveys will eliminate any other costs incurred by the need for postage, paper, and any other resources that other survey methods may require. The web-surveys 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.

For the data extraction, a clinic data manager or staff will be asked to extract service data from their own clinical data management systems and input information into a user-friendly Excel spreadsheet (data extraction instrument), a common office software application.

The final instrument to be conducted will be the Medical Director interview. It will be conducted via telephone, rather than a survey, in order to gather qualitative data and allow for discussion on facilitators, barriers and any inconsistencies found in the data previously collected from the surveys and data extraction.

4. Efforts to Identify Duplication and Use of Similar Information

There have been no previous studies conducted on the provision of primary and preventive care to people living with HIV (PLWH) in Ryan White HIV/AIDS Program (Ryan White Program) clinics. Though Guidelines[3] on primary care for PLWH have recently been released to help

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[3] JA Aberg, JE Gallant, KG Ghanem, P Emmanuel, BS Zingman and MA Horberg. *Primary Care Guidelines for the Management of Persons Infected with HIV: 2013 Update by the HIV Medicine Association of the Infectious Disease Society of America;* CID 201_58 (January 1, 2014).

New York State Department of Health AIDS Institute, Office of the Medical Director. *Primary Care Approach to the HIV-Infected Patient;* http://www.hivguidelines.org/clinical-guidelines/adults/primary-care-approach-to-the-hiv-infected-patient/ (Updated November 2014)

providers navigate the integration of primary and preventative care into HIV care, there are no studies that examine the practice or application of the guidelines to PLWH.

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 April 10, 2015, vol. 80, No. 69; pp. 19325-19326. See Attachment E for the 60-Day FRN. We received and responded to one request to review the study data collection instruments during the 60-Day Notice period.

   Section 8B

   The study team sought the views and advice of 5 Ryan White agencies on the development and piloting of the data collection instruments. Consultations took place regularly from the March to May 2015 via teleconference calls or individual calls, e-mail and in-person.

   The following Ryan White agencies and staff were directly consulted:

   1. Robin Bradley, Sr. Director, Programs/Corporate Compliance Officer
      North County Health Services
      150 Valpreda Road
      San Marcos, CA 92069
      (760) 736-8629

   2. Kristine Gual, Director of IT and Paolo Troia, Chief Medical Director
      Cares Community Health
      1500 21st St.
      Sacramento, CA 95811
      916.914.6326

3. Tony Sillemon, Clinical Service Director
   Alta Bates Summit Medical Center
   350 Hawthorne Ave.,
   Oakland, CA 94609
   510-655-4000

4. Dr. Maya Bryant, Medical Director; Jhansi Gajjala, MD; Mohamed I. Jalloh, M.D; and Candice Daniels, Quality Care Program Coordinator
   Howard University Hospital
   2139 Georgia Ave N.W Suite 3D
   Washington D.C 20001
   (202) 865-6456

5. Shanese Baylor, Director for Grants Management; Stephen Rader, Data Manager; Gebeyehu Teferi, MD; Yolonda Taylor, MD; and Anne Cardile, MD
   Unity Health Care, Inc.
   1220 12th Street SE, Suite 120
   Washington, DC 20003
   202-715-6561

In addition, the following medical officers were consulted at HAB:

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9. Explanation of any Payment/Gift to Respondents

Respondents will be remunerated for their participation in the study. Previous studies have found that incentives for mail and telephone surveys do increase response rates.[4] Another study on incentives with clinical mental health professions, a similar population to the health professionals in our study, recognized that clinicians typically have a low response rate to surveys. This study sampled 500 clinicians to respond to a 7-page survey and offered no incentive, a non-monetary incentive and 3 different levels of monetary incentive. Results showed that monetary incentives significantly increased response rates compared to those who received no incentives.[5]

For this study, all respondents will receive a monetary incentive. A number of the sampled clinics and clinicians are not directly funded by HRSA and may not be motivated to respond to a HRSA-initiated study nor work full-time providing Ryan White HIV/AIDS Program services. The study also targets dedicated and time-strapped professionals who may appreciate that the study will provide remuneration to their clinic for participation. We can also learn from Medicare and Medicaid Electronic Health Record Incentive Programs that data collection of clinical and performance measures are a hardship for these professionals and clinics, but that incentives encourage participation.[6]

For the first part of the study, clinic directors will receive a $50 retail gift card (Staples, Target or Amazon) for completing the online survey. The clinics who participate in the in-depth data collection will receive a check up to $300, depending on their participation level -- $50 for each clinic survey (up to three), $100 for the data extraction, and $50 for the medical director interview. The $50 amount for the surveys and interview were considered "typical" incentives in the health field and pilot respondents agreed. The

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[4] Berk, M., Mathiowetz, N., Ward, E., and White, A. (1987). The effect of prepaid and promised incentives: Results of a controlled experiment. *Journal of Official Statistics 3*: 449-457.

Center for Disease Control and Prevention (2010). Using incentives to boost response rates. *Evaluation TA Evaluation Briefs* (22). Available at: http://www.cdc.gov/healthyyouth/evaluation/pdf/brief22.pdf

James, J., and Bolstein, R. (1990). The effect of monetary incentives and follow-up mailings on the response rate and response quality in mail surveys. *Public Opinion Quarterly 54*: 346-361.

Singer, E., Van Hoewyk, J., Gebler, N., Raghunathan, T., and McGonagle, K. (1999). The effect of incentives on response rates in interviewer-mediated surveys. *Journal of Official Statistics 15*: 217-230.

Willimack, D., Schuman, H., Pennell, B., and Lepkowski, J. (1995). Effects of a prepaid nonmonetary incentive on response rates and response quality in a face-to-face survey. *Public Opinion Quarterly 59*: 78-92.

[5] Hawley, K. M., Cook, J. R., & Jensen-Doss, A. (2009). Do Noncontingent Incentives Increase Survey Response Rates among Mental Health Providers? A Randomized Trial Comparison. *Administration and Policy in Mental Health*, *36*(5), 343–348. doi:10.1007/s10488-009-0225-z

[6] https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html

incentive for the data extraction was doubled due to the higher burden in completing the task.

10. Assurance of Confidentiality Provided to Respondents

Clinician contact information (i.e., names, titles, e-mail addresses, and telephone numbers) will be collected for survey recruitment purposes only. Respondent contact information will be kept separately from data collected by the data collection instruments. Respondents will be assured that their identities and information will be kept private to the maximum extent allowable by law. Responses will be kept confidential, and no reported data will be attributed to any individual respondent.

A list of possible respondents will be collected from the Ryan White HIV/AIDS Program recipients and used to send emails to introduce the study and invite clinicians to participate in the survey, data extraction, or interview. Contact information will also be to follow-up on the invitation, answer questions, and provide any technical assistance necessary to complete the data collection. Once a respondent agrees to participate, they will receive a follow-up email with instructions for participation. Study team members will continue to monitor the completion of the data collection instruments via email and telephone.

Survey respondents will receive a link to the survey with their own unique identification number. This unique identification number will be linked to their survey responses, and stored in the SNAP survey software. The survey does ask respondents to provide their name, agency name, and telephone number for follow-up purposes (i.e. if their data show some inconsistencies). Once the data are cleaned, contact information will be deleted. Data extraction respondents will also receive their own unique identification number that will be printed on their Response Sheets. Each medical director interview will also be given a unique identification number when entering their data into the qualitative analysis software. The unique identifier will be used if individual respondent's data need to be retrieved.

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 F for the 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 and Cost Burden

There are four data collection instruments in this study. The burden estimate below is based on the average time per response as indicated by the different respondents for each data collection instrument who participated in the pilot. Approximately 0.5 hour is the average time for completing the web-based clinic director survey that will be completed by about 130 clinic directors. Thirty clinics will participate in completing the remaining three data collection instruments. Each clinic will complete three clinician surveys (by three different clinicians), a data extraction and a telephone interview with the medical director. Approximately 0.5 hour is the average time for completing the web-based clinician survey approximately 4 hours for the data extraction and 0.5 hour for the telephone interview with the medical director.

12A. 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
Clinic Director Online Survey	130	1	130	.5	65
Clinician Online Survey	90	1	90	.5	45
Data Extraction	30	1	30	4	120
Medical Director Interview Guide	30	1	30	.5	15
Total	280		280		245

The estimated annualized burden costs table below was developed using the Bureau of Labor Statistics[7] to determine salaries for each respondent.

[7] The following links to the Bureau of Labor Statistics website were used to determine salaries for the clinic director, clinician, data manager and medical director:
http://www.bls.gov/ooh/management/medical-and-health-services-managers.htm,
http://www.bls.gov/ooh/healthcare/physicians-and-surgeons.htm,
http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.

Completion of the clinic director survey is estimated to each cost $42.59 per hour with the clinician survey estimated to each cost $90.00 per hour. Completion of the data extraction by a data staff person is estimated to each cost $16.42 per hour with the medical director interview estimated to each cost $90.00 per hour. The total cost for the completion of all data collection instruments is $10,138.75

The annual burden is based upon the average hourly salary of the clinic director, clinician, data manager and medical director.

12B. Estimated Annualized Burden Costs

Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Clinic Director Online Survey	65	42.59	2,768.35
Clinician Online Survey	45	90.00	4,050.00
Data Extraction	120	16.42	1,970.40
Medical Director Interview Guide	15	90.00	1,350.00
Total	245		10,138.75

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 Costs to Federal Government

The estimated contract costs to the government for all data collection activities under Contract No. HHSH250201400042I is $313,124 annually for 21 months. These costs include study design, preparation of the OMB clearance submission, design and development of the data collection instruments, piloting of the data instruments, study recruitment, study participant incentives and all other aspects of data collection, analysis, and reporting. In addition, we estimate about 200 hours of federal staff involved in oversight over the same time period. The cost is broken out into 100 hours of federal staff time at an average hourly wage of $68.56 (GS-15 equivalent), for a total of $6,856 and

100 hours of federal staff time at an average hourly wage of $49.32 (GS-13), for a total of $4,932. The total annualized cost to the government of data collection for the project is estimated at $324,912.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation, Publication, and Project Timeline Schedule

Data collection is scheduled for 7 months after OMB approval (October 2015 – February 2016). In the first month, the online survey targeting clinic directors from about 130 Ryan White-funded clinics will be the first data collection implemented. This first set of data will be analyzed during the second month using SPSS to conduct simple statistical analysis get a general overview of the various HIV care models and insight into possible facilitators and barriers to providing primary and preventative care services. Quantitative analyses may include various descriptive statistics, plus t-tests and chi square tests. Using this first set of data, the study team will use a stratified random sample to get 30 clinics to provide additional information on their HIV care model and operations. See Attachment G for more details on the analysis plan.

The subset of clinics will complete three data collection instruments. The completion of the first two instruments, the online clinician survey and the data extraction, will occur in the third and fourth months. In the fifth month, we will analyze the results of these data collections using simple statistical analysis similar to that used for the clinic director survey. This analysis will be used to inform the telephone interviews with the medical directors, the last data collection effort. In the sixth and seventh month, we will conduct the telephone interviews with the medical directors to gather qualitative data and follow-up on findings from the first two instruments. We will use Atlas.ti to analyze the results of the medical director interviews. Qualitative analyses may include coding and organizing data to look for frequencies and themes.

The overall objectives of the data analysis is to gain a better understanding of how clinics are providing or ensuring that their PLWH patients are receiving primary and preventative care services and how patient care and information is coordinated among the patients' various clinicians. The analysis plan focuses on description, explanation and identification of best practices, using both quantitative and qualitative methods from the various data collection instruments. The quantitative analysis will help describe the clinic's practices in providing or ensuring the provision of primary can preventative services to PLWHA as well as any barriers and facilitators faced in providing these services. The qualitative analyses will be used to elaborate on barriers and facilitators and identify best practices. See Part B for more information on the analysis plan.

The research team will submit to HAB a final summary report on June 23, 2016 that will include a summary of findings, recommendations, and the study's limitations. A formal

presentation will also take place with HAB staff on May 26, 2016. See Attachment H for the Study Timeline.

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

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

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

List of Attachments

Attachment A - Clinic Director Survey

Attachment B - Clinician Survey

Attachment C - Data Extraction Instrument

Attachment D - Medical Director Interview

Attachment E - IRB Exemption Memo

Attachment F – Analysis Plan

Attachment G – Study Timeline