**Supporting Statement Part B**

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

# Collection of Information Employing Statistical Methods

1. **Respondent Universe and Sampling Methods**

### Study Population

The study population will include Ryan White clinics who meet all of the following criteria:

* Served at least one Ryan White-funded client receiving Outpatient Ambulatory Medical Care (OAMC) services
* Served at least one Ryan White eligible client receiving OAMC services

Clinics will be selected based on the most recent data available from the Ryan White HIV/AIDS Program Services Report (RSR). Based on RSR data from 2013 reports, 839 clinics meet both of these criteria. Additionally, there are two grantee-providers characteristics that are important to have represented in the completed survey responses. These include:

* Provider Type
* Provider Size

### Provider Type

We anticipate that patterns of primary and preventative care provision are likely to relate to the type of provider (as defined in the RSR). That is, health departments, hospital clinics, community health centers, and community-based service organizations may each follow different strategies in providing primary and preventative care, given their settings. For this reason, provider type will be a critical data element for the sample selection. We propose to exclude providers that do not have service provision models conducive to the study goals. Based on RSR data from the 2013 report, this would exclude 3 providers.

### Provider Size

In addition to provider type, we will stratify the target population by provider size based on number of OAMC clients. On average, providers served 453 OAMC clients, with hospital and university clinics serving the most, and private medical practices and other provider types serving the fewest. Overall, more than half of the providers served fewer than 250 OAMC clients, while 104 served more than 1,000.

### Stratified Random Sample by Study Population by Key Characteristics

Table 1 below organizes the study population into the Provider Type and Provider Size characteristics discussed above. The study population columns represents the number of providers with each combination of provider type and provider size. We will use a stratified random sample with a replacement approach to select providers. We plan on sampling about 19.2% from each combination of provider type by provider size to get the sample size. The sample size columns in Table 1 display the associated sample size for each combination and the total.

**Table 1. Sampling Distribution of Study Population by Key Characteristics**

| **Type** | **1-249 OAMC Clients** | **250 or more OAMC Clients** | **Total** |
| --- | --- | --- | --- |
|  | StudyPopulation | Samplesize | StudyPopulation | Samplesize | StudyPopulation | Samplesize |
| Health Department | 75  | 14 | 50  | 10 | **125** | ***24*** |
| Hospital or University Based Clinic | 124  | 24 | 161  | 31 | **285** | ***55*** |
| Publicly Funded Community Health Center | 119  | 23 | 86  | 16 | **205** | ***39*** |
| Other Community-Based Service Org | 111  | 21 | 70  | 14 | **181** | ***35*** |
| Other Provider Type including Private Practice | 25  | 5 | 15  | 3 | **40** | ***8*** |
| **Total** | **454** | ***87*** | **382** | **74** | **836** | ***161*** |

Each clinical director within this sample will be given the clinical director survey.

From this sample of approximately 130 clinics (161 sampled \* 80% response rate), we would select a stratified subsample of 30 clinics for in-depth study. A list of alternate clinics for the in-depth study will also be defined in case clinics sampled decline to participate or are unresponsive to follow-up. Within the in-depth study subsample of clinics:

* The clinician survey would be administered to three clinicians
* A record extract or data report will be requested to enable record review of patient-level data to validate clinical director/clinician survey responses
* The medical director will be given the Medical director interview
1. **Procedures for the Collection of Information**

For the study, a sample size of 161 was selected to provide estimates with a good level of precision. For example, if the proportion of clinics providing a particular service in-house is 50%, the proportion of survey respondents reporting providing this service in-house will range from 43% to 57% with 95% confidence.

Prior to OMB approval and to launch recruitment efforts, HAB will identify the contact person for the Ryan White grantees and send a letter by e-mail, to all the grantees in the universe to advise them of the study and a possible invitation to participate in the study. See Attachment A for the Letter to All Participations From HAB. Once the study is approved by the OMB, a second e-mail from HAB to the study sample will be sent as an alert that recruitment efforts for the study will be starting, and that they have been selected to participate in the Clinic Director Survey. See Attachment B for the Letter to Study Sample From HAB. Shortly after this last e-mail from HAB, the recruitment team will follow up with a formal invitation via e-mail. See Attachment C for the Study Invitation email to Clinic Director. The invitation will again introduce the study and describe the two components. The e-mail will ask grantees if their clinic (or additional clinics) would be interested in participating in the first part of the study by completing the clinic director survey. A Clinic Respondent Form will be included in this e-mail. See Attachment D for the Clinical Director Survey Respondent Form. They will also be told that they may be invited to the second part of the study at a later date. Within a week of receiving this invitation, the recruitment team will call the grantees to ensure receipt of the invitation, answer any questions, and then confirm participation. If a grantee declines participation, the recruitment team will replace the grantee with the next grantee in the sample. Responses will be monitored to ensure representative of clinic type and size as well as a response rate of 80%. Clinic directors who complete the survey will receive a $50 gift card.

After the first invitation letter is sent to grantees, the study team will begin tracking responses using an MS Excel tracking tool (Tracker) to ensure high response rates for completing the survey. The Tracker will be used to record participation responses, survey completion, and any communication between the study team and grantees to support follow-up efforts. This Tracker will be used in conjunction with a sampling frame to ensure that sample categories are well represented.

After the analysis of the clinic director survey data, the study team will choose a subset from the 130 clinics that completed the survey to recruit for in-depth study of their clinic operations. Clinics chosen will receive another e-mail letter from the study team to invite them to participate in the second part of the study. See Attachment E for the In-depth Clinic Study Invitation. The letter will explain that the clinic must be willing to complete all three different data collection instruments in order for their data to be included in the final data results. The recruitment team will also be available to answer questions and assist in situations that may hinder a clinic’s full participation. Specifically, the study team will also be available to conduct webinars to help clinics use the data extraction instruments. In addition, the grantee will receive a $300 honorarium for completing 3 clinician surveys, the data extraction and an interview with the Medical Director. A Respondents Form will be included in this e-mail for grantees to suggest possible respondents at their clinic (or one of their clinics). See Attachment F for the Clinic Study Respondents Form. The recruitment team will follow up with a phone call to ensure receipt of the invitation, answer any questions and confirm participation. Once the recruitment team receives the Respondents Form, they will contact the respondents for the clinician survey and the data extraction with the appropriate data collection instrument and instructions. The recruitment team will also ensure timely completion of the data collections instruments via follow-up e-mails and phone calls. Once these two data collection instruments have been completed, the study team will contact the medical director to schedule a telephone interview.

Again, the Tracker will be used to record participation responses, completion of data collection instruments, and any communication between the study team and grantees to support follow-up efforts. This Tracker will again be used in conjunction with a sampling frame to ensure that sample categories are well represented.

**After OMB Approval**

**Study Recruitment**

**Prior to OMB Approval**

Clinical Director Survey

In-depth Clinic Study

HAB to Grantees

HAB sends a second letter to the sample to alert them that the study recruitment will begin

HAB to Grantees

HAB determines the contacts for Ryan White grantees and sends emails to introduce the study

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Study team emails a selection from the 130 grantees who participated in the Clinic Director Survey and are asked to participate in 2nd phase of study. Email contains: Participant Form and Overview of the study and data instrument

161 Grantees receive email (email #1) from Study team to invite them to participate in study. Email contains the Clinical Director Participant Form

Study team receives the Participant Form back from the Grantees and reaches out to the respondents listed on the Participant Form

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130 Clinical Directors Participate in Survey

3 Clinicians from each clinic participate in the clinician Survey

Data Extraction is completed by Data Staff

Clinical Director receives $50 honorarium

Study Team Reaches out to Medical Director

Medical Director is interviewed

Clinic receives $300 honorarium

1. **Methods to Maximize Response Rates and Deal with Nonresponse**

***Consent to Participate***

A recruitment team will be assembled and trained in knowing the study goals and objectives, the study components, and techniques to persuade grantees to participate. During the recruitment process, the recruitment team will follow up with potential respondents and remind them to respond to the e-mail invitation. Respondents will be asked to complete the data instrument within a week. In the event that we do not receive a response, the team will make a second attempt via e-mail and also make telephone calls. The team will attempt to reach the respondent via telephone every other day thereafter. A third e-mail attempt will also be made three days after the second one is sent. If a clinic director or a grantee declines to participate in the study, a replacement will be drawn from the sample.

***Completion of the Data Collection Instruments***

After the study team receives consent to participate in the study from the grantees, efforts will be made to remind them to complete the data collection instrument. The recruitment team will monitor the completion of instruments and will focus follow-up efforts to reach a response rate of at least 80 percent.

Using our recruitment plan, we plan to achieve an overall response rate of 80 percent. This response rate will assure an overall confidence interval for item response percentage estimates of +/-4 percent at the 95 percent confidence level for a population and a sample n=130 (≈0.8 x 161). This will produce reliable data that can be generalized to the study population and is well within the generally accepted standard of +/-5 percent at the 95 percent confidence level for evaluation research studies.

1. **Tests of Procedures or Methods to be Undertaken**

The study team started pilot-testing the data collection instruments in March. The goal of the pilot is to test the appropriateness and validity of the questions, determine whether questions were consistently understood, whether respondents had the information needed to answer questions, and to obtain a basis for burden estimates. Feedback will be gathered from respondents via follow-up telephone calls or in-person. In addition to the pilots, the study team will use feedback provided by external project consultants and HAB to enhance the survey.

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

The study design, data collection activities, and data analysis are being conducted for HRSA and by the contractor, Walter R. McDonald & Associates, Inc. (WRMA) and its partner, Mission Analytics Group, Inc.

The following persons provided guidance and input into the survey design, sampling and statistical analysis approaches:

|  |  |  |
| --- | --- | --- |
| **Name**  | **E-mail** | **Telephone Number** |
| Harry Day, Ph.D | hday@wrma.com | 703-402-8059 |
| Carolyn Lichtenstein, Ph.D | clichtenstein@wrma.com | 301-881-2590 |
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The person responsible for receiving and approving the contract deliverables is Contracting Officer Representative, Tracy Matthews, CAPT, USPHS, Deputy Director, Division of Policy and Data HRSA/HIV/AIDS Bureau, 301-443-7804, tmatthews@hrsa.gov<mailto:tmatthews@hrsa.gov

Attachments:

A: Letter to All Participations from HAB

B: Letter to Study Sample from HAB

C: Study Invitation email to Clinic Director

D: Clinical Director Survey Respondent Form

E: In-depth Clinic Study Invitation

 E1: Table for Data Instruments

F: Clinic Study Respondents Form