

Supporting Statement B

Chart Abstraction of Ryan White HIV/AIDS Program (RWHAP) Recipient Data
OMB Control No. 0906-XXXX-New

B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

A sample will be drawn from the Health Resources and Services Administration (HRSA) Ryan White HIV/AIDS Program (RWHAP) recipients or subrecipients funded to provide outpatient ambulatory health services with at least 150 patients in calendar year 2017. The sample will total 250 of the 920 RWHAP recipients and subrecipients. The sample will be invited via email to participate in a site screening interview with a recruitment specialist. The site screening will be used to collect information on recipient or subrecipient’s electronic health record (EHR), other facility record systems, approvals required such as International Review Board (IRB) or data use agreements (DUAs), the site model of care and site availability/interest in participating in the data collection. Criteria are designed to capture a pre-determined number of recipients or subrecipients in the Department of Health and Human Services (HHS) regions (Table 1), and representation based on recipient type, geographic location, and clinic size (Table 2). It is anticipated that the response rate will be at least 40%, resulting in a minimum of 100 responses. Fifty RWHAP recipients or subrecipients will participate in the health record abstraction.

Table 1 – Number of Recipients/Subrecipients Specified by HRSA to Visit

Department of Health and Human Service Region	Number of Site Visits
01 Boston	4
02 New York	7
03 Philadelphia	6
04 Atlanta	12
05 Chicago	5
06 Dallas	4
07 Kansas City	1
08 Denver	2
09 San Francisco	8
10 Seattle	1

Table 2 - Site Criteria

Type of Recipient	Geographic Region	Size of Clinic (# of patients)
Hospital or university-based clinic	Rural	Small (150 - 400)
Publicly funded community health center	Suburban	Medium (401 - 1000)
State or local health department	Urban	Large (1001 +)

Selected RWHAP recipients and subrecipients will be asked to participate in pre-site visit interview. This interview will be conducted by the contractor and the recipient or

subrecipient’s director or a senior service provider. The interview will collect information on the number of health care providers and demographics at the site, tools used and documentation procedures for mental health, substance use, opioid dependence, sexually transmitted infections and hepatitis and considerations for site visit logistics.

The contractor will abstract clinical information from 64-80 patient health records per recipient or subrecipient using a random sample based upon study focus (see tables below). The default review period for the chart abstraction pilot was from January 1, 2017 through January 1, 2019, with certain variables instead requiring 12 or 36 month lookback period.

The following table describes the sampling design and measures for each of the data sources in the information collection.

<i>Chart Abstraction of Ryan White HIV/AIDS Program (RWHAP) Recipient Data</i>	
Data Sources	
Site Screening Interview	<p><u>Sampling:</u> Invite via email 250 RWHAP recipients or subrecipients funded to provide outpatient ambulatory health services to a minimum of 150 patients in calendar year 2017 to complete a short phone screening interview with a recruitment specialist. The 250 recipients and subrecipients will receive the invitation with 100 projected responses to schedule the interview (or roughly a 40% response rate).</p> <p><u>Measures:</u> The site screening interview will be by conducting calls with the recipients and subrecipients to assess interest in participation. Each screening call will be conducted with the recipient or subrecipient’s RWHAP director and/or a senior service provider. Screeners will be used to collect information on facility EHR, other facility record systems, approvals required such as IRB or DUA, the site model of care and availability/interest in participating in a site visit.</p>
Pre-Site Visit Interview	<p><u>Sampling:</u> A list of recipients and subrecipients determined as eligible and interested through the site screening process will be provided to HRSA for final selection and approval of the 50 recipients and subrecipients.</p> <p><u>Measures:</u> Once the 50 recipients and subrecipients are identified, a pre-site visit interview will be schedule with the recipient and subrecipient’s director or a senior clinical staff to collect information on number and demographics of health care providers, tools used and documentation procedures for mental health, substance use, opioid dependence, sexually transmitted infections and hepatitis and logistical considerations for the site visit.</p>

<i>Chart Abstraction of Ryan White HIV/AIDS Program (RWHAP) Recipient Data</i>	
Data Sources	
Medical Charts/Administrative Records Abstraction	<p><u>Sampling:</u> Randomly select 64-80 patients who received one outpatient ambulatory health services visit in 2018 and 24 months prior at each of the 50 recipients and subrecipients for health record abstraction.</p> <p><u>Measures:</u> Measures collected via our abstraction tool will include health outcomes data related to HIV, provision of primary care, screening, diagnosis and treatment of hepatitis, STIs, and opioid use disorder.</p> <p><u>Power:</u> We assume 50 recipients and subrecipients, a minimum of 45 abstractions completed per recipients and subrecipients, an intra-class correlation of 0.1 due to clustering of patients within clinic, and three rounds of data collection – one for each option year. We will create one year, two-year, and three-year estimates, covering 2,250, 4,500, and 6,750 charts abstracted, respectively. With a prevalence for a hypothesized abstraction measure of 0.25, the predicted standard error will be 0.032 (on-year estimate), 0.031 (two-year estimate), and 0.031 (three-year estimate).</p> <p><u>Representation:</u> The samples are designed to be weighted to a national estimate of RWHAP patient population receiving at least one outpatient ambulatory health services visit in 2017 and 24 months prior. The sample may be adjusted in subsequent years if the RWHAP patient population changes.</p>

2. Procedures for the Collection of Information

Provider Site Screening Interview Form

The contractor will conduct a phone interview with the recipients and subrecipient’s director or a senior clinical staff who replied to the invitation. Interviews will be conducted by phone at the convenience of the participant. Detailed notes will be taken during the course of the interviews and responses will be recorded in a web-based data collection tool. Screening interviews will utilize purposive sampling and are not intended to be statistically representative or generalizable to all RWHAP-funded program sites.

Provider Pre-Site Visit Interview Form

The contractor will conduct a phone interview with the recipients and subrecipient’s director or a senior clinical staff who met the study criteria, completed a site screening interview and have been approved as a study site by HRSA. Interviews will be conducted by phone at the convenience of the participant. Detailed notes will be taken during the course of the interviews and responses will be recorded in a web-based data collection tool. Pre-Site Visit

interviews will utilize purposive sampling and are not intended to be statistically representative or generalizable to all RWHAP-funded program sites.

Medical Records Data Abstraction: On site

The contractor will conduct the health records abstraction during site visits using a secure electronic web-based abstraction tool that is a modified version of one that has already been developed by the contractor and reviewed as part of the RWHAP outcomes data collection (OMB#: 0906-0039, Expiration 12/31/2021). The tool contains predefined data entry fields as well as a free text notes section, and will employ business specifications developed to promote data quality. After the data has been entered, the contractor will immediately upload the data into the contractor's secure servers using a secure file transfer protocol (FTP). The contractor will assess the data are complete and the response valid. The contractor will transfer the data to HRSA via the FTP in SAS formatted files. The data will be in a format appropriate for import into SAS.

3. Methods to Maximize Response Rates and Deal with Nonresponse

The contractor will conduct the screening and pre-site visit interviews with recipients and subrecipient's director or a senior clinical staff via phone and by appointment.

The screening and pre-site visit interview guides were developed with consideration to length and content for collection of only elements necessary to support site selection and promote ease in the site visit process. HRSA anticipates achieving a 40% or better response rate for completion of screening interviews and 95% or better for the pre site visit interview.

4. Tests of Procedures or Methods to be Undertaken

The contractor has pilot-test each of the data collection form for this study at nine RWHAP recipient clinics selected by the contractor and approved by HRSA. The contractor abstracted data from 64-80 patient health records at each recipient and subrecipient. The overarching goals of the pilot-test was to refine validate the data collection forms and implementation process, increase efficiency, and assist with burden estimates. Comments provided will be incorporated into revised versions of the data collection forms and implementation process.

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

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