

**Supporting Statement A**  
**Partnerships for Care (P4C) Progress Reports**  
**OMB Control No. 0915-XXXX**

**A. Justification**

**1. Circumstances Making the Collection of Information Necessary**

This is a new request for collection of bi-annual progress reports from 22 health centers funded under Section 330 of the Public Health Service (PHS) Act and receiving supplemental funding under a new project titled, "Partnerships for Care: Health Departments and Health Centers Collaborating to Improve HIV Health Outcomes."

*Background*

The Health Resources and Services Administration, Bureau of Primary Health Care (HRSA/BPHC) has responsibility for the administration of health center programs under Section 330. A key component of success of the Health Center Program has been the ability to demonstrate to payers and patients the value of care delivered to those receiving health center services. The expansion of the Health Center Program and the resulting growth in the number of health center patients and services, along with provider incentive programs and technological advances, have underscored the importance of demonstrating health center provision of high quality care to underserved populations. This long-standing emphasis on demonstrating value is consistent with the Department of Health and Human Services (HHS) initiatives to increase transparency in health care and promote value-based purchasing; transparency and information technology are essential facilitators of increasing value in health care.

Recent advances in pharmacologic therapies for HIV have improved the safety, tolerability, and efficacy of treatments, leading to improved adherence and health outcomes. These same advances enable more primary care practices, including health centers, to actively manage the care and treatment needs of people living with HIV (PLWH). To reduce AIDS-related mortality, guidelines recommend routine HIV testing and the provision of antiretroviral treatments soon after infection. This recommendation requires substantial increases in the availability, accessibility, and quality of HIV services. Health centers are well positioned to help meet this demand.

Partnerships for Care (P4C) is a three-year, multi-agency project designed to support health centers in expanding their HIV service delivery. HRSA/BPHC and the Centers for Disease Control and Prevention Division of HIV/AIDS Prevention (CDC/DHAP) are designated leads for project leadership, monitoring and reporting by the HHS Office of the Assistance Secretary of Health, Office of HIV/AIDS and Infectious Disease (OHAIDP). P4C is funded through the Secretary's Minority AIDS Initiative Fund (SMAIF) administered by OHAIDP and the Community Health Center Fund established by section 10503 of the Affordable Care Act. The goals of the P4C project are to build sustainable partnerships between CDC-funded state health departments (including MA, NY, MD and FL) and HRSA-funded health centers (22 across the four-funded states) to support expanded HIV service delivery and improved coordination of care in communities highly impacted by HIV, especially among racial/ethnic minorities. State health departments and health centers will work together to increase the identification of undiagnosed HIV infection, establish new access points for HIV care and treatment, and improve HIV outcomes along the continuum of care for people living with HIV (PLWH) (see project website <http://www.p4chivtac.com/>).

Participating health centers will receive up to \$500,000 annually in HRSA supplemental funding

(totaling \$33M across the three-year project period) to integrate high-quality, comprehensive HIV services into their primary care programs; and to work in collaboration with their state health department to (1) identify people with undiagnosed HIV infection, (2) link newly diagnosed individuals to care, and (3) retain patients living with HIV in care. Health centers must implement activities in five focus areas, including workforce development, infrastructure development, HIV service delivery, partnership development, and quality improvement and evaluation. As part of quality improvement and evaluation, health centers are required by the terms of the supplemental funding application (see <http://www.hrsa.gov/grants/apply/assistance/bphchiv/supplementalinstructions.pdf>) to demonstrate progress toward implementing all required P4C activities and improving health care outcomes across the HIV care continuum (see <http://aids.gov/federal-resources/policies/care-continuum/>).

### *Need*

The Uniform Data System (UDS) annual reporting requirement for all health centers funded under Section 330 was approved under OMB No. 0915-0193 and expires on 2/28/2018. UDS includes 14 clinical core measures as the basis for HRSA/BPHC-wide quality improvement initiative focused on health center delivery sites that provide clinical care and/or provide referrals for clinical care. Measures were selected as a "starter set" with the understanding that there are many other areas of importance to BPHC and the people and programs we serve. Most of the measures chosen are commonly used by Medicare and healthcare insurance/managed care organizations to assess the quality of healthcare services. Quality measures span the life cycle, represent clinically important conditions and services to program populations, and assess program impact.

UDS data pertaining to HIV are limited to the following: 1) patients newly diagnosed with HIV, 2) newly diagnosed patients who received follow-up care within 90 days, 3) HIV tests conducted by patients and visits, 4) HIV/AIDS related diagnoses by patients and visits, and 5) pregnant women known to be positive. These data are not adequate to ensure participating health centers are in compliance with P4C terms and requirements. Additional data are needed to make evidence-based statements about the impact of the P4C project on increasing access to HIV care and treatment and improving health outcomes for PLWH in primary care settings.

HRSA/BPHC proposes submission of bi-annual progress reports by the 22 health centers participating in the P4C project using two different forms. The first form will request information on project implementation, including work plan progress in each of the project's five focus areas; budget modifications; established and actual projections for service delivery, workforce development and partnership development; successes or promising practices; and training and technical assistance needs. The second form will request information on both project implementation and outcomes, including the implementation information requested in the first form along with reporting of 14 HIV outcome measures listed below.

1. Percent of medical patients aged 15-65 years seen during the reporting period who had at least one HIV test in their lifetime by race/ethnicity and gender
2. Percent of medical patients aged 15-65 years in need of HIV testing who were tested for HIV as part of a medical care visit during the reporting period
3. Percent of medical patients aged 15-65 years in need of HIV testing who were tested for HIV as part of a non-medical care visit during the reporting period
4. Percent of medical patients aged 15-65 years and tested for HIV who had a new, confirmed diagnosis of HIV during the reporting period

5. Percent of medical patients tested for HIV between October 1st of the previous reporting period and September 30th of the current reporting period who had a new, confirmed diagnosis of HIV
6. Percent of medical patients with a new, confirmed diagnosis of HIV between October 1st of the previous reporting period and September 30th of the current reporting period who received HIV medical care within 90 days after HIV diagnosis
7. Percent of medical patients with a new, confirmed diagnosis of HIV between October 1st of the previous reporting period and September 30th of the current reporting period who were provided HIV risk reduction screening/counseling within 90 days after HIV diagnosis
8. Percent of medical patients with a new, confirmed diagnosis of HIV between October 1st of the previous reporting period and September 30th of the current reporting period who were screened for chlamydial infection and gonorrhea and syphilis within 90 days of HIV diagnosis
9. Percent of HIV-positive medical patients during the previous reporting period who had at least one HIV medical care visit during each half of the current reporting period at least 60 days apart by race/ethnicity and gender
10. Percent of HIV-positive medical patients during the reporting period who were prescribed ART
11. Percent of HIV-positive medical patients during the reporting period who had a viral load <200 copies/mL at most recent test by race/ethnicity and gender
12. Percent of HIV-positive medical patients during the reporting period who had a viral load <75 copies/mL at most recent test
13. Percent of HIV-positive patients during the reporting period who had at least one HIV medical care visit at the health center during the reporting period
14. Percent of medical patients aged 15-65 years seen during the reporting period who were known to be HIV-positive

Proposed outcome measures are intrinsically tied to P4C goals and objectives, and closely align with HIV measures established by other federal programs or through national, consensus-driven efforts, including:

1. Ryan White HIV/AIDS Program use of performance measures for program evaluation (<http://hab.hrsa.gov/deliverhivaidscares/habperformmeasures.html>),
2. HHS efforts to streamline HIV data collection and reporting and establish core HIV indicators (see <http://blog.aids.gov/2012/08/secretary-sebelius-approves-indicators-for-monitoring-hhs-funded-hiv-services.html>),
3. National Quality Forum (NQF) review and endorsement of measures (see [http://www.qualityforum.org/News\\_And\\_Resources/Press\\_Releases/2013/NQF\\_Endorses\\_Infectious\\_Disease\\_Measures.aspx](http://www.qualityforum.org/News_And_Resources/Press_Releases/2013/NQF_Endorses_Infectious_Disease_Measures.aspx)).

Proposed outcome measures also align with and support the goals of the following federal initiatives:

1. The National HIV/AIDS Strategy (NHAS), which calls for federal implementation of activities to prevent new HIV infections, provide access to high quality care for people living with HIV/AIDS (PLWH), and reduce HIV-related health disparities.

2. The Minority AIDS Initiative (MAI), which was established in 1999 in response to growing concern about the impact of HIV/AIDS on racial and ethnic minorities in the United States. MAI provides resources intended to complement, rather than replace, other Federal HIV/AIDS funding and programs (see <https://blog.aids.gov/2011/05/evolutions-in-the-minority-aids-initiative-secretary%E2%80%99s-fund.html>).
3. Secretary's Minority AIDS Initiative Fund (SMAIF), which is administered and allocated by the HHS Office of HIV/AIDS and Infectious Disease Policy (OHAIDP) to federal agencies to support the goals of NHAS within racial and ethnic minority communities (see <http://www.hhs.gov/ash/ohaidp/initiatives/>).

## **2. Purpose and Use of Information Collection**

P4C progress reports will be used to monitor and report progress toward meeting established goals and objectives, including: (1) the provision of HIV services and the improvement of health outcomes across the HIV care continuum; (2) the use of patient data to improve quality of HIV care; (3) the identification of effective models and promising practices for the integration of HIV services into primary care that can be disseminated for use across the public health and primary care safety net; and (4) the appropriate stewardship of federal funds.

Data and information received through P4C progress reports will be reported to OHAIDP to ensure fulfillment of Section 2686 of the Public Health Service Act which mandates a Government Accountability Office (GAO) report “describing MAI activities across the Department of Health and Human Services... Such report shall include a history of program activities within each relevant agency and a description of activities conducted, people served and types of grantees funded, and shall collect and describe best practices in community outreach and capacity-building of community based organizations serving the communities that are disproportionately affected by HIV/AIDS.”

Furthermore, Public Law 111-87, Section 2(f)(3) also requires that “not later than 6 months after the publication of the Government Accountability Office Report on the Minority AIDS Initiative described in section 2686, the Secretary of Health and Human Services shall submit to the appropriate committees of Congress a Departmental plan for using funding under section 2693 of the Public Health Service Act in all relevant agencies to build capacity, taking into consideration the best practices included in such Report.” Additional federal reports requiring information about this project include the annual HIV Testing Report to Congress and annual reports regarding NHAS.

P4C progress reports also will assist in meeting broader reporting requirements under Section 330(r)(3) of the Public Health Service Act for the annual preparation and submission to Congress of “a report concerning the distribution of funds under this section that are provided to meet the health care needs of medically underserved populations,... and the appropriateness of the delivery systems involved in responding to the needs of the particular populations. Such report shall include an assessment of the relative health care access needs of the targeted populations and the rationale for any substantial changes in the distribution of funds.”

Finally, P4C progress reports will be used to demonstrate to payers and patients the value of care delivered to those receiving services under the Health Center Program. The expansion of the Health Center Program and the resulting growth in the number of health center patients and services, along with provider incentive programs and technological advances, have underscored the importance of demonstrating health centers' high quality care to underserved populations. This long-standing emphasis on demonstrating value is consistent with the HHS initiatives to increase transparency in health care and promote value-based purchasing; transparency and information technology are essential facilitators of increasing value in health care.

If OMB approves the P4C progress reports, then HRSA will:

- Officially notify 22 health centers of the approval.
- Disseminate P4C progress report forms to health centers via email and EHB.
- Review the P4C progress report forms during a remote web-based training that will include a question and answer period in which health centers can pose specific questions. The training will be archived for future viewing.
- Monitor a designated inbox for P4C related questions ([bphcp4c@hrsa.gov](mailto:bphcp4c@hrsa.gov)) and respond within 48 hours to all inquiries.

If OMB does not approve the P4C progress reports, then HRSA's ability to monitor and report progress and understand the impact of the P4C project will be compromised due to a lack of relevant and comparable information across all participating health centers.

### **3. Use of Improved Information Technology and Burden Reduction**

Advancements in Electronic Health Record (EHR) technology have been proceeding at a rapid pace. EHRs can help grantees achieve larger quality and efficiency goals, and the use of EHR can also streamline and simplify health center reporting to UDS measures. The 14 HIV outcome measures included in the Outcomes Report are tied to ICD-9, CPT and other standard codes and fields utilized by most EHRs, with few exceptions (i.e., new diagnosis of HIV for which no ICD-9 code currently exists).

One of the eligibility criteria for health center participation in the P4C project was use of EHR across all health center service delivery sites. Health centers can use P4C supplemental funding as needed to build report templates that can extract data from their EHR to provide requested data. These data can be entered into tables appearing in the proposed Outcomes Report and submitted to HRSA/BPHC through the Electronic Handbook (EHB), the mechanism for grantee reporting of all required data and documentation.

The BPHC Help Desk has a toll-free hotline to address questions and provide assistance, including EHB concerns and constraints. Health centers can reach the help desk on-line at <http://www.hrsa.gov/about/contact/bphc.aspx> or by phone at (877)-974-2742 Monday through Friday (except federal holidays) from 8:30 AM to 5:30 PM (ET). In addition, health centers have a HRSA/BPHC assigned project officer involved in the development of the progress report who can address questions regarding report completion.

### **4. Efforts to Identify Duplication and Use of Similar Information**

Data and information included in P4C progress reports are not consistently captured by any other existing source for all 22 health centers participating in the project, as determined through review of current Health Center Program reporting requirements and in consultation with other HHS agencies. Two exceptions include reporting of proposed outcome measures #5 and #6 regarding newly diagnosed patients and linkage to HIV care (see Section #1 above). These measures also are reported to UDS; however, the data do not become available for programmatic use until four to six months after the information is needed for project monitoring due to UDS data aggregation, cleaning and validation efforts for the entire UDS report across over 1,300 health centers. These two measures in the Outcomes Report are identical to the corresponding measures in UDS and do not require any additional hours to calculate.

### **5. Impact on Small Businesses or Other Small Entities**

Every effort has been made to ensure that proposed P4C progress reports contain the minimum amount of data and information necessary to meet monitoring and reporting requirements.



Proposed HIV outcome measures build on data currently collected and maintained by health centers for internal administrative and clinical needs. In addition, one of the eligibility criteria for health center participation in the P4C project was use of EHR across all health center service delivery sites.

## **6. Consequences of Collecting the Information Less Frequently**

P4C supplemental funding is awarded annually. If P4C progress reports are collected less frequently, the ability to identify poor performance and intervene through increased monitoring, training and technical assistance, or termination of funding will be compromised. Information regarding project implementation is collected in both the Implementation and Outcomes Reports to ensure ongoing compliance with P4C requirements and appropriate stewardship of federal funds. Information regarding the 14 outcome measures collected in the Outcomes Report is required to monitor program performance and ensure improvement in outcomes along the HIV care continuum during each year of the project.

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

The data are collected in a manner consistent with guidelines contained in 5 CFR 1320.5(d)(2).

## **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 23, 2014, vol. 79, No. 205; pp. 63408-09. There were/were no public comments.

### ***Section 8B***

To develop an initial set of measures, HRSA/BPHC worked in collaboration with CDC/DHAP (co-lead on the P4C project) and in consultation with the HRSA HIV/AIDS Bureau to develop and refine outcome measures for the P4C project. Weekly meetings were held over a five-month period to review and confirm the purpose of the proposed data collection, establish guiding questions of interest, review existing HIV-related measures and their specifications, identify gaps in available data, discuss potential measures, align and streamline measure language and specifications, and refine a final set of draft measures.

In December 2014, HRSA/BPHC and CDC/DHAP shared draft HIV outcome measures with all 22 health centers funded under the P4C project and invited their feedback regarding measure clarity, utility and feasibility. During the first P4C All Partners Meeting in January 2015, HRSA/BPHC and CDC/DHAP used part of the two-day meeting to review and facilitate discussion of draft measures. In addition to the 22 health centers, the meeting was also attended by the four state health departments funded under the P4C project; two HRSA-funded health center controlled networks (see <http://www.hrsa.gov/healthit/networkguide/>); and a federal official from OHAIDP (the names, organizations, and email addresses of those participating in the January 2015 all partners meeting were provided with this statement in a separate document). HRSA/BPHC and CDC/DHAP used feedback to further refine proposed measures. Prior to finalizing measures in March 2015, HRSA/BPHC and CDC/DHAP requested OHAIDP's review and approval. Major comments received during the consultation process are summarized in Table 1 below.

Table 1. Summary of Comments Received Regarding Draft HIV Outcome Measures Proposed for the P4C Project

Area	Comment	Federal Response
Alignment with UDS	<ul style="list-style-type: none"> <li>- Aligning measures with ICD-9 and CPT codes will enhance clarity. Specifying all applicable codes is not necessary. Referencing established measures and guidance is sufficient and preferable (e.g., UDS, National Quality Forum, Ryan White HIV/AIDS Program).</li> </ul>	<ul style="list-style-type: none"> <li>- P4C outcome measure specifications are tied to ICD-9 and CPT codes where possible. References to established measures will be included in progress report templates.</li> </ul>
	<ul style="list-style-type: none"> <li>- Similar to UDS, focus measures on patients that have at least one medical care visit at the health center during the reporting period</li> </ul>	<ul style="list-style-type: none"> <li>- All measures focus on health center medical patients, with one exception which requires reporting of all HIV positive patients seen at the health center for any reason. This measure helps to quantify health center capacity to provide HIV medical care services to people living with HIV.</li> </ul>
EHR Complexities	<ul style="list-style-type: none"> <li>- Concerns expressed regarding the best ways to modify EHRs and build templates to support data extraction and reporting.</li> </ul>	<ul style="list-style-type: none"> <li>- Through the technical assistance contractor funded under the P4C project, a series of webinars will be held for health centers providing additional insights into the use of different EHR platforms for P4C reporting and quality improvement efforts. In addition, the technical assistance contractor will partner with HRSA-funded health center controlled networks to facilitate opportunities for additional support.</li> </ul>
	<ul style="list-style-type: none"> <li>- EHR reporting templates may not allow federal officials to interchange denominators across measures. Be sure that outcome measure numerators and denominators are specified for what is needed.</li> </ul>	<ul style="list-style-type: none"> <li>- All P4C outcome measure numerators and denominators have been specified and include all applicable inclusion and exclusion criteria. In calculating percentages for performance measures, federal officials will not interchange reported denominators.</li> </ul>

Table 1. Summary of Comments Received Regarding Draft HIV Outcome Measures Proposed for the P4C Project

Area	Comment	Federal Response
	<ul style="list-style-type: none"> <li>- Using measures that have been e-specified or endorsed is useful for building report templates. Reference established measures where possible to support measure specifications.</li> </ul>	<ul style="list-style-type: none"> <li>- Comparisons to existing measure will be provided throughout the progress report, where applicable.</li> </ul>
Routine testing	<ul style="list-style-type: none"> <li>- Clarification requested regarding what types of HIV tests must be reported under the measure.</li> </ul>	<ul style="list-style-type: none"> <li>- P4C outcome measures require reporting of HIV tests conducted among patients aged 15 to 65 years using any and all types of test devices or technologies, including laboratory-based tests and rapid tests.</li> <li>- Due to greater accuracy and cost-effectiveness, health centers are strongly encouraged to develop the capacity for laboratory based HIV testing.</li> </ul>
	<ul style="list-style-type: none"> <li>- Concerns expressed regarding limiting reporting of routine testing to those tested conducted among patients aged 15-65 years. Ignores tests that may be conducted among those outside the age group in need of testing.</li> </ul>	<ul style="list-style-type: none"> <li>- According to US Preventive Services Task Force Recommendations, the population recommended for routine screening (i.e., at least once in a lifetime screening) are patients aged 15 to 65 years. Patients under 15 and over 65 are recommended for testing if at risk for infection (i.e., targeted testing). P4C outcome measures are limited to reporting of data that is most useful for assessing implementation of routine testing.</li> <li>- UDS currently captures all patients receiving HIV testing regardless of age.</li> </ul>
Services Rendered	<ul style="list-style-type: none"> <li>- Since it is not likely that all HIV positive patients will require risk reduction counseling, measuring behavioral risk screenings alone or in combination with risk reduction counseling is preferable.</li> </ul>	<ul style="list-style-type: none"> <li>- P4C outcome measure pertaining to risk reduction includes both screening and counseling to ensure that an assessment is used to guide the provision of appropriate interventions as needed.</li> </ul>



Table 1. Summary of Comments Received Regarding Draft HIV Outcome Measures Proposed for the P4C Project

Area	Comment	Federal Response
	<ul style="list-style-type: none"> <li>- STI screening measure does not include hepatitis C or tuberculosis which or common co-occurring illnesses.</li> </ul>	<ul style="list-style-type: none"> <li>- P4C outcome measure pertaining to STIs is limited to those that contribute to the transmission or acquisition of HIV infection. In addition, this measure is aligned with the Ryan White HIV/AIDS Program and the National Quality Forum’s endorsed measures for HIV.</li> </ul>
	<ul style="list-style-type: none"> <li>- When determining the start date for the 90 day window during which linkage to HIV medical care must occur for newly diagnosed patients, consider using a surveillance-based measure or guidance (e.g., date of first specimen collection).</li> </ul>	<ul style="list-style-type: none"> <li>- P4C outcome measure pertaining to linkage to care will use date of specimen collection to establish the start date for the 90 day linkage to care window.</li> </ul>
	<ul style="list-style-type: none"> <li>- Additional guidance needed regarding what constitutes an HIV medical care visit.</li> </ul>	<ul style="list-style-type: none"> <li>- For applicable P4C outcome measures, HIV medical care visit is determined by the type of provider rendering the service. Applicable measures require that services be provided by a medical provider who provides comprehensive HIV care at the health center as determined by a health center established list. In addition, HIV medical care can include services rendered through a formal written agreement or contract, or as determined by health department follow-up.</li> </ul>
Viral Suppression	<ul style="list-style-type: none"> <li>- Consider changing viral suppression threshold from &lt;200 copies to &lt;75 copies to mirror what is being used in the field.</li> </ul>	<ul style="list-style-type: none"> <li>- P4C outcome measures will include two viral suppression measures to capture both what is required under the DHHS approved core measures for HIV reporting (viral load &lt;200 copies/mL) and what is commonly used in the field for clinical decision making (viral load &lt;75 copies/mL).</li> </ul>

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

Respondents will not receive any payments or gifts.

**10. Assurance of Confidentiality Provided to Respondents**

P4C progress reports do not involve the reporting of any personally-identifiable information about individuals. The Outcomes Report requires the reporting of aggregate data only. Data will be reported in aggregate across all patients and service delivery sites for each responding health center.

## **11. Justification for Sensitive Questions**

There are no questions of a sensitive nature. All information is reported in aggregate across all patients and service delivery sites. Individual patients cannot be identified based on these aggregate totals. When reporting results from this project, HRSA will use “fewer than 10” when publicly referring to or reporting outcomes representing fewer than 10 patients. This approach is also used by HRSA’s HIV/AIDS Bureau when reporting data from the Ryan White HIV/AIDS Program.

## **12. Estimates of Annualized Hour and Cost Burden**

Bi-annual P4C progress reports are proposed using two forms, including the Implementation Report and the Outcomes Reports. The Implementation Report will request information pertaining to project implementation, including work plan progress across each of the project’s five focus areas; budget modifications; established and actual projections for service delivery, workforce development and partnership development; successes or promising practices; and training and technical assistance needs. The Outcomes Report will request aggregate data for the 14 HIV outcome measures in addition to information requested in the Implementation Report.

### ***12A. Estimated Annualized Burden Hours***

Hour burden estimates for report preparation are provided in Table 2 below.

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Health centers	Implementation Report	22	1	5	110
Health centers	Outcomes Report	22	1	25	550
<b>Total</b>		<b>44</b>			<b>660</b>

The Implementation Report requires five hours to complete based on the average amount of time needed to review instructions and discuss responses to questions with members of the health center team working on the project (1.25 hour), draft corresponding text (2 hours), integrate feedback received during internal review (1.5 hours), and submit the report into EHB (0.25 hour).

The Outcomes Report requires 25 hours to complete based on the average amount of time required to review instructions and answer questions regarding program implementation (five hours as described in previous paragraph), in addition to the time required to review instructions and report on HIV outcome measures (20 hours).

Estimates for reporting HIV outcome measures are based on recent estimates for UDS reporting given similarities in the structure of reporting tables and the process used to gather requested data. Health centers were provided opportunities to review and comment on measures prior to finalization. In March 2015, HRSA facilitated and archived a webinar for the 22 health centers to review and discuss the definitions and criteria for each outcome measure. Therefore, health centers are familiar with the proposed measures and have begun internal dialogues regarding their reporting. Upon OMB approval of the report forms, HRSA will facilitate and archive a second webinar to review report form instructions.

### 12B. Estimated Annualized Burden Costs

Hour burden costs for report preparation are provided in Table 3 below.

Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Hour Cost
Implementation Report	22	1	5	110	\$30.53	\$3,358.30
Outcomes Report	22	1	25	550	\$30.53	\$16,791.50
<b>Total</b>	<b>44</b>					<b>\$20,149.80</b>

Activities associated with health center completion of the Implementation and Outcomes Reports can be performed by various mid-level health center staff (e.g., project managers or leads, information technology staff, quality control staff) with an estimated average wage rate of \$30.53 per hour (comparable to federal government salary for GS-11 Step 1 2015 for DC-MD-VA-WV-PA).

Since health centers were required to have an EHR to participate in the P4C project, all responding health centers will use an automated system to generate the required reports; however, systems may vary in their ease of use and flexibility. Most responding health centers use relational databases that can easily accommodate reporting specifications. Other health centers use hierarchically-structured systems, or some combination of relational and hierarchically-structured systems, requiring more time to retrieve data in required formats. For some outcome measures, health centers in year one of the project have the option of reporting data through sample chart audits using procedures identical to those established for UDS.

In addition to the burden costs associated with report completion, health centers may incur one-time costs associated with systems preparation to extract necessary data. Burden hours and costs for system preparation are not report specific and estimated as follows:

1. Abstracting data from paper charts and/or electronic systems to report the new measures totaling \$23,508 (35 hours x 22 health centers x \$30.53 per hour).
2. Responding to questions regarding EHR capabilities totaling \$1,343 (2 hours x 22 health centers x \$30.53 per hour).

As health centers develop reporting proficiencies and advance from initial start-up activities to establishing routine data abstraction methods for the new outcome measures, it is expected that burden hours and costs will decrease by 20% each year. Furthermore, it is expected that health centers will experience cost "economies" from reporting the outcome measures as they are consistent with those currently endorsed by national standard setting organizations, used by other federally funded programs, or proposed for Meaningful Use.

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

One-time capital costs associated EHR programming or re-programming to facilitate reporting on new outcome measures in the required format are estimated to average \$1,000 per health

center, totaling \$22,000 (22 health centers x \$1,000).

#### **14. Annualized Cost to Federal Government**

The annualized cost to the federal government for P4C data collection and analysis is estimated to be \$132,659, as summarized in Table 4 below. HRSA/BPHC (Rockville, MD) and CDC/DHAP (Atlanta, GA) are working in collaboration to monitor, analyze and report results of the project; therefore, federal staff from each agency will support this information collection. There are no new printing, equipment or other non-hourly costs incurred as a result of this data collection.

Position	Role	Years on Project	Average FTE per year	GS scale	Total FTE Cost
BPHC Project Co-Lead	<ul style="list-style-type: none"> <li>- Progress report (PR) development</li> <li>- Provision of technical assistance</li> <li>- Conduct PR data analysis</li> <li>- Support public dissemination of results</li> <li>- Preparation of mandatory reports</li> </ul>	3	.40	GS14-4 \$118,057	\$47,223
BPHC Management Analyst	<ul style="list-style-type: none"> <li>- Administrative support</li> </ul>	3	.08	GS7-1 \$43,057	\$3,445
BPHC Intern	<ul style="list-style-type: none"> <li>- Conduct PR data cleaning and extraction</li> <li>- Summarize PR data</li> </ul>	3	.15	GS1-1 \$22,560	\$3,384
CDC Project Co-Lead	<ul style="list-style-type: none"> <li>- Support PR data analysis</li> <li>- Support preparation of mandatory reports</li> <li>- Support public dissemination of results</li> </ul>	3	.25	GS14-1 \$103,065	\$25,766
CDC Evaluation Lead	<ul style="list-style-type: none"> <li>- Lead PR analytical approach</li> <li>- Lead public dissemination of results</li> </ul>	3	.25	GS13-2 \$90,126	\$22,532
CDC Medical Officer	<ul style="list-style-type: none"> <li>- Conduct PR data analysis</li> <li>- Prepare for public dissemination of results</li> </ul>	3	.25	GS15-1 \$121,234	\$30,309
<b>Total Cost</b>					<b>\$132,659</b>

#### **15. Explanation for Program Changes or Adjustments**

This is a new information collection.

#### **16. Plans for Tabulation, Publication, and Project Time Schedule**

Reviews will be performed on each submitted progress report to ensure that all requested information is provided and appears valid. Any concerns will be discussed with the responding health center and individualized technical assistance provided as needed to support submission of a revised report. Advanced statistical methods such as sampling, imputation or estimation will

not be used to analyze progress reports. Basic analytical techniques will be used given the small sub-set of health centers from which data is collected (i.e., 22 out of over 1,300 health centers nationally), including:

1. **Data and information preparation** to create, format, document and back-up complete analytical files for analysis.
2. **Content analysis of qualitative information** to describe and make logical conclusions about health center implementation of the project and compliance with project requirements; and establish categorical data for further analysis.
3. **Univariate analysis of quantitative and categorical data** to describe variation and trends in project implementation and outcomes along the HIV care continuum.
4. **Correlation analysis** to measure relationships between project implementation and outcomes, and identify promising practices.
5. **Case study analysis** to explore patterns in the data, understand outliers, and validate conclusions.

Results of these analyses will be used to draft mandatory federal reports pertaining to the project, including: 1) SMAIF-funded project outcome reports submitted to OHAIDP (internal federal use), 2) progress reports regarding the National HIV/AIDS Strategy and HIV Care Continuum released by HHS or the Office of National HIV/AIDS Policy (publicly disseminated), and 3) the annual HIV Testing Report to Congress prepared by the CDC (internal federal and Congressional use). Results from these analyses will also inform the development of a health center toolkit regarding promising practices for the integration of HIV services into primary care (publicly disseminated on HRSA website). The toolkit may present some quantitative results from conducted analyses to illustrate the effectiveness of proposed practices. Publication plans are still to be determined, but will likely involve abstracts for national professional conferences and one or more peer-reviewed journal publications regarding project implementation, outcomes, promising practices, and lessons learned.

The P4C project period for participating health centers is September 1, 2014 through August 31, 2017; therefore, a three-year clearance period is requested. Analysis, reporting and publication of collected data may continue for up to two-years after the end of the project period.

#### **17. Reason(s) Display of 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.