

Integrating Community Pharmacists and Clinical Sites for Patient-Centered HIV Care

OMB No. 0920-1019

Supporting Statement A

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Kathy Byrd, MD, MPH, Project Officer
Centers of Disease Control and Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB
Prevention
Division of HIV/ AIDS Prevention- Surveillance and Epidemiology
HIV Epidemiology Branch
1600 Clifton Rd., MS E-45
Atlanta, GA 30333
Phone: 404-639-3083
Fax: 404-639-6127
Email: gdh8@cdc.gov

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- Goal of the project: Develop and implement a model of HIV care that integrates community pharmacists with primary medical providers for patient-centered HIV care.
- Intended use of the resulting data: The expected outcomes, of the model program, are improved retention in care, adherence to medication therapy and viral load suppression, among the project cohort. Data will be used to adjust the project model as needed.
- Methods to be used to collect: A one-time retrospective medical record abstraction will occur at participant enrollment into the project. Most data collected from the project clinics and pharmacies are routinely collected as part of normal patient care. In addition, the project sites will participate in key informant interviews, a staff questionnaire and sites will collect time and cost data related to project activities.
- The subpopulation to be studied: HIV infected adults.
- How data will be analyzed: Both quantitative and qualitative methodologies will be utilized to analyze the data collected.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests OMB approval for information collection of a pilot program to establish patient-centered HIV care entitled Integrating Community Pharmacists and Clinical Sites into a Model of Patient-Centered HIV Care (OMB No. 0920-1019, expires 05/31/2017) - [Revision] The data collection is authorized under the Section 301 of the Public Health Service Act (42 U.S.C. 241) (**Attachment 1**). Revisions to the IC include addition of an Interviewer data collection worksheet, Key Informant Interviewer script, Staff communication questionnaire, Clinic cost form, Pharmacy cost form and estimations of annualized burden hours for each data collection. The additions are needed in order to determine changes to clinic and pharmacy work systems, processes and outcomes in relation to the model project and how and if the model program improves patient outcomes through improved communication and collaboration between patients' clinical providers and pharmacists. In addition, in order to determine the general feasibility of the model program, the time required

conducting program activities and the associated cost of program activities must be determined.

Collection of data from the previously approved Initial patient information forms, Quarterly patient information forms, Pharmacy record abstraction forms, Project clinic characteristics forms, and Project pharmacy characteristics forms is ongoing.

Under a request for non-substantive change, the project consent form was replaced on July 17, 2014 with a project *Information Sheet (Attachments 9a, 9b)* which details the services participants will receive, the information that will be shared between the pharmacist, clinic medical provider and the project team. Clinic staff will use the Information Sheet to explain the project to patients. No additional time burden on project staff resulted in this change.

Background

Due to the growing numbers of persons living with HIV infection, the demand for HIV care providers is greater than ever. Unfortunately, the HIV workforce may be declining rather than growing. A survey of the American Academy of HIV Medicine members revealed that 45% of the HIV care workforce is greater than 50 years of age and expects to retire within 10 years. These statistics, when coupled with a trend in declining numbers of healthcare providers seeking training in HIV care, have raised concerns about the future adequacy of the HIV care workforce. In the National HIV/AIDS Strategy (NHAS) released in 2010, the White House emphasized the growing mismatch between patient needs and provider availability. Accordingly, the NHAS specifically recommends that the nation should *increase the number and diversity of health care practitioners to strengthen the current provider workforce* and to ensure quality HIV care.

Also among the goals, listed within NHAS, is the goal to increase the proportion of HIV diagnosed minorities with undetectable HIV viral load by 20% by 2015. Achieving this goal will depend on patients learning their HIV status, engaging in care, remaining in care and adhering to prescribed therapy. However, barriers within the existing healthcare infrastructure can impede access to, retention in, and adherence to care. These barriers may be particularly challenging for minorities living in medically underserved areas in both urban and rural settings. In urban areas, busy clinics are often inadequately resourced to maintain high levels of investment in retention and adherence activities.

In rural settings, the long distances many patients must travel to receive competent HIV care is a key obstacle to retention and adherence.

In 2011, the American Academy of HIV Medicine began to credential pharmacists working in HIV-specific care environments as "HIV Pharmacists (American Academy of HIV Pharmacists - AAHIVP);" the credential is designed for clinically-experienced pharmacists who specialize in HIV care and who have direct clinical activity on a regular basis. During the same year, the HIV Medicine Association of the Infectious Disease Society of America and the Ryan White Medical Providers Coalition published a policy statement on the essential components of effective HIV care that emphasized the importance of pharmacist involvement as a member of the HIV Care Team.

Though some pharmacy networks offer Specialty Pharmacy HIV/AIDS Support services in select pharmacies, expanding upon pharmacists' success in the clinic setting to broader programs adapted for community pharmacists (pharmacists whose primary duties are conducted in pharmacies within the community which are not associated with a medical clinic or hospital) would be an innovative model for collaboration and division of labor between healthcare providers and pharmacists.

Pharmacists can support medical providers and enhance patient care through Medication Therapy Management (MTM). Medication Therapy Management is a group of pharmacist provided services that is independent of, but can occur in conjunction with, provision of medication. Medication Therapy Management encompasses a broad range of professional activities and cognitive services within the licensed pharmacist's scope of practice and can include monitoring prescription filling patterns and timing of refills, checking for medication interactions, patient education, and monitoring of patient response to drug therapy. HIV specific MTM programs have demonstrated success in improving HIV medication therapy adherence and persistence. While MTM programs have been shown to be effective in increasing medication adherence for HIV-infected persons, no MTM programs have been expanded to incorporate primary medical providers in an effort to establish patient-centered HIV care.

Project overview

To address these problems, CDC has entered into a partnership with Walgreen Company (a.k.a Walgreens pharmacies, a national retail pharmacy chain) and the University of North Texas Health Science Center (UNTHSC) to develop and implement a model of HIV care that integrates community pharmacists with primary medical providers for patient-centered HIV care. The model program will

include the core elements of MTM which include: Medication Therapy Review, Personal Medication Record, Medication-related action plan, Intervention and/or referral and Documentation and follow-up. In addition, project pharmacists will perform additional services such as individualized medication adherence counseling, active monitoring of prescription refills and active collaboration with medical clinic providers to identify and resolve medication related treatment problems such as treatment effectiveness, adverse events and poor adherence.

The service model will be developed by CDC in collaboration with Walgreens pharmacies and UNTHSC. The University of North Texas Health Science Center is a CDC grantee funded through a co-operative agreement who will manage and coordinate project sites, collect data from the project sites and transmit the data to CDC.

The pilot program will be conducted in ten project sites. Each project site will be made up of at least one Walgreens pharmacy and one medical clinic with which the pharmacy will partner. Each project pharmacy will be a Walgreens HIV Center of Excellence (COE). Walgreens COEs are pharmacies that are staffed with specially-trained pharmacists who work closely with HIV patients to offer guidance and support with their medication therapy. A total of 1000 HIV-infected persons (~100 patients per site) will be enrolled in the patient-centered HIV care pilot project. The project sites will enroll minority populations disproportionately affected by HIV (i.e. Black, Latino and American Indian/Alaska Native populations). Walgreens will provide expanded MTM services to participants of the pilot program and will work with medical clinic providers to implement the service model.

The project clinics will be funded to participate in the project through a sub-contract of the co-operative agreement. Walgreens is donating its time and resources in-kind. Project staff at project clinics and pharmacies will collect data from their respective clinics and pharmacies. Most data collected from the project clinics and pharmacies are routinely collected as part of normal patient care. In addition, the project sites will participate in key informant interviews and will collect time and cost data related to project activities. Program data will then be sent to the grantee (UNTHSC) who will clean the data and resolve any data discrepancies before sending the data to CDC.

The patient-centered HIV care model program is a 3 year pilot project. No statistical sampling will be used to identify or enroll project participants. Project outcomes will be compared within the project cohort (i.e. outcomes pre- and post-intervention) and are not meant to be generalizable to the general public. Rather, the purpose of the project is to develop

a patient-centered HIV care model to increase clinic and pharmacy collaboration and to determine the service model's performance within the project cohort. The expected outcomes, of the model program, are improved retention in care, adherence to medication therapy and viral load suppression, among the project cohort. The project has been determined to not be human subjects' research.

2. Purpose and Use of Information Collection

CDC will use the information collection for the following purposes:

- 1) To monitor the implementation of the pilot program. The IC will allow CDC to determine if the project sites are conducting the core elements of the service model. Without this information CDC will not be able to intervene if project sites fall behind project timelines, fail to perform or ineffectively perform model services.
- 2) To determine barriers to effective implementation of the service model and to derive solutions to those barriers in order to improve the service model and more effectively serve clients. The data will be used to address general program implementation problems. For example, if upon review of the data, it is determined that targeted minority groups (Black, Latino and American Indian/Alaska Native populations) are not being enrolled into the program in sufficient numbers, a corrective course of action will be taken.
- 3) To determine if the pilot program improves patient outcomes through improved collaboration between patients' clinical providers and pharmacists. Adverse events, medication interactions, inappropriate regimens, suboptimal regimens, ineffective regimens, contradicted regimens and poor compliance are all therapy related problems that can be recognized by pharmacists. Increased interaction and collaboration between project pharmacists and clinic providers may decrease these therapy related issues potentially leading to improved adherence and viral load suppression. As such, data on project clinic providers' and project pharmacists' interactions and the nature of those interactions will be collected to determine if active collaboration improves patients' health outcomes.
- 4) To determine if the pilot program improves retention in care, adherence to medication therapy and HIV viral load suppression. Without collecting data the service model cannot be determined to be either effective or ineffective. Data on indicators of retention in HIV care (e.g. clinic appointments

kept) and adherence to HIV medication therapy (e.g. prescription refills) are necessary to measure whether the service model achieves its goal of improving retention in care and adherence to HIV medication therapy. Laboratory test values are necessary to determine effectiveness of HIV medication therapy (i.e. viral load suppression) and to identify possible medication adverse effects (e.g. elevated liver function tests and creatinine) both of which can affect adherence.

- 5) To determine if the pilot program improves non-HIV health outcomes such as hypercholesterolemia and co-infection with viral hepatitis. Since the advent of antiretroviral therapy (ART), HIV has become a chronic, rather than an acute, disease which has necessarily led providers of HIV-infected patients to treat and manage more chronic co-morbidities which can affect overall morbidity among HIV-infected persons. As such, data on co-morbidities, and therapies related to those co-morbidities, will be collected to determine if the model improves adherence to therapy for co-morbid conditions.
- 6) To determine the feasibility of the program by determining the time required to conduct program activities and the associated cost of the model program.

3. Use of Improved Information Technology and Burden Reduction

The grantee will submit data to CDC in an Excel or Access database or by using another similar data software package.

4. Efforts to Identify Duplication and Use of Similar Information

CDC personnel have conducted extensive computerized searches of electronic databases of published articles and abstracts. Those databases include MEDLINE and PubMed. While there is literature available that details MTM programs, we could find no interventions that incorporated community pharmacists with primary medical providers to deliver patient-centered HIV care. The intervention to be implemented and the supportive data collection needed to monitor the performance of the model, in order to determine program outcomes, has not been previously conducted.

5. Impact on Small Businesses or Other Small Entities

Each project site will contain at least one Walgreens pharmacy and at least one medical clinic. While Walgreens is a large national pharmacy chain, project medical clinics may be small clinics. Project clinic participation is voluntary. The data

collection will be the same for both large and small project clinics. To reduce the burden of collecting data, each project site will be limited to enrolling 100 clients for the duration of the three year project.

6. Consequences of Collecting the Information Less Frequently

A one-time retrospective medical record data collection will occur at the beginning of the project in order to document clients' baseline characteristics and history. These data are necessary in order to compare health outcomes prior to and after implementation of the pilot program. After program implementation, project staff will collect medical record and pharmacy record data on a quarterly basis. The quarterly data collections are needed for program performance monitoring and for adjustment of the program model. As such, less frequent data collection would result in a delay between the occurrence and the identification of program problems. Less than quarterly data collection would result in the inability to identify and correct program problems early, which would result in program inefficiencies and/or deficiencies and result in a delay in the development of the final program model. There are no legal obstacles to reducing the burden.

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

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.

A 60-day federal register notice to solicit public comments was published on 01/30/2015, Volume 80, Number 20, Page Number 5114-5115. A copy of this publication is attached (**Attachment 2**). One comment was received from the public in response to the 60-day Federal Register Notice, and a CDC standard response was sent (**attachment 2a**).

The development of data collection instruments, for this project, has been a collaborative effort between CDC, Walgreens and the University of North Texas Health Science Center. The following persons have reviewed the data collection instruments for content, clarity, frequency of collection and necessity. Each individual was consulted in 2013 and each is either an expert on pharmacy MTM programs, HIV medications, HIV clinical care or community advocacy.

Glen Petrandoni RPh, Senior Manager, HIV/AIDS and Hepatitis, Walgreens, (847) 315-7162, glen.pietrandoni@walgreens.com

Ambrose Delpino PharmD, Manager, Virology, Walgreens, (847) 315-8003 ambrose.delpino@walgreens.com

Michael Taitel PhD, Director of Clinical Outcomes, Walgreens (847) 964-8102, michael.taitel@walgreens.com

Michael Johnson BS, Manager MTM programs, Walgreens (847) 315-7152, Michael.Johnson@walgreens.com

Leonard Fensterheim MPH, Manager Health Outcomes and Analytics, Walgreens (847) 964-8986, leonard.fensterheim@walgreens.com

Patrick Clay PharmD, University of North Texas Health Science Center (817) 735-2798, Patrick.Clay@unthsc.edu

Michael Shankle MPH, Director of Prevention and Policy, HealthHIV (202) 232-6749, michael@healthhiv.org

Kristin Darin PharmD, Research Assistant Professor, Northwestern University Feinberg School of Medicine, (228)327-3844, k-hurt@northwestern.edu

Kim Scarsi PharmD, Associate Professor, University of Nebraska Medical Center, (402)555-4333, kim.scarsi@unmc.edu

Katura Bullock PharmD, Assistant Professor of Pharmacotherapy, University of North Texas Health Science Center, (817)735-2907, Katura.Bullock@unthsc.edu

Shara Elrod PharmD, Assistant Professor of Pharmacotherapy, University of North Texas Health Science Center, (817) 735-0169, Shara.Elrod@unthsc.edu

Ben Bluml BSPHarm, American Pharmacists Association (APhA) Foundation, (202) 268-4410, Bbluml@aphanet.org

Staff from the Health Resources and Services Administration (HRSA), and the National Minority AIDS Coalition were also consulted on data collection:

Polly Ross MD, Deputy Director Division of Community HIV/AIDS Programs, Health Resources and Services Administration, HIV/AIDS Bureau
(301) 443-7602, PRoss@hrsa.gov

Seiji Hayashi MD, MPH, Chief Medical Officer for the Bureau of Primary Health Care, Health Resources and Services Administration
301-443-1454, SHayashi@hrsa.gov

Daniel Montoya BBA, Deputy Executive Director, National Minority AIDS Coalition, (202) 680-3824, dmontoya@nmac.org

9. Explanation of Any Payment or Gift to Respondents

No payment or gifts will be provided to participants of the patient-centered HIV care model. Project clinics will be funded to participate in the project through a contract.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act does not apply because the survey does not collect name, social security number, or other personally identifying information.

The project clinics and pharmacies will send data to the grantee who will clean the data, resolve data discrepancies and then transmit the data to CDC. Data will be electronically transmitted to CDC through the CDC Secure Data Network (SDN). All data transmissions are automatically encrypted by the software that generates the transfer files. Security certificates are used to control access to the SDN. None of the data received by CDC will be identifiable, and no information will be used for any purpose other than the purpose for which it was supplied. None of the data received by CDC will include patient names, addresses, phone numbers, social security numbers, medical record numbers, or full birthdates (just month and year). In the data sent to CDC, program participants will be identified only by a unique participant ID number. The unique ID number will be assigned and maintained by the project sites. Neither the grantee nor CDC will have access to the participant ID key. Once at CDC, the data will be stored in a secure CDC server. All CDC project desktop computers and laptops will be password protected. Further, CDC employees will not be intervening or interacting with program participants.

The following procedures will be used to protect participant records:

- CDC will not receive patient names, initials, medical record numbers, social security numbers, locator or other personally identifiable information.
- Data records received by CDC will only be identified by a unique participant ID number. CDC will not be able to link that participant ID number to any personal identifier.
- All data from the project will be encrypted and stored on a secure CDC server.
- Only authorized and authenticated CDC-based project staff (e.g. project officer, project coordinator, data manager) will have access to the data at CDC.
- The Grantee will complete the computer-based NIH ethics training annually and provide proof of course completion to CDC.
- CDC project staff will complete the Information Security Awareness Training annually.
- Papers and presentations, on project results, will report aggregated information and will not contain any identifying information that can be traced back to a program participant.

Program participants (clients of the project medical clinics and of the project pharmacies) will be given an informational sheet (**Attachment 9a and 9b**) about the project. Program participants will be informed that participation is voluntary. Patients who do not wish to participate in the model program will continue to receive their usual care at the medical clinics and pharmacies. Program participants give consent to medical clinics and pharmacies for receipt of medical care, collection of personally identifying information and for sharing of information for the improvement of medical care. Although medical clinics and pharmacies collect personally identifying patient information, in order to conduct their normal business operations and for clinics and pharmacies to collaborate on patient care, no personally identifying information will be sent to CDC.

In no case will patient personally identifying information be reported to CDC. All identifiers will be maintained at the local project clinic and pharmacy level as required for medical care and follow-up. Data collection and reporting will be consistent with the CDC Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, STD and TB Programs: (http://www.cdc.gov/hiv/resources/guidelines/security_confidentiality_hiv.htm)

11. Justification for Sensitive Questions

Information on drug and alcohol use, history of mental illness, history of incarceration, housing and employment status will be collected and may be considered sensitive information. This information is routinely collected by clinical providers, as part of routine care for HIV-infected persons, and will be obtained from the medical record abstraction. Two of the goals of the project are improved retention in care and adherence to HIV medication therapy. Since drug and alcohol abuse, mental illness, incarceration, homelessness and unemployment can all affect both retention and adherence to therapy, collection of this information is necessary for determining factors associated with retention and adherence within the pilot program. Collection of these data will be used to understand barriers to retention and adherence to therapy and the impact these barriers have on HIV health outcomes such as poor HIV viral load suppression, among participants of the pilot program.

In addition, the project will collect information on race and ethnicity. This information is routinely collected by clinical providers, as part of routine care for HIV-infected persons, and will be obtained from the medical record abstraction. The project is being funded by the Assistant Secretary of Health's Minority AIDS Initiative. The Minority AIDS Initiative is part of the Department of Health and Human Services' larger *Initiative to Eliminate Racial and Ethnic Disparities in Health*. Its purpose is to address the HIV/AIDS epidemic within disproportionately affected minority populations. As such, the patient-centered HIV care model project goal is to enroll 70% of participants from African-American and Hispanic populations. Race and ethnicity data must, therefore, be collected to ensure that the targeted populations are being enrolled in the pilot program.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

Project clinic characteristics and project pharmacy characteristics will be collected retrospectively for 2 years at the beginning of the project and annually thereafter. The forms are entitled *Project Clinic Characteristics (Attachment 3)* and *Project Pharmacy Characteristics (Attachment 4)*. Each form will be completed by staff at the project clinics and project pharmacies and each form is estimated to take 30 minutes to complete. One form per project clinic and one form for each project pharmacy will be collected per year of data collection.

A total of 15 hours, for all project clinics and all project pharmacies each, will be spent collecting these data, in the first year, which includes two years of retrospective data and the first year data. A total of 5 hours, for all project clinics and all project pharmacies each, will be spent collecting these data in the second and third year of the project.

Demographic characteristics of persons who did not agree to participate in the project but who gave permission to collect basic demographic information will be collected using the form entitled *Patient Demographic Information (Attachment 5)*. Each form will be completed by project clinic staff and each form is estimated to take 5 minutes to complete. It is estimated that each clinic will complete 100 forms. Thus each clinic will spend an estimated 8 hours completing the *Patient Demographic Information* form for a total of 83 burden hours, for all project clinics.

A one-time initial medical record abstraction will be completed by each of the ten project clinics at the beginning of the project using the form entitled *Initial Patient Information form (Attachment 6a and 6b)*. Project staff at each clinic will complete the form for 100 patients and each form will take an estimated 60 minutes to complete. Thus, each clinic will spend 100 hours completing the *Initial Patient Information* form for a total of 1000 burden hours for all project clinics. This form will be completed in year 1 only.

The *Quarterly Patient Information* form will be collected quarterly (**Attachment 7a and 7b**). Project staff at each clinic will complete the form for 100 patients and each form will take an estimated 30 minutes to complete. Thus, each clinic will spend 50 hours completing the *Quarterly Patient Information* form, in each quarter, for a total of 2000 burden hours for all project clinics per year.

Similar estimates are made for the *Pharmacy Record Abstraction* form (**Attachment 8**): Project staff at each project pharmacy will complete the pharmacy record abstraction form for 100 patients and each form will take an estimated 30 minutes to complete. Thus, each pharmacy will spend 50 hours completing the pharmacy record abstraction form, in each quarter, for a total of 2000 burden hours for all project pharmacies per year.

Interviewer data collection worksheet (Attachment 10a and 10b): Key informant interviews will be conducted twice during the project period. A total of 60 project staff will participate in the each of the two interviews. The interviews are estimated to last 30 minutes. Thus, each interviewee will spend one hour being interviewed for a total of 60 burden hours for all project sites.

Staff communication questionnaire (Attachment 11): A total of 70 project staff will complete the questionnaire. The questionnaire is estimated to take 30 minutes to complete and will be administered twice. Thus, each respondent will spend a total of 60 minutes completing the questionnaires for a total of 70 burden hours for both collection periods for all project sites.

Clinic cost form (Attachment 12): Two project staff at each project clinic will complete the clinic cost form and each form will take an estimated 30 minutes per day or 2.5 hours/week and 10 hours/month. The clinic cost form will be completed for two one-month periods. Thus, each clinic will spend 20 hours completing the clinic cost form for each one-month collection period for a total of 400 burden hours for both collection periods for all project clinics.

Pharmacy cost form (Attachment 13): Two project staff at each project pharmacy will complete the pharmacy cost form and each form will take an estimated 30 minutes per day or 2.5 hours/week and 10 hours/month. The pharmacy cost form will be completed for two one-month periods. Thus, each pharmacy will spend 20 hours completing the pharmacy cost form for each one-month collection period for a total of 400 burden hours for both collection periods for all project pharmacies.

Table A12-1: Estimated Annualized Burden Hours

| Type of respondent | Form Name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|---------------------|--|-----------------------|------------------------------------|--|-------------------------|
| Clinic Data Manager | Project clinic characteristics form Att3 | 10 | 3 | 30/60 | 15 |
| Pharmacist | Project pharmacy | 10 | 3 | 30/60 | 15 |

| | | | | | |
|---------------------|---|----|-----|-------|-------|
| | characteristics form Att4 | | | | |
| Clinic Data Manager | *Patient Demographic Information form Att5 | 10 | 100 | 5/60 | 83 |
| Clinic Data Manager | *Initial patient information form Att6a | 10 | 100 | 1 | 1000 |
| Clinic Data Manager | Quarterly patient information form Att7a | 10 | 400 | 30/60 | 2000 |
| Pharmacist | Pharmacy record abstraction form Att8 | 10 | 400 | 30/60 | 2000 |
| Key informants | Interviewer data collection worksheet Att10a | 60 | 2 | 30/60 | 60 |
| Project staff | Staff communication questionnaire Att11 | 70 | 2 | 30/60 | 70 |
| Clinic staff | Clinic cost form Att12 | 20 | 2 | 10 | 400 |
| Pharmacy staff | Pharmacy cost form Att13 | 20 | 2 | 10 | 400 |
| Total | | | | | 6,043 |

*One time data collection

B. Estimated Annualized Burden Costs

The table below presents the estimated burden costs. The annualized burden cost is \$284,013. The Clinic Data Managers will complete the Project Clinic Characteristics form, the Patient Demographic Information form, the Initial Patient Information form, the Quarterly Patient Information form and the Clinic Cost form. The mean hourly wage of a data manager is \$39.56.

Pharmacists at each of the project sites will complete the Project pharmacy characteristics form, the Pharmacy Record Abstraction form and the Pharmacy Cost form. The mean hourly wage of a Pharmacist is \$56.96.

Six project staff from each project site will participate in key informant interviews. Data from the interviews will be collected on the Interviewer Data Collection worksheet. It is anticipated that three project site pharmacists, two physicians and one nurse from each site will participate in the key informant interviews. The mean hourly wage of a Pharmacist is \$56.96. The mean hourly wage of a Physician is \$91.23. The mean hourly wage of a Nurse is \$33.55.

It is anticipated that three project site pharmacists, two physicians and two nurses from each site will complete the Staff Communication Questionnaire. The mean hourly wage of a Pharmacist is \$56.96. The mean hourly wage of a Physician is \$91.23. The mean hourly wage of a Nurse is \$33.55. All estimates of hourly wage rates are based on the Bureau of Labor Statistics, National Occupational Employment and Wage Estimates for the United States (May 2014).

Table A12-2: Estimated Annualized Burden Costs

| Type of respondent | Form Name | Total burden hours | Hourly wage rate | Total respondent costs |
|---------------------|---------------------------------------|--------------------|------------------|------------------------|
| Clinic Data Manager | Project clinic characteristics form | 15 | \$39.56 | \$593 |
| | *Patient Demographic Information form | 83 | \$39.56 | \$3,283 |
| | *Initial patient information form | 1000 | \$39.56 | \$39,560 |
| | Quarterly patient information form | 2000 | \$39.56 | \$79,120 |
| | Clinic cost form | 400 | \$39.56 | \$15,824 |
| Pharmacist | Project | 15 | \$56.96 | \$854 |

| | | | | |
|-----------------------------|---------------------------------------|------|---------|-----------|
| | pharmacy characteristics form | | | |
| | Pharmacy record abstraction form | 2000 | \$56.96 | \$113,920 |
| | Pharmacy cost form | 400 | \$56.96 | \$22,784 |
| †Key informant (pharmacist) | Interviewer data collection worksheet | 30 | \$56.96 | \$1,709 |
| †Key informant (physician) | Interviewer data collection worksheet | 20 | \$91.23 | \$1,825 |
| †Key informant (nurse) | Interviewer data collection worksheet | 10 | \$33.55 | \$336 |
| ^Project staff (pharmacist) | Staff communication questionnaire | 30 | \$56.96 | \$1,709 |
| ^Project staff (physician) | Staff communication questionnaire | 20 | \$91.23 | \$1,825 |
| ^Project staff (nurse) | Staff communication questionnaire | 20 | \$33.55 | \$671 |
| Total | | | | \$284,013 |

*One time data collection †Key informants will be made up of pharmacists, physicians and nurses. ^Project staff will be made up of pharmacists, physicians and nurses

13. Estimates of other Total Annual Cost Burden to Respondents or Record Keepers

There are no direct costs to respondents other than their time to participate in the data collection.

14. Annualized Cost to the Government

The annualized cost to the government is \$990,016. The information collection described in this request will be funded, coordinated and managed through a cooperative agreement with an implementing partner (i.e. grantee). The federal personnel involved in the patient-centered HIV care model include a Project Officer at the GS 14 equivalent level, a CDC investigator at the GS 15 equivalent level, a Project Coordinator who is a CDC contractor, a Statistician at the GS-14 level, a Data Manager at

the GS-12 level, an Economist at the GS-12 level and two HRSA consultants at the GS-15 level. All CDC and HRSA personnel are assumed to be at the step 10 level with the exception of the Project Coordinator, Data manager and Economist who are assumed to be at the step 5 level. Travel is related to providing technical assistance and conducting site visits to the project clinics and pharmacies.

Table A14: Annualized Cost to the Government

| | Federal salary grade | Salary | % effort | Annualized cost |
|------------------------------|----------------------|-----------|----------|-----------------|
| Co-operative agreement grant | ---- | ---- | ---- | \$799,381 |
| CDC Project Officer | GS 14-10 | \$131,342 | 50% | \$65,671 |
| CDC Investigator | GS 15-10 | \$154,501 | 20% | \$30,900 |
| Project Coordinator | Contractor | \$54,017 | 50% | \$27,009 |
| CDC Statistician | GS 14-10 | \$131,342 | 10% | \$13,134 |
| CDC Data manager | GS 12-5 | \$81,487 | 20% | \$16,297 |
| CDC Economist | GS 12-5 | \$81,487 | 5% | \$4,074 |
| HRSA consultant | GS 15-10 | \$155,500 | 5% | \$7,775 |
| HRSA consultant | GS 15-10 | \$155,500 | 5% | \$7,775 |
| CDC travel | ---- | ---- | ---- | \$18,000 |
| Total | | | | \$990,016 |

Salary estimates were obtained from the US Office of Personnel Management salary scale at <http://www.opm.gov/oca/13TABLES/>

15. Explanation for Program Changes or Adjustments

Key informant interviews, staff communication questionnaire and clinic and pharmacy cost data collection have been added to this information collection. Project staff will be asked to participate in interviews and to complete a questionnaire, twice within the project period. Staff will also be asked to document the time spent on program activities and the associated costs. The addition of the key informant interviews, questionnaires and cost data collection will increase the total burden hours from 5,113 to 6,043. The annualized burden costs will increase from \$220,790 to \$264,979. A detailed explanation of the changes is listed in **Attachment 14**.

16. Plans for Tabulation and Publication and Project Time Schedule

Table A16: Plans for Tabulation and Publication and Project Time Schedule

| Activity | Time Schedule |
|---|---|
| Conduct patient-centered HIV care model | 1-33 months after OMB approval |
| Data collection | 1-33 months after OMB approval |
| Data analysis | 3-36 months after OMB approval (ongoing for program performance monitoring) |
| Final data analysis | 33-36 months after OMB approval |
| Manuscript preparation | 33-36 months after OMB approval |

Data analysis will serve two main functions: 1) to monitor program performance and 2) to determine if the pilot program improves retention in care, adherence to medication therapy and HIV viral load suppression, within the project cohort. No statistical sampling will be used to identify or enroll project participants. Program outcomes will be compared within the project cohort and are not meant to be generalizable to the general public.

Program performance monitoring

Program performance monitoring will focus on the following key elements of the patient-centered HIV care model:

- Number of targeted minority participants (i.e. Black, Hispanic and American Indian and Alaska Native participants) enrolled in model program
- Medication therapy review - number completed, number problems identified, nature of problems identified
- Personal medication record - number completed, number of records updated at least quarterly
- Medication-related action plan - number completed
- Intervention and/or referral - number of problems acted upon, nature of problems, outcomes of interventions
- Documentation and follow-up - number of pharmacy interventions accepted by clinic sites
- Number of clients who received individualized adherence support
- Number and nature of pharmacy and clinic contacts and collaborations

Program outcomes

The three main program outcomes (retention in care, adherence to therapy and viral load suppression) will be compared within the project cohort pre- and post- implementation of the patient-centered HIV care model. Analysis of program outcomes will focus on the following:

- Percentage of participants who have at least one HIV medical care visit in each 6 month period in the measurement period, with a minimum of 60 days between medical visits
- Percentage of HIV-infected persons adherent to their HIV medication regimen
- Percentage of HIV-infected persons with a viral load <200 copies/mL during the last test in the measurement period

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

The OMB expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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