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

OMB No. 0920-1019

Supporting Statement A

February 10, 2016

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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: Determine if model improves retention in HIV care, adherence to therapy and viral load suppression. Data will also be used to adjust the model as necessary.

- Methods to be used to collect: In this revision request, a *Staff communication questionnaire for medical providers* will be administered to determine how and if the model program improves patient outcomes through improved communication and collaboration between patients' clinical providers and pharmacists. All previously approved data collection is ongoing or will commence over the next several months. .

- 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 a three year 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 08/31/2018) – [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 a *Staff communication questionnaire for medical providers*. This addition is needed in order to determine how and if the model program improves patient outcomes through improved communication and collaboration between patients' clinical providers and pharmacists. This addition is different from the previously approved Staff communication questionnaire; the previously approved Staff communication questionnaire is to be administered to program pharmacy staff and the Staff communication questionnaire for medical providers is to be administered to program clinic staff. (Attachment 11b) In

addition, the number of project staff who will complete the previously approved Staff Communication Questionnaire has been reduced from 70 to 30. This reduction is because only the project pharmacists will now complete the Staff Communication Questionnaire while the project clinic staff will only complete the Staff Communication Questionnaire for Medical Providers.

Collection of data from the previously approved Initial patient information forms, Quarterly patient information forms, Pharmacy record abstraction forms, Project clinic characteristics forms, Project pharmacy characteristics forms, Pharmacy cost forms, and Clinic cost forms, is ongoing. Collection of data from the previously approved Interviewer data collection worksheet and Staff communication questionnaire will begin over the next several months.

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 used the Information Sheet to explain the project to patients. No additional time burden on project staff resulted from 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 be 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.

To address the aforementioned 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 includes 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 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 was 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 is being conducted in ten project sites. Each project site is made up of at least one Walgreens pharmacy and one medical clinic with which the pharmacy will partner. Each project pharmacy is 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) are enrolled in the patient-centered HIV care pilot project. Walgreens provides expanded MTM services to participants of the pilot program and works with medical clinic providers to implement the service model.

The project clinics are 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 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 participate in key informant interviews and collect time and cost data related to project activities. Program data is sent to the grantee (UNTHSC) who cleans the data and resolves data discrepancies before sending the data to CDC.

The patient-centered HIV care model program is a 3 year pilot project that began enrollment in August 2014. No statistical sampling was 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

The patient-centered HIV care model project information collection has six primary components: 1) description of project clinics and pharmacies 2) description of non-participant patients 3) medical record abstraction 4) pharmacy record abstraction 5) key informant (project staff) interviews and staff questionnaires 6) time and cost documentation. All information collected is for the purpose of program performance monitoring, adjustment of the project model, as needed, and for determination of program outcomes within the project cohort cost and program costs. Project clinic and pharmacy staff complete the descriptions of each respective project clinic and pharmacy. Medical and pharmacy record abstraction is conducted by project clinic and pharmacy staff for all participants of the pilot program. Most data collected from the medical and pharmacy record abstraction are routinely collected information used by medical clinics and pharmacies for normal patient care. Key project staff participate in key informant interviews and project staff complete a staff communication questionnaire (separate questionnaires for pharmacy and clinic staff) and collect the time spent on and the cost of program activities.

Project clinic and pharmacy characteristics: Project site clinic **(Attachments 3)** and pharmacy **(Attachments 4)** characteristics is collected retrospectively for two years prior to project site enrollment and annually throughout the project period. Project clinic and pharmacy staff at each respective project site collect the information. Project sites send the data to the project

grantee who investigates and resolves data discrepancies. Data is then sent to CDC through a secure network.

Description of non-participant patients: Patients who choose not to participate in the project will be given an opportunity to allow their basic demographic information to be collected (**Attachment 5**). This allows the project team to understand if the people in the project are similar or different to the people who are not in the project.

Medical record abstraction: Medical record abstraction is conducted by project clinic staff at each respective project clinic. De-identified client-level data is collected. Project clinics send the data to the project grantee who investigates and resolves data discrepancies. Data is then sent to CDC through a secure network. All identifiers are removed before data are reported to CDC; each program participant will be assigned a unique program ID. The grantee and CDC store and access data by the assigned participant ID. A one-time retrospective medical record abstraction occured at the beginning of the project in order to document participants' baseline characteristics and history **(Attachment 6a).** After program implementation, project staff collect data on a quarterly basis **(Attachment 7a).** The grantee reports data to CDC on a quarterly basis.

Pharmacy record abstraction: Pharmacy record abstraction is conducted by project pharmacy staff at each respective project pharmacy. **(Attachment 8)** De-identified client-level data is collected. Project pharmacies send the data to the project grantee who investigates and resolves data discrepancies. Data is then sent to CDC through a secure network. All identifiers are removed before data are reported to CDC; each program participant will be assigned a unique program ID. The grantee and CDC store and access data by an assigned participant ID. Project staff collect data on a quarterly basis. The grantee reports data to CDC on a quarterly basis.

Key informant interviews: Each project site chooses six project staff, who have in-depth knowledge of the project processes, to participate in key informant interviews. It is anticipated that the key informants will be made up of three pharmacists, two physicians and one nurse although the make-up of the key informants may be different per site depending on staff knowledge of the project. Interviews will be conducted twice during the project period. Each interview is estimated to last approximately 30 minutes and will focus on changes to clinic and pharmacy work

systems, processes and outcomes in relation to the model project. (**Attachment 10a**)

Staff communication questionnaire: Project staff from each project site will complete a project Staff Communication Questionnaire. It is anticipated that three pharmacists will complete the questionnaires. The questionnaire will be administered twice during the project period The questionnaire is estimated to take 30 minutes to complete and focuses on communication between project pharmacists and medical providers. (**Attachment 11a**)

Staff communication questionnaire for medical providers: Project staff from each project clinic will complete a Staff communication questionnaire for medical providers. It is anticipated that two physicians and two nurses, at each project site, will complete the questionnaires, although the make-up of the respondents may be different per site depending on current project site staffing. The questionnaire will be administered twice during the project period. The questionnaire is estimated to take 30 minutes to complete and focuses on communication between project pharmacists and medical providers. (**Attachment 11b**)

Time and costs associated with project activities: Each project clinic (**Attachment 12**) and pharmacy (**Attachment 13**) documents the time spent on project activities and details associated costs. Each site collects time and cost information for a one month period near the beginning of the project and for a one month period toward the end of the project period.

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

Project sites submit the Quarterly Patient Information forms through an electronic data system, thereby, reducing the need to complete, send and validate paper data forms. The grantee submits all 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 contains 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 is the same for both large and small project clinics. To reduce the burden of collecting data, each project site is 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 occurred 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 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.

8A. A 60-day federal register notice to solicit public comments was published on 11/17/2015, Volume 80, Number 221, Page Number 71806. A copy of this publication is attached (**Attachment 2**). No comments were received from the public in response to the 60-day Federal Register Notice.

8B. 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 or 2013 – 2015 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

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

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Patrick Clay PharmD, University of North Texas Health Science Center

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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

There are no unresolved problems from the consultations. No other public contacts or opportunities for public comment were made.

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. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The Privacy Act does not apply because the data collection does not include name, social security number, or other personally identifying information.

The project clinics and pharmacies send data to the grantee who cleans the data, resolves data discrepancies and then transmit the data to CDC. Data is electronically transmitted to CDC through a secure network. All data transmissions are automatically encrypted by the software that generates the transfer files. Activities do not involve the collection of individually identifiable information. 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 are identified only by a unique participant ID number. The unique ID number is assigned and maintained by the project sites. Neither the grantee nor CDC have access to the participant ID key. Once at CDC, the data is stored in a secure CDC server. All CDC project desktop computers and laptops are password protected. Further, CDC employees do not intervene or interacte with program participants.

The following procedures are used to protect participant records:

- CDC does not receive patient names, initials, medical record numbers, social security numbers, locator or other personally identifiable information.
- Data records received by CDC are only identified by a unique participant ID number. CDC is not 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) have access to the data at CDC.
- CDC project staff have completed 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) were given an informational sheet (**Attachment 9a and 9b**) about the project. Program participants have been informed that participation is voluntary. Patients who did not wish to participate in the model program continued 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 is sent to CDC.

In no case is patient personally identifying information reported to CDC. All identifiers are maintained at the local project clinic and pharmacy level as required for medical care and follow-up. Data collection and reporting is 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. Institutional Review Board (IRB) and Justification for Sensitive Questions

This project underwent review by the National Center of HIV, Hepatitis, STD and Tuberculosis Prevention at CDC and was determined to be non-research. As such, the project did not require IRB review.

Information on drug and alcohol use, history of mental illness, history of incarceration, housing and employment status are 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 is 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 collects information on race and ethnicity. This information is routinely collected by clinical providers, as part of routine care for HIV-infected persons, and is 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 are 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 is 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 is 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, is 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 is collected using the form entitled *Patient Demographic Information* **(Attachment 5)**. Each

form is 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 spends 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 is 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 complete the form for 100 patients and each form takes an estimated 60 minutes to complete. Thus, each clinic spends 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 is collected quarterly **(Attachment 7a and 7b).** Project staff at each clinic complete the form for 100 patients and each form takes an estimated 30 minutes to complete. Thus, each clinic spends 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 complete the pharmacy record abstraction form for 100 patients and each form takes an estimated 30 minutes to complete. Thus, each pharmacy spends 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 are conducted twice during the project period. A total of 60 project staff participate in each of the two interviews. The interviews are estimated to last 30 minutes. Thus, each interviewee spends one hour being interviewed for a total of 60 burden hours for all project sites.

Staff communication questionnaire **(Attachment 11)**: A total of 30 project pharmacy staff (three from each project pharmacy) complete the questionnaire. The questionnaire is estimated to take 30 minutes to complete and is administered twice. Thus, each respondent will spend a total of 60 minutes completing the

questionnaires for a total of 30 burden hours for both collection periods for all project sites.

Staff communication questionnaire for medical providers **(Attachment 11b)**: A total of 40 project clinic staff (four from each project site) will complete the questionnaire. The questionnaire is estimated to take 30 minutes to complete and will be administered twice. Thus, each respondent spends a total of 60 minutes completing the questionnaires for a total of 40 burden hours for both collection periods for all project sites.

Clinic cost form (**Attachment 12**): Two project staff at each project clinic complete the clinic cost form and each form takes an estimated 30 minutes per day or 2.5 hours/week and 10 hours/month. The clinic cost form is completed for two one-month periods. Thus, each clinic spends 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 completes the pharmacy cost form and each form takes an estimated 30 minutes per day or 2.5 hours/week and 10 hours/month. The pharmacy cost form is completed for two one-month periods. Thus, each pharmacy spends 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

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 characteristics form **Att4**	10	3	30/60	15
Clinic	*Patient	10	100	5/60	83

Data Manager	Demographic Information form **Att5**				
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 (pharmacist)	Staff communication questionnaire **Att11a**	30	2	30/60	30
Project staff (medical providers)	Staff communication questionnaire for medical providers **Att11b**	40	2	30/60	40
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. <u>Estimated Annualized Burden Costs</u>

The table below presents the estimated burden costs. The annualized burden cost is $284,013. The Clinic Data Managers

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 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 participate in key informant interviews. Data from the interviews is collected on the Interviewer Data Collection worksheet. Three project site pharmacists, two physicians and one nurse from each site 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.

Three project site pharmacists complete the Staff Communication Questionnaire and two physicians and two nurses from each site complete the Staff Communication Questionnaire for Medical Providers. 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 (Att3)	15	$39.56	$593
	*Patient Demographic Information form (Att5)	83	$39.56	$3,283
	*Initial patient information form (Att6a)	1000	$39.56	$39,560
	Quarterly patient information form (Att7a)	2000	$39.56	$79,120

	Clinic cost form (Att12)	400	$39.56	$15,824
Pharmacist	Project pharmacy characteristics form (Att4)	15	$56.96	$854
	Pharmacy record abstraction form (Att8)	2000	$56.96	$113,920
	Pharmacy cost form (Att13)	400	$56.96	$22,784
†Key informant (pharmacist)	Interviewer data collection worksheet (Att10a)	30	$56.96	$1,709
†Key informant (physician)	Interviewer data collection worksheet (Att10a)	20	$91.23	$1,825
†Key informant (nurse)	Interviewer data collection worksheet (Att10a)	10	$33.55	$336
^Project staff (pharmacist)	Staff communication questionnaire (Att11a)	30	$56.96	$1,709
^Project staff (physician)	Staff communication questionnaire for medical providers (Att11b)	20	$91.23	$1,825
^Project staff (nurse)	Staff communication questionnaire for medical providers (Att11b)	20	$33.55	$671
Total				$284,013

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

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

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

14. Annualized Cost to the Federal Government

The annualized cost to the government is $990,016. The information collection described in this request is 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

A *Staff Communication Questionnaire for Medical Providers* has been added to this information collection. Project clinic staff will be asked to complete the *Staff Communication Questionnaire for Medical Providers* twice during the project period. This addition is needed in order to determine how and if the model program improves patient outcomes through improved communication and collaboration between patients' clinical providers and pharmacists. The number of project staff who will complete the previously approved *Staff Communication Questionnaire* has been reduced from 70 to 30. In addition, the *Staff Communication Questionnaire* will only be completed by project pharmacists rather that project pharmacists, physicians and nurses. This reduction is because only the project pharmacists will now complete the *Staff Communication Questionnaire* while the project clinic staff will only complete the *Staff Communication Questionnaire for Medical Providers*. The addition of the *Staff Communication Questionnaire for Medical Providers* will not increase the total burden hours because the clinic staff will no longer complete the *Staff Communication questionnaire* (but will instead complete the *Staff Communication questionnaire for Medical Providers*)and, therefore, the total burden hours remain the same. The clinic staff will complete the *Staff Communication questionnaire for Medical Providers* rather than the Staff Communication questionnaire in order to capture clinic staff specific communication. 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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