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

**OMB No. 0920-1019**
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## Supporting Statement A

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## 1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests a New three year OMB approval for information collection of a pilot program to establish patient-centered HIV care entitled *Improving HIV Prevention and Treatment Outcomes Among HIV-Infected Persons by Integrating Community Pharmacists and Clinical Sites into a Model of Patient-Centered HIV Care*; this was the title published under the 60 day federal register notice. The data collection is authorized under the Section 301 of the Public Health Service Act (42 U.S.C. 241) (**Attachment 1).**

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. (1) 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 (2). 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 (3). 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 (4). However, barriers within the existing healthcare infrastructure can impede access to, retention in, and adherence to care (5). 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 (6).

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 (7).

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 (8). HIV specific MTM programs have demonstrated success in improving HIV medication therapy adherence and persistence.(9-12) 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.

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.(8) 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. 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. 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.

## 1.1 Privacy Impact Assessment

Overview of the data collection system

The patient-centered HIV care model project information collection has four primary components: 1) description of project clinics and pharmacies 2) description of non-participant patients 3) medical record abstraction 4) and pharmacy record abstraction. 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. Project clinic and pharmacy staff will complete the descriptions of each respective

project clinic and pharmacy. Medical and pharmacy record abstraction will be 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.

*Project clinic and pharmacy characteristics:* Project site clinic **(Attachments 3)** and pharmacy **(Attachments 4)** characteristics will be 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 will collect the information. Project sites will send the data to the project grantee who will investigate and resolve data discrepancies. Data will then be sent to CDC through the CDC Secure Data 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 will allow 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 will be conducted by project clinic staff at each respective project clinic. De-identified client-level data will be collected. Project clinics will send the data to the project grantee who will investigate and resolve data discrepancies. Data will then be sent to CDC through the CDC Secure Data Network. All identifiers will be removed before data are reported to CDC; each program participant will be assigned a unique program ID. The grantee and CDC will store and access data by the assigned participant ID. A one-time retrospective medical record abstraction will occur at the beginning of the project in order to document participants' baseline characteristics and history **(Attachment 6a).** After program implementation, project staff will collect data on a quarterly basis **(Attachment 7a).** The grantee will report data to CDC on a quarterly basis.

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

Items of Information to be Collected

| Data collection | Attachment number |
|---|---|
| *Project Clinic Characteristics.* An annual collection of project clinics' characteristics including city and state, type of clinic, total number of patients, demographics of patients, clinic patient volume, number and type of medical providers employed at clinic. | 3 |
| *Project Pharmacy Characteristics.* An annual collection of project pharmacies' characteristics including city and state, type of pharmacy, length of time as an HIV Center of Excellence, number of HIV clients filling prescriptions, number and average number of clients filling prescriptions, prescription filling volume, insurance status of clients, preventive services offered, number and type of providers employed at pharmacy | 4 |
| *Patient demographic information form.* A one-time collection of basic demographics of project clinic patients who choose not to participate in the project but who agree to have their basic demographic characteristics recorded. Variables include month and year of birth, sex, race/ethnicity, education level, household income, housing, employment and insurance status | 5 |
| *Initial Patient Information form*. A one-time retrospective medical record abstraction will be conducted at the beginning of the project. Variables include patient demographics, date and stage at diagnosis, laboratory test results, antiretroviral and other prescribed medications, opportunistic illnesses, other clinical diagnoses, immunizations, history of tobacco, drug and alcohol use and adherence to clinic appointments. | 6 |
| *Quarterly Patient Information form*. Medical record abstraction of variables routinely collected by clinics, as part of routine patient care, will be conducted quarterly after implementation of the pilot project. Variables include laboratory test results, changes in medication therapy and medical conditions, immunizations, drug and alcohol use and adherence to clinic appointments. | 7 |
| *Interim Pharmacy form*. Pharmacy record abstraction will be conducted quarterly after implementation of the pilot project. The pharmacy record abstraction will collect data from pharmacy records on pharmacy services received, the nature of pharmacy services received, pharmacists' recommendations and interventions, pharmacists' consultation with partnered clinics and prescription | 8 |

| | |
|---|---|
| refills. | |

## 2.0 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 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 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.

The patient-centered HIV care model project is a pilot program. 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 among the project cohort) and are not meant to be generalizable beyond the program participants.

**2.1 Privacy Impact Assessment**

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)

**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 notice to solicit public comments was published on June 18, 2013, Volume 78 (no. 117), page numbers 36550-36551. A copy of this publication is attached (**Attachment 2**). No comments were received.

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 has been consulted in 2013 and each is either an expert on pharmacy MTM programs, HIV medications, HIV clinical care or community advocacy.

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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
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Seiji Hayashi MD, MPH, Chief Medical Officer for the Bureau of Primary Health Care, Health Resources and Services Administration
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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

**Privacy Impact Assessment Information / Privacy impact assessment information**

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 information sheet which details the services participants will receive, the information that will be shared between the pharmacist, clinic medical provider and the project team (**attachments 9a and 9b**). Clinic staff will use the Information Sheet to explain the project to patients. 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. 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.

The submission has been reviewed by CDC and was determined not to be human subjects research. IRB approval is, therefore, not required.

**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 6)**. 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 7).** 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.

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 characteristics form **Att4** | 10 | 3 | 30/60 | 15 |
| Clinic Data Manager | *Patient Demographic Information form **Att5** | 10 | 100 | 5/60 | 83 |
| Clinic Data Manager | *Initial patient information form **Att6a&6b** | 10 | 100 | 1 | 1000 |
| Clinic Data Manager | Quarterly patient information form **Att7a&7b** | 10 | 400 | 30/60 | 2000 |
| Pharmacist | Pharmacy | 10 | 400 | 30/60 | 2000 |

| | | | | | |
|---|---|---|---|---|---|
| | record abstraction form **Att8** | | | | |
| Total | | | | | 5113 |

*One time data collection

B. Estimated Annualized Burden Costs

The table below presents the estimated burden costs. The annualized burden cost is $220,790. The Clinic Data Managers will complete the Project Clinic Characteristics form, the Patient Demographic Information form, the Initial Patient Information form and the Quarterly Patient Information form. The mean hourly wage of a data manager is $35.32. Pharmacists at each of the project sites will complete the Project pharmacy characteristics form and the Pharmacy Record Abstraction form. The mean hourly wage of a Pharmacist is $55.27. 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 2012).

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 | $35.32 | $530 |
| | *Patient Demographic Information form | 83 | $35.32 | $2,932 |
| | *Initial patient information form | 1000 | $35.32 | $35,320 |
| | Quarterly patient information form | 2000 | $35.32 | $70,640 |
| Pharmacist | Project pharmacy characteristics form | 15 | $55.27 | $829 |
| | Pharmacy record | 2000 | $55.27 | $110,540 |

| | | | | |
|---|---|---|---|---|
| | abstraction form | | | |
| Total | | | | $220,791 |

*One time data collection

**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**

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 |

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.

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**

This is a new collection of information.

**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 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.

**References**


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