Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–16–1019; Docket No. CDC–2015–0102]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

This notice invites comment on Integrating Community Pharmacists and Clinical Sites for Patient-Centered HIV Care. CDC is requesting a 3-year approval for revision to the previously approved project to administer a staff communication questionnaire for medical providers in order to determine how and if the model program improves patient outcomes through improved communication and collaboration between patients' clinical providers and pharmacists.

DATES: Written comments must be received on or before January 19, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2015–0102 by any of the following methods:

- Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Integrating Community Pharmacists and Clinical Sites for Patient-Centered HIV Care (OMB 0920–1019, expires 8/31/2018)—Revision—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Medication Therapy Management (MTM) 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 pharmacists' 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 this problem, CDC has entered into a public-private partnership with Walgreen Company (a.k.a. Walgreens pharmacies, a national retail pharmacy chain) 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 be implemented in ten sites and will provide patient-centered HIV care for approximately 1,000 persons.

The patient-centered HIV care model will include the core elements of MTM as well as additional services such as individualized medication adherence counseling, active monitoring of prescription refills and active collaboration between pharmacists and medical clinic providers to identify and resolve medication related treatment problems such as treatment effectiveness, adverse events and poor adherence. The expected outcomes of the model program are increased retention in HIV care, adherence to HIV

medication therapy and viral load suppression.

On May 16, 2014 OMB approved the collection of standardized information from ten project sites over the three-year project period and one retrospective data collection during the first year of the three-year project period. The retrospective data collection will provide information about clients' baseline characteristics prior to participation in the model program which is needed to compare outcomes before and after program implementation. On August 17, 2015 OMB approved the conduct of key informant interviews with program clinic and pharmacy staff in order to evaluate the program processes, administration of a staff communication questionnaire, and OMB approved the collection of time and cost data to be used to estimate the cost of the model program.

CDC seeks approval to administer a staff communication questionnaire for medical providers 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 staff communication questionnaire for medical providers will be administered twice to program clinic staff. The staff communication questionnaire for medical providers is different from the previously improved staff communication questionnaire; the staff communication questionnaire for medical providers will be administered to program clinic staff whereas the staff communication questionnaire will be administered to program pharmacy staff.

Pharmacy, laboratory, and medical data will be collected through abstraction of all participant clients' pharmacy and medical records. Pharmacy, laboratory and medical data are needed to monitor retention in care, adherence to therapy, viral load suppression and other health outcomes. Program specific data, such as the number of MTM elements completed per project site and time spent on program activities, will be collected by program. Qualitative data will be gathered from program staff through in-person or telephone interviews and through a questionnaire to program pharmacy staff and a separate questionnaire to program clinic staff.

The data collection will allow CDC to conduct continuous program performance monitoring which includes identification of barriers to program implementation, solutions to those barriers, and documentation of client health outcomes. Performance monitoring will allow the model program to be adjusted, as needed, in order to develop a final implementation model that is self-sustaining and which can be used to establish similar collaborations in a variety of clinical settings. Collection of cost data will allow for the cost of the program to be estimated.

There is no cost to participants other than their time. The total estimated annualized burden hours are 6,043.

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	10	3	30/60	15
Pharmacist	Project pharmacy characteristics form.	10	3	30/60	15
Clinic Data Manager	*Patient Demographic Information form.	10	100	5/60	83
Clinic Data Manager	*Initial patient information form	10	100	1	1,000
Clinic Data Manager	Quarterly patient information form	10	400	30/60	2,000
Pharmacist	Pharmacy record abstraction form	10	400	30/60	2,000
Key informants	Interviewer data collection worksheet.	60	2	30/60	60
Project staff (pharmacists)	Staff communication questionnaire	30	2	30/60	30
Project staff (medical providers)	Staff communication questionnaire for medical providers.	40	2	30/60	40
Clinic staff	Clinic cost form	20	2	10	400
Pharmacy staff	Pharmacy cost form	20	2	10	400
Total					6,043

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Injury Prevention and Control: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92–463) of October 6, 1972, that the Board of Scientific Counselors, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS), has been renewed for a 2-year period through November 5, 2017.

For information, contact Gwendolyn Cattledge, Ph.D., Designated Federal Officer, Board of Scientific Counselors, National Center for Injury Prevention and Control, CDC, HHS, 1600 Clifton Road NE., M/S F63, Atlanta, Georgia 30329–4027, Telephone 770/488–4655.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and