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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-16-1019]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of

the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

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 newly requests 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)
Clinic Data Manager	Project clinic characteristics form	10	3	30/60
Pharmacist	Project pharmacy characteristics form	10	3	30/60

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

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