

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.

[FR Doc. 2015-29273 Filed 11-16-15; 8:45 am]

BILLING CODE 4163-18-P

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
been shown to be effective in increasing
medication adherence for HIV-infected
persons, no MTM programs have been
expanded to incorporate primary
medical providers in an effort to
establish patient-centered HIV care. 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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[FR Doc. 2015-29274 Filed 11-16-15; 8:45 am]

BILLING CODE 4163-18-P

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 Cattleidge, 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