

and other STDs; and (6) advance the education of health professionals and the public from HIV, viral hepatitis, and other STDs.

The CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment meets at least two times each calendar year, or at the discretion of the Designated Federal Officer in consultation with the CHACHSPT co-chairs.

The CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment shall advise the Director, CDC, and the Administrator, HRSA, regarding objectives, strategies, policies, and priorities for HIV, viral hepatitis, and other STD prevention and treatment efforts, including surveillance of HIV infection, Acquired Immunodeficiency Syndrome (AIDS), viral hepatitis, other STDs, and related behaviors; epidemiologic, behavioral, health services, and laboratory research on HIV, viral hepatitis, and other STDs; identification of policy issues related to HIV/viral hepatitis/STD professional education, patient healthcare delivery, and prevention services; agency policies about prevention of HIV, viral hepatitis and other STDs, treatment, healthcare delivery, and research and training; strategic issues influencing the ability of CDC and HRSA to fulfill their missions of providing prevention and treatment services; programmatic efforts to prevent and treat HIV, viral hepatitis, and other STDs; and support to the agencies in their development of responses to emerging health needs related to HIV, viral hepatitis and other STDs.

Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to the accomplishments of the committee's objectives. Nominees will be selected based on expertise in the fields of public health; epidemiology; laboratory practice; immunology; infectious diseases; drug abuse; behavioral science; health education; healthcare delivery; state health programs; clinical care; preventive health; medical education; health services and clinical research; and healthcare financing. The Committee shall also include representation of persons with HIV and other affected populations; state and local health and education agencies; HIV/viral hepatitis/STD community-based organizations; and the ethics or faith-based community. Federal employees will not be considered for membership. Members may be invited to serve for up to four-year terms.

Selection of members is based on candidates' qualifications to contribute to the accomplishment of CHACHSPT

objectives. The U.S. Department of Health and Human Services policy stipulates that committee membership be balanced in terms of points of view represented, and the committee's function. Appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, gender identity, HIV status, disability, and cultural, religious, or socioeconomic status. Nominees must be U.S. citizens, and cannot be full-time employees of the U.S. Government. Current participation on federal workgroups or prior experience serving on a federal advisory committee does not disqualify a candidate; however, HHS policy is to avoid excessive individual service on advisory committees and multiple committee memberships. Committee members are Special Government Employees (SGEs), requiring the filing of financial disclosure reports at the beginning and annually during their terms. Individuals who are selected for appointment will be required to provide detailed information regarding their financial interests and, for example, any work they do for the federal government through research grants or contracts. Disclosure of this information is required in order for CDC ethics officials to determine whether there is a conflict between the SGE's public duties as members of CHACHSPT and their private interests, including an appearance of a loss of impartiality as defined by federal laws and regulations, and to identify any required remedial action needed to address the potential conflict. CDC reviews potential candidates for CHACHSPT membership when a vacancy arises and provides a slate of nominees for consideration to the Secretary of HHS for final selection. HHS notifies selected candidates of their appointment near the start of the term in December 1, 2021, or as soon as the HHS selection process has been completed. Note that the need for different expertise varies from year to year and a candidate who is not selected for an open position may be reconsidered for a subsequent open position. SGE nominees must be U.S. citizens, and cannot be full-time employees of the U.S. Government. Candidates should submit the following items:

- Current curriculum vitae or resume, including complete contact information (telephone numbers, mailing address, email address).
- At least one letter of recommendation from person(s) not employed by the U.S. Department of Health and Human Services.

(Candidates may submit letters(s) from current HHS employees if they wish, but at least one letter must be submitted by a person not employed by an HHS agency (e.g., CDC, NIH, FDA, etc.).

- A biographical sketch of the nominee (500 words or fewer).
- A letter of interest or personal statement from the nominee stating how their expertise would inform the work of CHACHSPT.

Nominations may be submitted directly by the individual seeking nomination or by the person/organization recommending the candidate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, 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 Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-21-21GH; Docket No. CDC-2021-0065]

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 effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Using Real-time Prescription and Insurance Claims Data to Support the HIV Care Continuum. This proposed collection will collect data to evaluate

the efficacy of using administrative insurance and prescription claims (billing) data to identify and intervene upon persons with HIV who fail to fill antiretroviral (ARV) prescriptions.

DATES: CDC must receive written comments on or before September 10, 2021.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2021–0065 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.

- *Mail:* Jeffrey M. Zirger, 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. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments 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 Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7118; 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 the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;

2. Evaluate the accuracy of the agency's estimate of the burden of the

proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. 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 submissions of responses; and

5. Assess information collection costs.

Proposed Project

Using Real-time Prescription and Insurance Claims Data to Support the HIV Care Continuum—New—National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Use of HIV surveillance data to identify out-of-care persons is one strategy for identifying and re-engaging out-of-care persons, and is called Data-to-Care or “D2C.” Data-to-Care uses laboratory reports (*i.e.*, CD4 and HIV viral load test results) received by a health department's HIV surveillance program as markers of HIV care. In the current D2C model, there is a delay in the identification of out-of-care persons due to the time interval between recommended monitoring tests (*i.e.*, every three to six months) and the subsequent reporting of these tests to surveillance.

Insurance and prescription administrative claims (billing) data can be used to identify persons who fail to fill antiretroviral (ARV) prescriptions and who are at risk for falling out of care. Because most ARVs are prescribed as a 30-day supply of medication, prescription claims can be used to identify persons who are not filling ARV prescriptions on a monthly basis. Tracking ARV refill data can, therefore, be a more real-time indicator of poor adherence and can act as a harbinger of potential poor retention in care. Using real time insurance and prescription claims data to identify persons who fail to fill ARV prescriptions, and to intervene, could have a significant impact on ARV therapy adherence, viral suppression and potentially on retention in care.

The purpose of the Antiretroviral Improvement among Medicaid Enrollees (AIMS) study is to develop, implement and evaluate a D2C strategy that uses Medicaid insurance and prescription

claims data to identify; (1) persons with HIV who have never been prescribed ARV therapy, and (2) persons with HIV who fail to pick up prescribed ARV medications in a timely manner, and to target these individuals for adherence interventions.

A validated HIV case identification algorithm will be applied to the Virginia Medicaid database to identify persons with HIV who have either never filled an ARV prescription or have not filled an ARV prescription within >30 to <90 days of the expected fill date. Deterministic and probabilistic methods will be used to link this list to the Virginia Department of Health's (VDH) Care Markers database (an extract of the VDH HIV surveillance database). Individuals that are matched across the two databases (indicating that the persons are both enrolled in Medicaid and confirmed HIV positive) are eligible for study participation. Additional eligibility criteria include age 19–63 years and continuous enrollment in Virginia Medicaid for the preceding 12 months.

Cluster randomization will occur at the healthcare provider level and will be conducted concurrently with the initial potential participant screening. Providers will be randomized to either the intervention arm or to the usual care arm (*i.e.*, no intervention or control arm). Study participants are the patients of the randomized healthcare providers. Participants in the intervention arm will be delegated to either a patient-level or provider-level intervention, depending on need; participants who are >30 to <90 days late filling their ARV prescription(s) will receive the patient-level intervention, and participants who have never filled an ARV prescription will be delegated to the provider-level intervention. Participants of the provider-level intervention will not receive direct intervention. Instead, the healthcare providers of these patients (“provider participants”) will receive the provider-level intervention. Potential participants will be contacted by a study Linkage Coordinator to explain the study and obtain consent for participation.

The patient-level intervention has two phases. Phase I is intended for patients who are >30 to <60 days late filling their ARV prescription(s). In Phase I, a Linkage Coordinator will contact participants to discuss the participants' adherence barriers. Once the participant's adherence barriers are identified, the participant will be referred to appropriate resources to assist them in overcoming their adherence barrier(s). Phase II is intended for patients who were enrolled

in Phase I but who failed to fill their ARV prescriptions in the subsequent 30 days of the Phase I consultation, and for participants who are >60 to <90 days late at the time the participant was determined to be study eligible. In Phase II, the Linkage Coordinator will lead a similar consultation as in Phase I, but will probe for more complex adherence barriers (e.g., mental health concerns) and referrals will be made accordingly. The participant will also be offered an evidence-informed mobile application (“app”) which is designed to support ART adherence and retention in care.

The provider-level intervention will consist of a peer-to-peer clinician consultation delivered by clinicians from the Virginia Department of Health’s Advisory Committee to the Virginia Medication Assistance Program or by another HIV clinical expert. The

peer-to-peer clinician consultations will involve introduction or reinforcement of HIV clinical guidelines for ART initiation, strategies to optimize ART adherence, and resources for supporting adherence for people with HIV. The consultation will be tailored to the needs of the provider participant.

All analyses will be conducted at the patient level. Persons within the intervention arm will be followed prospectively for 12 months. At the end of the intervention arm follow-up period, persons within the usual care arm will be followed retrospectively for 12 months. The primary study outcome of HIV viral suppression (HIV RNA <200 copies/mL) will be compared between study arms.

CDC requests OMB approval to collect standardized information from 500 AIMS study participants (460 participants of the patient-level

intervention and 40 participants of the provider-level intervention) and 500 controls over the three-year project period. Secondary data will be abstracted from the Virginia Medicaid and Virginia Care Markers databases to determine study eligibility, to conduct the patient- and provider-level interventions, and to determine study outcomes. During the patient-level intervention, data will be collected on participants’ adherence barriers; this information will be used to refer participants to appropriate resources to assist their adherence to ART. During the provider-level intervention data will be collected to inform the peer-to-peer clinician consultation.

CDC requests OMB approval for an estimated 687 burden hours annually. There are no costs to respondents other than their time to participate.

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 hours
Participants	Verbal consent—participants	460	1	15/60	115
Provider participants	Verbal consent—provider participants.	40	1	15/60	10
Participants	Verbal consent—control participants (for participants of provider-level intervention).	40	1	15/60	10
Control participants	Verbal consent—control participants	500	1	15/60	125
PositiveLinks participants	PositiveLinks enrollment	100	1	60/60	100
Participants	Phase I interview	460	1	30/60	230
Participants	Phase II interview	100	1	30/60	50
Advisory Committee to the Virginia Medication Assistance Program member and other HIV clinical experts.	Clinician consultation	10	4	30/60	20
Provider participants	Clinician consultation	40	1	30/60	20
Advisory Committee to the Virginia Medication Assistance Program member and other HIV clinical experts.	Post-consultation questionnaire	10	4	10/60	7
Total	687

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day-21-0530; Docket No. CDC-2021-0064]

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 effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Energy Employees Occupational Illness Compensation Program Act (EEOICPA) Dose Reconstruction Interviews and Forms. This data collection permits claimants under