DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-22-21GH]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Using Real-time Prescription and Insurance Claims Data to Support the HIV Care Continuum to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on July 12, 2021 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(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. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

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 (D2C). D2C 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 this information collection, also called 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), 500 controls and 40 provider participants 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.

OMB approval is requested for three years. Participation is voluntary and there are no costs to respondents other than their time. CDC requests approval for an estimated 256 annualized burden hours.

Estimated Annualized Burden Hours

Respondents	Form Name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Participants of patient-level intervention	Verbal consent—participants	153	1	15/60
Provider participants	Verbal consent—provider participants	13	1	15/60
Participants	Verbal consent—	13	1	15/60

of provider-level intervention	control participants (for participants of provider-level intervention)			
Control participants	Verbal consent—control participants	167	1	15/60
Participants of patient-level intervention	HIPPA authorization	153	1	5/60
Participants of provider-level intervention	HIPPA authorization	13	1	5/60
Control participants	HIPPA authorization	167	1	5/60
PositiveLinks participants	PositiveLinks verbal consent and enrollment	33	1	60/60
Participants of patient-level intervention	Phase I interview	153	1	30/60
Participants of patient-level intervention	Phase II interview	33	1	30/60
Advisory Committee to the Virginia Medication Assistance Program member and other HIV clinical expects	Clinician consultation guide	3	4	30/60
Provider participants	Clinician consultation guide	13	1	30/60
Advisory Committee to the Virginia Medication Assistance Program	Post-consultation questionnaire	3	4	10/60

member and other HIV clinical expects				

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