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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-20-20NT; Docket No. CDC-2020-0054]

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* which 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 [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2020-0054 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, N.E., 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: 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, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: 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; and
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.
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 becoming 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 Virginia Department of Health's (VDH) Care Markers (an extract of the VDH HIV surveillance database) 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 – 64 years and continuous enrollment in Virginia Medicaid for the preceding 12 months.

Once identified, individuals will be randomized to receive either an intervention or usual care. Participants in the intervention arm will be assigned to receive either a provider-

level intervention or a patient-level intervention, depending on need; providers of study eligible participants who have never been prescribed ARV therapy (ART) will receive a provider-level intervention and participants who are >30 to <90 days late filling their ARV prescriptions will receive a patient-level intervention. Potential participants will be contacted by a VDH Linkage Coordinator or Study Coordinator to explain the study and obtain consent for participation.

The provider-level intervention will consist of a peer-to-peer clinician consultation delivered by members of Virginia Department of Health's AIDS Drug Assistance Program (ADAP) Advisory Committee. 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.

The patient-level intervention has two phases. 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 PositiveLinks, an evidence-informed mobile application ("app") which is designed to support ART adherence and retention in care. PositiveLinks provides daily queries of stress, mood, and medication adherence; weekly quizzes on general and HIV-specific understanding; appointment and medication reminders, curated resources, a community message board, direct messaging with the Linkage Coordinator, and contact information for participants' providers.

All analyses will be conducted at the patient level. Persons within the intervention and control arms will be followed for 12 months to compare the primary study outcome of HIV viral suppression (HIV RNA < 200 copies/mL).

CDC requests OMB approval to collect standardized information, from 500 AIMS study participants (including 460 patients and 40 providers) and 500 controls over the three year project period. Secondary data will be abstracted from the Virginia Medicaid and Virginia Department of Health Care Marker

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.

Estimated Annualized Burden Hours

Respondents	Form Name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Linkage Coordinator	Verbal consent (patient)	460	1	15/60	115
Study Coordinator	Verbal consent (provider)	40	1	15/60	10
Linkage Coordinator	PositiveLinks Program and Services Agreement	100	1	60/60	100
VCU Data Manager	Medicaid data abstraction	1	12	60/60	12
VDH Surveillance Epidemiologist	Care Marker data abstraction	1	12	60/60	12
Linkage Coordinator	Phase I interview and Phase I	460	1	30/60	230

	data elements				
Linkage Coordinator	Phase II interview and Phase II data elements	100	1	30/60	50
Linkage Coordinator	PositiveLinks data abstraction	1	4	15/60	1
ADAP Advisory Committee member	Clinician consultation and Clinician consultation data elements	40	1	30/60	20
Total					550

Jeffrey M. Zirger,

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Office of Scientific Integrity,

Office of Science,

Centers for Disease Control and Prevention.

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