BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-17-17AUZ; Docket No. CDC-2017-0065]

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 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 "Project NICE: Navigating Insurance Coverage Expansion". Project NICE will evaluate the efficacy of an in-person health insurance enrollment assistance intervention among Black and Hispanic men who have sex with men (MSM) and Transgender persons living in the Chicago, Illinois metropolitan area.

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-2017-0065 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, 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 Leroy A. Richardson, 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

Project NICE: Navigating Insurance Coverage Expansion - New - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC seeks to request a three-year OMB approval to evaluate the efficacy of an in-person health insurance enrollment assistance intervention among 1,000 Black and Hispanic MSM and Transgender persons ages ≥18 years living in the Chicago, Illinois metropolitan area. CDC will invite individuals attending HIV testing outreach events, or seeking care in select clinics in Chicago to participate in the study after an HIV testing session. Researchers will collect study participants' sociodemographic, risk behavior, and insurance coverage information as part of study enrollment. Each quarter, researchers will abstract outcome evaluation data (linkage to and retention in HIV-related care, referrals for mental health or substance use, and other health outcomes) from study participant's electronic medical records (EMRs). Researchers will also assess intervention cost-effectiveness.

CDC funded this study through a cooperative agreement with the University of Chicago Medicine (UCM). Three partner agencies will conduct the intervention: 1) University of Chicago Medicine (UCM) (the lead partner agency), 2) Howard Brown Health, and 3) Chicago House and Social Service Agency (Chicago House). The three partner agencies each have a history of providing clinical care, HIV testing outreach, and in-person health insurance enrollment assistance for Chicago's MSM and Transgender communities.

As part of this study, CDC will evaluate the in-person health insurance enrollment assistance. Specifically, researchers will evaluate whether moving the delivery of in-person health insurance enrollment assistance, from the first clinic visit after receipt of an HIV test result, to earlier in the care continuum, during the HIV testing event, will impact health outcomes. Therefore, this study does not introduce new intervention activities or burden on the participants or the agency staff; it reorders the sequence of delivery of standard practice. Only the addition of data collection forms and procedures will be new, and the additional burden will be to partner agency staff workload and participant experience.

In 2013, MSM accounted for 81% of new HIV infections among males and 65% of all new HIV infections. In 2010, health

officials reported 10,600 new HIV infections for African-American (Black) MSM, 11,200 for White MSM, and 6,700 for Hispanic MSM. Through a 2008 systematic review, researchers found HIV rates among Black and Hispanic Transgender women to be 56% and 16%, respectively.

Black and Hispanic MSM and Transgender persons face obstacles in seeking medical care and following through with referrals or appointments, including lack of health insurance.

This study will implement a structural intervention. The goal of this study is to test whether providing in-person assistance for first-time private health insurance or Medicaid enrollment, changing to a different insurance plan, or understanding how to use current insurance policies following HIV testing will: (1) increase the proportion of participants who obtain health insurance; (2) result in better health outcomes among participants (e.g., achieving viral suppression, remaining HIV negative); (3) improve the linkage and retention rates for HIV care (i.e., HIV treatment, Pre-exposure Prophylaxis (PrEP)) and other HIV-associated health services (e.g., mental health counseling, substance use treatment) of participants, especially those diagnosed with HIV; and (4) increase HIV care linkage and retention rates sufficiently to justify the cost of implementing the intervention (cost-benefit

analysis) among Black and Hispanic MSM and Transgender persons age 18 or older in the Chicago, Illinois metropolitan area.

Randomized controlled trials (RCTs) of structural interventions are rare. Nevertheless, CDC will use a RCT design to enhance scientific validity and the policy impact of the intervention, and help researchers assess the efficacy of this intervention as an emerging practice prior to dissemination to HIV prevention service providers nationwide.

This project aligns with National HIV/AIDS Strategy 2020 and Health People 2020 objectives. This structural intervention aligns with the OMB's emphasis on application of behavioral insights in that it restructures the context (i.e., after HIV testing) in which health-related decision-making (i.e., health insurance enrollment) occurs in order to promote the selection of beneficial options. The proposed health insurance enrollment assistance project has the potential for widespread health improvements for Black and Hispanic MSM and Transgender persons regardless of their HIV status.

The study will enroll 1,000 participants over 12 months to reach adequate power calculations (500 into the intervention arm, and 500 into the control arm).

After an HIV testing session at an outreach event or clinic visit, a partner-agency staff person will invite an individual to participate in the study. If interested, participants will

complete a consent form. Staff will screen individuals using the Eligibility Form, which will take approximately five minutes to complete. Researchers would need to screen approximately 1,500 individuals in order to identify and enroll 1,000 eligible study participants. If eligible and interested in participating, individuals will complete the Participant Enrollment Form, which will take approximately 35 minutes to complete. Researchers then will offer in-person health insurance enrollment to randomized intervention arm participants. This enrollment will take a maximum of 60 minutes to complete. The study's in-person health insurance enrollment assistance will take the same amount of time as standard practice health insurance enrollment assistance.

The total estimated annualized hourly burden anticipated for this study is 1,458 hours.

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
Study participant	Consent Form	1,500	1	10/60	250
Study participant	Eligibility Form	1,500	1	5/60	125

Study participant	Participant Enrollment Form	1,000	1	35/60	583
Study participant (Intervention arm ONLY)	ACTIVITY: In-person health insurance enrollment assistance	500	1	1	500
Total					1,458

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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. 2017-24473 Filed: 11/9/2017 8:45 am; Publication Date: 11/13/2017]