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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-18-17AUZ]

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 "Project NICE: Navigating Insurance Coverage Expansion" 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 November 13, 2017, 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 or send an email to omb@cdc.gov. 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

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 is requesting a three-year approval to evaluate the efficacy of an in-person health insurance enrollment assistance intervention among 1,000 Black and Hispanic men who have sex with men (MSM) and transgender persons ages ≥18 years living in the Chicago, Illinois metropolitan area.

In 2013, MSM accounted for 81% of new HIV infections among males and 65% of all new HIV infections. In 2010 African Americans comprised only 12% of the US population, but Black MSM nearly equaled White MSM in numbers of new HIV infections (10,600 and 11,200, respectively). In 2010 Hispanics comprised 17% of the US population, and Hispanic MSM accounted for 22% (6,700) of all new HIV infections. A 2008 systematic review found HIV rates among Black and Hispanic transgender women to be 56% and 16%, respectively. Contributing to these disproportionate HIV rates are that 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.

The intervention being evaluated in this study (in-person health insurance enrollment assistance) is not a new activity. This study 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. Because this study does not introduce new intervention activities, only reorders the sequence of delivery of standard practice, the burden to the participant experience will be data collection forms and research procedures only.

The goal of this study is to test whether providing a point of care, in-person assistance in enrolling in private health insurance or Medicaid for the first time, 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.

This study is funded through a cooperative agreement between CDC and the University of Chicago Medicine. Three partner agencies will conduct the intervention: 1) University of Chicago Medicine (the lead partner agency), 2) Howard Brown Health, and 3) Chicago House and Social Service Agency (Chicago House). These three partner agencies currently provide in-person health insurance enrollment assistance, linkage to care (HIV-related treatment, primary care), and patient navigation services to the study population.

This study uses a randomized controlled trial design, which will enhance scientific validity and the policy impact of the intervention, and help researchers assess the efficacy of this intervention as an emerging practice. This study aligns with National HIV/AIDS Strategy 2020 and Healthy People 2020 objectives of reducing new HIV infections, increasing access to care and improving health outcomes for people living with HIV, and reducing

HIV-related health disparities. This study also aligns with the Office of Management and Budget'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 (i.e., attending HIV-related medical care appointments). This proposed health insurance enrollment assistance study has the potential for widespread health improvements for Black and Hispanic MSM and transgender persons regardless of their HIV status.

At this time, CDC is not partnering with other HHS agencies for this study. However, we have discussed the study with HRSA/HAB and HHS/OD, and plan to apprise CMS and HRSA of the project before implementation and invite CMS and HRSA representatives to serve as consultants. HHS may also direct us to the CMS regional officer for Chicago, Illinois. Additionally, there is the potential to have CMS grantee navigators supplement partner agency navigators during outreach HIV testing events. For this study, CDC is not engaged in research, and therefore not involved in data collection activities. The grantee is responsible for implementing the intervention and collecting data from the proposed 1,000 participants. Thus, CDC will not need an interagency data-sharing agreement if we do consult with HRSA or CMS.

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). Approximately 1,500 individuals will need to be screened to identify and enroll 1,000 eligible study participants. After an HIV testing session at an outreach event or clinic visit, partner agency staff will invite individuals to participate in the study. If individuals are interested, staff will screen individuals for eligibility using the Participant Eligibility Form (Attachment 5) which will take approximately 5 minutes to complete. If they are determined eligible to participate, and still interested in participating, the individual will complete an Informed Consent Form (Attachment 6), which will take approximately 10 minutes to complete, and the Participant Enrollment Form (Attachment 7), which will take approximately 35 minutes to complete. The total estimated annualized hourly burden anticipated for this study is 875 hours. There is no cost to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per respondent	Average Burden per Response (in hours)

Study participant	Participant Eligibility Form (Att 5)	1,500	1	5/60
Study participant	Informed Consent Form (Att 6)	1,000	1	10/60
Study participant	Participant Enrollment Form (Att 7)	1,000	1	35/60

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