



**BILLING CODE: 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-17-17AZI; Docket No. CDC-2017-0075]**

**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 a proposed study titled "Understanding Decisions and Barriers about PrEP Use and Uptake among Men Who Have Sex with Men." This study will provide insight on individual and community level PrEP-related decision-making, and identify barriers and facilitators to successful PrEP initiation and PrEP acceptability.

**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-2017-0075 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 Federal 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 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

Understanding Decisions and Barriers about PrEP Use and Uptake among Men Who Have Sex With Men - New - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

### Background and Brief Description

This project involves original, formative research toward improving the uptake and adherence necessary to achieve efficacious levels of protection offered by pre-exposure prophylaxis (PrEP) among the most affected population. HIV incidence and prevalence are higher among gay, bisexual, and other men who have sex with men (MSM) than any other risk group in the U.S. Approximately half of all diagnosed HIV infections are among gay, bisexual, and other MSM. The FDA-approved PrEP regimen, daily Tenofovir/emtricitabine (aka Truvada®), has shown greater than 90% efficacy in reducing HIV infections among MSM when taken in accordance with its prescribed daily schedule. In 2014, CDC published clinical practice guidelines for the use of PrEP in high-risk populations, and began national promotion of PrEP as an effective HIV prevention strategy for MSM. While hailed as an HIV-prevention "game-changer," in reality PrEP

uptake has been slow. Some studies report a wide range in the percentages of MSM (28-81%) interested in PrEP. In addition, other studies indicate that specific cities have alarmingly low rates of PrEP uptake (for example, the estimate for Atlanta is 2%). Moreover, recent survey findings have shown that less than 1 in 10 MSM on PrEP are adherent to their PrEP regimen; adherence is necessary to optimize efficacy.

In order to develop effective programs that increase PrEP uptake among MSM at greatest risk for HIV, studies are needed to better understand the decisions men make about their HIV prevention needs. Qualitative methods will be used to explore in-depth the "Whys" and "How's" of MSM's decisions to refuse or use PrEP, and barriers and challenges to successfully undertake a PrEP medication regimen. Quantitative methods will be used to understand the HIV risk behavior context, attitudes towards PrEP, health seeking behavior, and acceptability of new modes of PrEP delivery (that differ from current recommendation of daily PrEP and that are in development or discussion) and emerging biomedical HIV prevention options.

The purpose of this research is to explore decisions, barriers, and facilitators about PrEP use among MSM: 1) who were offered PrEP but refused it; 2) who were interested in or started a PrEP regimen but did not follow through; and (3) who are eligible for PrEP per CDC guidelines (report condomless anal

sex within last 3 months).

This study will provide insight on individual and community level PrEP-related decision-making, and identify barriers and facilitators to successful PrEP initiation and PrEP acceptability. Findings will improve programming, in line with the CDC Division of HIV/AIDS Prevention goal of high-impact prevention to reduce HIV infections in the United States. Findings will also assist the CDC and frontline public health programs in identifying and designing programs and intervention approaches that encourage, support, and maintain appropriate PrEP uptake among eligible MSM and anticipate future HIV prevention needs, including anticipated changes in PrEP delivery.

The total annual burden hours are 335. There are no costs to the respondents other than their time, travel costs, and the total estimated annual burden 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
General Public-Adults	Screeners #1	600	1	5/60	50
General Public-Adults	Consent Forms	300	1	1/60	5

General Public-Adults	In-depth Interview Guide	60	1	45/60	45
General Public -Adults	Focus Group Moderator Guide	60	1	1	60
General Public -Adults	Eligibility verification (verification of continuing eligibility)	300	1	5/60	25
General Public-Adults	Behavioral Assessment	300	1	30/60	150
Total					335

**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. 2017-21750 Filed: 10/6/2017 8:45 am; Publication Date: 10/10/2017]