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.

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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 December 11, 2017.

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 NE., 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 NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *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 Unite 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	Screener #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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Re-designation of the Delivery Area for the Passamaquoddy Tribe at Indian Township

AGENCY: Indian Health Service, Department of Health and Human Services.

ACTION: Final Notice.

SUMMARY: This final notice advises the public that the Indian Health Service (IHS) has decided to expand the geographic boundaries of the Purchased/Referred Care Delivery Area (PRCDA) for the Passamaquoddy Tribe's reservation at Indian Township (Passamaquoddy at Indian Township or Tribe) in the State of Maine.

DATES: October 10, 2017.

Inspection of Public Comments: The IHS published a **Federal Register** Notice entitled, ''Notice To Propose the Re-Designation of the Service Delivery Area for the Passamaquoddy Tribe at Indian Township,'' on March 8, 2017 (82 FR 12968), and did not receive any comments regarding the notice.

FOR FURTHER INFORMATION CONTACT: Terri Schmidt, Acting Director, Office of Resource Access and Partnerships, Indian Health Service, 5600 Fishers Lane, Mailstop: 10E85C, Rockville, Maryland 20857. Telephone (301) 443–2694 (This is not a toll free number).

SUPPLEMENTARY INFORMATION: The Passamaquoddy PRCDA previously covered Aroostook and Washington Counties in the State of Maine. The expanded PRCDA for the Tribe's reservation at Indian Township includes Hancock County in the State of Maine. This notice only relates to the expansion of the Tribe's PRCDA for the Indian Township reservation.

The Maine Indian Claims Settlement Act of 1980 (Pub. L. 96–420; H. Rept. 96–1353) includes the intent of Congress to fund and provide Purchased/Referred Care (PRC) to the Passamaquoddy Tribe. The Passamaquoddy Tribe has two reservations: Indian Township and Pleasant Point. The PRCDA for the Indian Township reservation is Aroostook County, Maine, and Washington County, Maine. The PRCDA for the Pleasant Point reservation is Washington County, Maine, south of State Route 9, and Aroostook County, Maine.

Background: The IHS currently provides services under regulations codified at 42 CFR part 136, subparts A through C. Subpart C defines a PRCDA, formerly referred to as a Contract Health Service Delivery Area or Purchased/Referred Care Service Delivery Area, as the geographic area within which PRC will be made available by the IHS to members of an identified Indian community who reside in the area. Residence in a PRCDA by a person who is within the scope of the Indian health program, as set forth in 42 CFR 136.12, creates no legal entitlement to PRC, only potential eligibility for services. Services needed but not available at an IHS or Tribal facility are provided under the PRC program depending on the availability of funds, the person's relative medical priority, and the actual availability and accessibility of alternate resources in accordance with the regulations.

As applicable to the Tribes, these regulations provide that, unless otherwise designated, a PRCDA shall consist of a county that includes all or part of a reservation and any county or counties that have a common boundary with the reservation, 42 CFR 136.22(a)(6). The regulations also provide that after consultation with the Tribal governing body or bodies on those reservations included within the PRCDA, the Secretary may from time to time, re-designate areas within the United States for inclusion in or exclusion from a PRCDA. The regulations require that certain criteria must be considered before any re-designation is made. The criteria are as follows:

(1) The number of Indians residing in the area proposed to be so included or excluded;

(2) Whether the Tribal governing body has determined that Indians residing in the area near the reservation are socially and economically affiliated with the Tribe;

(3) The geographic proximity to the reservation of the area whose inclusion or exclusion is being considered; and