

Leroy A. Richardson,
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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 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 | 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 |

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 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