



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-19-1178; Docket No. CDC-2019-0065]

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 the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Comprehensive HIV Prevention and Care for Men Who Have Sex with Men of Color. This study is designed to support state and local health departments to develop and implement demonstration projects for provision of comprehensive human immunodeficiency virus (HIV) prevention and care services for men who have sex with men (MSM) of color by creating a collaborative with community based organizations (CBOs), clinics

and other health care providers, and behavioral health and social services providers in their jurisdiction.

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-2019-0065 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, 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 Jeffrey M. Zirger, 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

Comprehensive HIV Prevention and Care for Men Who Have Sex With Men of Color (OMB Control No. 0920-1178, Exp. 4/30/2020) - Extension - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Approximately 40,000 people in the United States are newly infected with HIV each year. Gay, bisexual, and other men who have sex with men (MSM) remain the population most affected by HIV infection in the United States (US). Among MSM, those who are black and Hispanic comprise 64% of all new infections. Goals of the National HIV Prevention Strategy and the new initiative "Ending the HIV Epidemic: A Plan for America" include increasing the number of MSM of color living with HIV infection who achieve

HIV viral suppression with antiretroviral treatment (ART), and decreasing the number of new HIV infections among MSM of color at risk of acquiring an HIV infection.

Achieving these outcomes requires that men utilize a broad variety of HIV prevention and care services. The continuum of HIV prevention services includes HIV testing, offering HIV-negative men at risk for acquiring HIV infection biomedical interventions such as preexposure prophylaxis (PrEP) or postexposure prophylaxis (PEP), prescribing the medications needed for PrEP or PEP, adhering to these medications as prescribed, returning for follow-up visits to support adherence, and monitoring potential medication side effects. Lab-based Antigen/Antibody HIV testing is recommended because it is the most sensitive HIV diagnostic test, allowing acute HIV infection to be diagnosed, and allowing health departments to prioritize initiation of treatment early in the course of infection to improve long-term health outcomes and prevent secondary HIV transmission. State and local health departments are authorized to provide HIV testing, prevention, and care services, and are essential partners in carrying out Thrive's programmatic goals. The continuum of HIV care services includes HIV testing and notifying HIV-positive men of their results, linking HIV-positive men to their initial HIV clinic visit, prescribing antiretroviral medications to treat HIV infection, adhering to

antiretroviral medications, being retained or re-engaged in care, and achieving HIV viral suppression.

These services will be provided by a community collaborative led by the health department, which consists of several partners: community-based organizations (CBOs), healthcare providers, behavioral healthcare providers, and social service providers. But, because of the fragmented nature of U.S. healthcare system, and the independent management and diverse funding streams and administration of each collaborative member, the health departments will need to work cooperatively with CDC to form and sustain this collaborative and to provide technical assistance and support for them to deliver high quality HIV prevention and care services to men who require them. CDC needs to understand facilitators and barriers to developing and sustaining a community collaborative to guide the technical assistance it provides to the collaborative so it can optimally deliver all of the required HIV prevention and care services to all men who require them.

Because many of the service providers in the collaborative are not part of the health department organizational structure or co-located within a health department facility or clinic, the health departments will support navigators to help MSM of color to utilize all of the services. In order to provide technical assistance to ensure effective navigation models, CDC must

understand the characteristics of the various models; how they integrate service utilization within the collaborative structure, and the number of men who they assist in utilizing services. CDC requests approval for 1,543 annual burden hours. There are no other costs 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)	Total Burden (in Hours)
THRIVE Partners	Monitoring and Evaluation Data Elements on HIV Prevention and Care Services	80	2	9	1,440
	Qualitative Interview: Collaborative Process Evaluation	80	1	40/60	53
	Collaborative Assessment Tool	80	1	20/60	27
THRIVE Awardees	Monitoring and Evaluation Data Elements on HIV Prevention and Care Services	7	2	1	14
	Qualitative Interview: Collaborative Process Evaluation	7	1	40/60	5
	Collaborative Assessment Tool	7	1	20/60	2
	Funding Allocation Report	7	1	20/60	2

	Total				1,543
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Jeffrey M. Zirger,

Lead,

Information Collection Review Office,

Office of Scientific Integrity,

Office of Science,

Centers for Disease Control and Prevention.

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