Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-17-17BZ]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (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. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Project PrIDE (PrEP Implementation, Data to Care & Evaluation) - New - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Approximately 50,000 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 US population most heavily affected by HIV infection. Among MSM, those who are black and

Hispanic comprise 58% of all new infections. To address the burden of HIV in this population, high impact HIV prevention approaches should be implemented by state, local, and territorial health departments to reduce new HIV infections among MSM of color, and to improve outcomes along the HIV continuum of care for MSM of color living with HIV.

Antiretroviral (ARV) medications for pre-exposure prophylaxis (PrEP) can be used for HIV prevention by MSM at substantial risk for HIV acquisition or by those with a possible HIV exposure in the past 72 hours post-exposure prophylaxis (nPEP). The daily use of co-formulated tenofovir disoproxil fumarate and emtricitabine (marketed as Truvada) for PrEP has been proven to significantly reduce the risk of HIV acquisition among sexually active MSM. In July 2012, the US Food and Drug Administration approved an HIV prevention indication for Truvada, and in May 2014 CDC published clinical practice guidelines for provision of PrEP. Given the high incidence of HIV among MSM of color, those who are sexually active are considered at risk for HIV acquisition and thus could benefit from prevention services such as routine and frequent HIV screening with lab-based 4th generation HIV tests, routine screening for STDs, assessment of PrEP eligibility, provision of PrEP (if at substantial risk for HIV acquisition), provision of

nPEP (if a possible HIV exposure occurred in the past 72 hours), and/or other risk reduction interventions.

Among people living with HIV (PLWH), ARV treatment can suppress HIV viral load, which both improves health outcomes of individuals and reduces the risk of HIV transmission. Two studies, one that demonstrated the effectiveness of ARV treatment in preventing HIV transmission, and one that demonstrated improved health outcomes for individuals whose ARV treatment was initiated immediately, have led to increased public health focus on interventions and strategies designed to initiate ARV treatment, link, retain, and re-engage PLWH in HIV care, and to provide support for adherence to ARV medications.

The purpose of the project is to implement PrEP demonstration projects. Health departments that are funded under this cooperative agreement will be required to prioritize their services to MSM and transgender persons at high risk of HIV infection, particularly persons of color. PrEP services may also be provided to HIV-negative persons at substantial risk for HIV who are not MSM or transgender. Additionally, Data to Care services may be provided to persons diagnosed with HIV infection and out of care, those who are in care but not virally suppressed, or those who have ongoing risk behavior who are not MSM or transgender.

The goals of PrIDE are consistent with the long-term goals of the National HIV/AIDS Strategy (NHAS) including reducing HIV incidence, increasing access to HIV care and optimizing health outcomes, and reducing HIV-related health disparities.

To evaluate the impact of PrIDE in the 12 jurisdictions, data will be collected from both existing CDC data sources and through new data collection activities.

CDC HIV program grantees will collect, enter or upload, and report agency-identifying information, budget data, information on the HIV prevention and care services, and client demographic characteristics. The total annual burden hours are 1,104.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per response (in hours)
Clients	Data Elements	2400	1	25/60
Health Departments	Data Management Upload	12	2	20/60
Health Departments	Performance Progress Report	12	1	8

_____

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. 2017-12060 Filed: 6/9/2017 8:45 am; Publication Date: 6/12/2017]