BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-2018-1091; Docket No. CDC-2018-0022]

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 ”Using Qualitative Methods to Understand Issues in HIV Prevention, Care and Treatment in the United States.” CDC’s goal for this generic information collection mechanism is to conduct qualitative studies to quickly identify barriers and facilitators to HIV prevention, care and treatment in specific regions with high HIV burden in the US.

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-2018-0022 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 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 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

Using Qualitative Methods to Understand Issues in HIV Prevention, Care and Treatment in the United States (OMB Control Number 0920-1091; expires 12/31/2018)– Extension – National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC's National Center on HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Division of HIV/AIDS Prevention (DHAP) seeks a three-year extension to conduct qualitative studies to quickly identify barriers and facilitators to HIV prevention, care and treatment in specific regions with high HIV burden in the US. Proposed activities remain consistent with the national HIV prevention goals, the CDC Division of HIV/AIDS Prevention (DHAP) Strategic Plan, and DHAP's High-impact HIV Prevention approach.

The purposes for each data collection study supported under this umbrella generic information collection plan will be to understand specific barriers and facilitators to local HIV prevention, care and treatment in the United States and territories. For example, each study will seek to identify ways to improve programmatic activities along the continuum of HIV prevention, treatment and care for different populations residing in different geographic settings with greatest burden of HIV.

The target populations for the studies include, but are not limited to: (1)persons living with HIV who are in treatment; (2) persons living with HIV who are out of treatment and who may or may not be seeking treatment at healthcare facilities; (3) persons at high risk for HIV acquisition (HIV negative) and HIV transmission (HIV positive); (4) persons from groups at high risk for HIV including gay, bisexual and other MSM, transgender persons, and injection and non-injection drug users; (5) persons from racial and ethnic minorities; and (6) healthcare providers or other professionals who provide HIV prevention, care and treatment services. Other populations may include individuals who provide non-HIV services or otherwise interact with persons living with HIV or persons at risk for HIV acquisition.

Studies will only provide local contextual information about the barriers and facilitators to HIV prevention, care, and

treatment experienced by specific communities at risk for acquiring HIV infection, by HIV-positive persons across the HIV care continuum, and by organizations or individuals providing HIV prevention, care, treatment, and related support services.

Data collection methods used in any of the specific studies primarily will consist of rapid qualitative assessment methodologies, such as semi-structured and in-depth qualitative interviews, focus groups; direct observations; document reviews; and short structured surveys. Data will be analyzed using well-established qualitative analysis methods, such as coding interviews for themes about barriers and successes to HIV prevention, care, and treatment. Structured response surveys will be analyzed using descriptive statistics and other appropriate statistical methods.

CDC will use the results from each specific data collection study to help identify ways to improve local programmatic activities for specific communities along the continuum of HIV prevention, treatment and care for populations and areas with the greatest HIV burden. CDC will communicate study outcomes to local stakeholders and organizations in positions to consider and implement site-specific improvements in HIV prevention, care, and treatment for each of the study sites examined. For stakeholders, organizations, or agencies outside the local affected communities, all communications will include clear

discussion of the limitations of the region-specific, qualitative methods and the non-generalizability of the study outcomes.

For a given year, each separate data collection will range from 30 (minimum) to 200 (maximum) respondents, based on the nature and scope of the research purposes. For example, if there are three data collections, the maximum combined number of expected respondents is 600. In a given year, CDC anticipates the need to screen 1,600 persons to identify 800 eligible persons, of which 600 persons will agree to participate.

CDC anticipates that screener forms will take 5 minutes to complete each, contact information forms will take 1 minute to complete each, and consent forms will take 5 minutes to complete each. CDC anticipates study eligibility for 50 percent of the targeted populations screened. Of eligible persons, 75% will agree to participate.

Brief structured surveys will take 15 minutes to complete. In-depth interviews or focus groups with respondents are expected to take 60 minutes (1 hour) to complete. In-depth interviews or focus groups with healthcare providers are expected to take 45 minutes to complete.

The total annual response burden, based on an average of 600 study respondents per year (assuming three large data collections involving 200 participants each), is 918 hours.

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
General Public-Adults	Study Screener	1,600	1	5/60	133
General Public-Adults	Contact Information Form	600	1	1/60	10
General Public-Adults	Consent Form	600	1	5/60	50
General Public-Adults	Demographic Survey	500	1	15/60	125
General Public-Adults	Interview Guide	500	1	1	500
General Public-Adults	Provider Demographic Survey	100	1	15/60	25
General Public-Adults	Provider Interview Guide	100	1	45/60	75
Total					918

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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