

6,125 hours. There are no other costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondent	Form	Number of respondents	Number of responses per respondent	Average burden per response (hours)	Total burden (in hours)
Persons Screened	Eligibility Screening Form	10,499	1	5/60	875
Informed Consent	Informed Consent Form	9000	1	5/60	750
Eligible Participants	IDU Survey	9000	1	30/60	4,500
Total	6,125

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 Office of Scientific Integrity, Office of Science,
 Centers for Disease Control and Prevention.*
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-20-20HR; Docket No. CDC-2020-0019]

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 Community-Based Organizations' Changes in Preparedness and Resources for Support of Biomedical HIV Prevention. The information collection project will be used to assess community-based organizations' (CBOs) awareness of, intentions to provide, and provision of Treatment as Prevention (TasP), non-occupational post-exposure prophylaxis (nPEP), or pre-exposure prophylaxis (PrEP) among clinical and non-clinical CBOs that have received funding from CDC's Division of HIV/AIDS Prevention (DHAP) and those that applied but did not receive funding.

DATES: CDC must receive written comments on or before May 8, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2020-0019 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 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 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 Jeffrey M. Zirger, 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

Community-Based Organizations' Changes in Preparedness and Resources for Support of Biomedical HIV Prevention—New—Division of HIV/AIDS Prevention (DHAP), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Antiretroviral (ARV) medications can be effectively used to reduce the number of new HIV infections. In persons without HIV infection, ARVs can be given as either: (1) For 28 days following a potential HIV exposure through sexual or injection behaviors as nPEP or (2) begun before potential sexual HIV exposures and taken daily for months to years as PrEP. In persons with HIV infection, beginning treating with ARVs early in their infection (e.g., with high CD4 cell counts) can greatly lower their risk of transmitting infection

to uninfected sexual partners; this is also called treatment as prevention or TasP. PrEP is 99% effective at reducing the risk of HIV through sexual contact when taken daily. PrEP is also 74%–84% effective at reducing the risk of HIV infection through injection drug use when taken daily. Persons living with HIV who are taking ARVs as prescribed as well as achieving viral suppression effectively have no risk for transmitting the virus to an HIV-negative partner through sexual contact. CDC is working with various jurisdictions with high HIV prevalence to increase capacity of ARV provision, build collaborative efforts between health departments and community-based organizations, and engage multi-sector provider systems to reach individuals with high risk of HIV infection as part of the End the HIV Epidemic Initiative. CBOs will play a crucial role in the End the HIV Epidemic Initiative. In a previous survey conducted by CDC’s Division of HIV/AIDS Prevention, CBOs reported high awareness of nPEP, PrEP, and TasP, but their ability to meet client need was low. Although clinical CBOs were more prepared to support the expansion of biomedical HIV prevention interventions, the likelihood that all CBOs would incorporate these interventions if they had additional resources was somewhat high.

Research is needed to better understand the capacity of CBOs to incorporate biomedical HIV prevention

interventions into their existing infrastructure. It is unclear whether the provision of and capacity to provide nPEP, PrEP, and TasP has increased among CBOs since the original survey was conducted. Furthermore, it is unclear whether non-clinical CBOs have achieved parity in linking clients to biomedical HIV prevention interventions with their clinical counterparts. This new survey will assess current capacity and provision of nPEP, PrEP, and TasP among CBOs providing HIV services to populations with increased risk for HIV acquisition. In addition, the results of this survey will be compared to the results of the 2015 survey to assess differences in awareness, capacity, and provision of biomedical HIV prevention interventions. Respondents will include organizations engaged in HIV prevention and outreach. Up to 330 respondents (N=330; 175 funded CBOs and 155 CBOs that did not receive funding) will be recruited to complete the survey. This project will employ a cross-sectional survey design. All CBOs within each of the two strata (1. Clinical and non-clinical CBOs directly funded by CDC, and 2. Clinical and non-clinical CBOs that did not receive CDC funding) will receive phone calls to elicit interest in participating in the survey and to receive the contact information of an organization’s representative to complete the survey on behalf of the organization. Potential respondents will

be contacted from a list of CBOs that completed the 2015 survey. In addition, CBOs that received DHAP funding through PS15–1502 and PS17–1704 will also be contacted to determine their interest in participating in the data collection effort and to nominate a staff member to complete the survey. Each organization’s representative will receive an email with a link to the survey website (created with Survey Monkey). The email will instruct the representative on how to complete the survey. Three email reminders will be sent to organizations for those that do not complete the survey. Where possible, data from the 2015 survey will be combined with data from the 2020 survey. Analyses will include completeness (non-response rates per item) as well as frequency of item responses for awareness, intentions, and provision of PrEP, nPEP, and TasP will be assessed for all respondents combined. Frequency and differences in item responses will be analyzed for relationship to CBO characteristics (e.g., clinical CBOs vs non-clinical CBOs). Frequency and differences in item responses will be analyzed across survey years. We will perform multivariable analysis as needed (to assess interactions between time and type of CBO). The total annualized burden hours is 165 hours. There are no other costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Community Based Organization	Community Based Organization HIV Prevention Needs Assessment Survey.	330	1	30/60	165
Total	165

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–0043]

Contact Dermatitis From Topical Drug Products for Cutaneous Application: Human Safety Assessment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is

announcing the availability of a draft guidance for industry entitled “Contact Dermatitis From Topical Drug Products for Cutaneous Application: Human Safety Assessment.” This draft guidance provides recommendations for the characterization, during product development, of local safety of topical drug products regarding the risk for contact dermatitis. These recommendations are specifically directed to development of topical new drug products intended for cutaneous application.

DATES: Submit either electronic or written comments on the draft guidance