DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
[60Day-20-20KH; Docket No. CDC-2020-0027]

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 Injection Drug Use Surveillance Project, which proposes to assess 1) the risk behaviors, injection risk networks, receipt of prevention services, and barriers to prevention and care among persons who inject drugs (PWID) and their drug-using
peers; and 2) the prevalence of HIV and Hepatitis C infections among PWID and their drug using peers.

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-2020-0027 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 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, 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

Background and Brief Description
The purpose of the Injection Drug Use Surveillance Project (IDU-SP) is to develop a surveillance system to monitor drug use risk and prevention behaviors and the infectious disease
consequences of high-risk drug use in 6-30 select urban and non-urban areas of the US that have been impacted by the opioid crisis. Such a surveillance system is needed to inform prevention efforts and policy. The specific objectives of the project are to assess the following among persons who use drugs (i.e., via injecting and non-injecting routes of administration) who are recruited in syringe services programs (SSPs) and through peer-driven recruitment: 1) drug use and sex risk behaviors, injection risk networks, receipt of prevention services, and barriers to prevention and care; and 2) the prevalence of HIV and Hepatitis C (HCV) infections.

The project will involve a two-stage sampling approach. First, 6-30 SSPs will be selected to ensure geographic diversity and representation of key program characteristics, such as syringe distribution model (needs-based vs all other) and length in operation (<5 years, 5 years or longer). Second, SSP clients and their drug using peers will be recruited through a combination of random recruitment at SSPs, and social network strategies to partake in a survey and HCV and HIV testing. Clients of SSPs and their peers who meet eligibility criteria will complete a survey using the Research Electronic Data Capture (REDCap) system, a secure web-based application for administering online surveys.
The survey will include questions on drug use and sex risk behaviors, risk networks, transitions from non-injection drug use to drug injection, drug treatment history, history of drug use related adverse health outcomes, such as overdose, experiences with law enforcement, experiences with violence and access, HIV and HCV testing experience, and use of prevention and health care services. Lastly, participants will be offered anonymous HIV and HCV testing in conjunction with the survey, which they may refuse with no effect on participation in the survey.

Approximately 10,500 individuals will complete the eligibility screener. Our target population is 300 participants per site or 9,000 from up to 30 sites. We anticipate that, on average, 16.66% or 1,499 persons (from up to 30 SSPs), will be either not interested in completing a questionnaire, yielding a maximum of 10,499 eligible participants.

Data from the IDU-SP will be used to inform planning and evaluation of prevention programs at the local and national level that aim to reduce adverse health outcomes of injecting and non-injecting drug use and to contribute to the overall opioid crisis response efforts. Data from the IDU-SP will also inform establishing an ongoing surveillance system in the U.S. to monitor drug use and the infectious disease consequences of
drugs. The total annualized burden is 6,125 hours. There are no other costs to respondents other than their time.

**Estimated Annualized Burden Hours**

<table>
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<tr>
<th>Respondent</th>
<th>Form</th>
<th>No. of Respondents</th>
<th>No. of Responses per Respondent</th>
<th>Average Burden per Response (hours)</th>
<th>Total Burden (in hours)</th>
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<td>Persons Screened</td>
<td>Eligibility Screening Form</td>
<td>10,499</td>
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<td>5/60</td>
<td>875</td>
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<td>Informed Consent</td>
<td>Informed Consent Form</td>
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<td>Eligible Participants</td>
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<td><strong>Total</strong></td>
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<td></td>
<td></td>
<td></td>
<td><strong>6125</strong></td>
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**Jeffrey M. Zirger,**

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