

- In January 2024, CDC affirmed existing viral-first testing recommendations among people with recent HCV exposure (<https://www.cdc.gov/hepatitis-c/hcp/diagnosis-testing/#~:text=HCV%20RNA%20testing%20for,a%20syringe%20service%20program>);

- In January 2024, CDC began the process of updating HCV testing guidance for clinicians and laboratorians, including evaluating testing strategies for the general population that include tests for viral markers in the first testing step (e.g., “viral-first”); and

- In June 2024, the FDA authorized an HCV RNA CLIA-waived near point-of-care test for the diagnosis of current HCV infection.

Public Participation and Public Comment

Public engagement will entail listen-only observation of information shared on day 1 and day 2. If members of the public have input on the questions asked during the meeting, those public comments can be collected through [regulations.gov](https://www.regulations.gov) using Docket CDC–2025–0002 on or before February 19, 2025, and will be included in the final meeting report. Written comments must be submitted on or before February 19, 2025.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on <https://www.regulations.gov>. Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. Do not submit comments by email. CDC does not accept comment by email.

Noah Aleshire,

Chief Regulatory Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–25–24FS]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled “Needle Exchange Utilization Survey (NEXUS)” to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on May 28, 2024, to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(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. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open

for Public Comments” or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Needle Exchange Utilization Survey (NEXUS)—New—National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The opioid crisis in the U.S. has led to steep increases in overdose, Hepatitis C Virus (HCV) incidence, and HIV clusters and outbreaks among people who inject drugs (PWID). These alarming trends indicate an urgent need to strengthen interventions to prevent morbidity and mortality and transmission of infectious disease among PWID. Syringe services programs (SSPs) are evidence-based, highly effective prevention programs that have expanded in many areas in the United States to respond to the increasing needs of providing HIV and HCV prevention and other health and social services to PWID and their communities. Due to an increase in HCV and HIV related to injection drug use (IDU), it is now critical to understand current patterns of IDU for the prevention of these infectious diseases and other injection related harms. Data to inform these prevention efforts are needed nationally, particularly from non-urban settings that have experienced increases in IDU and where current surveillance activities are non-existent or limited.

The purpose of the Needle Exchange Utilization Survey (NEXUS) is to develop a surveillance system to monitor drug use, prevention behaviors, and the infectious disease consequences of drug use in 6–15 select urban and non-urban areas of the U.S. that the opioid crisis has impacted. 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 inject drugs who are recruited in SSPs and their peers who use drugs through peer-driven recruitment: (1) drug use and sexual behaviors, injection risk networks, receipt of prevention services, and barriers to prevention and care; and (2) the prevalence of HIV and HCV infections.

CDC requests OMB approval for an estimated 3,126 total annualized burden hours. Participation is voluntary and

there are no costs to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondent	Form	Number of respondents	Number of responses per respondent	Average burden per response (hours)
Persons Screened	Eligibility Screening Form English	5,400	1	5/60
Persons Screened	Eligibility Screening Form Spanish	600	1	5/60
Persons who give permission	Model Project Consent Form English	4,050	1	5/60
Persons who give permission	Model Project Permission Form Spanish	450	1	5/60
Eligible Participants	NEXUS Survey English	4,050	1	30/60
Eligible Participants	NEXUS Survey Spanish	450	1	30/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, 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

[30 Day-25-1360]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled “CryptoNet Case Report Form” to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on October 21, 2024 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(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. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

CryptoNet Case Report Form (OMB Control No. 0920-1360, Exp. 1/31/2025)—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Waterborne Disease Prevention Branch (WDPB) in the Division of Foodborne, Waterborne, and Environmental Diseases (DFWED) works

to prevent domestic and global water-related diseases. The WDPB is comprised of five teams, including the Domestic Waterborne Disease Epidemiology and Response (WDER) Team, which focuses on the prevention and control of waterborne-related diseases and outbreaks in the United States. One of the diseases included in the team’s work is cryptosporidiosis, an acute diarrheal disease caused by infection with *Cryptosporidium* parasites.

The Case Surveillance Program is a subunit within the Domestic WDER Team that focus on the data collection and management activities of five waterborne diseases, including cryptosporidiosis, in the United States. The Case Surveillance Program’s current scope of work includes modernizing data collection and management, enabling data connections, and improving public data access to aid public health action.

CryptoNet is the first molecular tracking system for *Cryptosporidium* in the United States. To meet the needs of the CryptoNet and Case Surveillance Program, and the needs of local officials, the CryptoNet case report form (CRF) was developed. The CRF includes a set of data elements that can be used to identify exposures trends in outbreak- and non-outbreak-associated *Cryptosporidium* cases, to generate hypotheses about the sources of infection in clusters or outbreaks, and to identify strategies to prevent and control *Cryptosporidium* cases, clusters, or outbreaks.

Data from the CRF will be used by federal, state, and local public health officials responsible for conducting interviews with reported cases of cryptosporidiosis in their jurisdiction in order to systematically assess core exposure elements and risk factors among cases of cryptosporidiosis. Collected data will be used by CDC staff to inform cryptosporidiosis sporadic