other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

National Program of Cancer Registries Cancer Surveillance System (OMB Control No. 0920–0469, Exp. 1/31/2026)—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In 2021, the most recent year for which complete incidence information is available, almost 620,000 people died of cancer and more than 1.8 million were diagnosed with cancer. It is estimated that 17 million Americans are currently alive with a history of cancer. In the U.S., State/Territory-based central cancer registries (CCR) are the only method for systematically collecting and reporting population-based information about cancer incidence and outcomes such as survival. These data are used to measure the changing incidence and burden of each cancer; identify populations at increased or increasing risk; target preventive measures; and measure the success or failure of cancer control efforts in the United States.

In 1992, Congress passed the Cancer Registries Amendment Act which established the National Program of Cancer Registries (NPCR). The NPCR provides support for State/Territory-based cancer registries that collect, manage, and analyze data about cancer cases. The State/Territory-based cancer registries report information to CDC through the National Program of Cancer Registries Cancer Surveillance System (NPCR CSS), (OMB Control No. 0920–0469). CDC plans to request OMB approval to continue collecting this information for three years. Data definitions will be updated to reflect changes in national standards for cancer diagnosis and coding. No changes to the total estimated annualized burden hours or number of respondents are anticipated.

The NPCR CSS allows CDC to collect, aggregate, evaluate, and disseminate cancer incidence data at the national level. The NPCR CSS is the primary source of information for the *United States Cancer Statistics* (*USCS*), which CDC has published annually since 2002. The latest *USCS* report published in 2024 provided cancer statistics for 98% of the U.S. population from all cancer registries in the United States. Prior to the publication of *USCS,* cancer incidence data at the national level were available for only 14% of the population of the United States. The NPCR CSS also allows CDC to monitor cancer trends over time, describe geographic variation in cancer incidence throughout the country, and provide incidence data on populations by race, ethnicity, and other demographic and tumor characteristics and data on rare cancers. These activities and analyses further support CDC's planning and evaluation efforts for state and national cancer control and prevention. In addition, datasets can be made available for secondary analysis.

Respondents are NPCR-supported CCRs in 46 U.S. States, three Territories, and the District of Columbia. Fifty CCRs submit data elements specified for the Standard NPCR CSS Report. Each CCR is asked to transmit two data files to CDC per year. The first NPCR CSS Standard file, submitted in January, is a preliminary report consisting of one year of data for the most recent year of available data. CDC evaluates the preliminary data for completeness and quality and provides a report back to the CCR. The second NPCR CSS Standard file, submitted in November, contains cumulative cancer incidence data from the first diagnosis year for which the cancer registry collected data with the assistance of NPCR funds (*e.g.,* 1995) through 12 months past the close of the most recent diagnosis year (*e.g.,* 2022). The cumulative file is used for analysis and reporting. The burden for each file transmission is estimated at two hours per response. Because cancer incidence data are already collected and aggregated at the state level, the additional burden of reporting the information to CDC is small.

All information is transmitted to CDC electronically. Participation is required as a condition of the cooperative agreement with CDC. CDC requests OMB approval for an estimated 200 annual burden hours. There are no costs to respondents except 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)
Central Cancer Registries in States, Territories, and the District of Columbia.	Standard NPCR CSS Report	50	2	2	200
Total	.....	.....	.....	.....	200

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2025–00163 Filed 1–7–25; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2025–0002]

Establishing a Road Map for Accelerated Diagnosis and Treatment of HCV Infection in the United States

AGENCY: Centers for Disease Control and Prevention, Health, and Human Services (HHS).

ACTION: Notice of public meeting and request for comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC) announces a two-day convening hosted and facilitated by the Association of Public Health Laboratories (APHL) to discuss hepatitis C diagnostics. Leaders from public health, laboratory, medical, academic, and industry sectors will have the opportunity to provide individual input, without building a consensus, on accelerating the diagnosis of current hepatitis C virus (HCV)

infection. Members of the public with interest and expertise in diagnosing HCV infection are also invited to provide individual input. Specifically, the convening will focus on how to leverage the following hepatitis C diagnostic methods: same-day diagnosis and treatment, and viral-first testing. The goal of the convening will be for each person to give their individual input, and not to build consensus. No discussions, recommendations, or advice to CDC will occur or be provided at the meeting. Day 1 will focus on the utility of point-of-care (POC) testing for accelerating same-day HCV diagnosis and rapid treatment i.nitiation. Day 2 will focus on the utility of viral-first testing strategies for accelerating HCV diagnosis and treatment initiation in the United States. Following the meeting, APHL will prepare a meeting report summarizing the discussion and public comment received through *regulations.gov,* developed and documented as individual input to ensure thorough and complete input from partners. CDC and APHL will disseminate the APHL-prepared report as a reference for partners and industry to follow in developing and implementing future hepatitis C testing strategies. The final report will be added to docket CDC–2025–0002 once it is available.

DATES: Written comments must be received on or before February 19, 2025.

Times: February 11–12, 2025, 1:00–5:00 p.m. EST.

Place: Virtual Meeting.

To register for this virtual meeting on the public line (listen-only access), please use the following link: *https://webster.eventsair.com/hepatitis-2025-meeting/hcvattendee.*

ADDRESSES: You may submit comments, identified by Docket No. CDC–2025–0002 by either of the methods listed below. Do not submit comments by email. CDC does not accept comments by email.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Office of Policy and Communications, Division of Viral Hepatitis, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road, MS US12–3 Atlanta, GA 30329–4018.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *http://regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Maxwell R. Rowshandel, Office of Policy and Communications, Division of Viral Hepatitis, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road, MS US12–3 Atlanta, GA 30329–4018, phone: 1 (202) 245–0627, email: *dvhpolicy@cdc.gov.*

SUPPLEMENTARY INFORMATION: CDC announces a convening to discuss hepatitis C diagnostics. Interested parties are invited to provide public comment on *regulations.gov* in Docket CDC–2025–0002 on or before February 19, 2025.

Background

More than 2.4 million adults in the United States are estimated to have hepatitis C virus (HCV) infection [Eric H, Hepatology 2024]. New infections continue to increase, primarily in association with injection drug use; nearly 67,400 cases of acute hepatitis C are estimated to have occurred in 2022 [CDC 2022 VH Surv Rpt]. More than half of new infections progress to chronic infection [Seo S, Clin Gastro Hepatol 2020]. Without treatment, HCV infection can lead to advanced liver disease, liver cancer, and death [Liang TF, Ann Intern Med 2000]. Since 2013, safe and effective treatment has been available that cures more than 95% of all treated persons, prevents future health complications, stops further transmission, and allows for the possibility of hepatitis C elimination [Falade-Nwulia O, Ann Intern Med 2017].

Testing is the first step to accessing life-saving treatment; however, about one-third of people with hepatitis C in the United States are unaware of their infection [Lewis KC, CID 2024]. The Centers for Disease Control and Prevention (CDC) recommends hepatitis C screening for all adults at least once, all pregnant persons during every pregnancy, and all persons with risk for HCV infection, including periodic testing if risk persists [Schillie S, MMWR Recomm Rep 2020]. Current testing guidance for clinicians and laboratorians begins with a hepatitis C antibody (anti-HCV) test followed, when reactive, by a nucleic acid test (NAT) to detect HCV RNA to diagnose current infection [CDC MMWR 2013]. Updated operational guidance was provided to ensure completion of the two-step approach using specimens collected during a single patient encounter. (Cartwright EJ, MMWR 2023)

A limitation of the antibody-first hepatitis C testing approach is that it takes an average of 7 to 8 weeks after HCV infection to develop a reactive HCV antibody (Abdel-Hamid M, Clin Micro 2002). Therefore, the current testing sequence fails to diagnose HCV infection in the window-phase/early acute phase, within the first 6 months following infection, and among immunocompromised people who may have delayed seroconversion. Fortunately, advancements in the diagnostic and regulatory landscape have created an opportunity to improve hepatitis C testing. Currently, there are two tests for viral markers that identify current HCV infection: (1) real-time (RT) polymerase chain reaction (PCR) testing of HCV ribonucleic acid (RNA) detects virus within 1 to 2 weeks of infection (Gowda C, Clin Infect Dis 2020); and (2) HCV core antigen (HCVcAg) testing, currently approved outside of the United States, that uses an immunoassay to detect HCV core antigen within 2 to 3 weeks of infection (Sepulveda-Crespo D, Rev Med Virol 2023). Such virologic tests have become faster to perform and more accessible in a variety of care settings including closer to the point-of-care.

With CDC support, the Association of Public Health Laboratories (APHL) held a 2-day convening of key stakeholders and subject matter experts in October 2021 to identify high-priority diagnostic tools needed to advance diagnosis of current HCV infection and linkage to treatment in a range of clinical and nonclinical settings. The published meeting report called for the US Food and Drug Administration (FDA) to reclassify HCV diagnostic tests from class III to class II, supported the availability of an FDA-cleared rapid CLIA-waived point-of-care (POC) HCV viral detection test, and encouraged CDC to review and update recommendations for HCV testing to identify current HCV infection, including testing sequences that detect HCV viral markers in the first step. (*https://www.aphl.org/aboutAPHL/publications/Documents/ID-HCV-2021-Meeting-Report.pdf*).

Subsequent to the APHL-led meeting:

- In November 2021, the FDA reclassified hepatitis C diagnostic tests from class III devices to class II devices with special controls (510k), providing a new, lower-barrier opportunity for manufacturers to introduce new hepatitis C diagnostic tools for FDA review, including tests that were available at that time outside of the United States, such as a nucleic acid test (NAT) for HCV RNA detection in a POC format and an assay for HCVcAg.

- 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* 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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BILLING CODE 4163–18–P

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.