

3. AMC Disclosure Requirements (IC #3)

State-regulated AMCs disclose to states information necessary to determine whether any person that owns more than 10 percent of the AMC has had an appraiser license or certificate refused, denied, cancelled, surrendered in lieu of revocation, or revoked in any state. The Agencies estimate the number of state-regulated AMCs for the next three years as 4,020, with an average of one report per AMC and one hour preparation time per report. The estimated number of respondents per year allocated to each of the four agencies (FDIC, FRB, OCC, and FHFA) is calculated by splitting the total estimated number of respondents using a ratio of 3:3:3:1. Thus, the estimated number of annual respondents attributable to FHFA for this IC is 402 (4,020 respondents \times 10% = 402).

C. Comments Request

In accordance with the requirements of 5 CFR 1320.8(d), FHFA published an initial notice and request for public comments regarding this information collection in the **Federal Register** on January 15, 2025.¹² FHFA did not receive any comments.

FHFA requests written comments on the following: (1) Whether the collection of information is necessary for the proper performance of FHFA functions, including whether the information has practical utility; (2) the accuracy of FHFA's estimates of the burdens of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Shawn Bucholtz,

Chief Data Officer, Federal Housing Finance Agency.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2025-0321]

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

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

ACTION: Notice.

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.

DATES: Written comments must be received on or before September 24, 2025.

Times: September 16, 2025, 2:00–5:30 p.m. EDT and September 17, 2025, 1:00–4:45 p.m. EDT. 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/hcvattende/Site/Register>.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2025-0321 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: D'Angela T. Green, 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 (404) 718-8539, 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-2025-0321 on or before September 24, 2025. 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 initiation. 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-2025-0321 once it is available.

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 69,000 cases of acute hepatitis C are estimated to have occurred in 2023 [CDC 2023 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

¹² See 90 FR 3865 (Jan. 15, 2025).

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 women 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 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 initial 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 U.S. 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). This action provided 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 for HCV RNA detection in a point-of-care format and an assay for HCVcAg.

In January 2024, CDC affirmed existing viral-first testing recommendations among people with recent HCV exposure ().

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”).

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

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 submitted through [regulations.gov](https://www.regulations.gov) using docket CDC–2025–0321 on or before September 24, 2025, and will be included in the final meeting report.

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

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information
Collection Request Title: Membership Forms for Organ Procurement and Transplantation Network OMB No. 0915–0184—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than October 20, 2025.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or by mail to the HRSA Information Collection Clearance Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Samantha Miller, the HRSA Information Collection Clearance Officer at (301) 443–9094.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting