VIRAL HEPATITIS

2023 Progress Report

Viral Hepatitis National Strategic Plan for the United States: A Roadmap to Elimination 2021–2025



VISION

The United States will be a place where new viral hepatitis infections are prevented, every person knows their status, and every person with viral hepatitis has high-quality health care and treatment and lives free from stigma and discrimination.

This vision includes all people, regardless of age, sex, gender identity, sexual orientation, race, ethnicity, religion, disability, geographic location, or socioeconomic circumstance.

INTRODUCTION

This report provides an overview of progress during fiscal year (FY) 2023 toward achieving the goals of the <u>Viral Hepatitis National Strategic Plan for the United States: A Roadmap to Elimination (2021–2025)</u> (National Strategic Plan). The National Strategic Plan sets five goals and has eight core and eight disparities indicators, with annual, 2025, and 2030 quantitative targets, to measure progress toward the goals. This is the second progress report on the National Strategic Plan, the previous <u>Progress Report</u> covers FYs 2021–2022.

In support of efforts across the federal government to implement the National Strategic Plan, the Office of Infectious Disease and HIV/AIDS Policy (OIDP), within the Office of the Assistant Secretary for Health (OASH) in the U.S. Department of Health and Human Services (HHS), convenes the Viral Hepatitis Implementation Working Group. The Working Group coordinates and monitors implementation of the National Strategic Plan. Its members include representatives from across HHS agencies and other federal departments engaged in implementing the National Strategic Plan (see Appendix A).

In FY 2023, the United States continued to make progress and was on track to meet or exceed 2025 targets to reduce acute hepatitis B infections, increase the rate of hepatitis B "birth dose" vaccination, and reduce the rate of hepatitis C-related deaths. Despite this progress, the United States is failing to meet 2025 targets and is moving in the opposite direction to reduce acute hepatitis C infections and reduce hepatitis B-related deaths in disproportionately impacted populations. The overall rate of hepatitis C infection increased by 7% from 2020 to 2021, with the highest rates among American Indian and Alaska Native people. Hepatitis B-related death rates increased among non-Hispanic Asian and Pacific Islander people.

To curb these trends, the federal government has leveraged resources to expand access to viral hepatitis prevention and treatment services. Federal partners are advancing the development of a hepatitis C vaccine candidate and rapid point-of-care diagnostics, expanding syringe services programs (SSPs), implementing the Centers for Disease Control and Prevention (CDC)'s updated hepatitis B screening and vaccination recommendations, and identifying strategies to successfully integrate viral hepatitis services. Additional federal actions to move the nation toward viral hepatitis elimination are described in this report.

This report includes the following information:

- · At-a-glance table of overall progress on the indicators based on 2021 data
- Highlights of federal actions undertaken during FY 2023
- · Challenges and next steps
- · Tables of each indicator and progress toward 2025 targets

This report uses the data reported in CDC's <u>2021 Viral Hepatitis Surveillance Report</u>. CDC cautions that the cases reported in 2021 may be lower than in prior years because of the impact of the COVID-19 pandemic on health-seeking behavior and public health capacity.

OVERALL PROGRESS ON NATIONAL STRATEGIC PLAN INDICATORS

The National Strategic Plan established eight core indicators to measure progress on meeting its goals. Five of the core indicators are stratified into an additional eight disparities indicators to measure progress toward reducing disparities within priority populations. The indicators were selected to measure national progress on viral hepatitis prevention and care based on the available data and in alignment with other national plans. The table below presents overall progress for each indicator measure toward 2025 targets. The 2023 status is based on 2021 surveillance data. Additional data are detailed in Appendix B.

Met or exceeded current annual target



Moving **toward** annual target, but annual target was not fully met



Annual target was not met and has not changed or moved **away** from annual target



Indicator and Measure 2023 Sta						
Goal 1: Prevent New Viral Hepatitis Infections						
1.	Reduce new hepatitis A infections by 40% by 2025	→				
2.	Reduce acute hepatitis B infections by 20% by 2025					
3.	Reduce acute hepatitis C infections by 20% by 2025	\bigotimes				
4.	Increase rate of hepatitis B "birth dose" vaccination to 75% by 2025					
Goal	2: Improve Viral Hepatitis–Related Health Outcomes of People with Viral Hepatitis					
5.	Increase proportion of people with hepatitis B infection aware of their infection to 50% by 2025	•				
6.	Reduce rate of hepatitis B-related deaths by 20% by 2025	→				
7.	Increase proportion of people who have cleared hepatitis C infection to 58% by 2025	•				
8.	Reduce rate of hepatitis C-related deaths by 25% by 2025	\checkmark				
Goal	3: Reduce Viral Hepatitis-Related Disparities and Health Inequities					
9.	Reduce acute hepatitis B infections among people who inject drugs by 25% by 2025					
10.	Increase proportion of people with hepatitis B infection aware of their infection among Asian and Pacific Islander people to 50% by 2025	•				
11a.	Reduce rate of hepatitis B–related deaths among Asian and Pacific Islander people by 25% by 202	25 😣				
11b.	Reduce rate of hepatitis B–related deaths among non-Hispanic Black people by 25% by 2025	→				
12a.	Reduce acute hepatitis C infections among people who inject drugs by 25% by 2025	→				
12b.	Reduce acute hepatitis C infections among American Indian and Alaska Native people by 25% by 2	2025 😣				
13a.	Reduce rate of hepatitis C–related deaths among American Indian and Alaska Native people by 30 by 2025)%				
13b.	Reduce rate of hepatitis C–related deaths among non-Hispanic Black people by 30% by 2025					

FEDERAL AGENCY ACTION HIGHLIGHTS

The <u>Viral Hepatitis Federal Implementation Plan</u> (Federal Implementation Plan) outlines federal partners' commitments to policies, research, and activities during FY 2021–2025 to meet the National Strategic Plan goals, pursuant to their respective missions, funding, and resources. This section provides high-level progress updates on select actions from the Federal Implementation Plan by federal partners during FY 2023. It does not provide a complete summary of all the actions detailed in the Federal Implementation Plan or others related to the National Strategic Plan goals. Federal partners reported the highest impact updates to highlight progress on select actions.



GOAL 1: Prevent New Viral Hepatitis Infections

Related Indicators

→ 1.	Reduce new hepatitis A infections
2 .	Reduce acute hepatitis B infections
3.	Reduce acute hepatitis C infections
4 .	Increase rate of hepatitis B "birth dose" vaccination

Agency Progress Update

CDC In March 2023, CDC issued <u>updated hepatitis B screening and testing recommendations</u> to screen for hepatitis B using three laboratory tests at least once during a lifetime for adults aged 18 years or older. The update adds three additional risk groups (people incarcerated, people with a history of sexually transmitted infections (STIs) or multiple sex partners, and people with hepatitis C virus (HCV) infection) for recommended periodic testing. In addition, anyone who requests hepatitis B virus (HBV) testing should receive it, regardless of disclosure of risk.

- **CDC** In FY 2023, CDC supported 18 jurisdictions to expand viral hepatitis and other infectious disease services in SSPs, correctional settings, and substance use disorder (SUD) treatment facilities through the Integrated Viral Hepatitis Surveillance and Prevention for Health Departments (<u>CDC-RFA-PS21-2103</u>).
- **CDC** CDC is increasing the nation's capacity to leverage SSPs as public health infrastructure. In FY 2023, one of CDC's <u>funded partners</u> made 65 sub-awards to SSPs around the country to support and expand SSP implementation in 31 unique jurisdictions. Total award to the 65 sub-recipients was \$6 million.

- **CDC** CDC supported the establishment of an <u>Extension for Community Healthcare Outcomes</u> (ECHO) training program for pediatric providers to increase awareness and implementation of the new hepatitis C perinatal testing recommendations, along with focus groups among pediatricians and caregivers of perinatally exposed infants.
- CDC CDC supports Medscape Education (part of WebMD Health Network) to provide free, accredited, on-demand, continuing education courses on hepatitis B and hepatitis C. Launched in 2023, a <u>video-based activity</u> supports clinicians in integrating updated CDC guidelines for hepatitis B screening, testing, and vaccination into primary care settings. To date, 3,555 learners have listened to the course.
- **FDA** Following a panel meeting in September 2023 in which the panel discussed and made recommendations regarding a potential reclassification from class III to class II of certain HBV diagnostic tests, the Center for Devices and Radiological Health (CDRH) intends to propose reclassification of those tests. If finalized, reclassification would allow manufacturers of HBV tests to seek marketing clearance through the premarket notification (510(k)) pathway rather than the premarket approval (PMA) pathway while still ensuring they provide a reasonable assurance of safety and effectiveness. Such reclassification may support the potential for more manufacturers to develop these tests, which can increase competition and increase access to these important tests.
- NIH NIH created a network of HCV Vaccine Development Centers to advance the development of hepatitis C vaccines, through three U19 grants (RFA-AI-20-19), a P01 grant, and an R01 grant. These grants are in year 3 of 5. In October 2023, investigators and National Institute of Allergy and Infectious Diseases (NIAID) staff met to review progress and assess future needs. Several vaccine candidates are being prepared, and immunological studies using these vaccines are being initiated in animal models.
- **ORHO** All ORHO regions have a substance use-related federal workgroup and incorporate syndemic approaches into their discussions and activities, amplifying viral hepatitis awareness events and news to stakeholders.
- SAMHSA SAMHSA announced the <u>Minority AIDS Initiative: Substances Use Disorder Treatment for Racial/</u> <u>Ethnic Minority Populations at High Risk for HIV/AIDS</u>. This program increases engagement in care for individuals from medically underserved racial and ethnic groups with SUDs and/or co-occurring SUDs and mental health conditions who are at risk for or living with HIV. Award recipients will take a syndemic approach to SUD, HIV, and viral hepatitis. This funding supports <u>44 grant recipients</u>.
- **SAMHSA** SAMHSA announced the <u>Minority AIDS Initiative: Substance Use and Human Immunodeficiency</u> <u>Virus Prevention Navigator Program for Racial/Ethnic Minorities</u>. This program provides substance use and HIV prevention services to racial and ethnic minority populations at high risk for SUDs and HIV infection. The program places emphasis on persons who identify as lesbian, gay, bisexual, transgender, queer/questioning and intersex persons who are not in stable housing and/or reside in communities with high rates of HIV, viral hepatitis, and/or STIs. This funding supports <u>35 grant recipients</u> in the *Ending the HIV Epidemic in the U.S.* jurisdictions.

- SAMHSA In 2023, the Addiction Technology Transfer Center Network Coordinating Office published a <u>Supplement</u> to <u>Your Guide to Integrating HCV Services into Opioid Treatment Programs</u>, summarizing how the landscape has changed since 2020, integrating COVID-19 challenges and considerations, and providing case studies of successful integration programs.
- VA VA generated data reports and data platforms for Veterans Health Administration (VHA) clinicians and managers to improve and coordinate care. Data reports included hepatitis B and hepatitis C testing rates, new hepatitis B and hepatitis C diagnoses, hepatitis C treatment outcomes, and untreated hepatitis C patients. Data platforms for customized reports included HCV Data Cube, HCV Clinical Dashboard, and HBV Clinical Dashboard.
- VA VA developed population health management clinical dashboards providing patient-level identification of subpopulations of potential harm reduction candidates, allowing focused patient contact and interventions. This included Viral hepatitis risk—Syringe service program dashboard, HIV risk—PrEP [Pre-Exposure Prophylaxis] dashboard, and HIV and STI risk—STI dashboard.



GOAL 2: Improve Viral Hepatitis-Related Health Outcomes of People with Viral Hepatitis

Related Indicators

5 .	Increase proportion of people with hepatitis B infection aware of their infection
<mark>→</mark> 6.	Reduce rate of hepatitis B-related deaths
7 .	Increase proportion of people who have cleared hepatitis C infection
8.	Reduce rate of hepatitis C-related deaths

Agency Progress Update

BOP BOP offered voluntary HCV screening to 87.0% of adults in custody (AIC) in FY 2022 and 90.3% in FY 2023. Of those offered, 82.8% of AIC were screened in FY 2022 and 85.6% in FY 2023.

BOP BOP obtained SAMHSA Opioid Treatment Program certification for 100% of its facilities. BOP released guidance modules for opioid use disorder in June 2023, and updates them regularly, as needed. The BOP Hepatitis Clinical Pharmacy Consultants added a section on opioid use disorder referral in their non-formulary request response for HCV treatment.

- CDC In July 2023, CDC issued <u>Updated Operational Guidance for Implementing CDC's</u> <u>Recommendations on Testing for Hepatitis C Virus Infection</u>. Because approximately one-third of patients have incomplete HCV testing where no HCV RNA test is performed upon receiving a reactive HCV antibody test, the new guidance recommends operational strategies that collect samples at a single visit and automatic HCV RNA testing on all HCV antibody reactive samples. Additionally, use of strategies that require multiple visits to collect samples should be discontinued. Automatic HCV RNA testing on all HCV antibody reactive samples will increase the percentage of patients with current HCV infection who receive curative antiviral therapy.
- **CDC** In April 2023, CDC developed the <u>Hepatitis C Treatment Locator Widget</u> to assist those seeking hepatitis C treatment find nearby treatment providers. Public health partners can <u>add this widget</u> to their website, and health organizations and providers that treat hepatitis C can <u>add their</u> <u>clinic</u> to the database of providers. Since its launch, more than 100 partners have embedded the widget on their webpage.
- **CDC** On September 12–13, 2023, the National Alliance of State & Territorial AIDS Directors (NASTAD) and the National Viral Hepatitis Roundtable hosted a <u>2-day virtual convening</u> supported by CDC to showcase promising models and best practices for integrating hepatitis C testing and treatment in federally qualified health centers, state correctional facilities, SSPs, and programs providing medications for opioid use disorder. There were approximately 215 attendees per presentation.
- **CDC** One of CDC's funded partners, Hep B United, launched the <u>Community Health Center Learning</u> <u>Collaborative</u> to help community clinics implement best practices for hepatitis B screening and vaccination. Program partners have hosted 400 educational and 230 screening events, which resulted in reaching and screening 28,640 people.
- **CMS** CMS released <u>guidance</u> in April 2023 to encourage states to apply for a new Medicaid Reentry Section 1115 Demonstration opportunity to help increase care for individuals who are incarcerated in the period immediately prior to their release to help them succeed and thrive as they reenter their communities. The new demonstration opportunity would allow state Medicaid programs to cover services that address various health concerns, including SUDs and other chronic health conditions. Prior <u>analysis</u> has shown that individuals who are incarcerated have higher rates of hepatitis B and hepatitis C.
- CMS In June 2023, HHS submitted a Report to Congress that provided a more extensive analysis of Medicaid coverage of non-emergency medical transportation (NEMT). CMS also issued a transportation coverage guide in September 2023 that updates NEMT guidance for states. A lack of transportation has been identified as barrier to treatment of viral hepatitis.
- **CMS** CMS issued a new place of service code for "outreach site/street," which can be used by payers to reimburse for services provided on the street or found environment for people who may be impacted by viral hepatitis.

- **FDA** On October 17, 2022, FDA approved the use of Vemlidy (tenofovir alafenamide) in pediatric patients aged 12 years and older for the treatment of chronic hepatitis B.
- **FDA** FDA's Division of Antivirals in the Center for Drug Evaluation and Research continued to work closely with external stakeholders to discuss clinical trial designs to evaluate new hepatitis B therapies.
- IHS IHS collaborated with tribal partners to expand nationwide ECHO availability for HCV-related topics such as harm reduction and peer education. These sessions help clinicians and non-licensed staff based in both health facilities and the community connect with experts with relevant cultural experience, increasing the understanding and response to inequities in social determinants of health (SDOH) that are recognized as foundational drivers of disparities in HCV incidence and barriers to care for patients with HCV who need treatment.
- IHS IHS continued to scale up HCV treatment capacity to all IHS, tribal, and urban clinics through telehealth support from a faculty team, composed of a specialist, pharmacist, and behavioral health lead familiar with Indian Country. Clinical pharmacists have a leadership role in many HCV services, which mitigates the impact of chronic shortages of providers.
- **NIH** NIH published a new Request for Applications (RFA) in 2023 (<u>RFA-AI-23-022</u>), calling for the development of animal models for the study of HBV and HCV, primarily for the evaluation of potential antiviral drugs against HBV and vaccine candidates to prevent HCV infection.
- NIH NIH received a three-fold increase (per FY) in the number of applications submitted after publication of the Notice of Special Interest (NOSI) NOT-AI-20-013 (expired on January 8, 2023) "Advancing Development of Rapid Point-of-Care Hepatitis C Virus Diagnostics," improving the success rate for funding to 14%. The NOSI (NOT-AI-23-013) was renewed (February 5, 2023, to January 8, 2026) to further encourage applications.
- NIHNIAID made two contract awards under the Small Business Innovation Research contract for
NIAID Topic 099 (Rapid, Point-of-Care Diagnostics for Hepatitis C Virus), SBIR PHASE II Point-of-
Care HCV Detection and Rapid and Point-of-Care Diagnostics for Hepatitis C Virus.
- NIHThe National Cancer Institute (NCI) published and funded RFA CA -23-023 for Liver CancerCollaborative Projects with the Liver Cirrhosis Network. Recipientswere-awarded-in-September-2023.

- **NIH** The National Institute of Diabetes and Digestive and Kidney Diseases initiated two studies: (1) an open-label, Phase 2a, single-site (NIH Clinical Center), single-arm, proof-of-concept study of an siRNA (VIR-2218) targeting all HBV mRNAs that is administered as a lead-in followed by the combination therapy with peginterferon alfa-2a to determine the effectiveness in reducing quantitative HBsAg (qHBsAg) levels and achieving HBsAg loss and functional cure in patients with chronic hepatitis B; and (2) an open-label, Phase 2a, single-site (NIH Clinical Center), single-arm, study of combination of Ionafarnib, ritonavir, and peginterferon lambda for 48 weeks in people with hepatitis D virus (HDV) and HBV co-infection to test the efficacy of the combination therapy in suppressing HDV viremia in HBV/HDV-infected patients.
- **NIH** In September 2023, NCI reissued and funded the Consortium on Translational Research in Early Detection of Liver Cancer, <u>RFA-CA-22-031</u> and <u>RFA-CA-22-032</u>. The Liver Cancer Consortium is focused on advancing translational research in the early detection of liver cancer. One of the main goals of the Consortium is to establish cohorts of cirrhotic patients to study risks for liver cancer associated with viral infections (HCV or HBV). Using these cohorts, the Consortium is developing biomarkers for early detection of hepatocellular carcinoma (HCC). During the first cycle, the Consortium published more than 15 articles focused on the association of viral infections as a risk factor for developing HCC and biomarkers for detection of viral-related HCC.
- NIH NCI reissued and funded the Early Detection Research Network: Clinical Validation Centers, RFA-CA-21-033. The focus of the Clinical Validation Centers (CVCs) is to conduct research to validate biomarkers and/or imaging methods for risk assessment and detection of early-stage cancers, to serve as resource centers for collaborative research by providing high-quality specimens for Phase 1 and 2 biomarker refinement studies, and to conduct biomarker validation studies. The CVCs have the expertise and ability to conduct Phase 4 clinical utility trials of validated early detection biomarkers and/or imaging methods. One of the funded CVCs is focused on HCC and has started a clinical utility trial to compare effectiveness of offering US +/- Alpha feto-protein (AFP) vs. GALAD-based surveillance to reduce late-stage HCC at diagnosis, including patients with HBV and HCV infections.
- OIDP OIDP continued to identify viral hepatitis payment levers in Addressing Reimbursement and Payment Barriers in Viral Hepatitis Integration of Prevention and Care Services Initiative. OIDP released preliminary hepatitis C findings and continued to identify hepatitis B payment solutions based on an extensive literature review, focus groups, and interviews.
- **OIDP** Through a cooperative agreement, OIDP supported the Cherokee Nation to expand and evaluate hepatitis C, HIV, and STI linkage to care strategies within community-based organizations for American Indian/Alaska Native people receiving services for SUD and housing insecurities.
- **OIDP** In May 2023, OIDP coordinated the <u>Federal Implementation of Updated Viral Hepatitis Screening</u> and <u>Vaccination Recommendations</u> webinar. Federal partners shared lessons learned from the implementation of the updated hepatitis C screening recommendations in 2020. The session also provided an update on the implementation of universal hepatitis B vaccination guidelines and how hepatitis B screening and vaccination recommendations will be integrated.

- **OIDP** OIDP and CMS supported testing for an HCV sustained virological response clinical quality measure. Testing will support submission of the measure to the 2024 Measures Under Consideration list and inclusion in the Merit-based Incentive Payment System.
- **OIDP** In September 2023, OIDP began a state viral hepatitis quality measures initiative to identify and develop national consensus on a measure that can be implemented within State Medicaid quality programs.
- VA Between 2020 and 2022, among Veterans aged 18–79 years in VHA care, the HCV testing rate increased from 76% to 77%. VHA has treated and cured greater than 95% of Veterans in care with HCV. Out of an original population of approximately 160,000 Veterans awaiting treatment in 2015, approximately 12,000 have not been treated.
- VA The VHA continued to conduct hepatitis B testing in at-risk subpopulations. Among Veterans identified as being in an at-risk population as of July 2023, prior HBV testing had occurred in 59.0% with increased alanine transaminase (ALT), in 96.4% of those on dialysis, in 87.1% of those who were hepatitis C-positive, in 92.7% of those who were HIV-positive, and in 92.3% of those receiving B-cell depleting therapy. Further, 71.1% of hepatitis B-positive Veterans in VHA care with cirrhosis received HBV antiviral treatment.

GOAL 3: Reduce Viral Hepatitis-Related Disparities and Health Inequities

Related Indicators

9. Reduce acute hepatitis B infections among people who inject drugs
10. Increase proportion of people with hepatitis B infection aware of their infection among Asian and Pacific Islander people
11a. Reduce rate of hepatitis B-related deaths among Asian and Pacific Islander people
11b. Reduce rate of hepatitis B-related deaths among non-Hispanic Black people
12a. Reduce acute hepatitis C infections among people who inject drugs
12b. Reduce acute hepatitis C infections among American Indian and Alaska Native people
13a. Reduce rate of hepatitis C-related deaths among American Indian and Alaska Native people
13b. Reduce rate of hepatitis C-related deaths among non-Hispanic Black people

- **CDC** CDC published an <u>MMWR</u> in June 2023 reporting that the prevalence of viral clearance among persons with diagnosed hepatitis C was only 34% overall and was even lower (16%) among persons aged 20–39 years with client or self-pay insurance.
- **CDC** CDC entered into and signed a contract with the American Correctional Association to update and disseminate hepatitis C educational materials for state correctional and large jails systems.
- **DOJ** The Disability Rights Section of the DOJ Civil Rights Division (CRD) continued to develop cases that present a pattern or practice of hepatitis-based discrimination, monitor private litigation, and work with organizations to identify opportunities to file Statements of Interest or amicus briefs in matters related to hepatitis-based discrimination. On December 5, 2022, the CRD executed a settlement agreement with the state of Alabama's Medicaid Agency under Title II of the Americans with Disabilities Act (ADA) to ensure that Alabama Medicaid recipients with hepatitis C who also have a SUD have equal access to medications to treat their hepatitis. Alabama Medicaid previously maintained a sobriety restriction policy that prevented any person with HCV who had used any alcohol or illicit drugs within the 6 months prior to treatment initiation from receiving medication to cure their HCV. Alabama Medicaid providers of these changes and prompt remediation of any instances where the prior policy is applied.
- **DOJ** The Disability Rights Section of the DOJ CRD continued to receive and review referrals of potential hepatitis-based discrimination through direct calls from the ADA Information Line and online at <u>http://www.ada.gov</u> and <u>https://www.justice.gov/crt</u>.
- **EEOC** During FY 2022, EEOC continued to conduct outreach, training, and education regarding Title I of the ADA and Section 501 of the Rehabilitation Act, addressing principles that may apply to applicants and employees with viral hepatitis, such as nondiscrimination, reasonable accommodation, and rules regarding disability-related inquiries and medical examinations as well as confidentiality. Target audiences included supervisors and managers, human resources staff, applicants and employees, and attorneys and advocates. In FY 2022, EEOC staff participated in 1,619 presentations, on all statutes enforced by EEOC, reaching more than 218,000 individuals. The Commission issued two new technical assistance documents as well as several updates to its COVID-19 technical assistance, *What You Should Know About COVID-19 and the ADA, Rehabilitation Act, and Other EEO Laws*. EEOC enhanced its Spanish-language outreach, issuing Spanish versions of 52 documents, while providing new translations into several other languages. EEOC boosted its outreach via social media, undertaking educational campaigns on Instagram, Twitter (now "X"), Facebook, and other platforms. See <u>2022 Annual Performance Report (APR)</u>.

- HRSA Over 3 years, the <u>SPNS Initiative: Curing Hepatitis C among People of Color Living with HIV,</u> 2017-2021 expanded HCV prevention, testing, care, and treatment, enhancing coordination for individuals living with both HIV and HCV. It also improved collaboration with SAMHSA-funded SUD treatment providers to offer behavioral health and SUD support, aiming for treatment completion and HCV infection prevention. Furthermore, it bolstered state, local, and tribal health department surveillance systems, increasing their capacity to monitor HIV and HCV infections in areas with high populations of low-income, underinsured, or uninsured racial and ethnic minorities living with HIV in the United States. A collection of papers focusing on innovative patient care has been published in a special edition titled "Innovations in HIV/HCV Care" within the peer-reviewed journal *Health Promotion Practice*.
- HRSA In April 2023, the Bureau of Primary Health Care's National Training and Technical Assistance Partners hosted a <u>Hepatitis C Virtual Symposium</u> with speakers from primary care and health care for the homeless settings, national hepatitis C experts, and people with lived experience. The symposium provided applicable clinical information on conducting pre-treatment assessments, common barriers to treatment, addressing complex clinical scenarios, models of care delivery, and lessons learned from provider and patient experiences. Three Continuing Education Units were offered for this symposium.
- **HUD** In March 2023, HUD published <u>Emerging Practices to Enhance Safety at Congregate Shelter</u>, a guide demonstrating ways to create safer, more accessible, and inclusive congregate shelters. HUD will work on additional materials to assist communities in operationalizing the guide.
- **HUD** HUD provided technical assistance to CDC Epidemiology and Laboratory Capacity grantees to improve coordination between Continuums of Care and public health departments in response to coronavirus and other infectious diseases.
- NIHThree projects were funded from the National Institute on Minority Health and Health
Disparities-led liver disease and cancer disparities Notice of Funding Opportunity (NOFO) in FY
2021 resulting in <u>37 publications</u> from 2021 to October 2023.
- OCRBetween January 2021 and November 2023, OCR resolved 51 Health Insurance Portability and
Accountability Act (HIPAA) Rules complaints with resolution agreements. In 2023, OCR initiated
two rulemakings to strengthen the HIPAA Privacy Rule and implement statutory changes to 42 CFR
Part 2 to enhance care coordination for SUD patients. The Final Rule was issued February 2024.
- **ONC** ONC continued hosting <u>SDOH Information Exchange Learning Forums</u>, bringing together health care providers, payers, health information technology (IT) developers, health information exchanges, community-based organizations, and other partners to share lessons learned, promising practices, and challenges related to exchanging SDOH data. Forums were held in February, March, May, and June 2023.
- **ONC** In February 2023, ONC released the SDOH Information Exchange Toolkit, a practical, on-theground resource designed to aid the health IT community in the implementation of initiatives that recognize the importance of SDOH information exchange.

CDC	In August 2023, CDC released the Viral Hepatitis Surveillance Report, United States - 2021. This
	report was distributed widely through direct partner communications and social media.

CDC CDC released new estimated prevalence and awareness of <u>hepatitis C virus</u> and <u>hepatitis B virus</u> among U.S. adults. In March 2023, CDC published analyses showing that among National Health and Nutrition Examination Survey participants aged 6 years and older evaluated from January 2017 through March 2020, an estimated 660,000 had HBV infection; of these 50% were unaware of their infection. In July 2023, CDC reported that approximately 2.2 million noninstitutionalized civilian U.S. adults had hepatitis C and one-third were unaware of their infection during January 2017–March 2020.

CDC CDC provided 59 state, local, and territorial health departments with core funding to conduct surveillance and outbreak response activities. Despite most jurisdictions receiving surveillance and outbreak federal support for the first time, good progress is being made to build national capacity. For example, CDC is now receiving greater than 60% of hepatitis A outbreak reports and 100% of hepatitis C outbreak reports from jurisdictions, and about one-half of funded jurisdictions have completed a longitudinal surveillance registry for chronic HCV (<u>CDC-RFA-PS21-2103</u>).

HRSA The Leveraging a Data to Care Approach to Cure Hepatitis C within the RWHAP project facilitated HCV/HIV initiatives in five Ryan White HIV/AIDS Program Part A and B jurisdictions, with the primary goals of enhancing jurisdictional capacity for comprehensive HCV screening, care, and treatment for people of color co-infected with HIV/HCV. Activities included patient education, provider training, clinic transformation to focus on HCV screening protocols and medication adherence for people with HIV, and evaluation at both local and multisite levels. Technical assistance and training materials are available at targethiv.org, including webinars and tools for jurisdictional-level approaches to HCV screening and care in people with HIV.

- IHS IHS continued to improve HCV screening coverage of baby boomers. Screening rates have increased from 11% in 2012 to 68% in 2021. Universal HCV screening (aged 18 years and older) was recommended by the IHS chief medical officer prior to recommendations by CDC and the U.S. Preventive Services Task Force. Universal screening coverage of all adults aged 18 years and older is 50% as of 2021.
- **OCR** From January 2021 to November 2023, OCR resolved 5,870 investigations as part of its right of access initiative. OCR created this initiative to support individuals' right to timely access to their health records at a reasonable cost under the HIPAA Privacy Rule.
- **ONC** ONC updated requirements for developers of certified health IT to include USCDIv3 beginning in 2026. USCDIv3 includes new data elements such as insurance information, functional status, substance use, alcohol use, and several laboratory data elements relevant to improving care related to SDOH.
- **ONC** In the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Rule, finalized on December 13, 2023, ONC included several revised Certification Program certification criteria, including for patient demographics and observations, electronic case reporting, and application programming interfaces for patient and population services.



- **CDC** In FY 2023, CDC supported 59 jurisdictional health departments with resources to expand viral hepatitis testing through the Integrated Viral Hepatitis Surveillance and Prevention for Health Departments (CDC-RFA-PS21-2103).
- **IHS** The HCV TeleECHO program met four times a month to review approximately three cases at each session for an annual total of 44–48 TeleECHO HCV clinics reviewing 132–144 cases. There were approximately 25 participants in each session.
- IHS The Indigenous HIV/AIDS Syndemic Strategy: Weaving Together the National HIV, STI and Viral Hepatitis Plans (Indigi-HAS) was released in December 2022 and developed to align strategic planning efforts among national, tribal, and urban organizations serving American Indian/Alaska Native communities.
- **OIDP** As part of its syndemic approach, OIDP continued an initiative to identify and promote successful strategies integrating HIV, viral hepatitis, STIs, SUDs, and mental health services. OIDP adapted a framework to assess program integration and started to conduct interviews with programs that integrate services.

CHALLENGES AND NEXT STEPS

In FY 2023, federal agencies continued to identify opportunities to address several challenges that affected progress toward achieving elimination targets. The below table is a select list of challenges and next steps that federal agencies have undertaken to address the challenges.

Challenges	Next Steps					
Prevention						
No hepatitis C vaccine	• NIH is advancing HCV vaccine research to support a pathway to regulatory approval.					
New infections due to injection drug use	 BOP is increasing opioid use disorder screening, evaluation, and treatment. ORHO is continuing to work with states/territories/tribes to increase syringe exchange and to promote harm reduction. VHA is expanding SSPs into additional sites. 					
Testing						
Lack of point-of-care hepatitis C diagnostic test and sample type	 NIAID is encouraging small businesses to develop rapid diagnostic platform systems. CDC provides technical assistance to NIH in supporting a framework for developing a rapid point-of-care hepatitis C diagnostic test. CDC is identifying opportunities, such as through laboratory assessments, to promote the importance of complete hepatitis C testing to labs and health care providers. FDA CDRH is exploring pathways to market for manufacturers interested in developing point-of-care hepatitis C diagnostic tests. 					
Linkage to Care						
Linking patients to care for treatment	 CDC continues to support the <u>Hepatitis C Treatment Locator Widget</u>, which helps users find nearby treatment providers. IHS is adding care navigators to settings such as emergency rooms. IHS is using clinical trainings and telehealth to increase the number of clinicians who can treat HCV, including pharmacists. IHS is implementing appointment reminders in electronic health records. VHA is using clinical dashboards and other population health tools to identify and engage Veterans at any point they enter the VHA system (i.e., homeless clinic, mental health, SUD clinic). 					
Payment/reimbursement	 OIDP is supporting and researching evaluation and reimbursement of linkage-to-care strategies in community-based settings. OIDP is supporting development and testing of viral hepatitis quality measures. 					

Challenges	Next Steps			
Treatment				
Access to direct acting antiviral (DAA) drugs because of cost	 IHS is encouraging sites to self-pay for DAAs if seeking third-party reimbursement, which result in delays. IHS is helping sites navigate patient assistance programs and other options for reduced cost DAAs. 			
Lack of research on hepatocellular carcinoma	 NIH continues to release liver cancer-specific NOFOs to encourage investigators into the field. 			
Federal funds unable to go toward purchase of hepatitis treatment	 SAMHSA's MAI: High Risk Populations grant program and the MHAF: Portable Clinical Care Pilot Project incorporated finding a source for hepatitis B and hepatitis C treatment into the allowable activities for case management services. 			
Recurrent cases of hepatitis B after liver transplantation	 The FDA Center for Biologics Evaluation and Research is researching pathways to improve hepatitis B immune globulin (HBIG) products to prevent reinfections following liver transplantation. 			
Social Determinants of Health				
People experiencing homelessness are at greater risk for poor health outcomes	 HUD is working to reduce entry into homelessness from foster care, the criminal justice system, and other institutions, and to improve the collection of gender identity, race, and ethnicity data. On November 1, 2023, HHS and HUD announced the launch of the Housing and Services Partnership Accelerator, which will support states in developing or expanding innovative housing-related supports and services for Medicaid-eligible people with disabilities and older adults who are experiencing or at risk of homelessness. 			
Capacity				
Competing priorities for front-line clinicians and public health	 VA is continuing development of clinical support tools to decrease workload for viral hepatitis screening, linkage to care, and treatment for clinicians. CDC is working to minimize burden on jurisdictional viral hepatitis program staff by streamlining funding applications and reporting and providing data dashboards and technical assistance. 			

APPENDIX A: VIRAL HEPATITIS IMPLEMENTATION WORKING GROUP

The <u>Viral Hepatitis Federal Implementation Plan</u> was developed by a working group of experts from federal agencies that serve populations at risk for or living with viral hepatitis. The implementation working group will continue to meet regularly through 2025 to monitor progress toward indicator targets, capitalize on lessons learned from epidemiological data and research findings, and identify strategies to overcome unexpected obstacles.

Department of Health and Human Services

Administration for Community Living (ACL) Agency for Healthcare Research and Quality (AHRQ) Centers for Disease Control and Prevention (CDC) Centers for Medicare & Medicaid Services (CMS) Food and Drug Administration (FDA) Health Resources and Services Administration (HRSA) Indian Health Service (IHS) National Institutes of Health (NIH) Office for Civil Rights (OCR) Office of the Assistant Secretary for Health (OASH) Office of Disease Prevention and Health Promotion (ODPHP) Office of Infectious Disease and HIV/AIDS Policy (OIDP) Office of Minority Health (OMH) Office of Population Affairs (OPA) Office of Regional Health Operations (ORHO) Office of the National Coordinator for Health Information Technology (ONC) Substance Abuse and Mental Health Services Administration (SAMHSA)

Department of Housing and Urban Development (HUD)

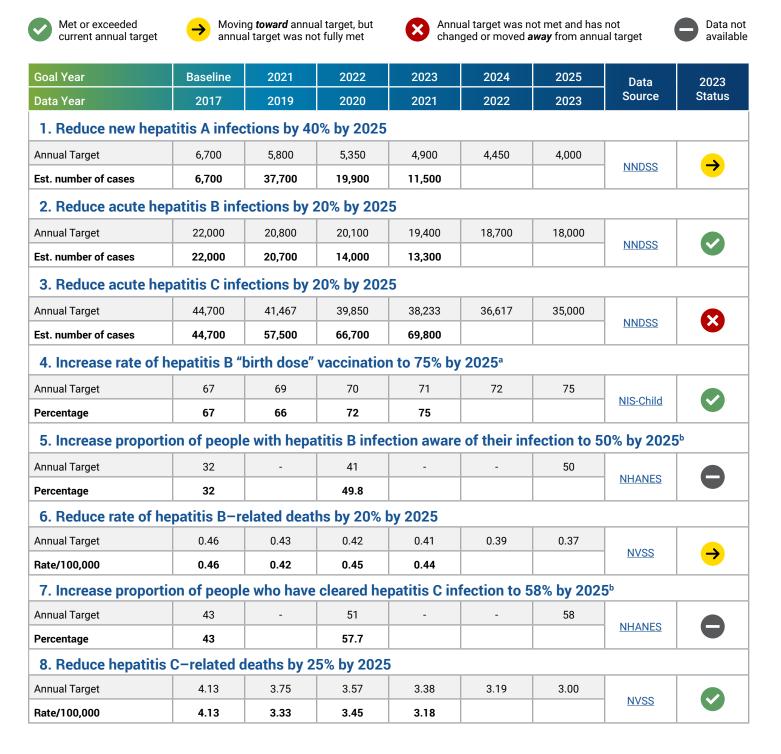
Department of Justice (DOJ)

Department of Veterans Affairs (VA)

Equal Employment Opportunity Commission (EEOC)

APPENDIX B: INDICATOR TABLE

The table below presents the nation's progress on meeting the 2025 targets set forth in the National Strategic Plan. Annual targets are based on a linear trend. The baseline year is 2017 for all indicators, except where noted. Due to the lag in surveillance data availability, the goal year will utilize data from 2 years prior (e.g., goal year 2023 utilizes surveillance data from 2021) to measure progress. Data sources use different data collection and reporting methodologies. Please refer to the data source for information on data collection and reporting methodologies. CDC's *2021 Viral Hepatitis Surveillance Report* and *2023 Viral Hepatitis National Progress Report* provide additional data and graphs.



Goal Year	Baseline	2021	2022	2023	2024	2025	Data	2023
Data Year	2017	2019	2020	2021	2022	2023	Source	Status
9. Reduce rate of ac	ute hepatiti	s B infectio	ons among	people who	o inject drug	gs by 25%	by 2025	
Annual Target	1.4	1.3	1.2	1.1	1.1	1.00		
Reported Rate/100,000	1.4	1.2	0.7	0.6			<u>NNDSS</u>	
10. Increase proport Pacific Islander peo			oatitis B inf	ection awaı	re of their in	nfection an	nong Asian a	and
Annual Target	39	-	43	-	-	50		
Percentage	39		62.3				<u>NHANES</u>	U
11a. Reduce rate of	hepatitis B	-related de	eaths amon	g Asian and	d Pacific Isl	ander peo	ple by 25% b	y 2025
Annual Target	2.45	2.25	2.15	2.04	1.94	1.84		
Reported Rate/100,000	2.45	2.13	2.51	2.54			<u>NVSS</u>	\mathbf{x}
11b. Reduce rate of	hepatitis B	-related de	eaths amon	g non-Hisp	anic Black	people by	25% by 202	5
Annual Target	0.74	0.68	0.65	0.61	0.58	0.55		
Rate/100,000	0.74	0.64	0.67	0.66			<u>NVSS</u>	→
12a. Reduce acute h	epatitis C i	nfections a	mong peop	ole who inje	ct drugs by	v 25% by 20	025	
Annual Target	2.3	2.1	2.0	1.9	1.8	1.7		
Reported Rate/100,000	2.3	2.8	2.9	2.8			<u>NNDSS</u>	→
12b. Reduce acute h	nepatitis C i	nfections a	among Ame	rican India	n and Alask	a Native p	eople by 25	% by 202
Annual Target	2.9	2.7	2.6	2.4	2.3	2.2		
Reported Rate/100,000	2.9	3.6	2.1	2.7			NNDSS	\mathbf{x}
13a. Reduce rate of by 2025	hepatitis C	-related de	eaths amon	g Americar	Indian and	l Alaska Na	ative people	by 30%
Annual Target	10.24	9.22	8.71	8.19	7.68	7.17		
Rate/100,000	10.24	8.55	10.64	9.99			<u>NVSS</u>	→
13b. Reduce rate of by 30% by 2025	hepatitis C	-related de	eaths amon	g non-Hisp	anic Black	people		
Annual Target	7.03	6.33	5.98	5.62	5.27	4.92		
Rate/100,000	7.03	5.53	5.72	5.01			<u>NVSS</u>	

^a Two birth cohort years are utilized to generate the baseline, targets, and progress update. For example, birth cohort years 2015–2016 are utilized for the baseline and birth cohort years 2018–2019 are utilized for goal year 2023 target and progress update.
 ^b For Indicators 5, 7, and 10, the sample size of annual data is too small to permit a stable estimate of the baseline and annual targets. Therefore, 4 years

^b For Indicators 5, 7, and 10, the sample size of annual data is too small to permit a stable estimate of the baseline and annual targets. Therefore, 4 years of survey data are utilized to generate baseline and targets. For example, data from 2013 to 2016 are utilized to generate the baseline and data from 2017 to 2020 are utilized for goal year 2022 target.

Notes: NHANES = National Health and Nutrition Examination Survey; NIS-Child = National Immunization Survey-Children; NNDSS = National Notifiable Diseases Surveillance System; NVSS= National Vital Statistics System.

APPENDIX C: ABBREVIATIONS

ADA	Americans with Disabilities Act
AIDS	acquired immunodeficiency syndrome
BOP	Bureau of Prisons
CDC	Centers for Disease Control and Prevention
CDRH	Center for Devices and Radiological Health (FDA)
CMS	Centers for Medicare & Medicaid Services
COVID-19	coronavirus disease 2019
CRD	Civil Rights Division (DOJ)
DOJ	U.S. Department of Justice
EEOC	U.S. Equal Employment Opportunity Commission
FDA	U.S. Food and Drug Administration
FY	fiscal year
HBV	hepatitis B virus
HCC	hepatocellular carcinoma
HCV	hepatitis C virus
HDV	hepatitis D virus
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HIV	human immunodeficiency virus
HRSA	Health Resources and Services Administration
HUD	U.S. Department of Housing and Urban Development
IHS	Indian Health Service
NASTAD	National Alliance of State & Territorial AIDS Directors
NCI	National Cancer Institute
NHANES	National Health and Nutrition Examination Survey
NIAID	National Institute of Allergy and Infectious Diseases (NIH)
NIH	National Institutes of Health
NIS	National Immunization Surveys
NNDSS	National Notifiable Diseases Surveillance System

NOFO	Notice of Funding Opportunity
NOSI	Notice of Special Interest
NVSS	National Vital Statistics System
OASH	Office of the Assistant Secretary of Health
OCR	Office for Civil Rights
OIDP	Office of Infectious Disease and HIV/AIDS Policy (OASH)
ONC	Office of the National Coordinator for Health Information Technology
ORHO	Office of Regional Health Operations
RFA	Request for Applications
SAMHSA	Substance Abuse and Mental Health Services Administration
SDOH	social determinants of health
SSP	syringe services program
SUD	substance use disorder
STI	sexually transmitted infection
VA	U.S. Department of Veterans Affairs
VHA	Veterans Health Administration