



SUPPORT CRITICAL FUNDING FOR LIVER DISEASE RESEARCH AND SERVICES

As Congress begins work on Fiscal Year (FY) 2025 appropriations, we urge Congress to do the following:

- Appropriate at least \$51.303 billion, an increase of \$3.579 billion over Fiscal Year (FY) 2023, for the National Institutes of Health (NIH); and
- Provide \$150 million, an increase of \$107 million, for the Centers for Disease Control and Prevention (CDC) Division of Viral Hepatitis.

Appropriate \$51.303 billion for NIH to Expand Research Opportunities

Robust, sustained, and predictable funding is essential to support continued advancements in biomedical research, including that related to liver disease. As Congress begins its work on funding for FY 2025, AASLD requests that Congress appropriate \$51.303 billion for NIH, which would allow for meaningful growth above inflation to expand NIH's capacity to support promising science. This would build on Congress' recent investments in NIH that have allowed advances in discoveries toward promising therapies and diagnostics, supported current and new scientists nationwide, and advanced the potential of medical research.

AASLD also requests that the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)—the home for liver disease research—receive an increase commensurate with the overall increase for NIH. This funding will allow NIH to support meritorious research in liver disease and address the gaps in the current state of the science that underlie the increasing incidence and mortality of liver disease.

Appropriate \$150 million for the CDC Division of Viral Hepatitis to Support Elimination

Viral hepatitis is a preventable public health crisis that puts people, particularly those who are disconnected from the health system, at increased risk for liver disease, cancer, and death. Besides the virus' mortality, treating these complications of hepatitis A, B, and C is extremely costly to the health care system.

Funding for the Division of Viral Hepatitis (DVH) has remained relatively flat during the last decade, leaving it unable to support the policies and programs necessary to bolster efforts toward the Department of Health and Human Services' stated goal to eliminate viral hepatitis. DVH does not have the resources to do the following:

- Stand up a viral hepatitis surveillance system that would enable timely detection and monitoring of outbreaks, leading to more effective interventions.
- Complete comprehensive case investigation work. Right now, DVH only knows what the risk factor is for half the reported infections.
- Support a comprehensive testing program, which is particularly important as we anticipate that the Food and Drug Administration will approve a hepatitis C point-of-care test this year.

Small increases in DVH's budget, which has grown from \$31.4 million in 2014 to \$43 million in 2023, have helped offset inflation, but this is not allowing for meaningful expansion of existing programs. For these reasons, we urge you to allocate \$150 million for DVH. We recognize that this request represents a \$107 million increase in the Division's funding. Yet, it does not come close to providing the funding required to put the United States on the path to eliminating viral hepatitis. Prioritizing funding for the DVH will help build the infrastructure and programs necessary to ensure that viral hepatitis surveillance, prevention, testing, and treatment services are widely available for all populations.

Take Action to Eliminate Hepatitis C

OUR REQUEST:

Support authorizing legislation to implement a plan to eliminate hepatitis C (HCV) in the United States in five years.

BACKGROUND

HCV is a liver infection spread through blood contact. In the short-term, most people infected with HCV will remain asymptomatic for many years. Without diagnosis and treatment, HCV generally becomes a long-term, chronic infection with challenging health implications, including liver cirrhosis, liver cancer, and potentially even death.

An estimated 2.4 million people in the United States are currently living with HCV, and just over half are unaware of their infection. Previously, HCV was difficult to treat. However, medical breakthroughs have brought forward oral direct-acting antivirals (DAAs) with a 95% success rate of curing HCV in 12 weeks. This means we can eliminate HCV. However, data show that this cure is not reaching patients.

According to a new report from the Centers for Disease Control and Prevention (CDC)[1], only one in three adults diagnosed with hepatitis C were cured between 2013-2022. The statistics are staggering:

- One in four individuals without health insurance were cured;
- One in four individuals under the age of 40 were cured. This age group has the highest rates of new hepatitis C infections;
- One in six individuals under the age of 40 and without health insurance was cured; and
- Less than half of adults 60 and older with private insurance or Medicare were cured.

Without action, the economic burden of chronic HCV is estimated to potentially exceed \$10 billion annually in the United States alone[2], and the federal government is already covering much of that cost. The average annual cost, excluding drug costs, is just over \$17,000 for non-disabled adults in Medicaid [3]. Over their lifetime, these costs far exceed those of treatment.

A PROPOSED NATIONAL PLAN

There is a proposed national plan to eliminate hepatitis C, which will help reduce the most common barriers to treatment – the challenges of diagnosing the virus, restrictive coverage policies, and the cost of the treatment. But Congress must authorize this plan into action. The plan consists of...continued on next page.

[1] https://www.cdc.gov/mmwr/volumes/72/wr/mm7226a3.htm?s_cid=mm7226a3_w

[2] Majethia, S., Lee, I.-H., Chastek, B., Bunner, S., Wolf, J., Hsiao, A., & Mozaffari, E. (2022). Economic impact of applying the AASLD-IDSA simplified treatment algorithm on the real-world management of hepatitis C. *Journal of Managed Care & Specialty Pharmacy*, 28(1), 48–57. <https://doi.org/10.18553/jmcp.2021.21246>

[3] <https://www.hhs.gov/sites/default/files/Assessing-the-Burden-of-Illness-of-Chronic-Hepatitis-C-and-Impact-of-DAA-Use-on-Healthcare-Costs-in-Medicaid-2019.pdf>

[4] Fleurence RL, Collins FS. A National Hepatitis C Elimination Program in the United States: A Historic Opportunity. *JAMA*. Published online March 09, 2023. doi:10.1001/jama.2023.3692

Take Action to Eliminate Hepatitis C

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Accelerate the availability of point-of-care (POC) diagnostic tests for HCV and hepatitis B (HBV).

Currently, testing for HCV and HBV is a two-step process during which patients are lost to care. POC diagnostics will allow patients to be linked directly to care—a cure for HCV and treatment for HBV. The tests will be developed through the Independent Test Assessment Program (ITAP), which will support the research needed to develop the tests and support the Food and Drug Administration's clearance process.

Provide broad access to curative DAAs by creating a national subscription model for the underserved, including Medicaid beneficiaries, justice-involved populations, uninsured individuals, and American Indian and Alaska Natives who are treated through the Indian Health Service (IHS).

State Medicaid programs and state and local correctional facilities can opt in to this program. For those who choose to participate, the DAAs will be procured by the federal government through a competitive procurement process.

A comprehensive public health effort to engage, inform, identify, and treat people with HCV by supporting universal screening and expanding the infrastructure needed for treatment.[4]

The Department of Health and Human Services will coordinate programs across its agencies—CDC, the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, IHS, and the Centers for Medicare & Medicaid Services (CMS) to support expanded testing, training programs, and linkage to care for HCV and HBV positive patients. Specifically, support will be provided to train front-line providers, state grants will facilitate linking patients to care, as will a national public awareness campaign, and CMS will implement related quality measures.

Support for research to develop an HCV vaccine.

Since patients can become reinfected once they have been cured of their initial HCV infection, a vaccine will protect the next generation of Americans from this virus.

Over five years, these components would be supported by a mandatory authorization—an investment of \$9.4 billion. The White House estimates that the plan if implemented, would save \$4 billion in the 10-year budget window. There are significant savings in Medicare and Medicaid; co-payments and health care services, including cancer treatments and liver transplants, would be avoided if patients were treated for their hepatitis C infections.

PLEASE CONSIDER INTRODUCING LEGISLATION AUTHORIZING THESE COMPONENTS TO ELIMINATE HCV.





FY 2025 REPORT LANGUAGE REQUEST

Report Language

Department of Health and Human Services

Office of the Secretary, General Departmental Management

METABOLIC DYSFUNCTION-ASSOCIATED STEATOTIC LIVER DISEASE

The Committee recognizes that liver disease is the ninth leading cause of death in the U.S. Metabolic dysfunction-associated steatotic liver disease (MASLD), formerly known as nonalcoholic fatty liver disease (NAFLD), is the most common cause of liver-related morbidity and mortality impacting more than 30% of Americans and is the leading indication for liver transplant in women. The Committee recommends that agencies implement recently updated nomenclature for MASLD throughout their programs to appropriately identify, diagnose, and treat this deadly disease. The Committee encourages agencies to build upon and expand current activities related to MASLD, focusing on research and therapeutic development and disseminating public health interventions for those living with the disease.



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JUSTIFICATION

Based on the results of a Delphi process, non-alcoholic fatty liver disease (NAFLD) has been renamed as metabolic dysfunction-associated steatotic liver disease (MASLD) to address the stigmatization and trivialization associated with the implications of the term "fatty" and the historical association with the word "alcohol." The new nomenclature, MASLD, aims to remove this stigma and provide a more accurate reflection of the condition's root causes. Moreover, the change was also prompted by the hope that it would stimulate much-needed research into a condition with limited treatment options. MASLD is rapidly becoming more prevalent, underscoring the urgency for increased understanding and effective therapies.

The nomenclature change will impact patients, providers, and the entire liver disease community in many ways. We want to assure you that there will be no disruption to the scientific achievements achieved under the previous term, as research indicates that at least 98% of patients previously diagnosed with NAFLD will now be categorized under the new MASLD nomenclature. Stakeholders recognize that changes to the use of the MASLD nomenclature won't happen overnight. Therefore, it's important for interested parties, including federal agencies, to use both nomenclatures for now while working to implement the updated nomenclature for MASLD throughout programs to appropriately identify, diagnose, and treat this deadly disease.

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