



HEPATITIS AWARENESS MONTH

May 31, 2024

Dear Director Marquardt,

In recognition of Hepatitis Awareness Month, the Center for Health Law and Policy Innovation (CHLPI) and the National Viral Hepatitis Roundtable (NVHR) seek your support in ensuring timely and equitable access to direct-acting antivirals (DAAs) to treat hepatitis C (HCV) in Minnesota. CHLPI advocates for legal, regulatory, and policy reforms to improve the health of marginalized populations, with a focus on the needs of low-income people living with chronic illnesses and disabilities. NVHR is the largest national network of patients, providers, and public health partners breaking down barriers to viral hepatitis care. CHLPI and NVHR collaboratively support the [Hepatitis C: State of Medicaid Access](#) project which tracks and documents HCV treatment prior authorization requirements across the country.

As of February 2024, Minnesota is one of only eight state Medicaid programs that still require providers to document they have counselled patients about substance use prior to initial treatment for HCV. This requirement is rooted in stigmatizing, non-evidence-based assumptions about people who use drugs and their ability to adhere to prescribed medication—even though peer-reviewed studies cited in the [AASLD/IDSA guidance](#) have long-since debunked these concerns ([Coffin, 2019](#)); ([Dore, 2016](#)); ([Hellard, 2014](#)); ([Aspinall, 2013](#)); ([Grebely, 2011](#)). Further, there is no evidence to support the utility of pretreatment screening for substance use in identifying patients who are more likely to successfully complete HCV therapy. CHLPI and NVHR wholeheartedly share Minnesota’s goal of improving comprehensive care for people with substance use disorders (SUD); but requiring documentation of counseling only discourages providers from treating people who use drugs, missing an opportunity to decrease HCV transmission.

Earlier this year, the Department of Justice and the Department of Health and Human Services encouraged state Medicaid programs to reassess whether they provide equitable, non-discriminatory access to health care to individuals with disabilities, “including SUD.” In a joint letter (enclosed), the Departments “urge all state Medicaid administrators to review their current and forthcoming policies, including those on HCV treatment, to determine if any changes are necessary to comply with the ADA.” **In line with these goals, we urge Minnesota to remove all substance use-related counseling criteria for both initial treatment and retreatment.**

Further, we urge Minnesota to join the [more than half of all state Medicaid programs](#) that have done away with prior authorization for most HCV patients entirely. Nationwide, prior authorization for DAAs hinders our ability to [eliminate hepatitis C by 2030](#), compounds burdens on health care providers, and leads to unnecessary delays, interruptions, and outright denials of care for communities who have limited access to healthcare. **We request that you remove prior authorization for preferred hepatitis C medications.**

We commend your efforts in expanding access to hepatitis C treatment in Minnesota. We eagerly await updates on ongoing initiatives aimed at streamlining care processes, and we welcome the opportunity to discuss strategies for enhancing access further.

Elizabeth Kaplan, JD
Director of Health Care Access
Center for Health Law & Policy Innovation
ekaplan@law.harvard.edu

Adrienne Simmons, PharmD, MS, BCPS
Director of Programs
National Viral Hepatitis Roundtable
adrienne@nvhr.org

Cc: Dave Hoang, PharmD, MBA; Nathan Chomilo, MD





January 24, 2024

Dear State Medicaid Administrators and Other Interested Parties:

The Departments of Justice (DOJ) and Health and Human Services (HHS) jointly write to encourage state Medicaid administrators to make sure that their Medicaid programs allow people who have both Hepatitis C (HCV) and substance use disorder (SUD) to access life-saving HCV medications called direct-acting antivirals (DAAs).

DOJ and HHS both enforce the Americans with Disabilities Act (ADA) with respect to state Medicaid programs. The ADA requires that states, in administering their services, programs, and activities, such as their Medicaid programs, avoid discriminating against individuals with disabilities, including SUD. This includes providing individuals with disabilities equal opportunity to participate in and benefit from a state's Medicaid program. While the ADA ordinarily does not prohibit discrimination based on a person's current illegal use of drugs, it does prohibit states from denying health services on that basis, if a person is otherwise entitled to the services.¹

DOJ entered into a [settlement agreement](#) with the state of Alabama's Medicaid Agency (Alabama Medicaid) to address a policy that denied Medicaid coverage for DAAs to patients who had consumed any alcohol or illicit drugs within the six months prior to starting treatment. HCV can result in a range of serious health conditions including liver disease, liver cancer, and death. However, highly effective DAA medications cure HCV in more than 95% of cases.² Alabama Medicaid's policy meant that people with HCV and SUD (who also had evidence of recent use of alcohol and/or illicit drugs) were denied potentially life-saving medication. Following the initiation of an investigation by DOJ, Alabama Medicaid withdrew this policy and entered into an agreement. The agreement requires Alabama Medicaid to notify Medicaid recipients and providers in Alabama of these changes and promptly remedy any case where coverage for DAAs was denied because of a person's SUD.

We urge all state Medicaid administrators to review their current and forthcoming policies and practices, including those on HCV treatment, to determine if any changes are necessary to comply with the ADA. In the years that DAAs have been available, information and research regarding these products have increased. Prior authorization criteria and policies should be reviewed in light of these developments. While states have the authority to manage their Medicaid programs in accordance with their State Plans, and have the flexibility to set prior authorization criteria based on their state program needs, those plans and criteria must be consistent with other applicable laws including the ADA.

Thank you for your attention to this important issue.

¹ 28 C.F.R. § 35.131(a), (b); *see also* 42 U.S.C. § 12132.

² *See* World Health Organization, [Hepatitis C Fact Sheet](#) (July 2023).

For more information on the Department of Justice Civil Rights Division, please visit www.justice.gov/crt. For more information on the ADA, please call the department's toll-free ADA Information Line at 800-514-0301 (TTY 833-610-1264) or visit www.ada.gov. ADA complaints may be filed online at <https://civilrights.justice.gov/report/>.

For more information on the Department of Health and Human Services Centers for Medicare & Medicaid Services, see www.cms.gov.

Sincerely,

A handwritten signature in blue ink that reads "Kristen Clarke". The signature is written in a cursive, flowing style.

Kristen Clarke
Assistant Attorney General for Civil Rights

A handwritten signature in blue ink that reads "Chiquita Brooks-LaSure". The signature is written in a cursive, flowing style.

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services