HEPATITIS C: THE STATE OF MEDICAID ACCESS

May 2021 National Progress Report

The Center for Health Law and Policy Innovation of Harvard Law School (CHLPI) and the National Viral Hepatitis Roundtable (NVHR) share a commitment to ensuring that all individuals living with hepatitis C (HCV) are able to access the cure for HCV, one of the deadliest infectious disease in the United States. We are pleased to report that our collective advocacy is working.

In particular, the launch of our Hepatitis C: The State of Medicaid Access report in 2017 has successfully supported efforts to eliminate treatment access restrictions. Since 2014, access to direct-acting antivirals (DAAs) in state Medicaid programs has been incrementally expanded, often in response to advocacy and impact litigation. Importantly, there has been immense progress in transparency. **In 2014, 18 states had unclear fibrosis restrictions, 15 states had unclear sobriety restrictions, and 23 states had unclear prescriber restrictions.** Now, all states have known criteria, in part due to pressure from advocates for this information to be publicly available.

Since 2017, 32 states have either eliminated or reduced their fibrosis restrictions, 21 have loosened their sobriety restrictions, and 25 have scaled back their prescriber restrictions. There are also now 7 states that, in addition to removing all restrictions, have removed prior authorization for treatment entirely: Washington, Louisiana, New York, California, Indiana, Wisconsin, and most recently Michigan. In these states the barriers to getting treatment in Medicaid have been paved over with a road to treatment.

We have made tremendous progress in removing barriers to treatment since the launch of the State of Hep C in 2017, particularly with fibrosis restrictions. But our work continues. Discriminatory sobriety restrictions persist and continue to undermine our collective efforts to address both hepatitis C and the growing opioid epidemic. CHLPI and NVHR remain committed to capitalizing on the momentum we enjoy today and to advocating for the removal of all states' HCV treatment access restrictions.

We have the tools to eliminate HCV in the U.S., but it requires the removal of all discriminatory HCV treatment access restrictions as well as leadership and resources to turn the promise of the cure into a reality for all.

For more information about *Hepatitis C: The State of Medicaid Access* please go to www.stateofhepc.org.

Published: May 19, 2021

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BACKGROUND

Building on the 2014 Annals of Internal Medicine survey, the Center for Health Law and Policy Innovation (CHLPI) and the National Viral Hepatitis Roundtable (NVHR) have been documenting access restrictions to direct-acting antivirals (DAAs) for hepatitis C treatment in state Medicaid Programs since 2017.[1] While the World Health Organization has challenged member states to eliminate viral hepatitis by 2030 and the U.S. Department of Health and Human Services published the first-ever national strategic plan committing to eliminate viral hepatitis, many public and private payers continue to limit access to DAAs, despite clear guidance from the Centers for Medicare and Medicaid Services that such restrictions often violate federal law.[2] The State of Hepatitis C focuses on three of the most significant restrictive criteria that Fee-for-Service Medicaid programs use as methods of rationing access to the HCV cure: 1) fibrosis (liver damage or disease progression required prior to treatment); 2) sobriety (periods of abstinence from alcohol and/or substance use required); and 3) prescriber (prescribing eligibility limited to certain categories of specialist practitioners). The following progress report summarizes changes in access to HCV treatment in Medicaid programs between 2014 and April 2021.

FINDINGS

States (n=52)[3] with Remaining Restrictions as of May 2021:

FIBROSIS	**# of states with fibrosis restrictions**	4 (8%)	**F2**: Nebraska, Texas **F3**: Arkansas, South Dakota
SOBRIETY	**# of states requiring a period of abstinence**	13 (6%)	**1 month**: Florida **3 months**: Arizona, Iowa, Kansas, North Dakota, Texas, West Virginia **6 months**: Alabama, Arkansas, Mississippi, Nebraska, South Dakota, Tennessee
	# of states who require drug or alcohol screening or counseling	15 (28%)	Alaska, Colorado, Delaware, District of Columbia, Georgia, Hawaii, Idaho, Illinois, Maryland, Minnesota, Montana, New Hampshire, Oklahoma, South Carolina, Wyoming
PRESCRIBER	**# of states with prescriber restrictions**	18 (35%)	**Specialist**: Arkansas, New Jersey **By or in consultation with a specialist**: Arizona, Colorado, District of Columbia, Hawaii, Illinois, Iowa, Mississippi, Nevada, New Hampshire, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Texas, West Virginia

[1]Barua S., Greenwald, R., Grebely, J., Dore, G., Swan, T., and Taylor, L. Restrictions for Medicaid Reimbursement of Sofosbuvir for the Treatment of Hepatitis C Virus Infections in the United States, 163 ANN INTERN MED. 215 (2015).

[2]Centers for Medicare and Medicaid Services, Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs (Release No. 172), Nov. 5, 2015, available at https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-172.pdf.

[3]For the purposes of analysis, the District of Columbia and Puerto Rico are treated as states.

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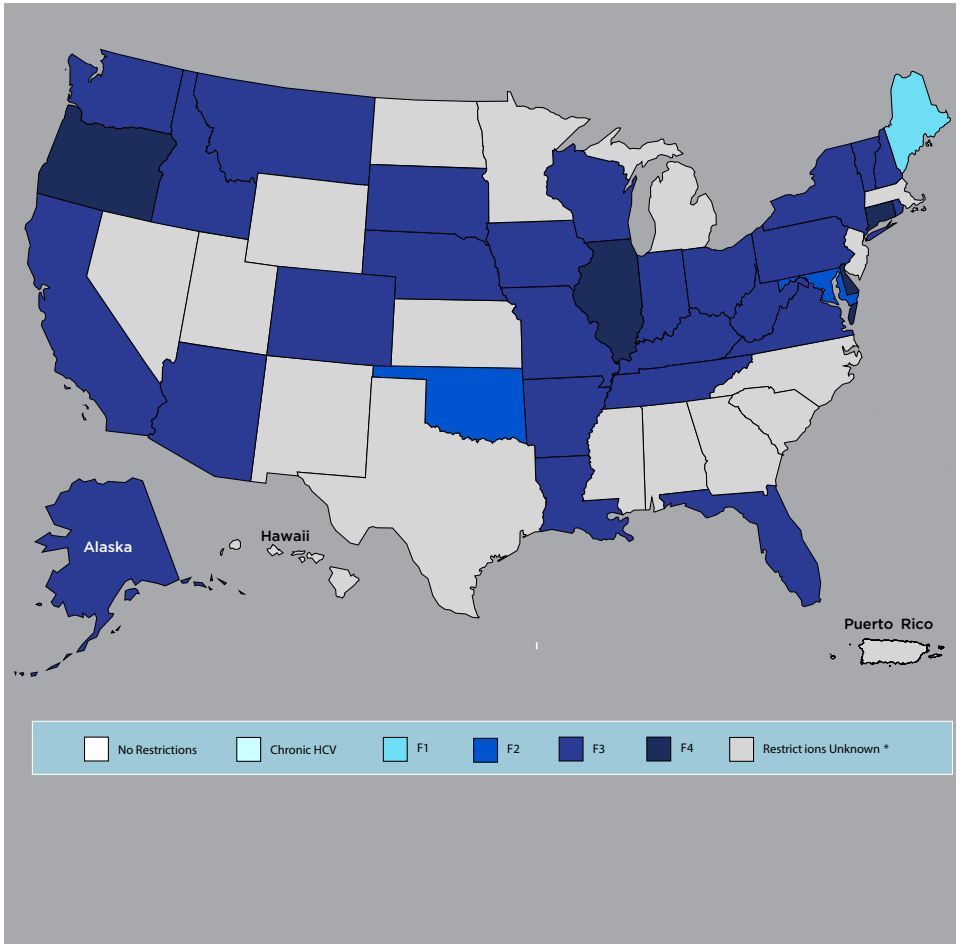
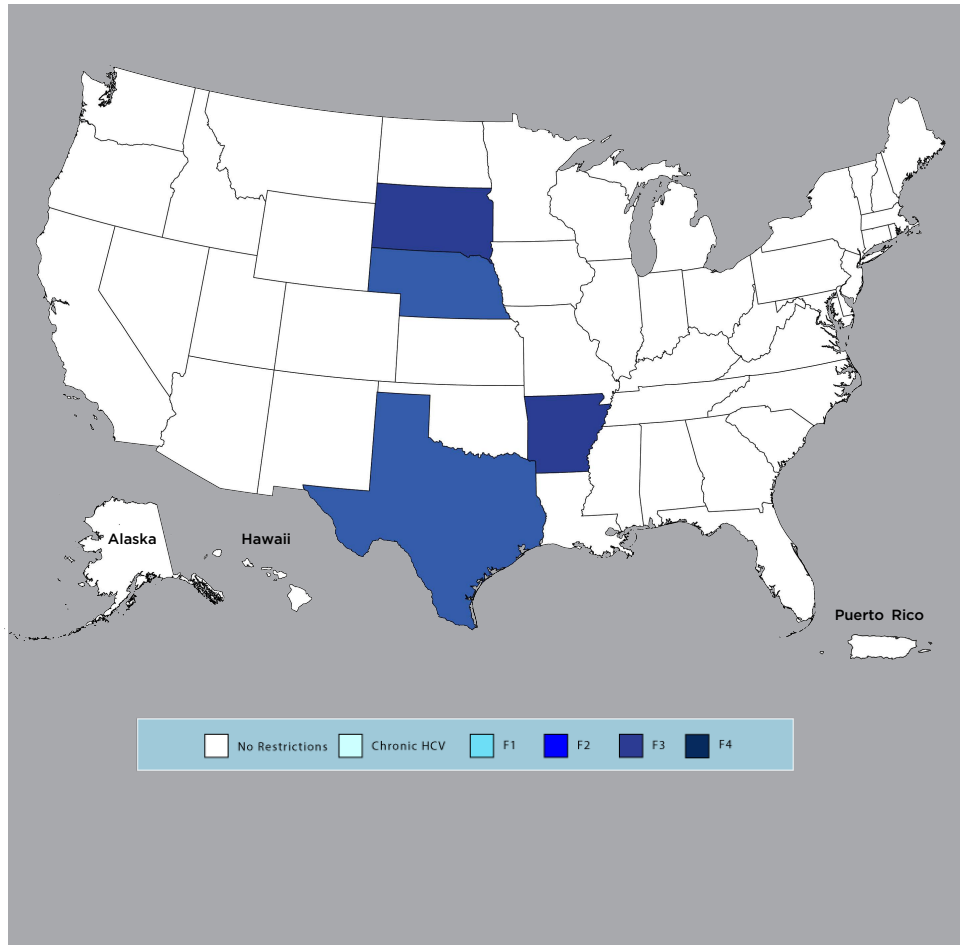
FIBROSIS RESTRICTIONS

In 2014, no state had open access to treatment, with most states requiring severe levels of fibrosis (i.e., F3 or F4). Overall, there has been the most progress on this restriction, because today, only four states have any fibrosis restrictions remaining in place, and no state still requires F4. This is of course due to legal and patient advocacy in many jurisdictions.

2014



2021



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FIBROSIS RESTRICTIONS AS OF 5/01/2021

No Restrictions

Alabama
Alaska
Arizona
California
Colorado
Connecticut
Delaware
District of Columbia
Florida
Georgia
Hawaii
Idaho
Illinois
Indiana
Iowa
Kansas
Kentucky
Louisiana
Maine
Maryland
Massachusetts
Michigan
Minnesota
Mississippi
Missouri
Montana
Nevada
New Hampshire
New Jersey
New Mexico
New York
North Carolina
North Dakota
Ohio
Oklahoma
Oregon
Pennsylvania
Puerto Rico
Rhode Island
South Carolina
Tennessee
Utah
Vermont
Virginia
Washington
West Virginia
Wisconsin
Wyoming

F1

Percentage of States | 92%

Number of States | 48

F2

Nebraska
Texas

Percentage of States | 0%

Number of States | 0

F3

Arkansas
South Dakota

Percentage of States | 4%

Number of States | 2

Percentage of States | 4%

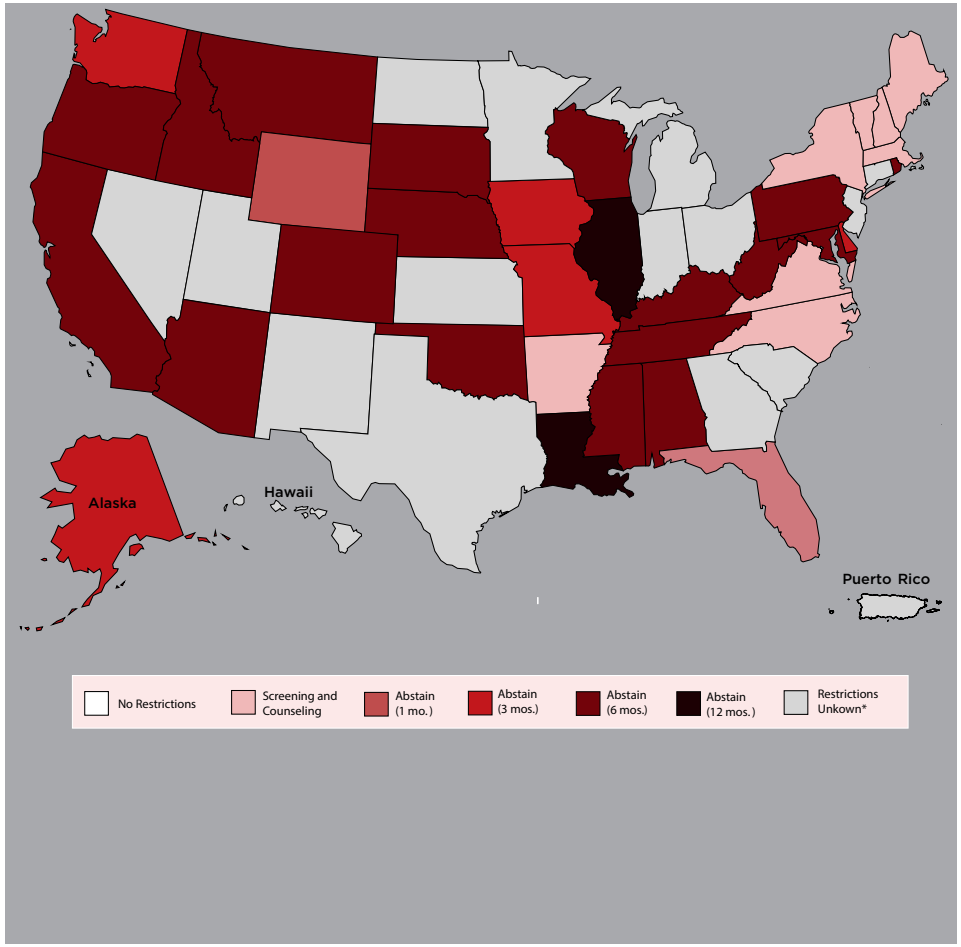
Number of States | 2

Bolded text indicates movement since October 2017

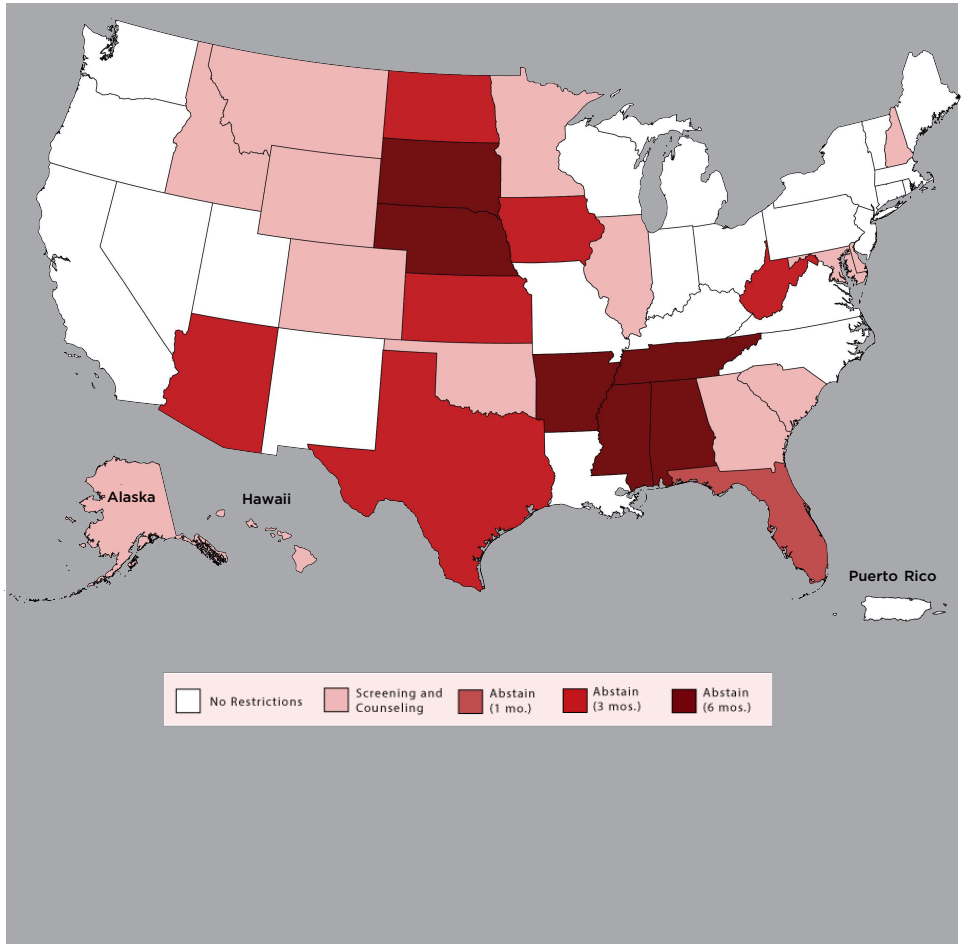
SOBRIETY RESTRICTIONS

In 2014, over half of states (n=28) required a period of abstinence from alcohol and/or substances before treatment was approved. Overall, from 2017 to 2021, the number of states requiring documented periods of abstinence has decreased. Currently, 74% of Medicaid programs impose no documented minimum period of abstinence to access treatment, up from just 41% of programs in 2017. Similarly, states that have persisted in requiring sobriety have shortened the requisite period of abstinence: no state requires a full year of sobriety any longer, and most states with restrictions require six months or less. Of the 39 states that do not require a period of sobriety, 15 states still inquire about substance use on the prior authorization form.

2014



2021



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SOBRIETY RESTRICTIONS AS OF 5/01/2021

No Restrictions

California
Connecticut
Indiana
Kentucky
Louisiana
Maine
Massachusetts
Michigan
Missouri
Nevada
New Jersey
New Mexico
New York
North Carolina
Ohio
Oregon
Pennsylvania
Puerto Rico
Rhode Island
Utah
Vermont
Virginia
Washington
Wisconsin

Percentage of States | 46%
Number of States | 24

Screening and Counseling

Alaska
Colorado
Delaware
District of Columbia
Georgia
Hawaii
Idaho
Illinois
Maryland
Minnesota
Montana
New Hampshire
Oklahoma
South Carolina
Wyoming

Percentage of States | 28%
Number of States | 15

1 Month

Florida

Percentage of States | 2%
Number of States | 1

3 Months

Arizona
Iowa
Kansas
North Dakota
Texas
West Virginia

Percentage of States | 12%
Number of States | 6

6 Months

Alabama
Arkansas
Mississippi
Nebraska
South Dakota
Tennessee

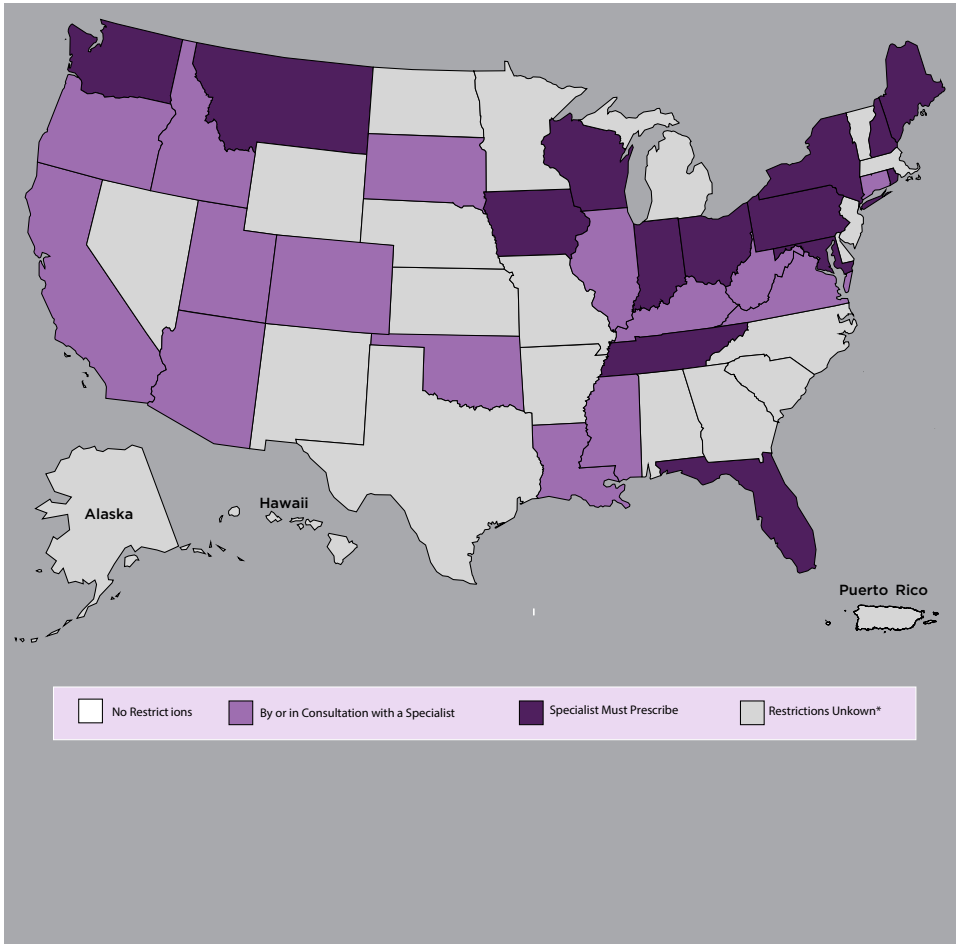
Percentage of States | 12%
Number of States | 6

Bolded text indicates movement since October 2017

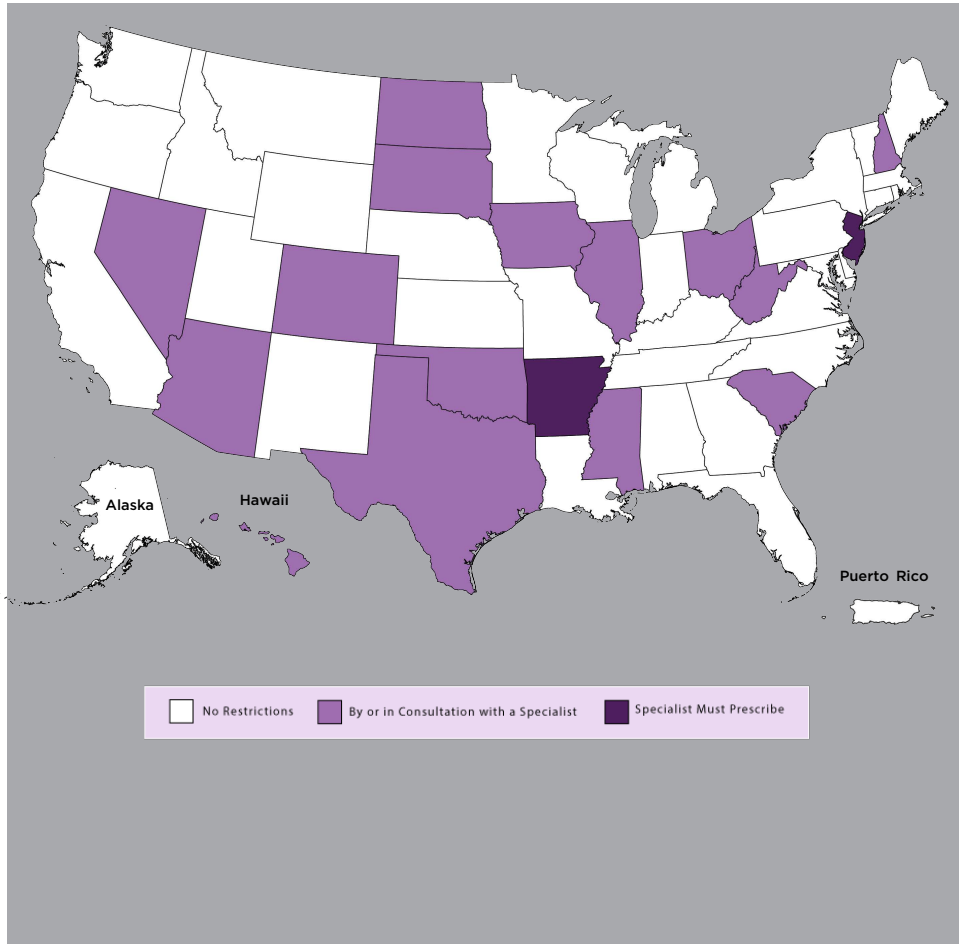
PRESCRIBER RESTRICTIONS

In 2014, 29 states required at least some specialist provider involvement, with 15 of those states requiring the specialist to be the actual prescriber. This has been reduced significantly as now only 18 states required specialist involvement, and only two of those require the specialist to be the prescriber. Additionally, many states have implemented provider training programs that give primary care providers and mid-level practitioners such as physician assistants, nurse practitioners, and pharmacists the confidence and tools to treat HCV. This has been made possible by the availability of medications that treat patients regardless of genotype and by changes to the guidelines established by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA), such as the simplified treatment algorithm.[4]

2014



2021



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[4]AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Accessed May 3, 2021.

PRESCRIBER RESTRICTIONS AS OF 5/01/2021

No Restrictions

Alabama
Alaska
California
Connecticut
Delaware
Florida
Georgia
Idaho
Indiana
Kansas
Kentucky
Louisiana
Maine
Maryland
Massachusetts
Michigan
Minnesota
Missouri
Montana
Nebraska
New Mexico
New York
North Carolina
Oregon
Pennsylvania
Puerto Rico
Rhode Island
Tennessee
Utah
Vermont
Virginia
Washington
Wisconsin
Wyoming

Percentage of States | 65%

Number of States | 34

By or in Consultation

Arizona
Colorado
District of Columbia
Hawaii
Illinois
Iowa
Mississippi
Nevada
New Hampshire
North Dakota
Ohio
Oklahoma
South Carolina
South Dakota
Texas
West Virginia

Percentage of States | 31%

Number of States | 16

Specialist

Arkansas
New Jersey

Percentage of States | 4%

Number of States | 2

Bolded text indicates movement since October 2017

DISCUSSION

As a result of advocacy, litigation, and decreasing costs of HCV treatment, significant progress has been made since 2014 to increase access to DAAs in state Medicaid programs. However, challenges remain and lack of access to sterile supplies for substance use continues to drive rising HCV infection rates in the United States. Even more concerning are the interruptions to historically under-resourced viral hepatitis prevention and treatment services during the COVID-19 pandemic. A survey conducted by NVHR and partners found that COVID-19 has forced clinical providers, community-based organizations, and health departments to limit hepatitis, HIV, and STI testing and treatment, further exacerbating the pre-existing syndemic and health inequities of hepatitis, HIV, STIs, and substance use. This stark reality coupled with growing liver cancer and mortality rates among baby boomers and Black, Indigenous, and People of Color presents an urgent need to remove all remaining barriers to the HCV cure.

Sobriety restrictions remain the most pressing and widespread barrier to accessing HCV treatment. When DAAs were first approved in 2013, the assumption was that the number of people living with HCV was stable and largely concentrated among people born between 1945 and 1965. In recent years, the opioid crisis has fostered a new wave of HCV infections among younger people who inject drugs whose needs are ill-served by sobriety restrictions. While many states have reduced restrictions regarding required periods of abstinence, screening and counseling restrictions continue to amplify stigma surrounding alcohol and drug use and create additional hurdles for patients seeking treatment. These restrictions exist on a spectrum and vary in level of restrictiveness. They can be as minimally cumbersome as providers attesting that they are addressing substance use via counseling and as severely restrictive as requiring patients to comply with toxicology screening or requiring that providers refer patients to a substance use disorder treatment program. The inclusion of questions about substance use and adherence on prior authorization forms creates the opportunity for providers to discriminate against patients based on non-evidence-based assumptions regarding adherence, often discouraging people who use drugs from seeking testing and treatment. Every new HCV infection represents a failure to cure the index case, and a generation struggling to survive the overdose crisis will face long-term health consequences from HCV if Medicaid policies are not revised to facilitate access to treatment now.

While some states have taken the much-needed step to remove prior authorizations altogether, other states continue to uphold previous restrictions or to impose additional restrictions that may not be captured by the State of Hepatitis C report. For example, some states require a diagnosis of chronic hepatitis C to access treatment, despite the AASLD/IDSA guideline recommendation to treat both acute and chronic hepatitis C.[5] Several states also limit Medicaid beneficiaries to one course of treatment in their lifetime, a discriminatory and stigmatizing criterion that is not imposed for treatment of other conditions such as a relapse in diabetes control or reinfection with sexually transmitted infections (STIs). Additionally, restrictions in Medicaid managed care organization programs are increasingly misaligned and more restrictive than those in Medicaid Fee-For-Service programs. Together, these restrictions delay and restrict access to care for tens of thousands of Americans, not only allowing the health of these individuals to deteriorate, but also undermining public health efforts to eliminate viral hepatitis by 2030.

[5]AASLD-IDSA. Management of Acute HCV Infection. Recommendations for testing, managing, and treating hepatitis C. https://www.hcvguidelines.org/unique-populations/acute-infection. Accessed May 3, 2021.

CONCLUSION

While significant progress has been made since 2014, many states continue to restrict access to HCV treatment despite strong, clear guidance from the Centers for Medicare and Medicaid Services that current restrictions violate federal law, as well as numerous court cases saying the same. Additionally, these restrictions do not align with the standard of care established by the AASLD/IDSA guidelines. As health inequities and lack of access to sterile supplies continue to drive rising HCV infection rates, we must continue to hold federal and state regulators accountable for ensuring that all people living with HCV have access to treatment consistent with established treatment guidelines and relevant federal and state laws. At a minimum, treatment access must not discriminate against people who use drugs or people without severe liver damage. Treatment coverage must also be consistent between Medicaid Fee-For-Service and Managed Care Organization programs. Everyone deserves a cure, and together, we will ensure that everyone gets a cure.

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