HEPATITIS C
State of Medicaid Access

2022 National Summary Report

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Introduction to Hepatitis C: State of Medicaid Access

Hepatitis C: State of Medicaid Access is a collaboration between the Center for Health Law and Policy Innovation of Harvard Law School (CHLPI) and the National Viral Hepatitis Roundtable (NVHR). The project evaluates hepatitis C (HCV) treatment restriction policies across state Medicaid programs, including all 50 states, the District of Columbia, and Puerto Rico (referred to in this report as "states"). The goal of this project is to encourage states and empower advocates to work toward improved access to curative HCV treatment across all Medicaid programs, in order to ensure that every Medicaid enrollee who can benefit from this treatment is able to access it.

Direct-acting antivirals (DAAs) came to market in 2013, signaling a vast improvement in the medical community's ability to effectively treat—and cure—HCV, the deadliest bloodborne infectious disease in the United States. However, many public and private payers choose to limit access to DAAs due to their high cost as well as other concerns. These limitations, generally expressed in prior authorization restrictions, form a significant barrier to care for millions of Americans enrolled in Medicaid. These barriers persist despite clear guidance from the Centers for Medicare and Medicaid Services that many such restrictions violate federal law.[1] Additionally, these restrictions are in direct opposition to the "Recommendations for Testing, Managing, and Treating Hepatitis C" as published by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA).[2]

Unfortunately, the restrictions that state Medicaid plans put in place not only limit access to treatment generally, but they also disproportionately restrict access to communities that are most severely impacted by the HCV epidemic, including people who use drugs and people of color.[3] The result is an HCV treatment landscape that is both overly limited and discriminatory in determining who is eligible for treatment. At a fundamental level, HCV treatment access is a health equity issue. Certain communities are more greatly impacted by HCV than others.[4] HCV is "most prevalent among people who use injection drugs," and "also disproportionately impacts racial and ethnic minorities, veterans, those who are incarcerated, the poor, and unstably housed persons," while also co-occurring at a high rate for people who are co-infected with HIV.[5]

Launched in 2017, *Hepatitis C: State of Medicaid Access* is a direct response to these widespread restrictions placed on HCV treatment by state Medicaid programs. In assessing treatment access in Medicaid programs, *Hepatitis C: State of Medicaid Access* evaluates and grades each state's policies and the national landscape to assess trends and opportunities for action. The project has historically assessed restrictions based on three criteria: liver disease severity ("fibrosis"), alcohol and drug use ("sobriety" or "substance use"), and prescriber limitations. Since these efforts began, we have observed the reduction or elimination of these restrictions in many states, increasing access to lifesaving treatment. Yet significant barriers remain. This 2022 report marks the newest iteration of these efforts. This report includes an expanded evaluation effort to include those restrictions tracked to date as well as novel analysis of restrictions related to prior authorization, retreatment, challenges within contracted managed care organizations, and other restrictions.

Our analysis shows that while important progress has been made in increasing access to treatment, there is much work to be done. Eliminating treatment access restrictions is vital to eliminating HCV as a public health threat in the United States. Further progress requires both leadership and advocacy to turn the promise of the cure into a reality for all.

History of Hepatitis C: State of Medicaid Access

Since 2017, *Hepatitis C: State of Medicaid Access* has served as a direct response to widespread restrictions placed on HCV treatment by state Medicaid programs following the advent of DAAs in 2013. These efforts were born out of research

conducted by CHLPI, in partnership with academic researchers at Brown University and the Miriam Hospital, University of New South Wales, and the Treatment Action Group. This group conducted a state-by-state survey of treatment access restrictions to DAAs as of December 2014, the results of which were published in the Annals of Internal Medicine.[6] The results of that survey showed both inappropriate treatment access restrictions across Medicaid programs, as well as a lack of public transparency about HCV treatment requirements.

Since December 2014, Medicaid programs have incrementally improved transparency and expanded access to DAAs, often in response to patient and provider advocacy and impact litigation. The inaugural *Hepatitis C: The State of Medicaid Access* report (2017) updated and expanded upon the initial survey to document the current state of access for Medicaid enrollees across the United States. This report provided an in-depth evaluation of DAA access in each state's Medicaid program, highlighting successes in access expansion as well as ongoing challenges. Alongside this report, *Hepatitis C: State of Medicaid Access* began releasing state-specific "report cards" that reflect overall HCV treatment access in each state.

Hepatitis C: State of Medicaid Access continues to track improvements in treatment access through updated report cards and landscape reports. The progress we have seen is encouraging. Between the launch of the first report and January 2022, 33 states either eliminated or reduced their fibrosis restrictions, 29 loosened their substance use restrictions, and 28 scaled back their prescriber restrictions in some form.[7] Eleven states also removed prior authorization altogether for most patients. This updated report aims to build on these historical efforts, by continuing to longitudinally track changes across state Medicaid programs, while also expanding the scope of our evaluation to address additional barriers to treatment.

2022 UPDATE: RATIONALE AND METHODOLOGY

Reassessing Tracked Restrictions

In 2022, *Hepatitis C: State of Medicaid Access* undertook a process to solicit provider and community feedback about how the project can be best updated to meet the current needs of patients, providers, and advocates. Specifically, the project team sought feedback on which treatment restrictions are the most significant barriers to meaningful treatment access. To this end, *Hepatitis C: State of Medicaid Access* organized a listening session, disseminated a public survey, and formed a provider steering committee to solicit thoughts from the community regarding what barriers to treatment should serve as the focus of future advocacy.

The listening session brought together more than 50 advocates, public health officials, medical professionals, and people with lived experience.

The survey (N=275 respondents) identified several possible barriers to treatment and asked respondents to evaluate the severity of each barrier and whether each barrier existed in their state. The survey also solicited additional information from people who are personally impacted (e.g., people who are living with or previously lived with HCV, family members and caretakers, etc.), inviting them to provide additional details about barriers they faced. Respondents to the survey hailed from 43 different states and included advocates, clinical providers, government staff, pharmaceutical company staff, and people with lived experience.[8]

Finally, the steering committee brought together practicing clinicians from across a wide range of disciplines. During facilitated meetings, the steering committee discussed recent developments in the Medicaid landscape and identified a

number of barriers to care. Participants also discussed and evaluated the survey results and offered candid advice regarding which restrictions to track. After data collection was complete, members of the steering committee also answered follow-up questions regarding certain restrictions.

Participants in the listening session, survey, and steering committee were in agreement about a number of the same barriers to treatment—and about key ways state Medicaid programs can expand access to care. For example, many participants noted that a growing number of states have removed prior authorization requirements completely for most HCV patients: a welcome change that reduces burdensome paperwork and testing requirements, improving linkage to care. On the other end of the spectrum, there was strong consensus that fibrosis restrictions and substance use restrictions are unscientific, against the standard of care, and illegal.

Participants also highlighted the ways in which apparently neutral administrative barriers—such as required documentation of chronic infection, genotype, or other required laboratory results—can create snowball effects, leading to months-long delays in treatment or even preventing treatment completely for historically marginalized patients. Participants were particularly concerned about the effects of specialty pharmacies, which survey respondents listed as the second most significant barrier to treatment, after prior authorization. Additionally, participants recognized that some barriers to treatment—such as restrictions on how many treatments a patient may receive in a lifetime, or other restrictions on patients who experience reinfection and must seek retreatment—are less common, but no less insidious.

Research Methods

To gather data about treatment restrictions, we evaluated Medicaid reimbursement criteria for available DAAs for all 50 states, the District of Columbia, and Puerto Rico. Data was extracted from state Medicaid websites, the websites of contracted MCOs, and from other publicly available sources regarding state Medicaid policies. All data was crosschecked by members of the project team. When a state's published clinical criteria appeared to conflict with other published documents, such as prior authorization forms or patient consent forms, the most restrictive version of the policy was tracked. In some cases, where a state's policy was public, but the application of the policy was unclear, we sent individual states specific inquiries via email to clarify the policy.

Tracked Restrictions

After considering the recommendations of the listening session, survey, and steering committee, *Hepatitis C: State of Medicaid Access* reevaluated the categories of restrictions that exist in state Medicaid programs and added additional restriction categories that will be tracked going forward.

Hepatitis C: State of Medicaid Access now tracks the following six categories of restrictions: Prior Authorization, Fibrosis Restrictions, Substance Use Restrictions, Prescriber Restrictions, Retreatment Restrictions, and Access in Managed Care. Because each state Medicaid program is unique, a seventh category, Additional Restrictions, captures individual state restrictions that may be less common but nevertheless create undeniable barriers to treatment in jurisdictions where they are imposed.

With one exception, the project tracks state fee-for-service (FFS) policies. The "Access in Managed Care" category tracks whether state Medicaid programs have parity between their FFS and managed care organizations (MCOs).

Prior Authorization

The overwhelming consensus from the listening session, survey, and steering committee was that removing prior authorization is a necessary step for state Medicaid programs to fully expand access to treatment and improve linkage to care. As of June 2022, 14 states have removed prior authorization requirements for preferred drug regimens, or for patients who qualify for simplified treatment.

Fibrosis Restrictions Restrictions

Disease severity, or restricted access to treatment based on a patient's fibrosis score, is one of the three historical categories *Hepatitis C: State of Medicaid Access* has tracked since its inception. In the past, the project tracked fibrosis score requirements based in part on their severity, differentiating between states that required severe liver damage (F3 or F4), and states that allowed access to treatment for patients with lower fibrosis scores (F1 or F2). However, now that all but two states have removed fibrosis restrictions entirely, the project no longer makes this distinction.

Substance Use Restrictions

Restrictions based on a patient's drug or alcohol use form the second of the three categories the project has tracked historically. In the past, *Hepatitis C: State of Medicaid Access* focused on substance use restrictions (also called "sobriety restrictions") that imposed a required period of abstinence from drugs or alcohol prior to treatment, while also tracking whether states imposed "screening and counseling" requirements. Now, the project tracks substance use restrictions with greater specificity, including required abstinence prior to treatment, required abstinence during treatment, required drug and alcohol lab tests, required enrollment in substance use treatment programs, and requirements for providers to counsel their patients regarding drug or alcohol use.

Prescriber Restrictions

Prescriber restrictions are the last of the three categories the project has tracked historically. Many states have removed the specialist requirement entirely. Only one state (Arkansas) still requires that prescriptions be written by a specialist, while other states require that prescriptions be written in *consultation* with a specialist or allow providers to prescribe after taking certain additional training courses. Even these lesser prescriber restrictions pose a barrier to care.

Retreatment Restrictions

Several states impose restrictions on patients seeking retreatment that are more severe than the restrictions imposed on patients seeking initial treatment ("treatment-naïve patients")" patients. Patients may seek retreatment either because the initial round of treatment failed, or because they have become reinfected. While there are important clinical considerations that may be relevant when a patient seeks retreatment, the project tracks restrictions that appear to be rooted in stigma, or that appear to blame the patient's behavior for the reinfection/treatment failure.

Access in Managed Care

In this category, the project tracks whether there is parity between a state's FFS program and the state's contracted MCOs. MCOs that contract with state Medicaid programs are required by law to provide the same or better access to treatment as FFS. Additionally, the rise in MCOs in Medicaid programs means that in many states, far more patients are enrolled in an MCO than in FFS. Therefore, ensuring that MCO policies are no more restrictive than FFS is an urgent concern.

Additional Restrictions

Recognizing that not all states impose the same requirements, the project also tracks certain additional restrictions to care that are less common but may pose severe barriers to care. Some "additional restrictions" that appeared in more than one state include the following barriers to care: time-based laboratory requirements, required documentation of chronic infection or genotype, past adherence to other prescribed medications, and policies that prohibit replacement of lost or stolen medication.

Common Restrictions Not Tracked

There are a few barriers to treatment imposed by state Medicaid programs that *Hepatitis C: State of Medicaid Access* is aware of but does not track at this time. For example, the project does not currently track requirements to fill prescriptions at specialty pharmacies or the total number of prescriptions a Medicaid enrollee may fill per month. We are monitoring these barriers to treatment in an effort to collect sufficient data that may allow us to track these requirements in future updates of *Hepatitis C: State of Medicaid Access*.

Specialty Pharmacies

Many state Medicaid programs contract with MCOs that require enrollees to obtain HCV medications from specialty pharmacies. Specialty pharmacies may sometimes be beneficial, because they can provide prior authorization, care coordination, and other patient support. Unfortunately, many specialty pharmacies impose additional restrictions to access on top of a state's prior authorization requirements, creating yet another barrier to access. For example, many specialty pharmacies require a phone call with the patient before they will put lifesaving medication in the mail—and they will often impose mandatory mail order policies, requiring patients to have a permanent mailing address. Both of these requirements disrupt access to care for people who are unhoused, and for people who may be in transition, such as people who were recently released from incarceration. Many such individuals are simply unable to meet these requirements.[9] Additionally, when each MCO contracts with a unique specialty pharmacy, each specialty pharmacy may have differing processes and requirements, causing confusion for providers and patients that can lead to delays in treatment.[10]

Unfortunately, this emerging issue is complicated by the fact that many specialty pharmacies' exact requirements remain opaque. Due to this lack of data, *Hepatitis C: State of Medicaid Access* does not track specialty pharmacy requirements at this time.

Monthly Prescription Limits

Some state Medicaid programs limit the number of prescription medications a Medicaid recipient may fill per month without prior authorization. This creates a barrier to care for people with HCV who may have co-occurring medical conditions requiring treatment via prescription drug. Although the Kaiser Family Foundation shed welcome light on this issue in 2019,[11] current data about these types of policies is not available, and the direct impact of these policies on HCV treatment access is unclear.

Specialty pharmacy requirements and monthly prescription limits are two examples of emerging and urgent concern, and more research is needed regarding both types of restriction. *Hepatitis C: State of Medicaid Access* will continue to monitor these restrictions, and it will continue to evaluate the state of HCV treatment access as state Medicaid policies continue to evolve, and as new restrictions potentially emerge.

WHY TREATMENT RESTRICTIONS MATTER

HCV affects millions of Americans nationwide from all backgrounds, but it "disproportionately impacts certain populations and communities," particularly people of color, people who use drugs, justice-involved communities, and people who are unhoused.[12] When state Medicaid programs impose treatment access restrictions, they exacerbate already existing health disparities, denying access to treatment to the communities who need it most.

People of color tend to experience worse health outcomes when infected with HCV, including worse HCV-related morbidity and mortality outcomes, and worse linkage to care. Communities of color also experience higher rates of hepatitis C. According to the Department of Health and Human Services' Viral Hepatitis National Strategic Plan, Native Americans

have higher rates of acute hepatitis C cases, and higher rates of hepatitis C-related mortality, than any other racial/ethnic population.[13] Non-Hispanic Blacks are "more likely … to have chronic hepatitis C than all other race/ethnicities."[14] And "despite similar HCV prevalence . . . Hispanics have worse HCV-related morbidity and mortality outcomes than non-Hispanic whites, including liver cancer and mortality attributable to hepatitis C."[15] One study from 2016 found significant disparities in lower DAA treatment rates for people of color, noting that compared to treatment rates for white people, "racial minority status remained an independent predictor of nontreatment even after controlling for socioeconomic factors and medical and psychiatric comorbidities."[16] For Black people, treatment disparities are particularly stark: "Black people with hepatitis C are more likely to be deemed ineligible for treatment than any other racial or ethnic group," despite "no differences in risk behaviors, psychiatric conditions, education status, employment status, or disease characteristics between Black and non-Black people."[17]

Disparities in linkage to care have also been identified for "those lacking private insurance, rural populations … those who use substances," and incarcerated populations.[18]

For people who may belong to multiple groups at higher risk for HCV infection, or to groups with worse treatment outcomes, disparities can multiply. For example, a 2013 study of men who were unhoused and had recently been paroled observed that "current parolees who are homeless may be at even greater risk for HCV infection than their non-homeless counterparts due to the added burden of uncertain and substandard living conditions."[19] Similarly, one recent study of HCV infections in transgender women suggested that although "trans women have been understudied in the [HCV] epidemic . . . data suggest they may be at elevated risk of the disease," in part due to high rates of "homelessness, substance use, and incarceration."[20]

Finally, new HCV infections–particularly among young people–have been linked to the opioid crisis and a rise in substance use disorder.[21] According to the AASLD/IDSA guidelines for HCV treatment, injection drug use is "the most common risk factor for HCV infection in the United States and Europe." Injection drug use is "the driving force in the perpetuation of the epidemic," accounting for approximately 70% of new HCV infections.[22]

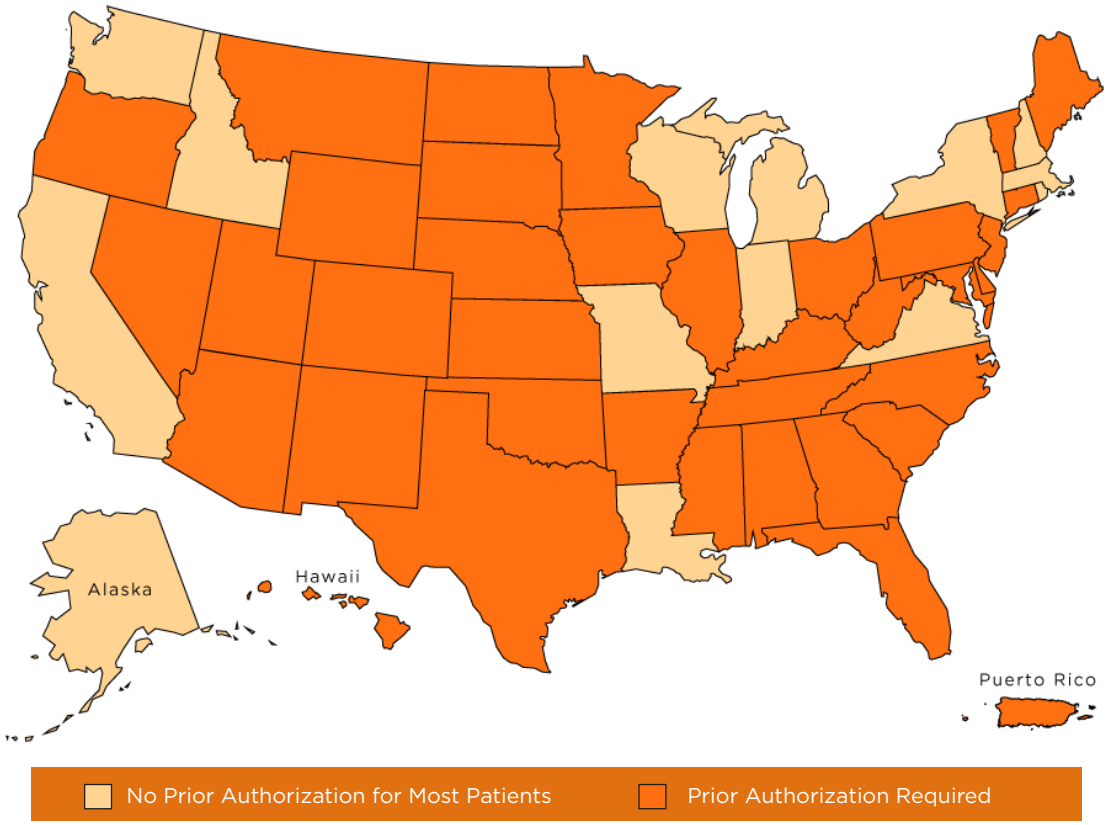
We would imagine that sound health policy would respond to these challenges by ensuring broad access to curative treatment for those disproportionately impacted by this epidemic. Instead, many state Medicaid programs place restrictions on HCV treatment that disproportionately limit access among members of these same communities.

For example, substance use restrictions, which remain widespread across state Medicaid programs, directly limit access to treatment to people who use drugs. Even in states that do not impose strict substance use restrictions, related policies such as treatment counseling requirements may dissuade providers and patients from initiating treatment if the patient is currently using alcohol or drugs.[23] Likewise, HCV treatment restrictions in state Medicaid programs disproportionately harm individuals who are unhoused or housing insecure.[24] People who are unhoused or housing insecure are much less likely to have access to the resources necessary to be able meet onerous prior authorization requirements, including being able to have multiple rounds of lab work.

These are just two examples of how treatment restrictions disproportionately impact those most affected by the HCV epidemic. Further, due to systemic racism, discrimination, and stigma, we know that these kinds of policies also fuel ongoing racial disparities in the HCV epidemic. Our response to the HCV epidemic must be directed toward those most severely impacted. In order to address the stark disparities we see in HCV infection and health outcomes, state approaches must be aligned with community need. To date, they have not been.

TRENDS IN ACCESS

Prior Authorization



No Prior Authorization for Most Patients (14 States, 27%)
Alaska, California, Idaho, Indiana, Louisiana, Massachusetts, Michigan, Missouri, New Hampshire, New York, Rhode Island, Virginia, Washington, Wisconsin

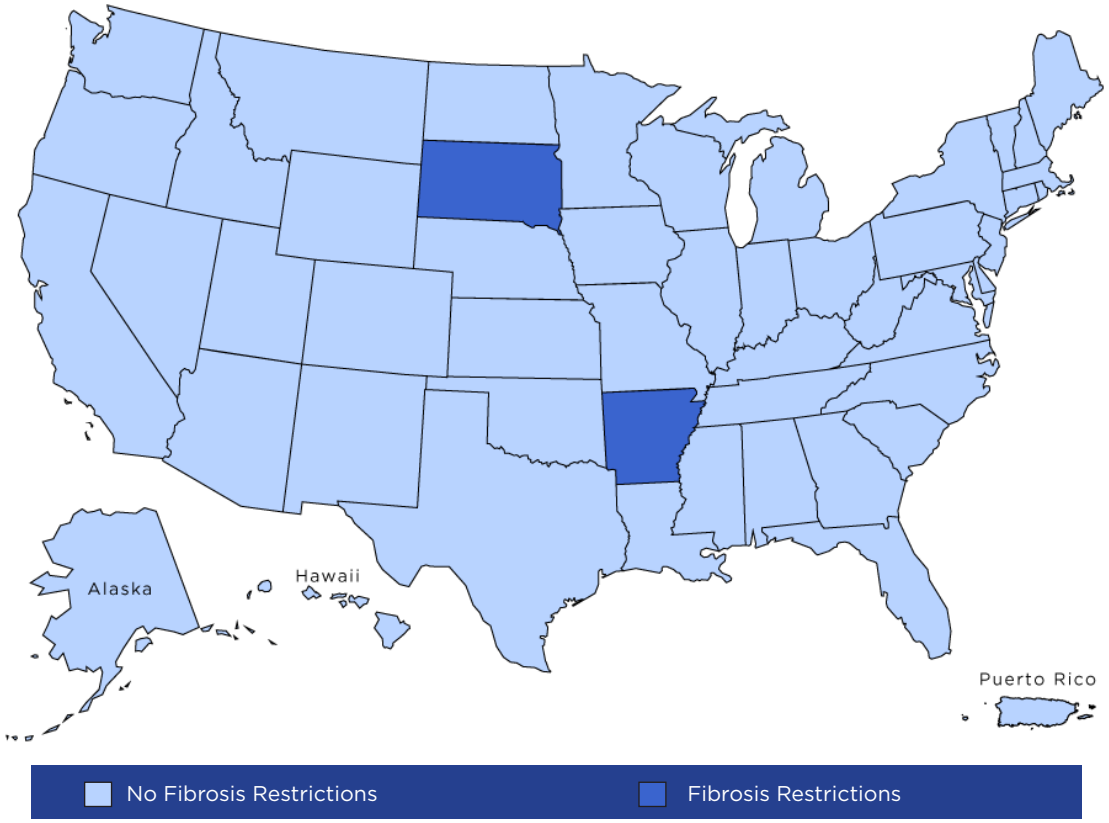
Prior Authorization Required (38 States, 73%)
Alabama, Arizona, Arkansas, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Iowa, Kansas, Kentucky, Maine, Maryland, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Puerto Rico, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, West Virginia, Wyoming

To date, 14 states (27%) have removed prior authorization requirements for most patients, greatly expanding access to treatment.

By eliminating prior authorization requirements for treatment-naïve patients, and/or for preferred drug regimens, states can greatly expand access to treatment by reducing the administrative burdens and delays associated with the prior authorization process, streamlining the process for patients and ensuring that more patients remain in care.

Because the removal of prior authorization is relatively new, the advantages or disadvantages of different state approaches to implementing prior authorization removal have yet to be fully understood; this will likely change as more states remove prior authorization and more data becomes available.

Fibrosis Restrictions



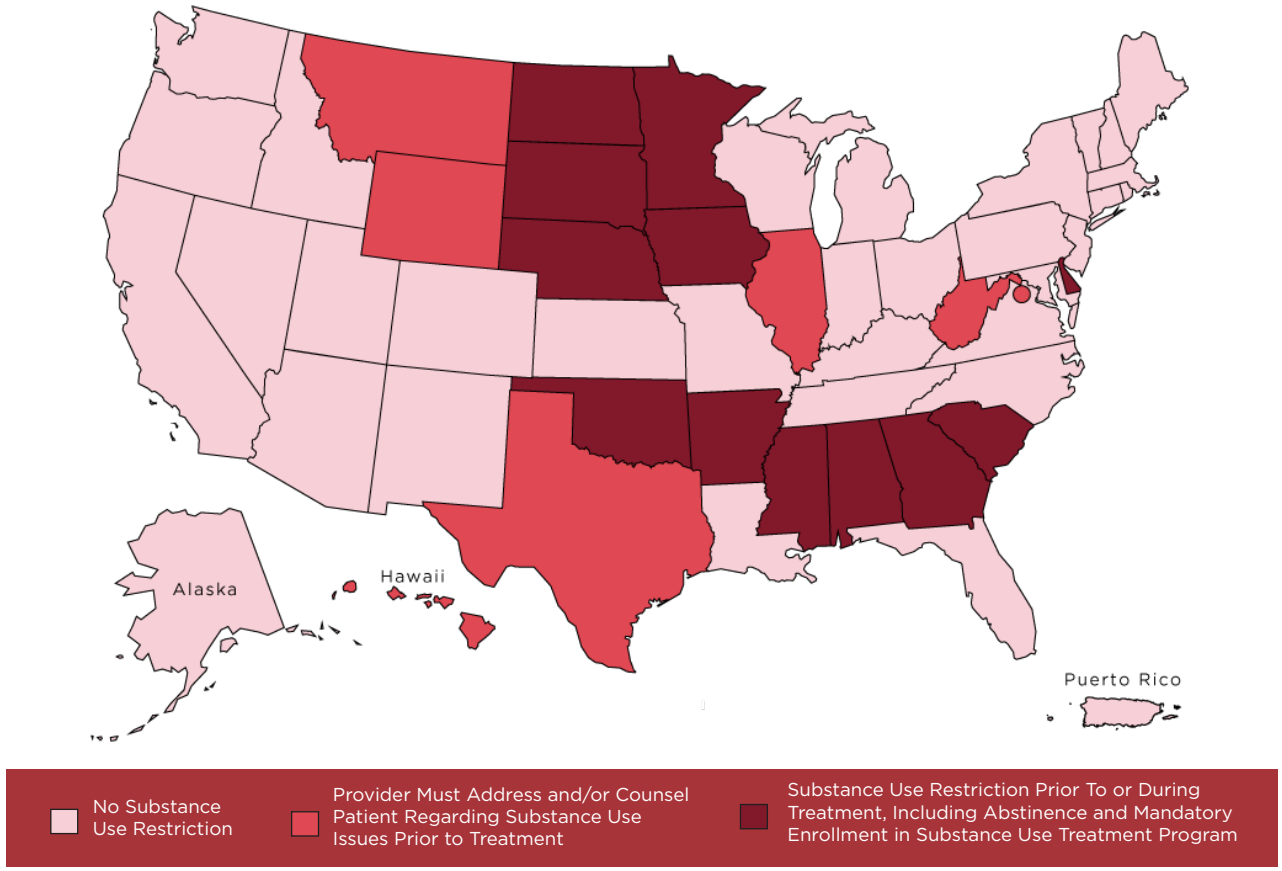
No Fibrosis Restrictions (50 States, 96%)
Alabama, Alaska, Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming

Fibrosis Restrictions (2 States, 4%)
Arkansas, South Dakota

In 2014, when treatment restrictions were first tracked, at least 34 states (65%) imposed fibrosis requirements, requiring patients to be extremely ill before they could access treatment; the other 18 states (35%) had unknown restrictions. As of June 2022, all but two states (4%), Arkansas and South Dakota, have completely removed fibrosis restrictions, expanding access to care regardless of disease severity. Arkansas still requires a minimum fibrosis score of F3. South Dakota requires a minimum score of F2.

Restricting access to treatment based on disease severity is contrary to the AASLD/IDSA treatment guidelines and the medical standard of care.[25] Fibrosis restrictions across the country have largely lifted, even in states that still restrict access in other ways. Arkansas and South Dakota must join the rest of the country and take action to eliminate fibrosis restrictions.

Substance Use Restrictions



No Substance Use Restriction (33 States, 64%)
Alaska, Arizona, California, Colorado, Connecticut, Florida, Idaho, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Missouri, Nevada, New Hampshire, New Jersey, New Mexico, New York North Carolina, Ohio, Oregon, Pennsylvania, Puerto Rico, Rhode Island, Tennessee, Utah, Vermont, Virginia, Washington, Wisconsin

Provider Must Address and/or Counsel Patient Regarding Substance Use Issues Prior to Treatment (7 States, 14%)
District of Columbia, Hawaii, Illinois, Montana, Texas, West Virginia, Wyoming†

Substance Use Restriction Prior To or During Treatment, Including Abstinence and Mandatory Enrollment in Substance Use Treatment Program (12 States, 23%)
Alabama*†‡, Arkansas*‡, Delaware‡, Georgia‡, Iowa*†, Minnesota*, Mississippi*†, Nebraska*†‡, North Dakota*†‡, Oklahoma‡, South Carolina*, South Dakota*

* Requires a strict period of abstinence prior to treatment.
† Requires drug testing prior to or during treatment.
‡ Requires abstinence and/or enrollment in substance use treatment program during treatment.

State Medicaid programs impose a variety of restrictions related to substance use, including strict periods of abstinence from drugs or alcohol prior to treatment; drug or alcohol screening requirements; required abstinence and/or enrollment in substance use counseling programs during treatment; and requirements that the prescriber counsel the patient regarding substance use issues.

In 2014, at least 37 states (71%) imposed some form of substance use restriction, while the other 15 (29%) had unknown requirements. As of June 2022, access has improved: 19 states (36%) still impose substance use restrictions, while 33 states (64%) impose no restrictions. Additionally, although no restrictions to treatment access based on substance use are acceptable or appropriate, the relative severity of sobriety restrictions has also improved. In 2014, 28 states (54%) imposed a required period of sobriety prior to treatment, sometimes requiring patients to remain sober for 12 months before they could access lifesaving treatment. In contrast, as of June 2022, just 9 states (17%) still impose required periods of sobriety prior to treatment.

As of June 2022, 12 states (23%) impose severe restrictions relating to patient substance use. Of the nine state Medicaid programs that require sobriety prior to treatment, some require proof of abstinence via lab result, while others require the prescriber to attest that the patient has been abstinent. For example, North Dakota requires patients with a history of injection drug use to submit "2 drug and alcohol tests, dated at least 3 months apart, with the most current test completed within 30 days," as well as "chart notes documenting that the member has maintained sobriety for the past year or since last substance use treatment program completion."[26] Other states, like South Dakota, do not appear to require the submission of drug screening tests, but do require the prescriber to "attest that the patient is drug and alcohol free for the past 6 months.[27]

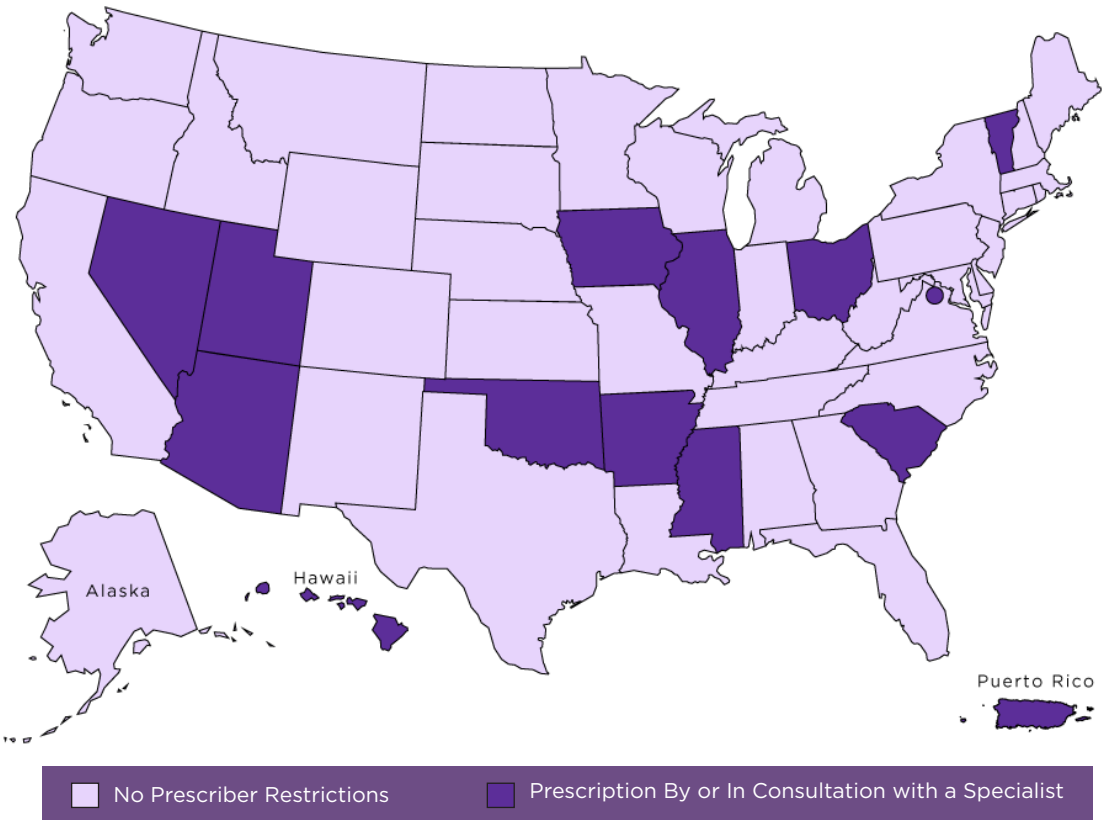
Seven states (13%) require the patient to be abstinent during treatment, or to be currently enrolled in a substance use program at the time prior authorization is requested. Of these states, some, like Alabama, Delaware, and North Dakota, require patients to sign consent forms agreeing to remain sober during treatment–and agreeing that "failure" to abide by the terms of the consent form may result in Medicaid terminating their treatment regimen.[28] One state, Nebraska, requires ongoing drug testing "periodically throughout treatment."[29]

Seven states (13%) have somewhat more lenient substance use restrictions, requiring the prescriber to address ongoing substance use issues with the patient prior to beginning DAA treatment, but without imposing additional barriers to treatment. For example, Illinois requires the prescriber to be "responsible for addressing ongoing misuse of alcohol and/or continued use of illicit IV drugs (if appropriate).[30]

But even these apparently more lenient substance use restrictions must be lifted. Restricting access to DAA treatment based on substance use does not reflect the current standard of medical care.[31] Despite the widespread and erroneous belief that individuals who use drugs are poor candidates for treatment, research shows us that strict abstinence from substances is not necessary for treatment to be successful.[32] To the contrary, when individuals who use drugs are able to access treatment, they demonstrate high rates of sustained virologic response (SVR).[33] In addition to inappropriately delaying care for patients who seek treatment for their HCV, substance use restrictions are rooted in discrimination and stigma, and can have the effect of discouraging patients from seeking care altogether.[34] Additionally, because HCV transmission has been associated with injection drug use, people who use drugs are the exact category of people who should be targeted for treatment. Research shows that aggressively treating individuals who use drugs is an important tool in eliminating HCV.[35]

Failure to treat people who use drugs is to the detriment of both the patient and the community. While the majority of states no longer impose substance use restrictions, the remaining 19 states that still do must expand access and remove these unscientific barriers to care.

Prescriber Restrictions



No Prescriber Restriction (40 States, 77%)
Alabama, Alaska, California, Colorado, Connecticut, Delaware, Florida, Georgia, Idaho, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming

Prescription By or In Consultation with a Specialist (12 States, 23%)
Arizona, Arkansas*, District of Columbia, Hawaii†, Illinois, Iowa, Mississippi, Nevada†, Oklahoma, Puerto Rico†, South Carolina, Utah

*Requires prescription by a specialist.

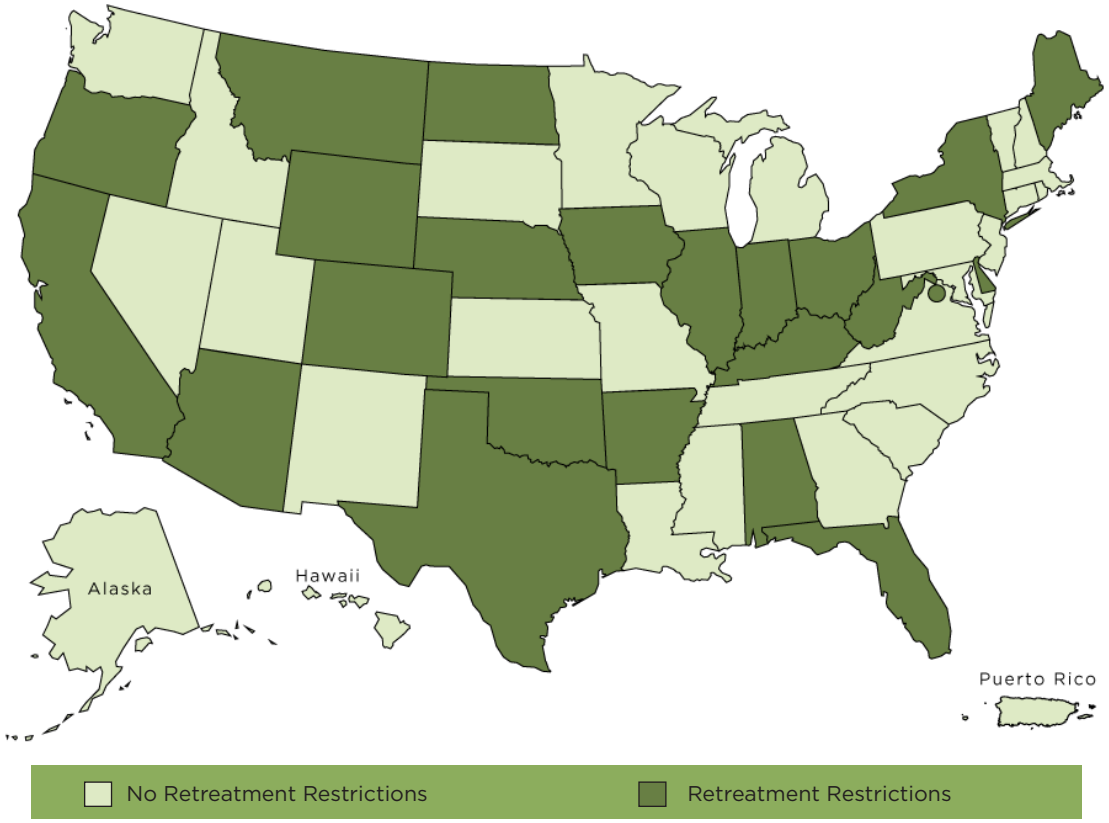
†Primary care physicians may prescribe if they undergo additional training and certification.

Medicaid programs sometimes restrict access to HCV treatment by requiring the prescribing provider to be a specialist, consult with a specialist, or complete certain additional certification requirements.

In 2014, 29 states (56%) imposed prescriber restrictions, while 23 states (44%) had unknown requirements. As of June 2022, only 12 states (23%) impose prescriber restrictions. And of the states that still impose prescriber restrictions, only Arkansas still requires a specialist to prescribe. In 8 states (15%), primary care physicians may prescribe if they do so in consultation with a specialist. And in 3 states (6%), primary care physicians may prescribe if they undergo additional training and certification. For example, in Puerto Rico, primary care physicians may prescribe if they are "certified by the Empire Liver Foundation or another comparable entity."[36]

Requirements to consult with a specialist or complete additional training may still be onerous for providers, particularly in networks that have a small total number of specialists with limited capacity to consult with other providers. Additionally, prescriber limitations create practical access barriers for people seeking treatment, particularly in rural areas. This can lead to delays in treatment, either because patient need exceeds specialist demand, or because of delays associated with the additional administrative burden to prove a specialist was consulted. States that previously took steps to reduce their prescriber restrictions should further expand treatment by doing away with specialist consultation requirements completely.

Retreatment Restrictions



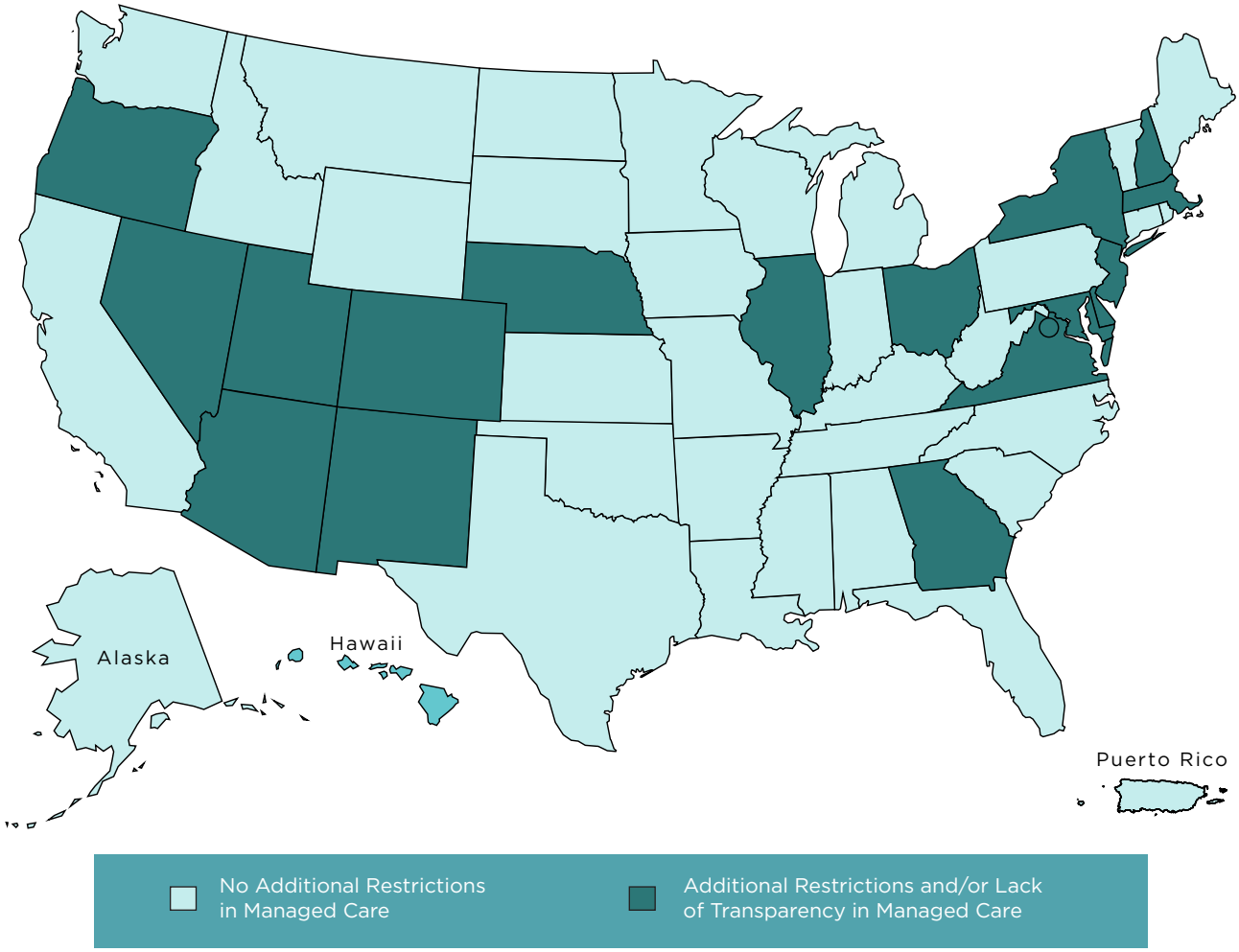
No Retreatment Restrictions (29 States, 56%)
Alaska, Connecticut, Georgia, Hawaii, Idaho, Kansas, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Virginia, Washington, Wisconsin

Retreatment Restrictions (23 States, 44%)
Alabama, Arizona, Arkansas, California, Colorado, Delaware, District of Columbia, Florida, Illinois, Indiana, Iowa, Kentucky, Maine, Montana, Nebraska, New York, North Dakota, Ohio, Oklahoma, Oregon, Texas, West Virginia, Wyoming

Treatment access criteria in state Medicaid programs may vary based on whether a patient is requesting treatment for the first time (treatment-naïve) or whether they are requesting retreatment (treatment-experienced). Individuals may require retreatment if their initial treatment fails or if they become reinfected. In either case, additional treatment may be necessary and appropriate.[37]

However, 23 states (44%) impose more severe restrictions on access to retreatment than they do initial therapy. Some states place annual or lifetime restrictions on treatment. Wyoming, for example, only allows patients one course of treatment over the course of their lifetime.[38] A number of states also restrict treatment in cases where initial treatment failed due to a lack of adherence, despite the fact that many patients experience serious barriers to adherence for a wide variety of reasons and nevertheless deserve access to care. Arizona is an example of a state that prohibits retreatment specifically in the case of treatment failure due to lack of adherence.[39] Some states, like Colorado, will further explore whether a patient has been adherent to *other* treatment regimens, unrelated to HCV, in determining whether to allow retreatment.[40]

A number of states also impose substance use requirements that they may not otherwise for treatment-naïve patients. For example, although Kentucky does not impose substance use restrictions for treatment-naïve individuals, the state requires that a patient requesting retreatment be evaluated for alcohol and substance use, and if the patient has a history of alcohol or substance use in the previous 6 months, the provider must provide documentation that the patient "has completed or is participating in a recovery program, receiving alcohol or substance abuse counseling services, or seeing an addiction specialist as part of HCV treatment" as well as a urine toxicology screening to confirm that "the patient is not actively participating in illicit substance use or alcohol abuse."[41] Although important changes have been made to improve access to initial treatment, states must take action to eliminate unnecessary restrictions in retreatment, to ensure full access to care.



No Additional Restrictions in Managed Care (33 States, 64%)
Alabama*, Alaska*, Arkansas, California†, Connecticut*, Florida, Idaho*, Indiana†, Iowa, Kansas, Kentucky, Louisiana†, Maine*, Michigan†, Minnesota, Mississippi, Missouri†, Montana*, North Carolina, North Dakota, Oklahoma, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota*, Tennessee, Texas, Vermont, Washington†, West Virginia, Wisconsin, Wyoming

Additional Restrictions and/or Lack of Transparency in Managed Care (19 States, 37%)
Arizona, Colorado, Delaware, District of Columbia, Georgia, Hawaii, Illinois, Maryland, Massachusetts, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, Ohio, Oregon, Utah, Virginia

*State does not contract with MCOs

†HCV treatment or all pharmacy benefits carved out of managed care

State Medicaid programs are responsible for setting standards for who is eligible for treatment under which circumstances. However, many states contract with MCOs and other types of private contractors to help administer benefits to some or all of their beneficiaries. As of 2019, about 70% of all Medicaid enrollees were enrolled in an MCO.[42] Federal regulations require that MCOs provide services in the "amount, duration, and scope" that they are provided in fee-for-service (FFS),[43] and that they may not deny services or reduce the amount, duration, or scope of those services because of an illness or condition that a beneficiary might have.[44] Unfortunately, many MCOs do set more restrictive criteria for accessing HCV treatment than their FFS programs. This can create serious barriers to access for individuals enrolled in those programs.

As of the publication of this report, 19 states (37%) have at least one MCO that imposes more severe restrictions than the state FFS program, or at least one MCO that does not make its criteria public. For example, although New Jersey's FFS program does not impose substance use requirements, WellCare, one of the state's MCOs, requires urine toxicology screening during treatment and recommends that "[p]atients with active substance or alcohol use disorders should be considered for therapy on a case-by-case basis."[45] Similarly, although New York FFS has removed prior authorization for treatment-naïve individuals prescribed preferred regimens, Visiting Nurse Service of New York Choice Health Plan requires prior authorization for all patients, including a requirement that a prescription be written by or in consultation with a specialist.[46] Additionally, although states like Nebraska and Nevada appear to have parity between FFS and the MCOs for which clinical criteria are available, two out of three MCOs in Nebraska, Healthy Blue and UnitedHealthcare, do not publish clinical criteria.[47] Similarly, two out of four MCOs in Nevada, Health Plan of Nevada and SilverSummit, do not publish their clinical criteria.[48]

The positive news is that most states do not have more restrictive criteria in their MCO programs (33 states, 64%). This is due to a few factors. First, a number of states do not contract with MCOs and only operate a FFS program. Additionally, a number of states "carve out" HCV treatment from their managed care programs, or carve out pharmacy benefits entirely. For example, beginning in 2022, California decided to administer all pharmacy benefits through a centralized system with a standardized set of clinical criteria, for both FFS and MCO beneficiaries.[49] Finally, some states mandate that all MCOs apply the same prior authorization forms and clinical criteria when approving HCV treatments. For example, after significant patient and provider advocacy, Massachusetts Medicaid issued a bulletin requiring all MCOs to apply the FFS utilization management criteria.[50] Massachusetts and other states who ensure parity between MCOs and FFS provide an important model for other states. More states must leverage their contracts with MCOs to appropriately enforce federal regulatory requirements and ensure equal access to all Medicaid beneficiaries in their programs.

Additional Treatment Restrictions

Genotype Documentation (27 States, 52%)
Alabama, Arizona, Arkansas, Connecticut, Delaware, District of Columbia, Florida, Iowa, Kansas, Maryland, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, North Dakota, Ohio, Oklahoma, Puerto Rico, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, West Virginia, Wyoming

Chronic Infection Documentation (15 States, 29%)
Arizona, Connecticut, Georgia, Hawaii, Illinois, Iowa, Kentucky, Maine, Maryland, Nevada, North Carolina, North Dakota, Oklahoma, Oregon, Tennessee

Time-Based Lab Values (20 States, 39%)
Arizona, Florida, Hawaii, Illinois, Iowa, Kentucky, Maryland, Minnesota, Mississippi, Nebraska, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Puerto Rico, South Carolina, Texas, Vermont, West Virginia

Adherence Requirement (23 States, 44%)
Alabama*, Alaska*, Arizona, Arkansas*, California*, Colorado, Delaware*, District of Columbia*, Hawaii*, Illinois*, Kansas, Maryland, Montana, Nebraska, New Mexico, North Dakota, Ohio, Oklahoma*, Oregon, Puerto Rico, South Carolina*, Texas*, Wyoming

*State explicitly limits treatment access as a result of poor adherence.

Barriers to Replacing Lost/Stolen Medication (9 States, 17%)
Alaska, Arizona, California, Connecticut, District of Columbia, Florida, Iowa, Nebraska, Texas

In addition to the categories described thus far in this report, many states also impose additional barriers to HCV treatment access. Some of these barriers are process barriers, such as documentation requirements. Requirements that prescribers document genotype (27 states, 52%) or chronic infection (15 states, 29%) during the prior authorization process –which are not necessary to begin treatment[51]–may cause unnecessary delays in treatment initiation. Such delays can result in more patients lost to follow up. Similarly, requirements that reported laboratory values be taken within a specific amount of time prior to the submission of a prior authorization request (20 states, 39%) can create months-long delays when patients are required to retake tests. All of these requirements pose particular risks for individuals who may have trouble attending numerous medical appointments or who have transportation issues, including people with substance use disorder and people who are unhoused.

Several states (23, 44%) inquire as to a patient's ability to adhere to treatment as part of the prior authorization process. For example, the District of Columbia requires providers to attest whether a patient "has a history of adherence problem to any prior therapy,"[52] while North Dakota asks about a patient's history of missed medical appointments and/or medication fills.[53] Other states, like Wyoming, note that "non-compliance with the prescribed Hepatitis C regimen may put the client in jeopardy for denial of coverage in the future."[54] Some states will even withhold access during an ongoing course of treatment in the case that a patient is deemed non-adherent (7 states, 13%) or their medication is lost or stolen (9 states, 17%). As explained elsewhere in this report, some patients may experience personal challenges that make adherence particularly difficult. Further, research shows that even low adherence to a DAA treatment regimen can lead to a high likelihood of cure.[55] Individuals who are unhoused or have unstable housing may be at higher risk of having medication lost or stolen. Instead of restricting access under these circumstances, state Medicaid programs should consider how to support patients to address social and economic barriers to adherence and complete their course of treatment.

States should consider how all aspects of their HCV treatment policy may inappropriately limit access to treatment. Hopefully, as more states move toward removing prior authorization for preferred regimens, some of these barriers will be eliminated as well. However, each state must continue to consider their HCV treatment policies holistically, with patient needs and opportunities for access in mind.

CONCLUSION

In evaluating each restriction category across all 50 states, the District of Columbia, and Puerto Rico, a few important trends emerge.

First, prior authorization removal offers an exciting opportunity for state Medicaid programs to increase HCV treatment access in a profound way, and states are beginning to adopt this important policy reform. Removing prior authorization is the most straightforward and impactful way to eliminate treatment access restrictions. Twenty-seven percent of states have now removed prior authorization for preferred regimens, and given the current trend, it appears likely that additional states will continue to consider and implement this approach.

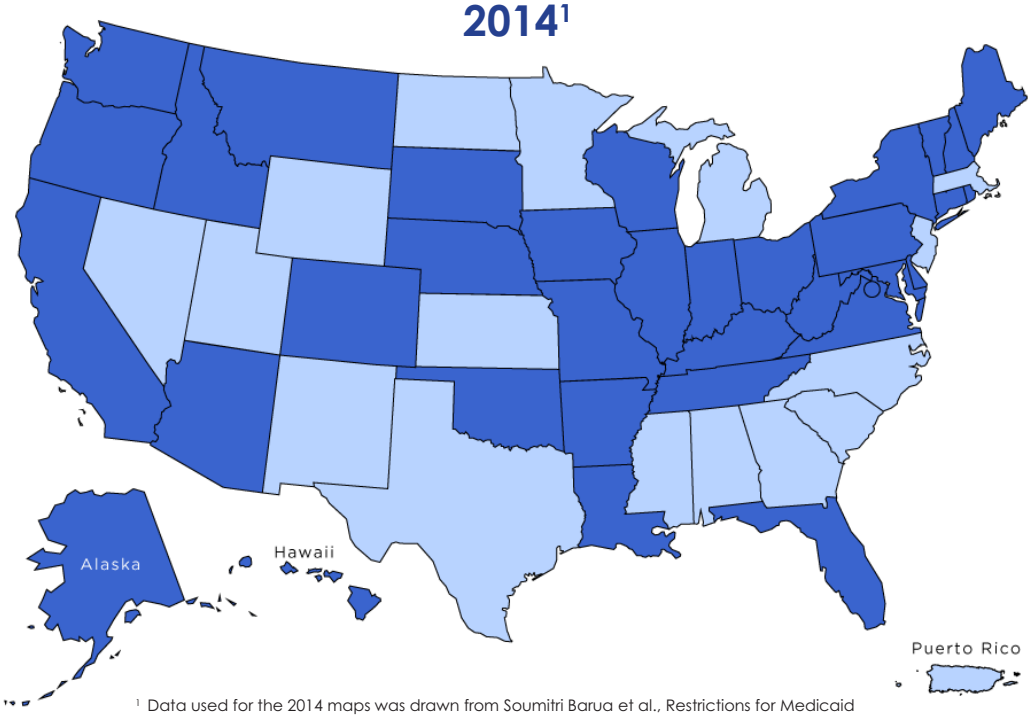
Second, substantial progress has been made since 2014 in reducing the number of states that impose fibrosis, substance use, and prescriber restrictions on HCV treatment access. At this time, only two states impose fibrosis requirements, compared to 34 in 2014. Twelve states currently have some kind of prescriber requirement, compared to 29 in 2014. Nineteen states impose substance use restrictions of some kind including 12 that require abstinence from substance use or enrollment in a drug treatment program, compared to 28 that required sobriety in 2014. These changes have improved access to treatment for thousands of people living with HCV.

Third, although progress has been made, it is clear that there is still much work to be done. Sobriety requirements remain prevalent and discriminate against individuals who use drugs, despite the fact that these same individuals are at significantly higher risk of acquiring HCV. MCO treatment access policies are frequently misaligned with their state FFS programs, to the detriment of patients. Further, this analysis shows that we must consider how to address other barriers to treatment access. Although states are opening up access for treatment-naïve patients on preferred regimens, restrictions on retreatment remain widespread and are frequently discriminatory and rooted in stigma. Unnecessary administrative barriers lead to missed treatment opportunities.

Moving forward, we must build on the progress that has been made and ensure that these kinds of restrictions are eliminated across all Medicaid programs, with the goal of removing prior authorization restrictions for HCV treatment on a wide scale. In order to achieve this goal, advocates must hold state and federal regulators accountable for ensuring that people living with HCV have access to treatment in a manner that is consistent with established treatment guidelines and best practices. With the availability of life-saving treatment for HCV, policymakers and advocates must push to eliminate unnecessary, discriminatory, and illegal barriers to care and help ensure that all Medicaid beneficiaries living with HCV can access the care that they need.

STATES WITH FIBROSIS RESTRICTIONS IN 2014 AND 2022

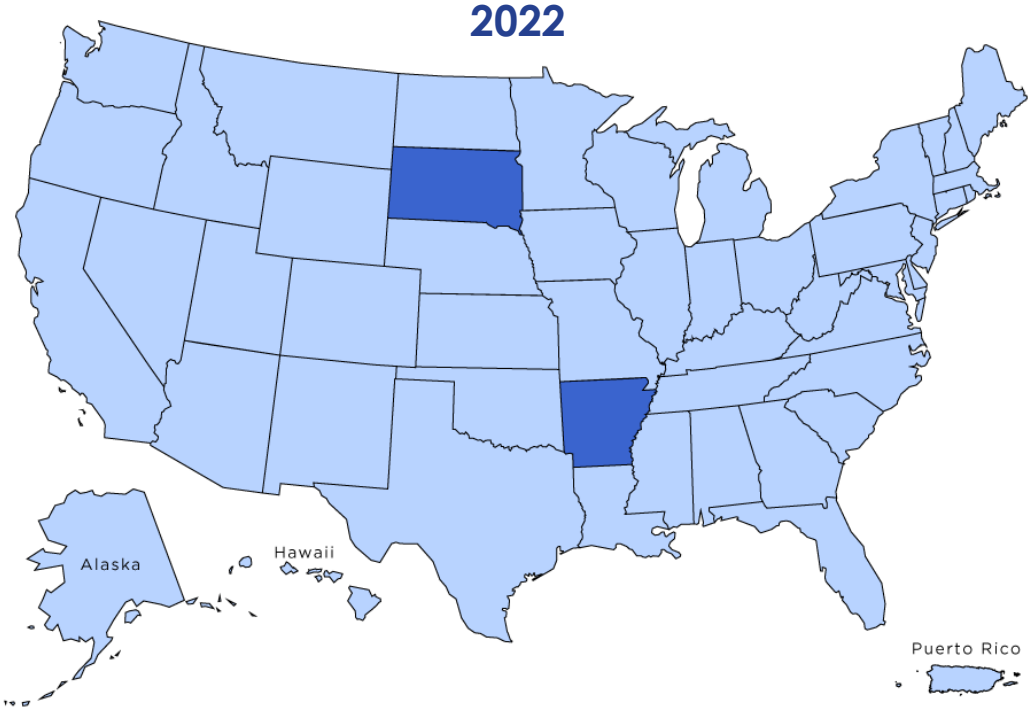
2014[1]



[1] Data used for the 2014 maps was drawn from Soumitri Barua et al., Restrictions for Medicaid Reimbursement of Sofosbuvir for the Treatment of Hepatitis C Virus Infections in the United States, Annals of Internal Medicine (2015), https://pubmed.ncbi.nlm.nih.gov/26120969/.

Unknown Fibrosis Restrictions | Fibrosis Restrictions

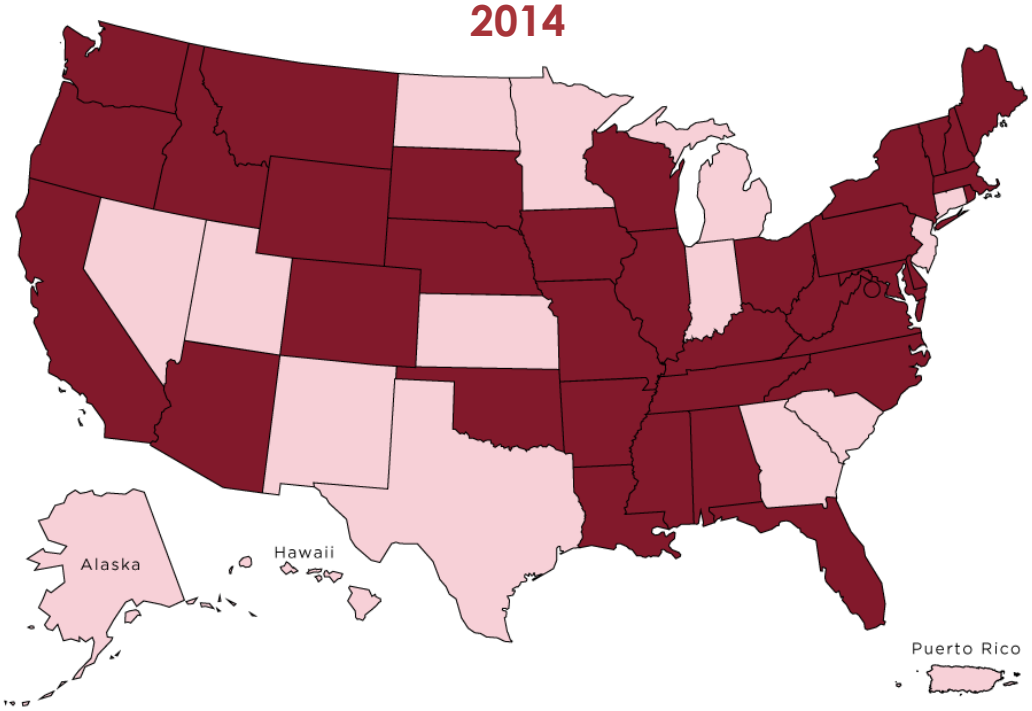
2022



No Fibrosis Restrictions | Fibrosis Restrictions

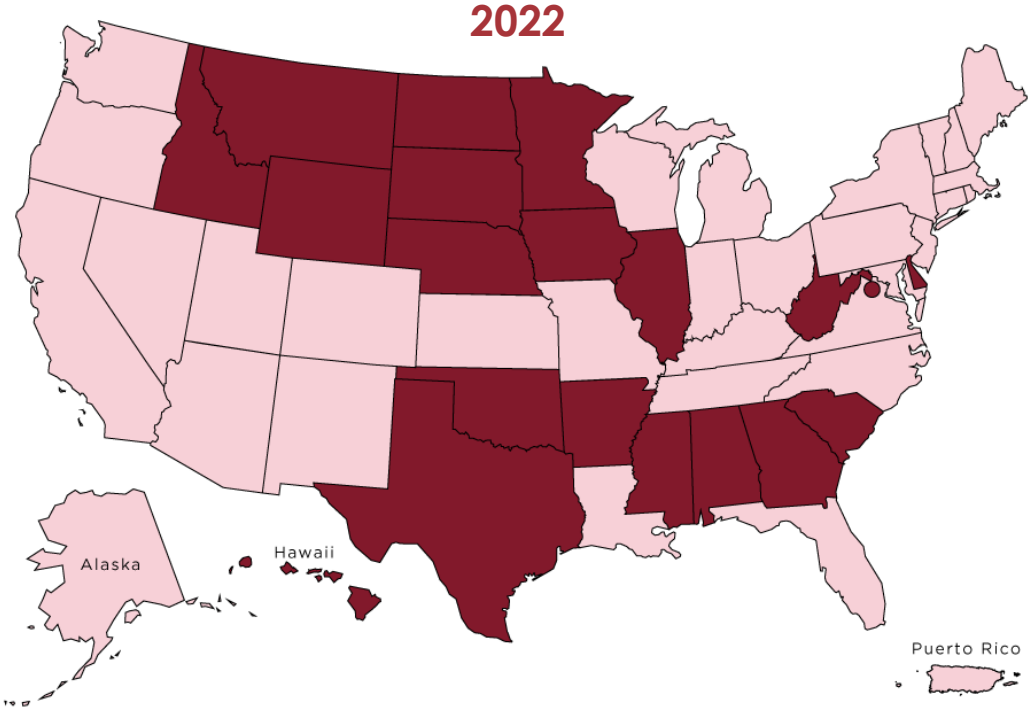
STATES WITH SUBSTANCE USE RESTRICTIONS IN 2014 AND 2022

2014



Unknown Substance Use Restrictions | Substance Use Restrictions

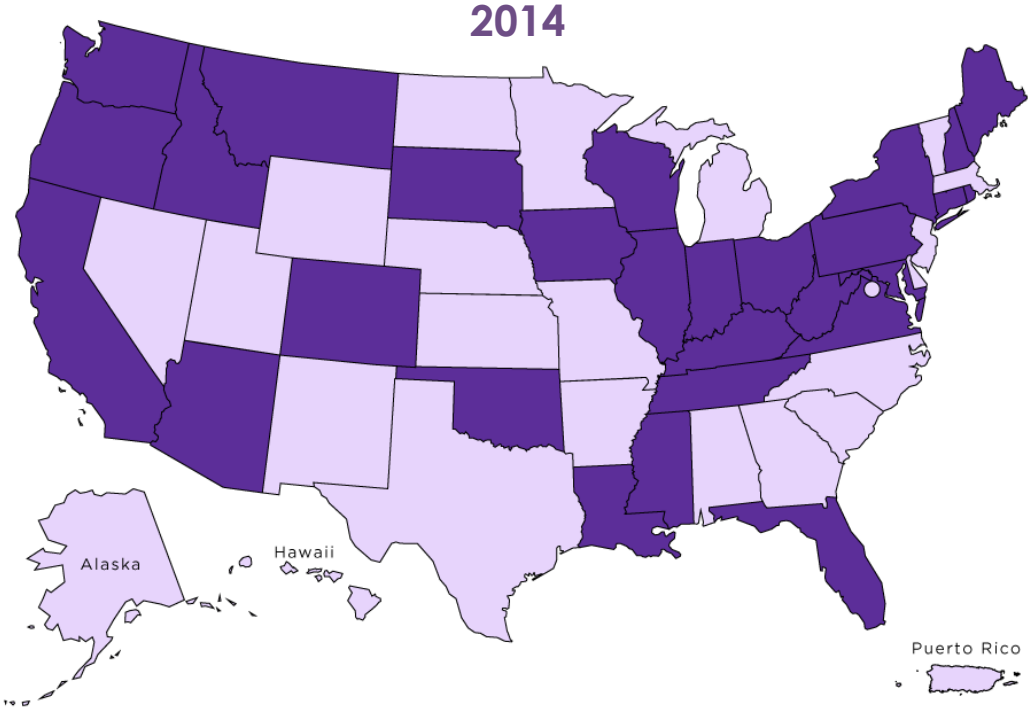
2022



No Substance Use Restriction | Substance Use Restrictions

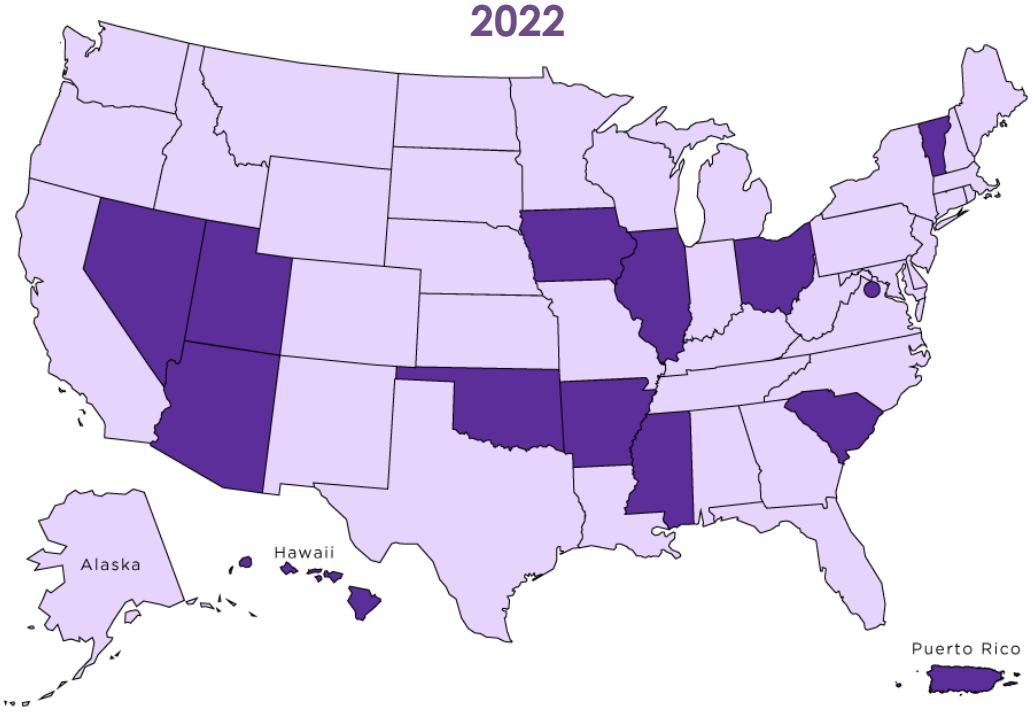
STATES WITH PRESCRIBER RESTRICTIONS IN 2014 AND 2022

2014



Unkown Prescriber Restrictions | Prescription Restrictions

2022



No Prescriber Restrictions | Prescription Restrictions

Endnotes

1 Centers for Medicare and Medicaid Services, "Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs (Release No. 172)," Nov. 5, 2015, https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-172.pdf [https://perma.cc/H77T-68EB].

2 American Association for the Study of Liver Diseases & Infectious Diseases Society of America [hereinafter AASLD & IDSA], HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C, https://www.hcvguidelines.org.

3 Department of Health and Human Services [hereinafter HHS], Viral Hepatitis National Strategic Plan: A Roadmap to Elimination for the United States 2021-2025 at 31, https://www.hhs.gov/sites/default/files/Viral-Hepatitis-National-Strategic-Plan-2021-2025.pdf [https://perma.cc/3JWF-AT5J] (describing "priority populations" in the viral hepatitis epidemic that "bear a disproportionately higher burden of infection and disease").

4 Id.

5 Kimberly Page et al., *HCV Screening in a Cohort of HIV Infected and Uninfected Homeless and Marginally Housed Women in San Francisco, California*, BMC Public Health (Feb. 2017), https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-017-4102-5; see also Heather Bradley et al., *Hepatitis C Virus Prevalence in 50 U.S. States and D.C. by Sex, Birth Cohort, and Race: 2013-2016*, Hepatology Communications (March 2020), https://aasldpubs.onlinelibrary.wiley.com/doi/epdf/10.1002/hep4.1457.

6 Soumitri Barua et al., *Restrictions for Medicaid Reimbursement of Sofosbuvir for the Treatment of Hepatitis C Virus Infections in the United States*, Annals of Internal Medicine (2015), https://pubmed.ncbi.nlm.nih.gov/26120969/.

7 Hepatitis C: State of Medicaid Access, January 2022 Report, https://stateofhepc.org/wp-content/uploads/2022/01/HCV_State-of-Medicaid-Access_Jan-2022_v2.pdf.

8 Survey respondents were asked to self-identify with one of six categories, and responded as follows: Advocate (n=29); Clinical provider or other health care team member (n=144); Government staff (n=63); Pharmaceutical company staff (n=7); Personally impacted (n=16); None of the above (n=16).

9 Letter to Marylou Sudders, Secretary of Massachusetts Executive Office of Health and Human Services, June 27, 2017, https://www.vpi.org/wp-content/uploads/2017/03/EndHepCMA-Coalition-Letter-to-EOHHS-Specialty-Pharmacies.pdf [https://perma.cc/2QDZ-4NYP].

10 One way for state Medicaid programs to mitigate these concerns may be to consider carving out HCV medications, requiring MCOs to bill through FFS.

11 Kaiser Family Foundations, "State Medicaid Prescription Limits," Jul. 1, 2019, https://www.kff.org/other/state-indicator/state-medicaid-prescription-limits/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

12 HHS, Viral Hepatitis National Strategic Plan, supra note 3 at 31.

13 HHS, Viral Hepatitis National Strategic Plan, supra note 3 at 33.

14 Id.

15 Heather Bradley et al., *Hepatitis C Virus Prevalence in 50 U.S. States and D.C. by Sex, Birth Cohort, and Race: 2013-2016*, supra note 5.

16 Philip Vutien et al., *Racial Disparities in Treatment Rates for Chronic Hepatitis C*, Medicine (May 2016), https://journals.lww.com/md-journal/fulltext/2016/05310/racial_disparities_in_treatment_rates_for_chronic.12.aspx.

17 James Myhre & Dennis Sifris, *Racial Disparities in Hepatitis C Treatment Eligibility*, Verywell Health (Mar. 30, 2022), https://www.verywellhealth.com/racial-disparities-in-hepatitis-c-treatment-eligibility-5218926; see also Omar T. Simms et al., *Racial Disparities in Hepatitis C Treatment Eligibility*, Annals of Hepatology (Jul.-Aug. 2017), https://reader.elsevier.com/reader/sd/pii/S1665268119310890?token=B03815A8523249DCEA7F22B97A561E7F86352737C0E42EDF2FE5F7A154ABBA45E8572ED39B9C98366B0A2F920D0F7571&originRegion=us-east-1&originCreation=20220516180844.

18 Jacqueline E. Sherbuk et al., *Disparities in Hepatitis C Linkage to Care in the Direct Acting Antiviral Era: Findings from a Referral Clinic With an Embedded Nurse Navigator Model*, Public Health (Nov. 2019), https://www.frontiersin.org/articles/10.3389/fpubh.2019.00362/full.

19 Philip Vutien et al., *Racial Disparities in Treatment Rates for Chronic Hepatitis C*, supra note 16.

20 Christopher J. Hernandez et al., *High Hepatitis C Virus Seropositivity, Viremia, and Associated Risk Factors Among Trans Women Living in San Francisco, California*, Plos One (Mar. 2021), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0249219; see also Philip Vutien et al., *Racial Disparities in Treatment Rates for Chronic Hepatitis C*, supra note 16.

21 Ronald O. Valdiserri, *What's A Syndemic? Hepatitis C Among Injection Drug Users Is An Urgent Example*, Health Affairs (Apr. 12, 2021), https://www.healthaffairs.org/do/10.1377/forefront.20210407.8040/full/.

22 See AASLD & IDSA, "Key Populations: Identification and Management of HCV in People Who Inject Drugs," https://www.hcvguidelines.org/unique-populations/pwid.

23 For example, research shows that people who inject drugs are likely to experience discrimination in health care settings as a

result of their injection drug use status, including through lower quality care. Requirements that providers assess for and identify people who use drugs may thereby lead to those individuals to experience discrimination and stigma and dissuade providers from engaging in treatment opportunities with them. See Brandon Muncan et al., *"They Look at Us Like Junkies": Influences of Drug Use Stigma on the Healthcare Engagement of People Who Inject Drugs in New York City*, Harm Reduction Journal (Jul. 2020), https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-020-00399-8.

[24] Marjan Javanbakht et al., *Will Prior Health Insurance Authorization for Medications Continue to Hinder Hepatitis C Treatment Delivery in the United States? Perspectives from Hepatitis C Treatment Providers in a Large Urban Healthcare System*, PLoS ONE (Nov. 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7641373/pdf/pone.0241615.pdf.

[25] AASLD and ISDA recommend treatment "for all patients with acute or chronic HCV infection, except those with a short life expectancy that cannot be remediated by HCV therapy, liver transplantation, or another directed therapy." AASLD & IDSA, "When and in Whom to Initiate HCV Therapy," HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C, https://www.hcvguidelines.org/evaluate/when-whom.

[26] North Dakota Department of Human Services, Medical Services Division, "Medical Billing Drug Clinical Criteria" (Effective April 20, 2022), http://www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf [https://perma.cc/6MUU-9DBH].

[27] South Dakota Department of Social Services, Hepatitis C Prior Authorization Request Form (May 2022), https://prdgov-rxadmin.optum.com/rxadmin/SDM/HepatitisC_SDM.pdf [https://perma.cc/2JXN-SAX2].

[28] Delaware Medicaid and Medical Assistance, "Request for Prior Authorization Hepatitis C Agents" (Aug. 2021), https://medicaidpublications.dhss.delaware.gov/docs/DesktopModules/Bring2mind/DMX/API/Entries/Download?Command=Core_Download&EntryId=536&language=en-US&PortalId=0&TabId=94 [https://perma.cc/YJ5D-LY7L].

[29] Nebraska Department of Health and Human Services, "Prior Authorization Criteria for Treatment of Chronic Hepatitis C (CHC)" (Jul. 2021), https://nebraska.fhsc.com/Downloads/NEcriteria_HepatitisC.pdf [https://perma.cc/D3JL-FUCT].

[30] Illinois Department of Healthcare and Family Services, "Criteria for Prior Approval of Direct-Acting Antivirals (DAAs) for Hepatitis C" (Nov. 2018), https://www2.illinois.gov/hfs/SiteCollectionDocuments/HFSHepCDAACriteriaWordFINAL11012018.pdf [https://perma.cc/5ZC9-3ENP].

[31] "Active or recent drug use or a concern for reinfection is not a contraindication to HCV treatment." AASLD & IDSA, "Key Populations: Identification and Management of HCV in People Who Inject Drugs," supra note 22 ("Active or recent drug use or a concern for reinfection is not a contraindication to HCV treatment.").

[32] Naveed Z. Janjua et al., *Effectiveness of Ledipasvir/Sofosbuvir and Sofosbuvir/Velpatasvir in People Who Inject Drugs and/or Those in Opioid Agonist Therapy*, Hepatology Communications (Nov. 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6442698/pdf/HEP4-3-478.pdf.

[33] Id.

[34] See, e.g., Magdalena Harris et al., *Conceptualising Hepatitis C Stigma: A Thematic Synthesis of Qualitative Research*, International Journal of Drug Policy (2021), https://www.sciencedirect.com/science/article/pii/S0955395921002255 (discussing the impact of stigma).

[35] Andrew Blake & James E. Smith, *Modeling Hepatitis C Elimination Among People Who Inject Drugs in New Hampshire*, JAMA (Aug. 2021), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2782630.

[36] Gobierno de Puerto Rico, Government Health Plan, Policy for the Management of Patients Diagnosed with Chronic Hepatitis C (Dec. 7, 2020) at 44, https://app.box.com/v/protocolosases/file/748224470661 [https://perma.cc/XSB3-PM9L].

[37] "Individuals in whom initial treatment fails should be evaluated by a specialist for retreatment, which often proves successful," and "With reinfection, treatment approaches are identical to those for initial treatment." AASLD-IDSA Guidance Panel, *Hepatitis C Guidance 2019 Update: American Association for the Study of Liver Diseases–Infectious Diseases Society of America Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection*, Hepatology (Nov. 2020), https://aasldpubs.onlinelibrary.wiley.com/doi/pdf/10.1002/hep.31060#.

[38] Wyoming Medicaid Pharmacy Services Program, "Prior Authorization Request Form Hepatitis C Treatment," http://www.wymedicaid.org/sites/default/files/ghs-files/pa-forms/2019-11-26/hepatitis-c-form-20191.pdf [https://perma.cc/75CM-VKKZ].

[39] Arizona Health Care Cost Containment System, Medical Policy Manual, "320-N - HEPATITIS C VIRUS (HCV) PRIOR AUTHORIZATION REQUIREMENTS FOR DIRECT ACTING ANTIVIRAL (DAA) MEDICATION TREATMENT" (Effective Oct. 1, 2021), https://www.azahcccs.gov/shared/Downloads/MedicalPolicyManual/300/320-N.pdf [https://perma.cc/3LZP-RZDH].

[40] Colorado Department of Health Care Policy and Financing, "Hepatitis C Treatment Prior Authorization (PA) Request Form" (Effective Jan. 1, 2022), https://hcpf.colorado.gov/sites/hcpf/files/Hep%20C%20PAR%202022.pdf [https://perma.cc/5XR3-DGMG].

[41] MagellanRx Management, "Kentucky Medicaid Single PDL Prior Authorization (PA) Criteria" (Effective May 5, 2022), https://kyportal.magellanmedicaid.com/public/client/static/kentucky/documents/KYRx_PDL_prior_authorization_criteria.pdf [https://perma.cc/BP7E-S4TK].

[42] Medicaid and CHIP Payment and Access Commission, Issue Brief: Medicaid Managed Care Capitation Rate Setting (March 2022), https://www.macpac.gov/wp-content/uploads/2022/03/Managed-care-capitation-issue-brief.pdf [https://perma.cc/9HU8-CCJH].

[43] 42 CFR § 438.210(a)(2).

[44] 42 CFR § 438.210(a)(3)(ii).

[45] WellCare Health Plans, Forms, Pharmacy: Hepatitis C Treatment Authorization Request Form, https://www.wellcare.com/New-Jersey/Providers/Medicaid/Forms [https://perma.cc/GB3L-7VL4].

[46] Visiting Nurse Service of New York Choice Health Plan, All Provider Forms, https://www.vnsnychoice.org/for-health-professionals-overview/all-forms/ [https://perma.cc/N9D9-GBG4].

[47] See UnitedHealthcare Nebraska Community Plan Pharmacy Prior Authorization Forms (accessed May 27, 2022), https://www.uhcprovider.com/en/prior-auth-advance-notification/prior-auth-specialty-drugs/comm-plan-pharmacy-prior-auth-forms/ne-uhccp-pharm-prior-auth-forms.html [https://perma.cc/T8JW-B4C8]; Healthy Blue, Nebraska Providers, Forms (accessed May 27, 2022), https://provider.healthybluene.com/nebraska-provider/resources/forms [https://perma.cc/S834-EYSZ].

[48] See Health Plan of Nevada, Provider Landing Page (accessed May 27, 2022), https://myhpnmedicaid.com/Provider [https://perma.cc/Y27K-U5HV; SilverSummit Health Plan, Pharmacy (accessed May 27, 2022), https://www.silversummithealthplan.com/providers/pharmacy.html [https://perma.cc/QMF6-QSLY].

[49] "All administrative services related to Medi-Cal pharmacy benefits billed on pharmacy claims from the existing Medi-Cal Fee-for-Service (FFS) or Managed Care Plan (MCP) intermediaries have transitioned to Medi-Cal Rx." *See* Medi-Cal Rx, https://medi-calrx.dhcs.ca.gov/home/ [https://perma.cc/SAN6-KAJ8].

[50] Letter from Daniel Tsai, Assistant Secretary for MassHealth to Managed Care Organizations Participating in MassHealth (July 2016), https://www.mass.gov/doc/managed-care-organization-bulletin-6-masshealth-contracted-managed-care-organization-mco/download [https://perma.cc/3BFH-LJL9].

[51] "With the advent of pangenotypic DAA regimens, HCV genotyping is no longer universally required prior to treatment initiation," and "[T]he HCV guidance panel strongly recommends antiviral treatment for all adults with *acute* or chronic HCV infection…" AASLD-IDSA Guidance Panel, *Hepatitis C Guidance 2019 Update*, supra note 37.

[52] Government of District of Columbia Department of Health Care Finance, Prior Authorization Request Form for Mavyret (Dec. 13, 2017), http://www.dc-pbm.com/provider/external/medicaid/dc/doc/en-us/District_PA_Request_Form_Mavyret.pdf [https://perma.cc/2Q8R-39XW].

[53] North Dakota Medicaid, Hepatitis C Treatments Prior Authorization Form (accessed May 27, 2022), https://nddruglookup.hidinc.com/forms/Hep_C_form.pdf [https://perma.cc/4A7H-AJMB].

[54] Wyoming Medicaid, Prior Authorization Request Form: Hepatitis C Treatment, http://www.wymedicaid.org/sites/default/files/ghs-files/pa-forms/2019-11-26/hepatitis-c-form-20191.pdf [https://perma.cc/2W82-KAQJ].

[55] Brianna L Norton et al., *Low Adherence Achieves High HCV Cure Rates Among People Who Inject Drugs Treated With Direct-Acting Antiviral Agents*, Open Forum Infectious Diseases (Oct. 2020) https://academic.oup.com/ofid/article/7/10/ofaa377/5897253.

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