Hepatitis C:
The State of Medicaid Access

2017 NATIONAL SUMMARY REPORT

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INTRODUCTION

The advent in 2013 of direct-acting antivirals (DAAs) to combat Hepatitis C (HCV) was a major development in curing the deadliest infectious disease in the United States. Unfortunately, despite the important individual and public health potential of these medications many public and private payers choose to limit access to DAAs due to their 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, despite clear guidance from the Centers for Medicare and Medicaid Services that such restrictions often 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]

In 2015, the Center for Health Law and Policy Innovation of Harvard Law School (CHLPI), along with academic researchers at Brown University and the Miriam Hospital, University of New South Wales, and the Treatment Action Group, published in the Annals of Internal Medicine a survey of access restrictions to DAAs in state Medicaid programs as of December 2014.[3] Since December 2014, access to DAAs in state Medicaid programs has been incrementally expanded, often in response to advocacy and impact litigation.

In the 2017 "Hepatitis C: The State of Medicaid Access" report, CHLPI and the National Viral Hepatitis Roundtable (NVHR) update and expand upon the initial survey to document the current state of access for Medicaid enrollees across the United States. The 2017 report provides 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, CHLPI and NVHR are releasing state-specific "report cards" that reflect overall HCV treatment access in each state. As policies continue to change on an ongoing basis, the data presented in this National Summary Report as well as the report cards is current as of the first half of 2017.

The 2017 report focuses on three of the most significant restrictive criteria 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).

Overall, our 2017 analysis of the data reveals that since 2014, transparency of state Medicaid program access restrictions has increased. The overwhelming majority of states now have their HCV treatment restriction criteria publicly available. In a few cases, however, states' HCV

[1] 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/prescription-drugs/hcv/index.html.
[2] The American Association for the Study of Liver Diseases and the Infectious Diseases Society of America, HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C, Sep. 21, 2017, *available at* https://www.hcvguidelines.org/.
[3] 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).

treatment requirements remain only available through direct communication with officials; in even fewer cases they remain unknown despite repeated efforts to identify restrictions. During this same time period, access to HCV treatment has improved. Among the progress made, several states have completely eliminated fibrosis restrictions, while a significant number of other states have reduced their restrictions. To a lesser extent, restrictions around sobriety and prescriber limitations have also improved.

As Medicaid programs increasingly funnel enrollees into managed care organizations (MCOs), the 2017 report provides us with a comprehensive national assessment of MCO coverage of HCV treatment. In general, the findings indicate that although some MCOs have low levels of restrictions, many follow their states' fee-for-service (FFS) Medicaid restrictions. While, consistent with federal Medicaid law, MCOs must at the very least offer similar or less restrictive coverage as their respective state's FFS program, some MCOs impose more onerous restrictions.[4]

As required by federal Medicaid law and national treatment guidelines, state Medicaid programs should eliminate the remaining restrictions around fibrosis, sobriety, and prescriber limitations identified in the 2017 report. Increased scrutiny must also focus on MCOs because of the increasing number of Medicaid enrollees funneled into managed care. As with Medicaid FFS, no MCO should require restrictive coverage criteria to access HCV treatment.

METHODS

We evaluated Medicaid reimbursement criteria for available DAAs for all 50 states, the District of Columbia, and Puerto Rico. The information for 2014 was gleaned from the survey published in the Annals of Internal Medicine. That survey drew upon state Medicaid website materials posted between June 23 and December 7, 2014. Data for 2014 was extracted by two co-authors in duplicate and entered into a spreadsheet, with two different co-authors evaluating the extracted data. Any differences were resolved by consensus.

For the 2017 survey, we first sent a form survey to each state's Medicaid officials requesting their FFS coverage criteria for DAAs. Where states were unresponsive, we again searched state Medicaid websites for publicly available reimbursement criteria. All of the data for 2017 was crosschecked by CHLPI and NVHR. Where survey responses conflicted with publicly available criteria, differences were resolved either by direct communication with Medicaid officials or by consensus. For each state, in both 2014 and 2017, data was extracted from Medicaid reimbursement criteria, including whether DAAs were covered (paid for by Medicaid) and the criteria for coverage. The preferred drug lists were also recorded and entered into each state's report card.

Coverage criteria was further broken down by restriction type. For criteria about liver disease staging, data was collected on the level of fibrosis (liver scarring) required prior to authorization of treatment. Criteria ranged from Meta-Analysis of Histological Data in Viral Hepatitis (METAVIR)

[4] 42 CFR § 438.210.

fibrosis stage F0 (no fibrosis) through F4 (cirrhosis). For sobriety criteria, data was collected on whether drug or alcohol screening and counseling was required and whether a period of abstinence (1, 3, 6, or 12 months) was required prior to authorizing HCV treatment. For prescriber type, data was collected on whether any provider may prescribe treatment, whether primary care physicians must consult a specialist, or whether the prescriber had to be a specialist, usually practicing in gastroenterology, hepatology, infectious diseases, or liver transportation.

Our 2017 survey expanded in scope from the 2014 examination of HCV treatment access criteria for both Medicaid fee-for-service (FFS) programs and MCOs. Because multiple MCOs may operate in a state and their restrictions may vary, MCO coverage may be expressed in a range. For example, in some states one MCO may offer access to DAAs for everyone who tests at F2 or higher whereas a competitor may not impose a minimum fibrosis score. For the purposes of the 2017 survey, we have categorized states with confirmed variation between their MCOs separately. Another challenge to categorize access to HCV treatment in managed care is that some MCOs refuse to clarify their access restrictions. If we were unable to confirm any MCO's treatment criteria, we classified that state as "Restrictions Unknown." However, if we were able to confirm at least one MCO's criteria where multiple MCOs operate, we categorized that state accordingly.

FINDINGS

Findings: Liver Damage Restrictions

Liver damage (fibrosis) restrictions are one of the foremost and common barriers to accessing DAAs in state Medicaid programs. These restrictions require patients to wait until HCV damages their liver to a certain level, as measured by the METAVIR fibrosis scale. A METAVIR score of F0 indicates no fibrosis, whereas F4 indicates damage to the liver that is so severe as to be considered cirrhosis.

Since 2014, progress has been made in easing these restrictions, but too many states continue to limit access to only those individuals whose HCV has progressed to at least moderate (F2) or advanced (F3) fibrosis. By requiring patients to demonstrate a minimum level of liver damage before they qualify for treatment with DAAs, Medicaid programs are forcing individuals to wait until their health worsens in order to access the cure for HCV.

Comparing 2014 and 2017 Medicaid Fee-for-Service Liver Damage Restrictions

Overall, transparency in liver damage restrictions has improved dramatically since the 2014 survey, with a significant number of states clarifying their fibrosis requirements for treatment with DAAs. In 2017, all states' fee-for-service programs have known criteria (including the District of Columbia's and Puerto Rico's programs). This is opposed to only 34 states (67%) in 2014. Most importantly, many states have eased their liver damage restrictions since 2014. In 2017, 18 states (35%) do not require patients to demonstrate a minimum level of liver damage to qualify for treatment with DAAs. In 2014, no state met this criterion. In 2017, 4 states (8%) require an

individual to demonstrate mild fibrosis (F1) as opposed to one state (3%) in 2014. In 2017, 18 states (35%) require an individual to demonstrate at least moderate fibrosis (F2) as compared to two states (6%) in 2014.

While many states continue to require patients to demonstrate serious liver damage before they can access the cure to HCV, the 2017 findings demonstrate a dramatic improvement over 2014. In 2014, of the 34 states with known criteria, 31 states (91%) limited access to DAAs to only those patients that could demonstrate advanced fibrosis or cirrhosis, with 27 states (79%) requiring advanced fibrosis (F3), and 4 states (12%) requiring cirrhosis of the liver (F4). In comparison, in 2017, 12 states (23%) require at least advanced fibrosis (F3) to qualify for treatment, and no states continue to require cirrhosis of the liver to qualify.

Chart 1: Comparing 2014 and 2017 Medicaid FFS Liver Disease Restrictions				
Category	**2014 Number of States with FFS Liver Damage Restriction**	**2014 States**	**2017 Number of States with FFS Liver Damage Restriction**	**2017 States**
No Restrictions	0 (0%)[5] [6]	None	18 (35%)[7]	Alaska, Connecticut, Florida, Georgia, Maine, Massachusetts, Minnesota, Mississippi, Nevada, New Hampshire, New York, North Dakota, Puerto Rico, South Carolina, Virginia, Washington, Wisconsin, Wyoming
F1	1 (3%)	Maine	4 (8%)	Hawaii, New Mexico*, Pennsylvania, Utah
F2	2 (6%)	Maryland, Oklahoma	18 (35%)	Alabama, Arizona, California, Colorado, Delaware, District of Columbia, Idaho, Indiana, Kentucky, Maryland, Michigan, New Jersey, North Carolina*, Ohio*, Oklahoma, Tennessee, Vermont, West Virginia
F3	27 (79%)	Alaska, Arizona, Arkansas, California, Colorado, District of Columbia, Florida, Idaho, Indiana, Iowa, Kentucky, Louisiana, Missouri, Montana, Nebraska, New Hampshire, New York, Ohio, Pennsylvania, Rhode Island, South Dakota, Tennessee, Vermont, Virginia, Washington, West Virginia, Wisconsin	12 (23%)	Arkansas, Illinois, Iowa, Kansas, Louisiana, Missouri*, Montana, Nebraska, Oregon, Rhode Island, South Dakota, Texas
F4	4 (12%)	Connecticut, Delaware, Illinois, Oregon	0 (0%)	None
Restrictions Unknown	18	Alabama, Georgia, Hawaii, Kansas, Massachusetts, Michigan, Minnesota, Mississippi, New Jersey, New Mexico, Nevada, North Carolina, North Dakota, Puerto Rico, South Carolina, Texas, Utah, Wyoming	0	None

[5] Percentages are calculated based on the number of states that had known restrictions in a given year. For 2014 FFS Medicaid programs, 34 states had known fibrosis restrictions.

[6] Due to rounding, percentages in each chart may not add up to 100%.

[7] Percentages are calculated based on the number of states that had known restrictions in a given year. For 2017 FFS Medicaid programs, all 52 jurisdictions surveyed had known fibrosis restrictions.

* Missouri, New Mexico, North Carolina, and Ohio are all in the process of completely eliminating their fibrosis restrictions, but have not done so yet at the time of this report.

Comparing 2017 Medicaid Managed Care Organization and Fee-for-Service Liver Damage Restrictions

In 2017, 40 states, including the District of Columbia and Puerto Rico, have Medicaid MCOs, as 12 states do not have commercial MCOs in their Medicaid programs. Additionally, 10 states have carved-out either DAAs or all prescription drugs from their MCO contracts. In these states, the FFS program sets the criteria for DAA treatment, even for beneficiaries enrolled in an MCO. Thus, 30 states contract with MCOs to provide DAA treatment for their Medicaid enrollees. As to transparency, 29 of these states have at least one MCO with published liver damage restrictions. Of the 29 states with MCOs with available information, 10 states (34%) have at least one MCO with liver damage restrictions that are more restrictive than their corresponding FFS program. This is the case despite the fact that Medicaid programs must, by law, ensure that their MCOs offer similar or less restrictive coverage to the FFS program in the state.[8]

Eight states (28%) with MCOs that provide DAAs to enrollees have no liver damage restrictions. Eighteen states' FFS programs (35%) do not impose liver damage restrictions, including seven states that have no restrictions in either their MCOs or FFS programs, nine states that either do not have MCOs or have carved out DAAs from their MCO contracts, one state whose MCO's restrictions are unknown, and one state (Georgia) that has at least one MCO which requires patients to demonstrate at least advanced fibrosis (F3) to qualify for treatment with DAAs. The District of Columbia has at least one MCO that does not impose liver damage requirements, although some MCOs require a patient to demonstrate at least moderate fibrosis (F2) to qualify. In contrast, the district's FFS program requires patients to progress to F2 prior to treatment. Two states (7%), Georgia and Illinois, have MCOs that do not impose minimum fibrosis requirements, although some MCOs in these states require patients to demonstrate F3. Pennsylvania is the only state whose MCOs require patients to demonstrate mild fibrosis (F1), whereas 4 states' FFS programs (8%) share this criterion. New Mexico and Hawaii's MCOs each require at least F1, although some MCOs require F2 and F3 respectively, despite the fact that both state's FFS programs only require patients to demonstrate F1. California is the only state whose MCOs require patients to demonstrate F2 to qualify, whereas 18 states' FFS programs (35%) share this criterion, including nine states with MCOs that provide DAAs to their enrollees. Seven states' (24%) MCOs vary in that while some only require F2, others require at least F3. Seven states' MCOs require at least F3 to qualify for treatment, whereas 12 states' FFS programs (23%) share this criterion, including ten states with MCOs that process DAA treatments. Fortunately, no state's MCOs require patients to demonstrate cirrhosis (F4) to qualify for treatment.

[8] 42 CFR § 438.210.

Chart 2: Comparing 2017 Medicaid MCO and FFS Liver Disease Restrictions				
Category	**Number of States with MCO Liver Damage Restriction**	**States**	**Number of States with FFS Liver Damage Restriction**	**States**
No Restrictions	8 (28%)[9]	Colorado, Florida, Massachusetts, Minnesota, Mississippi, Nevada, New York, Virginia	18 (35%)	Alaska, Connecticut, Florida, Georgia, Maine, Massachusetts, Minnesota, Mississippi, Nevada, New Hampshire, New York, North Dakota, Puerto Rico, South Carolina, Virginia, Washington, Wisconsin, Wyoming
No Restrictions-F2	1 (3%)	District of Columbia	N/A	N/A
No Restrictions-F3	2 (7%)	Georgia, Illinois	N/A	N/A
F1	1 (3%)	Pennsylvania	4 (8%)	Hawaii, New Mexico, Pennsylvania, Utah
F1-F2	1 (3%)	New Mexico	N/A	N/A
F1-F3	1 (3%)	Hawaii	N/A	N/A
F2	1 (3%)	California	18 (35%)	Alabama, Arizona, California, Colorado, Delaware, District of Columbia, Idaho, Indiana, Kentucky, Maryland, Michigan, New Jersey, North Carolina, Ohio, Oklahoma, Tennessee, Vermont, West Virginia
F2-F3	7 (24%)	Arizona, Delaware, Kentucky, Maryland, New Jersey, Ohio, Utah	N/A	N/A
F3	7 (24%)	Iowa, Kansas, Louisiana, Nebraska, Oregon, Rhode Island, Texas	12 (23%)	Arkansas, Illinois, Iowa, Kansas, Louisiana, Missouri, Montana, Nebraska, Oregon, Rhode Island, South Dakota, Texas
F4	0 (0%)	None	0 (0%)	None
No MCO Program	12	Alabama, Alaska, Arkansas, Connecticut, Idaho, Maine, Montana, North Carolina, Oklahoma, South Dakota, Vermont, Wyoming	N/A	N/A
HCV Medications Carved Out of MCO Contracts	10	Indiana, Michigan, Missouri, New Hampshire, Puerto Rico, South Carolina, Tennessee, Washington, West Virginia, Wisconsin	N/A	N/A
Restrictions Unknown	1	North Dakota	0	None

[9] Percentages are calculated based on the number of states that had MCOs with known restrictions in a given year. For 2017, 29 states had MCOs with known restrictions for fibrosis.

Findings: Sobriety Restrictions

Another widespread restriction on DAA treatment access are restrictions related to alcohol and/or substance use. Many Medicaid programs require individuals to abstain from use for a specified timeframe prior to starting treatment. Others require individuals to submit to screening or attest to maintaining abstinence during treatment, or require providers to counsel patients on substance use and in some cases, refer active users for treatment (a category this report calls "Screening and Counseling").

These common restrictions on care undermine the recommendations of the AASLD/ISDA that are widely recognized as the standard of care. Current research shows that people who inject drugs achieve similar cure rates (sustained virologic response) as compared to patients who do not use drugs.[10] Additionally, injection drug use is the foremost driving factor in the perpetuation of the HCV epidemic within the United States. As the AASLD/ISDA guidance notes, "testing and linkage to care combined with the treatment of HCV infection with potent interferon-free regimens [DAAs] has the potential to dramatically decrease HCV incidence and prevalence."[11] Thus, postponing access to care for people who use substances or otherwise do not maintain sobriety not only allows the health of these individuals to deteriorate, but also undermines public health efforts to end the HCV epidemic.

Comparing 2014 and 2017 Medicaid Fee-for-Service Sobriety Restrictions

In 2014 survey, 37 states (73% of those surveyed) had known sobriety requirements in their eligibility criteria for reimbursement. In the 2017 survey, all jurisdictions researched had known sobriety requirements, illustrating the progress made in terms of increasing transparency.

In 2017, 10 states (19%) do not impose abstinence periods or mandated screening as a requirement for treatment. No state met this criteria in 2014. The number and proportion of states that required screening and counseling but did not impose abstinence requirements changed from 9 states (24%) in 2014 to 15 states (29%) in 2017. As in 2014, two states (4%) continue to require individuals to demonstrate at least one month of sobriety before receiving treatment in 2017. Five states (10%) in 2017 require individuals to abstain from substance use for 3 months before receiving treatment as compared to 6 states (16%) in 2014. The number of states requiring that individuals abstain from substance use for 6 months prior to receiving treatment remained constant from 2014 to 2017 at 18 states, but decreased as a percentage of all states with known sobriety restrictions in their FFS programs from 49% in 2014 to 35% in 2017. Two states (4%) continue to mandate a full year of sobriety prior to treatment in 2017. Two states also imposed this restriction in 2014.

[10] Aspinall EJ, Corson S, Doyle JS, et al., *Treatment of hepatitis C virus infection among people who are actively injecting drugs: a systematic review and meta-analysis*, 57 CLIN INFECT DIS.S80 (2013).
[11] The American Association for the Study of Liver Diseases and the Infectious Diseases Society of America, HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C, Sep. 21, 2017, *available at* https://www.hcvguidelines.org/.

Chart 3: Comparing 2014 and 2017 Medicaid FFS Sobriety Restrictions				
Category	**2014 Number of States with FFS Sobriety Restriction**	**2014 States**	**2017 Number of States with FFS Sobriety Restriction**	**2017 States**
No Restrictions	0 (0%)[12]	None	10 (19%)[13]	California, Connecticut, Indiana, Massachusetts, Missouri, Nevada, New Jersey, Utah, Vermont, Washington
Screening and Counseling	9 (24%)	Arkansas, Maine, Massachusetts, New Hampshire, New York, North Carolina, Ohio, Vermont, Virginia	15 (29%)	Alaska, Colorado, Delaware, District of Columbia, Georgia, Illinois, Maryland, New Hampshire, New Mexico, New York, North Carolina, Pennsylvania, Rhode Island, South Carolina, Virginia
Abstain for 1 month	2 (5%)	Florida, Wyoming	2 (4%)	Florida, Wyoming
Abstain for 3 months	6 (16%)	Alaska, Delaware, District of Columbia, Iowa, Missouri, Washington	5 (10%)	Arizona, Hawaii, Iowa, Texas, West Virginia
Abstain for 6 months	18 (49%)	Alabama, Arizona, California, Colorado, Idaho, Kentucky, Maryland, Mississippi, Montana, Nebraska, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, West Virginia, Wisconsin	18 (35%)	Alabama, Arkansas, Idaho, Kansas, Kentucky, Maine, Michigan, Minnesota, Mississippi, Montana, Nebraska, Ohio, Oklahoma, Oregon, Puerto Rico, South Dakota, Tennessee, Wisconsin
Abstain for 12 months	2 (5%)	Illinois, Louisiana	2 (4%)	Louisiana, North Dakota
Restrictions Unknown	15	Connecticut, Indiana, Georgia, Hawaii, Kansas, Michigan, Minnesota, Nevada, New Jersey, New Mexico, North Dakota, Puerto Rico, South Carolina, Texas, Utah	0	None

Comparing 2017 Medicaid Managed Care Organization and Fee-for-Service Sobriety Restrictions

In 2017, 30 states, including the District of Columbia, have Medicaid MCOs that deliver DAA treatment to enrollees, and all but one state has at least one MCO with published criteria. Of the 29 states with known sobriety criteria, 8 states (28%) contract with at least one MCO that has

[12] Percentages are calculated based on the number of states that had known restrictions in a given year. For 2014 FFS Medicaid programs, 37 states had known restrictions for sobriety.

[13] Percentages are calculated based on the number of states that had known restrictions in a given year. For 2017 FFS Medicaid programs, all 52 jurisdictions surveyed had known sobriety restrictions.

sobriety restrictions that are more onerous than their corresponding FFS program. These further restrictions persist even though Medicaid programs must, by law, ensure that their MCOs offer similar or less restrictive coverage to the FFS program in the state.[14]

Four states (14%) of the 29 with MCOs with publicly available criteria do not impose any restrictions related to substance use, whereas 10 state FFS programs (19%) do not require sobriety or screening. In 4 states (14%), MCOs require screening and counseling as opposed to 15 state FFS programs (29%). In one state (3%), MCOs require patients to abstain for at least 1 month prior to treatment as opposed to 2 FFS programs (4%). The MCOs in 2 states (7%) require enrollees to abstain for at least 3 months, whereas 5 state FFS programs (10%) share this criterion. In 4 states (14%), the MCOs uniformly require individuals to abstain from substance use for at least 6 months prior to treatment. By contrast, 18 state FFS programs (35%) have the same requirements. Fortunately, no state contracts with MCOs that require a full year of abstinence prior to treatment, whereas two state FFS programs (4%) continue to impose this barrier. In a plurality of states with MCOs with known restrictions, 14 states (48%), including the District of Columbia, have MCOs whose sobriety restrictions vary significantly, generally with at least one MCO requiring only screening and counseling and at least one MCO requiring 3 to 6 months of abstinence for treatment to be authorized.

[14] 42 CFR § 438.210.

Chart 4: Comparing 2017 Medicaid MCO and FFS Sobriety Restrictions				
Category	**Number of States with Managed Care Sobriety Restriction**	**States**	**Number of States with FFS Sobriety Restriction**	**States**
No Restrictions	4 (14%)[15]	California, Massachusetts, Nevada, Rhode Island	10 (19%)	California, Connecticut, Indiana, Massachusetts, Missouri, Nevada, New Jersey, Utah, Vermont, Washington
Screening and Counseling	4 (14%)	Colorado, Georgia, New Mexico, Pennsylvania	15 (29%)	Alaska, Colorado, Delaware, District of Columbia, Georgia, Illinois, Maryland, New Hampshire, New Mexico, New York, North Carolina, Pennsylvania, Rhode Island, South Carolina, Virginia
Abstain for 1 month	1 (3%)	Florida	2 (4%)	Florida, Wyoming
Abstain for 3 months	2 (7%)	Iowa, Texas	5 (10%)	Arizona, Hawaii, Iowa, Texas, West Virginia
Abstain for 6 months	4 (14%)	Kansas, Mississippi, Nebraska, Oregon	18 (35%)	Alabama, Arkansas, Idaho, Kansas, Kentucky, Maine, Michigan, Minnesota, Mississippi, Montana, Nebraska, Ohio, Oklahoma, Oregon, Puerto Rico, South Dakota, Tennessee, Wisconsin
Abstain for 12 months	0 (0%)	None	2 (4%)	Louisiana, North Dakota
Varied	14 (48%)	Arizona, Delaware, District of Columbia, Hawaii, Illinois, Kentucky, Louisiana, Maryland, Minnesota, New Jersey, New York, Ohio, Utah, Virginia	N/A	N/A
No Managed Care Program	12	Alabama, Alaska, Arkansas, Connecticut, Idaho, Maine, Montana, North Carolina, Oklahoma, South Dakota, Vermont, Wyoming	N/A	N/A
HCV Medications Carved Out of MCO Contracts	10	Indiana, Michigan, Missouri, New Hampshire, Puerto Rico, South Carolina, Tennessee, Washington, West Virginia, Wisconsin	N/A	N/A
Restrictions Unknown	1	North Dakota	0	None

[15] Percentages are calculated based on the number of states that had MCOs with known restrictions in a given year. For 2017, 29 states had MCOs with known restrictions for sobriety.

Findings: Prescriber Restrictions

Medicaid programs sometimes restrict access to HCV treatment by limiting which providers are eligible to prescribe DAAs, often only allowing specialists such as hepatologists, gastroenterologists, or infectious disease practitioners to prescribe, or by requiring that patients at least obtain a consultation with one of these specialists prior to treatment. Medicaid programs that limit the ability to prescribe DAAs to certain specialists create a prescriber bottleneck because specialists often have limited bandwidth to treat the number of people in need of HCV treatment and/or to consult with other providers. Additionally, prescriber limitations may present practical access barriers for beneficiaries that live in rural or otherwise sparsely populated areas that may not have a specialist nearby. DAAs have relatively few side effects and are not difficult to monitor during the short course of treatment. Providers who are skilled and possess the requisite knowledge for treating HCV, whether or not they are a specialist, should be allowed to prescribe DAAs and treat people living with HCV.

Comparing 2014 and 2017 Medicaid Fee-for-Service Prescriber Restrictions

In 2017, transparency regarding prescriber restrictions increased significantly. Only one state (2%) in 2017 did not have known prescriber restrictions for HCV treatment, as compared to 22 states (42%) in 2014. Of the remaining 51 jurisdictions with available information, 14 states (27%) do not require a specialist to prescribe or consult, whereas no state met this criteria in 2014. Twenty-eight states (55%) with known prescriber restrictions require that a specialist must at least be consulted before DAA treatment will be authorized, as opposed to only 15 states (52%) in 2014. Nine states (18%) only approve treatment when a specialist prescribes DAA therapy, as compared to 14 states (48%) in 2014.

Chart 5: Comparing 2014 and 2017 Medicaid FFS Prescriber Restrictions				
Category	**2014 Number of States with FFS Prescriber Restriction**	**2014 States**	**2017 Number of States with FFS Prescriber Restriction**	**2017 States**
No restrictions	0 (0%)[16]	None	14 (27%)[17]	Alaska, Alabama, California, Connecticut, Delaware, Georgia, Massachusetts, Missouri, Nebraska, Nevada, New Mexico, North Carolina, Wisconsin, Wyoming
By or in consultation with specialist	15 (52%)	Arizona, California, Colorado, Connecticut, Idaho, Illinois, Kentucky, Louisiana, Mississippi, Oklahoma, Oregon, South Dakota, Utah, Virginia, West Virginia	28 (55%)	Arizona, Colorado, District of Columbia, Florida, Hawaii, Idaho, Illinois, Indiana, Kansas, Kentucky, Maine, Maryland, Michigan, Minnesota, Mississippi, New Hampshire, New York, North Dakota, Oklahoma, Oregon, Puerto Rico, South Carolina, Texas, Utah, Vermont, Virginia, Washington, West Virginia
Specialist must prescribe	14 (48%)	Florida, Indiana, Iowa, Maine, Maryland, Montana, New Hampshire, New York, Ohio, Pennsylvania, Rhode Island, Tennessee, Washington, Wisconsin	9 (18%)	Arkansas, Iowa, Louisiana, Montana, Ohio, Pennsylvania, Rhode Island, South Dakota, Tennessee
Restrictions Unknown	23	Alabama, Alaska, Arkansas, Delaware, District of Columbia, Georgia, Hawaii, Kansas, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Jersey, New Mexico, North Carolina, North Dakota, Puerto Rico, South Carolina, Texas, Vermont, Wyoming	1	New Jersey

[16] Percentages are calculated based on the number of states that had known restrictions in a given year. For 2014 FFS Medicaid programs, 29 states had known restrictions for prescribing privileges.

[17] Percentages are calculated based on the number of states that had known restrictions in a given year. For 2017 FFS Medicaid programs, 51 states had known restrictions for prescribing privileges.

Comparing 2017 Medicaid Managed Care Organization and Fee-for-Service Prescriber Restrictions

In 2017, 30 states, including the District of Columbia, have Medicaid MCOs that deliver DAA treatment to enrollees, and all but one state has at least one MCO with published criteria. Of these 29 states with known prescriber restrictions, 12 states contract with at least one MCO that has prescriber restrictions that are more burdensome than their state's corresponding FFS program. This is the case despite the fact that Medicaid programs may not, by law, allow their MCOs to provide more restrictive coverage than the FFS program in the state.[18]

Six states' MCOs (21%) uniformly do not require a specialist to prescribe or consult prior to treatment with DAAs, as opposed to 14 state (27%) FFS programs. Three states (10%) have at least one MCO that does not impose prescriber restrictions, as well as at least one MCO that requires either a specialist to consult or prescribe themselves. Five states' MCOs (17%) only require that a specialist is consulted before treatment, whereas 28 state FFS programs (55%) share this criterion. Ten states (34%) have at least one MCO that only requires consultation, as well as at least one MCO that requires a specialist to prescribe. Another 5 states' MCOs (17%) uniformly require a specialist prescribe DAA therapy, as opposed to 9 state FFS programs (18%).

[18] 42 CFR § 438.210.

Chart 6: Comparing 2017 Medicaid MCO and FFS Prescriber Restrictions				
Category	**Number of States with Managed Care Prescriber Restriction**	**States**	**Number of States with FFS Prescriber Restriction**	**States**
No restrictions	6 (21%)[19]	California, Georgia, Massachusetts, Nebraska, Nevada, New Mexico	14 (27%)	Alaska, Alabama, California, Connecticut, Delaware, Georgia, Massachusetts, Missouri, Nebraska, Nevada, New Mexico, North Carolina, Wisconsin, Wyoming
No restrictions-By or in consultation with specialist	1 (3%)	New York	N/A	N/A
No restrictions-Specialist must prescribe	2 (7%)	Kentucky, Utah	N/A	N/A
By or in consultation with specialist	5 (17%)	Colorado, Florida, Kansas, Mississippi, Texas	28 (55%)	Arizona, Colorado, District of Columbia, Florida, Hawaii, Idaho, Illinois, Indiana, Kansas, Kentucky, Maine, Maryland, Michigan, Minnesota, Mississippi, New Hampshire, New York, North Dakota, Oklahoma, Oregon, Puerto Rico, South Carolina, Texas, Utah, Vermont, Virginia, Washington, West Virginia
By or in consultation with specialist-Specialist must prescribe	10 (34%)	Arizona, District of Columbia, Hawaii, Illinois, Maryland, Minnesota, Ohio, Oregon, Pennsylvania, Virginia	N/A	N/A
Specialist must prescribe	5 (17%)	Delaware, Iowa, Louisiana, New Jersey, Rhode Island	9 (18%)	Arkansas, Iowa, Louisiana, Montana, Ohio, Pennsylvania, Rhode Island, South Dakota, Tennessee
No Managed Care Program	12	Alabama, Alaska, Arkansas, Connecticut, Idaho, Maine, Montana, North Carolina, Oklahoma, South Dakota, Vermont, Wyoming	N/A	N/A
HCV Medications Carved Out of MCO Contracts	10	Indiana, Michigan, Missouri, New Hampshire, Puerto Rico, South Carolina, Tennessee, Washington, West Virginia, Wisconsin	N/A	N/A
Restrictions Unknown	1	North Dakota	1	New Jersey

[19] Percentages are calculated based on the number of states that had MCOs with known restrictions in a given year. For 2017, 29 states had MCOs with known restrictions for prescribing privileges.

DISCUSSION

Moving Toward Transparency

The most striking difference between our 2014 and 2017 findings is the extent to which jurisdictions are transparent about the criteria that Medicaid beneficiaries must meet to qualify for HCV treatment. In 2014, 18 jurisdictions did not publish or disclose information about fibrosis restrictions, 15 did not publish sobriety restrictions, and 23 did not publish prescriber restrictions. In 2017, all jurisdictions disclosed their criteria, with one exception. In New Jersey, the FFS program's prescriber restrictions remain unclear.

The willingness of states to communicate clearly about their restrictions is welcome and necessary. Providers and patients deserve to know the impediments that exist or do not exist in obtaining HCV treatment within each plan offered in their state. By clarifying their requirements, states have alleviated some of the concerns and uncertainty about treatment in the HCV-affected community. Accurate, up-to-date information is vital to ensuring that individuals who need treatment receive it and that those who are denied treatment are clear as to the reasons why. Plain and simple language, regularly updated on each state's website, is also imperative to educate the public and policymakers about where progress is needed to achieve universal HCV treatment.

Fewer Restrictions Based on Disease Severity

Our findings reveal that more states are eliminating or reducing restrictions that ration treatment according to severity of illness. In 2014, FFS programs in 4 states (Connecticut, Delaware, Illinois, and Oregon) required patients to demonstrate cirrhosis (F4) to qualify for treatment. In 2017, that number stands at zero. Most notably, Connecticut opened access to all patients regardless of disease stage. After Connecticut became the first state to open access on this basis, 17 additional jurisdictions (16 states and Puerto Rico) have joined suit and have removed all disease severity restrictions from their FFS programs.

The number of jurisdictions requiring individuals to demonstrate advanced fibrosis (F3) in their FFS programs has also dropped from 27 (26 states and the District of Columbia) in 2014 to 12 states in 2017. Many of the jurisdictions that had required patients to demonstrate F3 now require them to demonstrate F2. The FFS programs of 18 jurisdictions (17 states and the District of Columbia) require individuals to demonstrate moderate fibrosis (F2) in order to obtain treatment. Four states (Hawaii, New Mexico, Pennsylvania, and Utah) mandate progression to mild fibrosis (F1) for treatment.

MCO programs in 10 states have more restrictive fibrosis criteria than their FFS counterparts despite the legal obligation that MCO programs must not offer less comprehensive or more restrictive treatment than their state's FFS programs.[20] Seven of those states operate MCOs that

[20] 42 CFR § 438.210.

demand progression to F2-F3. For example, Georgia has some MCOs that require progression to F3 although the FFS program maintains no fibrosis restrictions. Patients with HCV are entitled to treatment regardless of whether they are enrolled in an MCO or FFS program. State Medicaid programs must ensure that eligibility criteria remain consistent and that managed care does not equate to denial of care.

With over a third of states currently imposing no fibrosis restrictions on patients, progress toward full compliance with the law among Medicaid programs is now undeniable. However, a majority of states still withhold treatment until patients have progressed to F1 or higher. Among them, 30 states require individuals to demonstrate F2 or F3.[21]

Sobriety Requirements Remain Pervasive

Unfortunately, many states have maintained discriminatory sobriety restrictions to HCV treatment, even when they have relaxed restrictions based on disease severity and/or prescriber type.

The most drastic example is Louisiana, which since 2014 has required individuals to demonstrate 12 months of sobriety before qualifying for treatment. North Dakota also imposes a 12 month sobriety restriction. Illinois, which required 12 months of sobriety in 2014, has since moved in a more positive direction and now only requires screening and counseling before access to treatment.

In 2014 and 2017, 18 jurisdictions require 6 months of sobriety before initiating treatment (although some of the jurisdictions have changed). Five states impose a 3 month sobriety restriction (largely unchanged since 2014). Florida and Wyoming remain, as they did in 2014, the only two states that impose a 1 month sobriety requirement. Fifteen jurisdictions (14 states and the District of Columbia) impose the slightly less punitive – but still obstructive – requirement of screening and counseling.

Twenty-five states do not require individuals meet sobriety criteria before obtaining treatment, with 15 of those states requiring screening and counseling. Thus, 53% of jurisdictions impose mandated sobriety periods on Medicaid patients.

Remarkably, some states have clung to sobriety restrictions even as they have loosened fibrosis restrictions. North Dakota requires patients to abstain from drugs and alcohol for a full year, but does not require them to advance to a specific stage of liver damage. Four jurisdictions (Maine, Mississippi, Puerto Rico, and Wisconsin) impose no fibrosis restrictions but maintain a 6 month sobriety requirement. Neither Florida nor Wyoming impose fibrosis restrictions, yet both persist in requiring 1 month of sobriety.

[21] At the time of publication, four jurisdictions have announced plans to drop or to consider dropping fibrosis restrictions but have not done so yet: Missouri, New Mexico, North Carolina, and Ohio.

Despite evidence that injection drug use is now the cause of most new reported HCV infections,[22] some states with the highest rates of opioid overdose and HCV block patients from receiving treatment by imposing sobriety restrictions. Both Kentucky and Tennessee require individuals to demonstrate 6 months of sobriety before accessing treatment. West Virginia imposes a 3 month sobriety requirement. In contrast, Indiana, which suffered a notorious outbreak of HCV and HIV in 2015, treats patients without imposing any sobriety requirements.

Ample research disproves the dangerous contention that DAA therapy is less effective in people who use drugs or alcohol. A recent review of several studies examining treatment response in people who inject drugs revealed adherence, completion, and cure rates comparable to those in people who do not use drugs.[23] In another analysis involving 17,487 patients starting DAA therapy, researchers found no significant differences in cure rates between people who abstained from alcohol and people who drank alcohol.[24] The AASLD/IDSA treatment guidelines point to the high adherence rates and low reinfection rates among people who inject drugs in arguing that sobriety restrictions must be removed to combat the HCV epidemic most effectively.[25]

Policymakers in all jurisdictions must acknowledge the lack of medical and scientific evidence to support sobriety requirements. These discriminatory restrictions merely manifest the stigma surrounding alcohol and drug use, which can often discourage people who use drugs or alcohol from seeking HCV testing and treatment. When states impose sobriety-based barriers to treatment, they not only miss an opportunity to curb the spread of HCV, they also institutionalize and perpetuate stigma.

Finally, the unfortunate trend of some jurisdictions allowing MCOs to implement more restrictive criteria than their respective FFS program applies to sobriety restrictions as well. The MCOs in 8 states impose more restrictive sobriety requirements than their FFS counterparts. The governments of all jurisdictions must act to ensure that MCOs and FFS programs employ consistent criteria, as required by law, in their administration of treatment to HCV patients.

Clarifying Prescriber Limits

The trend toward transparency has dispelled some confusion about whether patients in certain states must first visit or consult a specialist before receiving treatment. In 2014, 23 jurisdictions (22 states and Puerto Rico) did not publish information about prescriber limitations. In 2017, prescriber restrictions are now unknown in only one state: New Jersey.

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[22] Campbell, Canary, Smith, et al., *State HCV Incidence and Policies Related to HCV Preventive and Treatment Services for Persons Who Inject Drugs — United States, 2015–2016*, 66 MMWR 1 (2017).
[23] Grebely J., Hajarizadeh B., and Dore G., *Direct-acting antiviral agents for HCV infection affecting people who inject drugs*, 106 NAT REV GASTROENTEROL HEPATOL 1 (2017).
[24] Tsui J, Williams E, Green P, Berry K, Su F, and Ioannou G., *Alcohol use and hepatitis C virus treatment outcomes among patients receiving direct antiviral agents*, 169 DRUG ALCOHOL DEPEND 101 (2016).
[25] The American Association for the Study of Liver Diseases and the Infectious Diseases Society of America, HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C, Sep. 21, 2017, *available at* https://www.hcvguidelines.org/.

Encouragingly, fewer jurisdictions now require patients to visit a specialist to receive treatment. Fourteen states impose no prescriber restrictions in 2017, whereas no state met this criteria in 2014. In 2014, 15 states required prescriptions by a specialist only. In 2017, 9 states require a specialist to prescribe. However, as more jurisdictions are transparent about prescriber restrictions, their barriers to treatment have emerged. While 14 jurisdictions required prescriptions by or in consultation with a specialist in 2014, 28 jurisdictions (26 states, the District of Columbia, and Puerto Rico) now impose this requirement.

Finally, just as some MCOs impose more restrictive fibrosis and sobriety criteria than the FFS program in their states, some impose more restrictive prescriber limits. Eleven states and the District of Columbia contract with at least one MCO with harsher prescriber restrictions than the FFS program in those jurisdictions. Seven of these states overlap with those operating MCOs that impose more restrictive fibrosis criteria.

CONCLUSION

In evaluating Medicaid HCV treatment criteria from 2014 to 2017, a few key trends emerge. Many states continue to violate their treatment obligations under the law despite strong, clear guidance from the Centers for Medicare and Medicaid Services that current restrictions violate federal law. Additionally, the restrictions in place directly contradict the standard of care outlined in the treatment guidelines established by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America.

Despite the persistence of too many restrictions, significant progress has been made:

- Many more states have publicly available information regarding access restrictions to HCV treatment than states did in 2014;
- Access restrictions, particularly for liver damage, have decreased since 2014; and
- We now have baseline information on MCO restrictions from which to evaluate future trends.

We must build on the progress that has been made in lessening liver damage restrictions and eliminate these restrictions nationwide. Similarly, we must work to ensure that restrictions based on sobriety and prescriber specialty follow suit. To accomplish this goal and work towards eliminating HCV, we must hold federal and state regulators accountable for ensuring that people living with HCV have access to treatment consistent with established treatment guidelines and relevant federal and state laws. Most importantly, we must ensure that the Centers for Medicare and Medicaid Services, as well as other federal and state regulators, monitor and enforce parity between Medicaid FFS and MCO programs. At a minimum, regulators must ensure that MCOs

do not impose more restrictive treatment access criteria than their corresponding FFS program, as required by law.

With the availability of live-saving cures for HCV, policymakers and advocates must push to eliminate unnecessary, discriminatory, and illegal barriers to care, and help ensure all Medicaid beneficiaries can access the cure for this deadly disease.