Hepatitis C:

The State of Medicaid Access

Preliminary Findings: National Summary Report

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CENTER *for* HEALTH LAW *and* POLICY INNOVATION
HARVARD LAW SCHOOL

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Introduction

The advent in 2013 of direct acting antiviral agents (DAAs) to combat Hepatitis C (HCV) is a major development in treating 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 limit access to DAAs due to cost concerns. These limitations, generally expressed in prior authorization requirements, form a significant barrier to care for millions of Americans enrolled in Medicaid, despite clear guidance from the Centers for Medicare and Medicaid Services[1] that such restrictions often violate federal law. Additionally, they 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 Disease 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 fee-for-service (FFS) restrictions in access to DAAs in state Medicaid programs from December 2014.[3] Since December 2014, access to DAAs in state Medicaid programs has been incrementally expanded, generally in response to advocacy and impact litigation. In our 2016 "Hepatitis C: The State of Medicaid Access" survey, CHLPI and the National Viral Hepatitis Roundtable (NVHR) are updating and expanding upon the initial survey to document the current state of access to DAAs for Medicaid enrollees across America. The 2016 survey of Medicaid restrictions on HCV treatment access provides an in-depth evaluation of DAAs access in each state's Medicaid program while highlighting successes in access expansion as well as ongoing challenges. It evaluates HCV treatment access through the end of October 2016. The data presented in this National Summary is preliminary and may be subject to revision in the coming months.

The 2016 survey focuses on three of the most significant restrictions to treatment: 1) fibrosis criteria (liver damage or disease progression requirements); 2) sobriety requirements (periods of abstinence from substance use requirements prior to and/or during treatment); and 3) prescriber limitations (medical provider requirements as to eligibility for reimbursement for treatment prescribed).

Overall, our analysis of the preliminary data generated by the 2016 survey reveals that from 2014-16 transparency as to state Medicaid program HCV treatment access restrictions has increased. The overwhelming majority of states now have their HCV treatment restriction criteria readily available. In a few cases, however, states' HCV treatment requirements remain only available through direct communication with officials and, in even fewer cases, despite repeated efforts to identify restrictions, they remain unknown. 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

[1] Centers for Medicare and Medicaid Services, Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs (Release No. 172), Nov. 5, 2015.
[2] AASLD-IDSA recommendations for testing, managing, and treating adults infected with hepatitis C virus. *Hepatology* 2015;62:932-954.
[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," *Ann Intern Med.* 2015; 163:215-223.

prescriber limitations have also improved. Lastly, as Medicaid programs increasingly enroll Medicaid beneficiaries into managed care organizations (MCOs), the 2016 survey provides us with a first-time national assessment of MCO coverage of HCV treatment. In general, the findings indicate that while there are some MCOs with low levels of restrictions, many follow their states' FFS Medicaid restrictions, and others impose more onerous restrictions.

The 2016 survey identifies the progress being made to ease Medicaid access to HCV restrictions as well as the next steps to further expand access to care. As required by federal Medicaid law and national treatment guidelines, state Medicaid programs should eliminate the remaining onerous restrictions around fibrosis, sobriety, and prescriber limitations. Increased scrutiny must also be given to the MCOs because of the increasing number of Medicaid enrollees funneled into managed care. As with Medicaid FFS, no MCO should require restrictive reimbursement criteria for access to HCV treatment.

Methods

We evaluated Medicaid reimbursement criteria for available DAAs for all 50 states and the District of Columbia. The information for 2014 was gleaned from the survey published in the Annals of Internal Medicine. That survey drew upon state Medicaid web site materials posted between June 23 and December 7, 2014. Data for 2014 was extracted by two coauthors in duplicate and entered into a standardized spreadsheet, with two different coauthors crossing the extracted data. Any differences were resolved by consensus. For the 2016 "Hepatitis C: The State of Medicaid Access" survey, we again searched state Medicaid web sites for publically available reimbursement criteria, beginning in May 2016 and ending on October 31, 2016. Data for 2016 was initially extracted by students working with CHLPI and then crosschecked by CHLPI and NVHR staff. Any differences were resolved by consensus. For each state, in both 2014 and 2016, the following data were extracted from Medicaid reimbursement criteria: whether DAAs were covered (paid for by Medicaid) and the criteria for coverage; the date of the state Medicaid reimbursement publication; and uniform resource locators of the prior authorization. The preferred drug lists were also recorded and entered either into a database or into a narrative document evaluating access to HCV treatment for that state's Medicaid program.

In 2016, when a state did not post information online, we placed calls to the applicable Medicaid office to clarify, if possible. States were only classified as "No Restrictions" if they publically confirmed that no restrictions existed, through reimbursement criteria, press and media materials, or if a Medicaid official was willing to go on the record as confirming that no restrictions existed. In some cases, states were listed as "Restrictions Unknown" because the reimbursement criteria were silent and Medicaid representatives were willing to state that no restrictions existed, but were not willing to go on the record with that confirmation.

Criteria for DAA coverage based on the following categories were recorded: liver disease stage, prescriber type, and drug or alcohol use. For criteria about liver disease staging, data were collected on the level of fibrosis required for reimbursement (either No Restrictions, Chronic HCV, Meta-Analysis of Histologic Data in Viral Hepatitis [METAVIR] fibrosis stage F1 through F4, or Restrictions Unknown). For criteria regarding sobriety, data were collected on any screening and abstinence requirements for reimbursement (either No Restrictions, Screening and Counseling, Abstain for 1 Month, Abstain for 3 Months, Abstain for 6 Months, Abstain for 12 Months, or Restrictions Unknown). For prescriber type, data were collected on whether there were limitations on which providers could write DAA prescriptions (either No Restrictions, By or in Consultation with Specialist, Specialist Must Prescribe, or Restrictions Unknown).

Our 2016 "Hepatitis C: The State of Medicaid Access" survey on HCV treatment access expanded in scope on the 2014 work by examining the HCV treatment access criteria for Medicaid managed care, in addition to the FFS Medicaid programs examined in 2014 and 2016. It is important to note that because multiple MCOs may operate in a state, the restrictions on access to HCV treatment for that state's Medicaid managed care plans 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 only require evidence of chronic HCV. For the purposes of the 2016 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 position on access restrictions. If we were unable to confirm any MCO's access restrictions, we classified that state as "Restrictions Unknown." If we were able to confirm at least one MCO's position, however, we categorized that state accordingly instead of relegating it to the "Restrictions Unknown" category.

Findings: Liver Disease Stage Requirements

Liver disease stage (fibrosis) restrictions are one of the foremost barriers to access for DAAs in state Medicaid programs. Since 2014, progress has been made in easing these restrictions, but too many states continue to limit access to only those individuals who's HCV has progressed to serious liver damage as evidenced by advanced fibrosis (F3) or cirrhosis (F4). By requiring patients to demonstrate serious liver damage before they can be treated for HCV, Medicaid programs are forcing individuals to wait until their health worsens in order to access the cure for HCV.

Comparing 2014 and 2016 Medicaid Fee-for-Service Liver Disease Requirements

Transparency in the liver disease stage requirement landscape improved dramatically since 2014, with a significant number of states clarifying their fibrosis requirements for HCV treatment. In 2016, including the District of Columbia, 50 states have a fee-for-service Medicaid program, and of these 49 states, 44 have known criteria (88%). This is opposed to only 34 states (67%) in 2014. Most importantly, in 2016, of the states with known criteria, many states eased their liver disease stage restrictions. In 2016, five states (11%) of states with known fibrosis reimbursement requirements have no fibrosis requirement for access to HCV medications. In 2014, no state met this criterion. In 2016, four states (9%) require individuals to demonstrate "chronic HCV," but explicitly do not require a fibrosis score to qualify for treatment. No state met this criterion in 2014. In 2016, two states (5%) require an individual to demonstrate mild fibrosis (F1) as opposed to one state (3%) in 2014. In 2016, ten states (23%) require an individual to demonstrate at least moderate fibrosis (F2) as compared to two states (6%) in 2014.

While it is clear that many states continue to require patients to demonstrate serious liver damage before they can be treated for HCV, the 2016 findings demonstrate that there is a dramatic improvement over 2014. In 2014, of the 34 states with known criteria, 31 states (91%) limited access to HCV treatment to only those experiencing advanced fibrosis or cirrhosis; with 27 states (79%) requiring advanced fibrosis (F3), and 4 states (12%) requiring cirrhosis of the liver (F4). In comparison, of the 43 states with known liver disease state restriction criteria in 2016, 22 states (50%) require at least advanced fibrosis

(F3) to qualify for treatment. In 2016, only one state (2%) requires the demonstration of cirrhosis of the liver.

Chart 1: Comparing 2014 and 2016 Medicaid FFS Liver Disease Requirements

Category	2014 FFS Liver Disease Restriction	States 2014 FFS Liver Disease Restriction	2016 FFS Liver Disease Restriction	States 2016 FFS Liver Disease Restriction
No Restrictions	0 (0%)[4][5]	None	5 (11%)[6]	Connecticut, Florida, Massachusetts, New York, Wyoming
Chronic HCV	0 (0%)	None	4 (9%)	Arizona, Georgia, Nevada, Washington
F1	1 (3%)	Maine	2 (5%)	North Dakota, Utah
F2	2 (6%)	Maryland, Oklahoma	10 (23%)	Alaska, California, District of Columbia, Idaho, Maryland, North Carolina, Oklahoma, Pennsylvania, Virginia, Wisconsin
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	22 (50%)	Arkansas, Colorado, Delaware, Hawaii[7], Indiana, Iowa, Kansas, Louisiana, Michigan, Minnesota, Missouri, Montana, Nebraska, New Jersey, Ohio, Oregon, Rhode Island, South Carolina, South Dakota, Texas, Vermont, West Virginia
F4	4 (12%)	Connecticut, Delaware, Illinois, Oregon	1 (2%)	Illinois
Restrictions Unknown	17	Alabama, Georgia, Hawaii, Kansas, Massachusetts, Michigan, Minnesota, Mississippi, New Jersey, New Mexico, Nevada, North Carolina, North Dakota, South Carolina, Texas, Utah, Wyoming	7	Alabama, Kentucky, Maine, Mississippi, New Hampshire, New Mexico, Tennessee

[4] 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 restrictions for fibrosis.
[5] Due to rounding, percentages in each chart may not add up to 100%.
[6] Percentages are calculated based on the number of states that had known restrictions in a given year. For 2016 FFS Medicaid programs, 44 states had known restrictions for fibrosis.
[7] Hawaii has confirmed that as of January 1, 2017, both its FFS and managed care programs will only require demonstration of mild fibrosis (F1). In 2016, both programs require demonstration of advanced fibrosis (F3).

Comparing 2016 Medicaid Fee-for-Service and Medicaid Managed Care Organization Liver Disease Requirements

In 2016, 46 states, including the District of Columbia, have Medicaid MCOs[8] as five states do not have MCOs in their Medicaid program. As to transparency, of the 46 states with MCOs, 42 states (91%) have known liver disease restriction criteria, as opposed to only 44 states (88%) out of the 50 jurisdictions with a FFS program. Of the 42 states with MCOs with available information, eight states (19%) have liver disease stage requirements for accessing HCV treatment that are more restrictive than their corresponding fee-for-service program. This is the case despite the fact that MCOs must, by law, offer similar or less restrictive coverage to the FFS program in the state.[9]

Two states with MCOs (5%) have no liver disease stage restrictions. Five state FFS programs (11%) have no restrictions, including the two states that have no restrictions in either their MCO or FFS programs, two states that do not have a managed care program, and one state that has unrestricted access in FFS but whose MCOs require individuals to demonstrate advanced fibrosis (F3) for treatment access. Three states with MCOs (9%) have at least one plan that requires individuals to demonstrate "chronic HCV," but explicitly does not require a fibrosis score to qualify for treatment. Three of the four states with MCOs that require the demonstration of chronic HCV also have at least one MCO plan with stricter fibrosis requirements, with two states having at least one MCO plan that requires advanced fibrosis (F3) and one state having at least one MCO plan that requires cirrhosis of the liver (F4). This is compared to the FFS program in four states (9%) that require individuals to demonstrate chronic HCV. One state with MCOs (2%) has an MCO that requires individuals to demonstrate mild fibrosis (F1), although it also has at least one MCO plan that requires advanced fibrosis (F3). Two state FFS programs (5%) require individuals to demonstrate mild fibrosis (F1). In seven states with MCOs (16%), all of the MCOs require individuals to demonstrate at least moderate fibrosis (F2). Two additional states with MCOs (5%) have at least one MCO plan that limits access to individuals with moderate fibrosis (F2), but also include at least one MCO plan in the state that requires individuals to demonstrate advanced fibrosis (F3). Ten states have FFS programs (23%) that require individuals to demonstrate at least moderate fibrosis (F2). Twenty-six states with MCOs (62%) require individuals to demonstrate advanced fibrosis (F3) to access HCV treatment. Twenty-two state FFS programs (50%) have a similar requirement. Only one state (2%) FFS program, and no state managed care program, requires individuals to demonstrate cirrhosis of the liver (F4) to access HCV treatment.

[8] In some cases, states did not have a managed care program, but did have a primary care case management (PCCM) model. States with PCCMs, such as North Carolina, were counted as having managed care.
[9] 42 CFR § 438.210.

Chart 2: Comparing 2016 Medicaid MCO and FFS Liver Disease Requirements				
Category	**MCO Liver Disease Restriction**	**States MCO Liver Disease Restriction**	**FFS Liver Disease Restriction**	**States FFS Liver Disease Restriction**
No Restrictions	2 (5%)[10]	Florida, Massachusetts,	5 (11%)	Connecticut, Florida, Massachusetts, New York, Wyoming
Chronic HCV	1 (2%)	Washington	4 (9%)	Arizona, Georgia, Nevada, Washington
Chronic HCV-F3	2 (5%)	Illinois, New Hampshire	N/A	N/A
Chronic HCV-F4	1 (2%)	Indiana	N/A	N/A
F1	0 (0%)		2 (5%)	North Dakota, Utah
F1-F3	1 (2%)	Minnesota	N/A	N/A
F2	7 (16%)	California, Missouri, New Mexico, North Carolina, Pennsylvania, Tennessee, Wisconsin	10 (23%)	Alaska, California, District of Columbia, Idaho, Maryland, North Carolina, Oklahoma, Pennsylvania, Virginia, Wisconsin
F2-F3	2 (5%)	District of Columbia, Maryland	N/A	N/A
F3	26 (62%)	Arizona, Arkansas, Colorado, Delaware, Georgia, Hawaii, [11] Iowa, Kansas, Kentucky, Louisiana, Michigan, Montana, Nebraska, Nevada, New Jersey, New York, Ohio, Oregon, Rhode Island, South Carolina, South Dakota, Texas, Utah, Vermont, Virginia, West Virginia	22 (50%)	Arkansas, Colorado, Delaware, Hawaii, Indiana, Iowa, Kansas, Louisiana, Michigan, Minnesota, Missouri, Montana, Nebraska, New Jersey, Ohio, Oregon, Rhode Island, South Carolina, South Dakota, Texas, Vermont, West Virginia
F4	0 (0%)	None	1 (2%)	Illinois
No MCO Program	5	Alaska, Connecticut, Idaho, Maine, Wyoming	N/A	N/A
Restrictions Unknown	4	Alabama, Mississippi, North Dakota, Oklahoma	7	Alabama, Kentucky, Maine, Mississippi, New Hampshire, New Mexico, Tennessee

Findings: Sobriety Requirements

Another common restriction on HCV treatment access is sobriety requirements. Some Medicaid programs require individuals to not have evidence of a diagnosis of drug and/or alcohol abuse within a certain timeframe prior to starting treatment. Other states require all individuals to submit to drug and/or alcohol testing before the start of treatment or to attest to a certain period of abstinence prior to beginning treatment. Medicaid programs

[10] Percentages are calculated based on the number of states that had known restrictions in a given year. For 2016 Managed Care Medicaid programs, 42 states had known restrictions for fibrosis.
[11] Hawaii has confirmed that as of January 1, 2017, both its FFS and managed care programs will only require demonstration of mild fibrosis (F1). In 2016, both programs require demonstration of advanced fibrosis (F3).

that do not require a period of sobriety may nevertheless require individuals who test positive for drug or alcohol use to undergo substance abuse treatment or obtain counseling.

These common restrictions on care undermine the recommendations of the AASLD. Research suggests that active or recent injection drug users show similar HCV treatment outcomes as compared to patients who do not use drugs.[12] Additionally, injection drug use is one of the driving factors in the perpetuation of the HCV epidemic in the United States. As the AASLD guidelines note, "testing and linkage to care combined with the treatment of HCV infection with potent IFN-free regimens [DAAs] has the potential to dramatically decrease HCV incidence and prevalence."[13] By postponing access to care for people who use substances or otherwise do not maintain sobriety, Medicaid programs are actually undermining public health efforts to end the HCV epidemic while also allowing the health of these individuals to further deteriorate.

Comparing 2014 and 2016 Medicaid Fee-for-Service Sobriety Requirements

At the time of the Annals of Medicine survey in 2014, 37 states (73% of states with an FFS program) had known sobriety requirements, including drug or alcohol use in their eligibility criteria for reimbursement. In 2016, 41 states (82% of states with an FFS program) had known sobriety requirements, so some progress has been made in terms of greater transparency.

In 2016, of the states with known sobriety criteria, four states (10% of states with an FFS program and known sobriety requirements) have confirmed that they have eliminated any abstinence period or mandated screening for substance use as a requirement for treatment. No state met these criteria in 2014. The number of states that required screening and counseling, but imposed no abstinence restrictions, changed from nine states (24%) in 2014 to eight states (20%) in 2016. As in 2014, two states (5%) in 2016 require individuals to demonstrate at least one month of sobriety before receiving treatment. Six states (15%) in 2016 require individuals to demonstrate at least three months sobriety before or receiving treatment as compared to six states (16%) in 2014. The number of states requiring that individuals abstain from drug and/or alcohol use for six months prior to receiving HCV treatment remained constant from 2014 to 2016 at 18 states (but decreased as a percentage of all states with FFS programs and known sobriety requirements from 49% in 2014 to 44% in 2016). Three states (7%) in 2016 require a year of abstinence before treatment, as opposed to two states (5%) in 2014.

[12] 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. *Clin Infect Dis.* 2013;57(Suppl 2):S80-S89.
[13] AASLD-IDSA recommendations for testing, managing, and treating adults infected with hepatitis C virus. *Hepatology* 2015;62:932-954.

Chart 3: Comparing 2014 and 2016 Medicaid FFS Sobriety Requirements				
Category	**2014 FFS Sobriety Restriction**	**States 2014 FFS Sobriety Restriction**	**2016 FFS Sobriety Restriction**	**States 2016 FFS Sobriety Restriction**
No Restrictions	0 (0%)[14]	None	4 (10%)[15]	Connecticut, District of Columbia, Massachusetts, Wyoming
Screening and Counseling	9 (24%)	Arkansas, Maine, Massachusetts, New Hampshire, New York, North Carolina, Ohio, Vermont, Virginia	8 (20%)	Delaware, Georgia, New York, North Carolina, Oregon, Pennsylvania, South Carolina, Virginia
Abstain for 1 Month	2 (5%)	Florida, Wyoming	2 (5%)	Florida, Texas
Abstain for 3 Months	6 (16%)	Alaska, Delaware, District of Columbia, Iowa, Missouri, Washington	6 (15%)	Alaska, Hawaii, Iowa, Missouri, New Jersey, 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 (44%)	Alabama, Arizona, Arkansas, Colorado, Idaho, Kansas, Maine, Maryland, Minnesota, Mississippi, Montana, Nebraska, Ohio, Oklahoma, Rhode Island, South Dakota, Vermont, Wisconsin
Abstain for 12 Months	2 (5%)	Illinois, Louisiana,	3 (7%)	Illinois, Louisiana, North Dakota
Restrictions Unknown	14	Connecticut, Indiana, Georgia, Hawaii, Kansas, Michigan, New Jersey, Minnesota, Nevada, New Mexico, North Dakota, South Carolina, Texas, Utah	10	California, Indiana, Kentucky, Michigan, Nevada, Tennessee, Utah, Washington, New Hampshire, New Mexico

Comparing 2016 Medicaid Fee-for-Service and Managed Care Organization Sobriety Requirements

In 2016, 42 states, including the District of Columbia, have Medicaid MCOs with known sobriety requirements, as five states do not have MCOs in their Medicaid program and four states do not have available information. Of the 42 states with known sobriety criteria, in five states (12%) at least one MCO has sobriety requirements for accessing HCV treatment that are more restrictive than their corresponding FFS program. This is the case despite the fact that MCOs must, by law, offer similar or less restrictive coverage to the FFS program in the state.[16]

[14] 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.
[15] Percentages are calculated based on the number of states that had known restrictions in a given year. For 2016 FFS Medicaid programs, 41 states had known restrictions for sobriety.
[16] 42 CFR § 438.210.

There was no state in which all the MCOs in the state confirmed that they had no sobriety restrictions, despite the four states with no such restrictions in their FFS program. In eight (19%) of the 42 states with publically available reimbursement criteria for managed care the MCOs require screening and counseling as opposed to 8 state FFS programs (20%). The MCOs in two states (5%) uniformly required one month of abstinence, consistent with their corresponding FFS programs' requirements. In three states (7%) individuals enrolled in an MCO must abstain for at least three months prior to treatment as opposed to six FFS programs (15%). In 15 states (36%), the MCOs uniformly required individuals to abstain from substance use for at least six months prior to treatment. By contrast, 18 FFS programs (44%) had the same requirements. There were no states in which all MCOs required a full year of abstinence, as opposed to three FFS programs (7%) that imposed that requirement. In 14 states (33%), the MCO requirements for sobriety varied significantly, generally with at least one MCO requiring only screening and at least one MCO requiring three to six months of abstinence prior to commencing treatment.

Chart 4: Comparing 2016 Medicaid MCO and FFS Sobriety Requirements

Category	MCO Sobriety Restriction	States MCO Sobriety Restriction	FFS Sobriety Restriction	States FFS Sobriety Restriction
No Restrictions	0 (0%)[17]	None	4 (10%)	Connecticut, District of Columbia, Massachusetts, Wyoming
Screening and Counseling	8 (19%)	Delaware, Iowa, Massachusetts, Missouri, New Mexico, North Carolina, Pennsylvania, South Carolina	8 (20%)	Delaware, Georgia, New York, North Carolina, Oregon, Pennsylvania, South Carolina, Virginia
Abstain for 1 Month	2 (5%)	Florida, Texas	2 (5%)	Florida, Texas
Abstain for 3 Months	3 (7%)	Hawaii, Nebraska, West Virginia	6 (15%)	Alaska, Hawaii, Iowa, Missouri, New Jersey, West Virginia
Abstain for 6 Months	15 (36%)	Alabama, Arizona, Colorado, Kansas, Minnesota, Mississippi, Montana, New Jersey, New Hampshire, North Dakota, Rhode Island, South Dakota, Tennessee, Vermont, Wisconsin	18 (44%)	Alabama, Arizona, Arkansas, Colorado, Idaho, Kansas, Maine, Maryland, Minnesota, Mississippi, Montana, Nebraska, Ohio, Oklahoma, Rhode Island, South Dakota, Vermont, Wisconsin
Abstain for 12 Months	0 (0%)		3 (7%)	Illinois, Louisiana, North Dakota
Varied[18]	14 (33%)	District of Columbia, Georgia, Illinois, Indiana, Kentucky, Louisiana, Maryland, Michigan, Nevada, New York, Ohio, Oregon, Utah, Virginia	N/A	N/A
No MCO Program	5	Alaska, Connecticut, Idaho, Maine, Wyoming	N/A	N/A

[17] Percentages are calculated based on the number of states that had known restrictions in a given year. For 2016 Managed Care Medicaid programs, 42 states had known restrictions for sobriety.
[18] Most states in this category had significant and problematic variation between MCOs for sobriety requirements. Generally in these states at least one MCO required only screening and at least one MCO required three to six months of abstinence prior to commencing treatment.

Restrictions Unknown	4	Arkansas, California, Oklahoma, Washington	10	California, Indiana, Kentucky, Michigan, Nevada, Tennessee, Utah, Washington, New Hampshire, New Mexico

Findings: Prescriber Requirements

Medicaid programs sometime restrict access to HCV treatment by limiting which providers are eligible to prescribe treatment, often only including specialists, such as hepatologists or gastroenterologists. Medicaid programs that limit reimbursement for prescriptions written only by or in consultation with 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. DAAs, as a category, have relatively few side effects and are not difficult to monitor during the short course of treatment. Providers who are skilled and experienced at treating people living with HCV, whether or not they are a specialist, should be allowed to write prescriptions for DAAs and to treat people living with HCV.

Comparing 2014 and 2016 Medicaid Fee-for-Service Prescriber Requirements

In 2016, transparency regarding prescriber limitations increased. Only 15 states (30%) of the 50 states with a FFS program in 2016 did not have known prescriber requirements for HCV treatment reimbursement as compared to 22 states (43%) of the states with a FFS program in 2014. Of the remaining 36 states with known prescriber requirements, two (6%) confirmed that there are no prescriber limitations in place whereas no state met this criteria in 2014. Twenty-three (64%) of the states with publically available information on this issue would reimburse if a specialist prescribed or was consulted, as opposed to only 15 states (52%) in 2014. Another 11 states (31%) required a specialist to prescribe HCV treatment in order for the treatment to be reimbursable, as compared with 14 states (48%) in 2014.

Chart 5: Comparing 2014 and 2016 Medicaid FFS Prescriber Requirements				
Category	**2014 FFS Prescriber Restriction**	**States 2014 FFS Prescriber Restriction**	**2016 FFS Prescriber Restriction**	**States 2016 FFS Prescriber Restriction**
No Restrictions	0 (0%)[19]	None	2 (6%)[20]	Connecticut, Massachusetts
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	23 (64%)	Arizona, Colorado, District of Columbia, Florida, Hawaii, Idaho, Illinois, Indiana, Kansas, Maine, Michigan, Minnesota, Mississippi, Montana, New York, North Dakota, Oklahoma, Oregon, Utah, Virginia, Washington, West Virginia, Wisconsin
Specialist Must Prescribe	14 (48%)	Florida, Indiana, Iowa, Maine, Maryland, Montana, New Hampshire, New York, Ohio, Pennsylvania, Rhode Island, Tennessee, Washington, Wisconsin	11 (31%)	Iowa, Louisiana, Maryland, New Jersey, Ohio, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont
Restrictions Unknown	22	Alabama, Alaska, Arkansas, Delaware, District of Columbia, Georgia, Hawaii, Kansas, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Jersey, New Mexico, North Carolina, North Dakota, South Carolina, Vermont, Texas, Wyoming	15	Alabama, Alaska, Arkansas, California, Delaware, Georgia, Kentucky, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, North Carolina, South Carolina, Wyoming

Discussion

Increased Transparency

A positive change from 2014 to 2016 has been the number of states that have published their reimbursement criteria and clarified what restrictions exist when it comes to HCV treatment access. The most progress has been made to clarify fibrosis requirements. In

[19] 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.
[20] Percentages are calculated based on the number of states that had known restrictions in a given year. For 2016 FFS Medicaid programs, 36 states had known restrictions for prescribing privileges.

2014, 17 states (33%), either did not have publically available reimbursement criteria or their reimbursement criteria were silent on fibrosis restrictions, including Alabama, Georgia, Hawaii, Kansas, Massachusetts, Michigan, Minnesota, Mississippi, New Jersey, New Mexico, Nevada, North Carolina, North Dakota, South Carolina, Texas, Utah, and Wyoming. In 2016, only 7 states (14%), had not clarified their liver disease requirements, including Alabama, Kentucky, Maine, Mississippi, New Hampshire, New Mexico, and Tennessee.

Only limited progress has been made in clarifying sobriety restrictions. In 2014, 14 states (27%), had not clarified their sobriety requirements, including Connecticut, Indiana, Minnesota, Nevada, Utah, Georgia, Hawaii, Kansas, Michigan, New Jersey, New Mexico, North Dakota, South Carolina, and Texas. In 2016, ten states (20%), declined to clarify their position on sobriety requirements, including California, Indiana, Kentucky, Michigan, Nevada, Tennessee, Utah, Washington, New Hampshire, and New Mexico. Notably, five states went from having clear sobriety requirements in 2014 to being silent on their sobriety requirements in 2016, including California, Kentucky, New Hampshire, Tennessee, and Washington, although some of this change may be clarified by follow up with state Medicaid officials.

As to prescriber limitations, in 2014, 22 states (43%), were silent on prescriber limitations, including Alabama, Alaska, Arkansas, Delaware, District of Columbia, Georgia, Hawaii, Kansas, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Jersey, New Mexico, North Carolina, North Dakota, South Carolina, Vermont, Texas, and Wyoming. We have made some progress here as, in 2016, only 15 states (30%), were silent on this issue, including Alabama, Alaska, Arkansas, California, Delaware, Georgia, Kentucky, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, North Carolina, South Carolina, and Wyoming.

The number of states in 2016 that were in the "Restrictions Unknown" category would have likely been lower had the verification criteria been less strict. The 2016 "Hepatitis C: The State of Medicaid Access only considered a state as having confirmed the current status of HCV treatment restrictions when reimbursement materials, such a prior authorization forms, were publically available, press materials or an official statement were released confirming the current status, or a state Medicaid official was willing to go on the record as stating the current status of HCV treatment access restrictions. In some cases, such as in Maine and New Hampshire, the prior authorization materials were silent as to liver disease or fibrosis restrictions and while Medicaid representatives stated that no restrictions existed they were unwilling to provide their names, title, or go on the record with their statement. As a result, we consider this information to be unreliable and categorize the states of Maine and New Hampshire as "Restrictions Unknown" for liver disease. This use of stringent criteria stands for the principle that Medicaid programs must make their reimbursement criteria publically available and unambiguous. In other cases, such as Illinois, we were told that the Medicaid program is considering making changes, such as reducing the fibrosis requirement from F4 to F3, but had not yet publically committed to do so. NVHR and CHLPI will be mailing surveys to state Medicaid officials in this situation in the coming months, in the hope of obtaining official statements on fibrosis, sobriety, and prescriber requirements. This will hopefully allow us to shift some states out of the "Restrictions Unknown" category.

States that either do not make their reimbursement criteria public or remain silent on this issue should be strongly encouraged to clarify their HCV treatment access restrictions. Silence cannot be interpreted as no restriction existing. For example, in 2014, Alabama,

Georgia, Hawaii, Kansas, Massachusetts, Michigan, Minnesota, Mississippi, New Jersey, New Mexico, Nevada, North Carolina, North Dakota, South Carolina, Texas, Utah, and Wyoming were all silent on any fibrosis requirements in their reimbursement criteria. Ultimately, Massachusetts and Wyoming confirmed that they did not have any FFS Medicaid fibrosis restrictions. Georgia has since clarified that an individual must demonstrate chronic HCV. North Dakota and Utah have clarified that their fibrosis requirement is mild fibrosis (F1). North Carolina has clarified that individuals must demonstrate moderate fibrosis (F2) to qualify for treatment. Hawaii, Kansas, Michigan, Minnesota, New Jersey, South Carolina, and Texas have since clarified that an individual must demonstrate advanced fibrosis (F3). Alabama, Mississippi, and New Mexico remain silent. People living with HCV and their health providers should not be in the dark as to treatment criteria and as necessary we must all advocate for increased transparency in HCV treatment access.

Reduction or Elimination of Requirements

The preliminary results of the 2016 "Hepatitis C: The State of Medicaid Access" survey demonstrate that we are making progress in reducing or eliminating restrictions that pose a barrier to HCV care, especially as to fibrosis restrictions. Sixteen states reduced or eliminated their Medicaid fibrosis restrictions since 2014, Alaska, Arizona, California, Connecticut, Delaware, District of Columbia, Florida, Idaho, Maine, Massachusetts, New York, Oregon, Pennsylvania, Virginia, Washington, and Wisconsin. Some of the most notable changes include Connecticut moving from F4 to no fibrosis requirement in its FFS program (it does not have managed care) and Florida moving to no fibrosis requirement in both its FFS and MCO programs. While New York, also moved from F3 to no fibrosis restrictions in its FFS program, it is important to note the MCOs in New York still restrict access to F3. Two states, Arizona and Washington, moved from F3 to a chronic HCV requirement. Seven states relaxed their restrictions from F3 to F2, including Alaska, California, District of Columbia, Idaho, Pennsylvania, Virginia, and Wisconsin. Two states, Delaware, and Oregon, relaxed their restrictions from F4 to F3. In the case of Delaware, this state not only moved to F3, it will remove all fibrosis requirements by January 1, 2018.

Seven states decreased their sobriety restrictions from 2014 to 2016. Delaware moved from a three months abstinence period to requiring only screening. The District of Columbia moved from a three months abstinence period to the elimination of all sobriety requirements. Massachusetts moved from a screening requirement to the elimination of all sobriety requirements. Both Oregon and Pennsylvania moved from a six months abstinence period to requiring screenings only. West Virginia lowered its abstinence period from six months to three months. Wyoming moved from requiring a one month abstinence period to the elimination of all sobriety requirements.

Unfortunately, four states, Maine, Arkansas, Ohio, and Vermont, have either clarified or heightened their actual sobriety requirements during this period, moving from screening to a six month abstinence requirement. Such trends indicate that ongoing education to remove the stigma of substance use and to highlight the importance of treating substance users in order to slow or end the HCV epidemic is needed.

Progress has also been made to ease, but not eliminate, prescriber restrictions since 2014. Seven states eased their prescriber limitations, including Connecticut, Florida, Indiana, Maine, Montana New York, and Wisconsin. Of those seven states, six relaxed their requirement from requiring a specialist to prescribe to allowing non-specialists to prescribe after a consultation. Connecticut and Massachusetts eliminated the consultation

requirement altogether. Louisiana and South Dakota, on the other hand, tightened their prescriber requirements from allowing consultations with specialists to mandating that a specialist must prescribe. All in all, the trend is to reduce prescriber limitations, but additional progress is needed to ensure that all such restrictions are eliminated in the coming years.

The Increasing Impact of Managed Care

The preliminary results of the 2016 "Hepatitis C: The State of Medicaid Access" survey provide new information on the impact that the increasing prevalence of Medicaid managed care has on HCV treatment access. In many states, the majority of Medicaid beneficiaries are enrolled in MCOs rather than receiving care through the FFS program. Given the important role that MCOs play in the provision of health care to Medicaid beneficiaries living with HCV, it is vitally important that the MCOs are not permitted to restrict access to a greater extent than the FFS programs, as required by law, and that they follow recent FFS trends in reducing and eliminating HCV treatment access restrictions.

Unfortunately, the MCOs tend to offer more restricted access to HCV treatment than their corresponding FFS programs. In eight states, MCOs offered more restrictive access to HCV treatment relatively to the corresponding FFS program due to fibrosis restrictions. For example, New York eliminated its FFS fibrosis restrictions, yet its MCOs continue to require advanced liver disease (F3) to access treatment. Similarly, Arizona, Georgia, and Nevada MCOs require individuals to demonstrate F3 while their FFS programs only require chronic HCV. The Utah MCOs also require F3, while its FFS program only requires individuals to demonstrate F1. The District of Columbia and Maryland FFS programs require moderate fibrosis (F2), and while some of their MCOs match this requirement, others require individuals to demonstrate F3 before they can access HCV care. Virginia's FFS program is also at F2, while all of its MCOs require F3 or F4. Similarly, MCOs in a variety of states are stricter than their corresponding FFS program as to sobriety requirements. In the District of Columbia, Georgia, New York, and Oregon least one MCO requires an abstinence period of six months despite the fact that all of the FFS programs in these states require only screenings.

In addition to concerning trends regarding MCOs HCV treatment access restrictions as compared to state FFS program, it is important to note that MCOs variation as to restrictions within a state is troubling. The preliminary results of the 2016 survey indicate that significant variation often exists between MCOs within a state. Fifteen states (36%) in which MCO restrictions were known had serious variation among their MCOs when it came to sobriety restrictions. Six states (14%), of states with MCOs in which restrictions were known, had significant variation among their MCOs when it came to fibrosis restrictions.

Conclusion

In evaluating Medicaid HCV treatment reimbursement criteria from 2014 and 2016, a few clear trends emerge. Many states still fail to meet their treatment obligations under the law despite clear guidance from the Centers for Medicare and Medicaid Services that current restrictions often violate federal law. Additionally, the restrictions in place remain in direct opposition to the treatment guidelines established by both the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA).

Despite too many restrictions remaining in place, progress has been made:

- Many more states have publically available information as to their HCV treatment access restrictions than in 2014;
- Access restrictions, particularly for liver disease stage (fibrosis), have decreased since 2014; and
- We now have baseline information on MCO restrictions in states by which to evaluate current and future state MCO restrictions in HCV treatment access.

We must build on the progress that has been made in lessening liver disease stage restrictions and eliminate all such restrictions. Similarly, we must ensure that restrictions based on sobriety and prescriber limitation follow suit. To accomplish this we must hold federal and state insurance regulators accountable for ensuring that people living with HCV have access to treatment that is in keeping with established HCV treatment guidelines and relevant federal and state laws. Most important, we must ensure that the Center for Medicare and Medicaid Services and other federal and state insurance regulators monitor and enforce Medicaid FFS and MCO treatment access restrictions. As required by law, they must ensure that MCOs do not have more restrictive treatment access criteria than their corresponding FFS program. Progress has been made, but improvement is still necessary to ensure that all Medicaid beneficiaries can access life-saving HCV treatment.

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