CHLPI

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

NVHR
National Viral Hepatitis Roundtable

HCV ELIMINATION BY 2030: CAN WE GET THERE FROM HERE?

ADDRESSING DISCRIMINATORY BARRIERS TO HCV TREATMENT IN THE U.S.

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MEDICAID HCV AFFINITY GROUP MEETING
WASHINGTON, DC - FEBRUARY 6, 2019

RESPONSE TO DAAS?

Unprecedented Restrictions

- Despite cure rates near 100% for HCV, many public and private insurance payors restricted HCV-treatment access
- Unprecedented restrictions include:
  - Disease severity
  - Sobriety
  - Prescriber specialty

Center for Health Law and Policy Innovation of Harvard Law School (CHLPI) and National Viral Hepatitis Roundtable (NVHR). 2017. https://stateofhepc.org/. Accessed April 16, 2018.

Federal Guidance to States

- **Centers for Medicare and Medicaid Services** (CMS), the federal agency that administers Medicaid, issues guidance on access to HCV drugs to State Medicaid Directors in November 2015
- States…
  - Must cover HCV drugs of manufacturers with rebate agreements
  - Cannot impose coverage conditions that unreasonably restrict access
  - Must provide parity between Medicaid fee-for-service and managed-care

However, following the 2015 guidance, there was little movement to eliminate restrictions!

CMS. 2015. https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-172.pdf. Accessed April 16, 2018.

MEDICAID LITIGATION

Litigated Results

- WA: BE vs Teeter (injunction granted; settlement approved, April 2017)

- MO: JEM vs Kinkade (policy reformed, November 2017)
- MI: JV vs Lyon (settlement reached, March 2018)
- CO: Ryan vs Birch (disease severity criteria removed and settlement pending, April 2018)

Pre-Litigation Settlements as a result of legal advocacy

- CT, DE, FL, IL, MA, NJ, NY, PA, RI, VT

Pending Cases

- Several states in development

Silverman E. 2017. https://www.chlpi.org/state-medicaid-programs-continue-restrict-access-hepatitis-c-drugs/. Accessed April 16, 2018.

MEDICAL NECESSITY

B.E. et al. v. Teeter

"The Court is satisfied that Plaintiffs' evidence will likely establish that the [Defendant] is failing to follow its own definition of medical necessity by refusing to provide DAAs to monoinfected enrollees with a F0–F2 score."

Justia US Law. 2016. https://cases.justia.com/federal/district-courts/washington/wawdce/2:2016cv00227/227539/40/0.pdf?ts=1464448747. Accessed April 16, 2018.

Irreparable Harm

B.E. v. Teeter

- “Plaintiffs argue persuasively that without an injunction “they are at imminent risk of deteriorating health, liver damage, and even death.”
- Patient L.B.: Missed treatment window during “observation period”

Justia US Law. 2016. https://cases.justia.com/federal/district-courts/washington/wawdce/2:2016cv00227/227539/40/0.pdf?ts=1464448747. Accessed April 16, 2018.

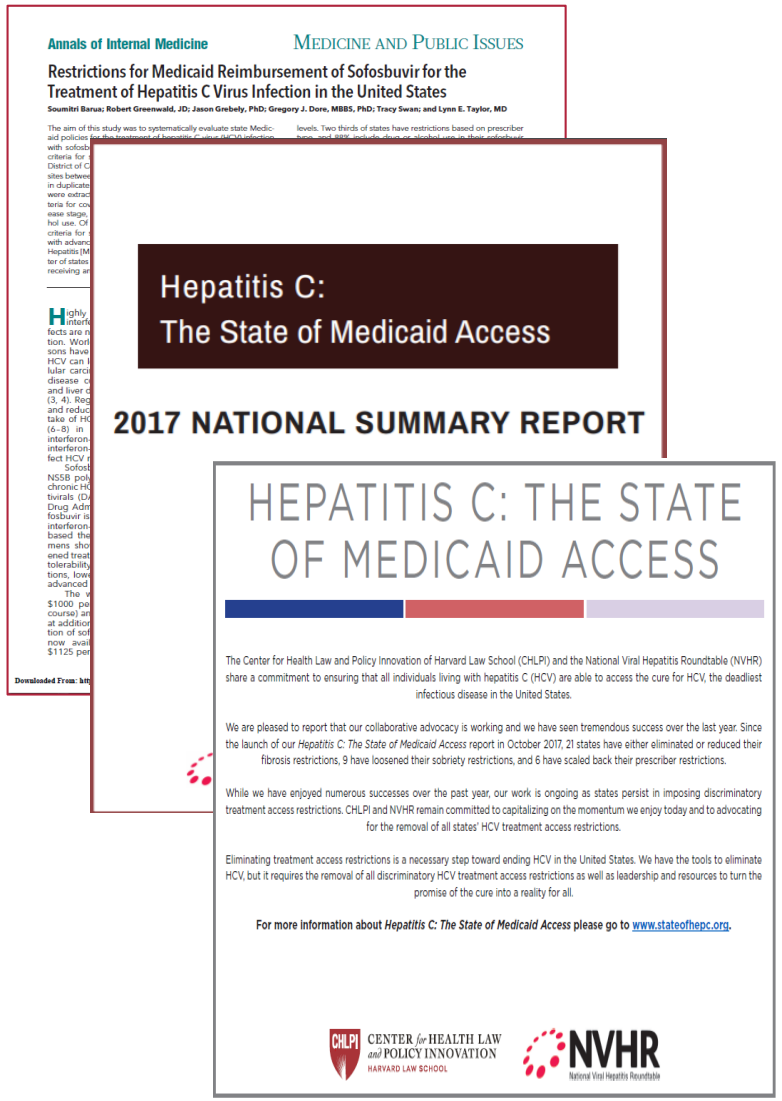
PUBLIC INTEREST

B.E. et al. v. Teeter

- "The balance of hardship favors beneficiaries of public assistance who may be forced to do without needed medical services over a state concerned with conserving scarce resources."
- "Faced with such a conflict between financial concerns and human suffering, we have little difficulty concluding that the balance of hardships tips decidedly in plaintiffs' favor."

Justia US Law. 2016. https://cases.justia.com/federal/district-courts/washington/wawdce/2:2016cv00227/227539/40/0.pdf?ts=1464448747. Accessed April 16, 2018.

THE RESEARCH: MEDICAID ACCESS TO HCV CURE



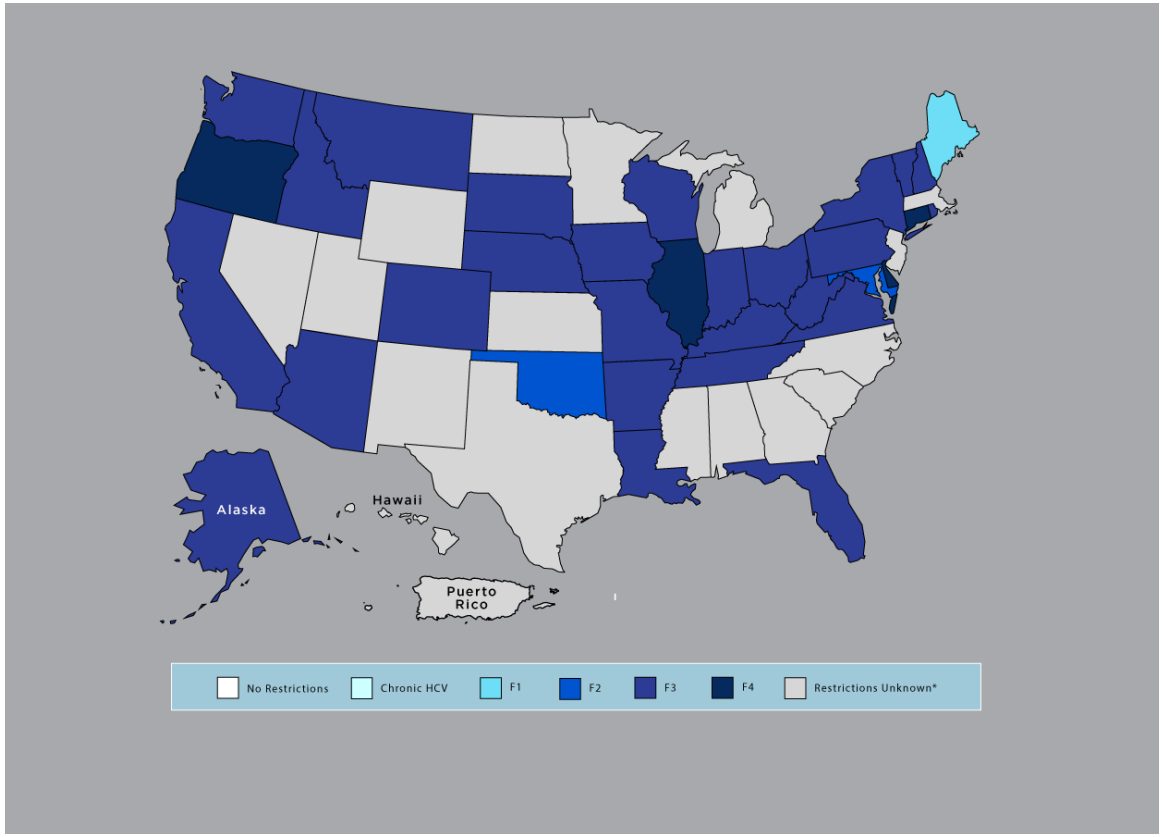
- *Hepatitis C: The State of Medicaid Access*, regularly updates HCV treatment access research
- The research evaluates treatment access in all 50 states, Washington, D.C., and Puerto Rico,
- Findings are based on surveys of Medicaid officials, publicly available documents, and official press or media releases

See up-to-date state reports at *www.StateofHepC.org*

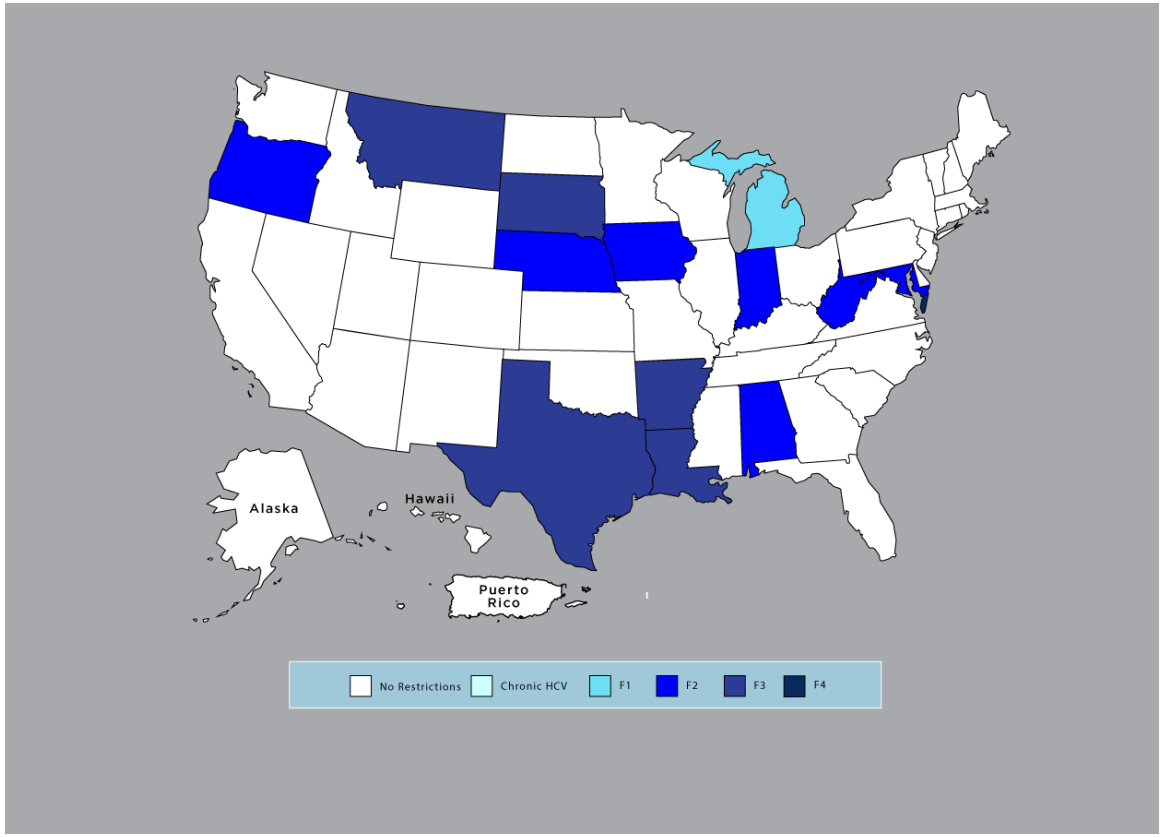
CHLPI and NVHR. 2017. https://stateofhepc.org/. Accessed April 16, 2018

FIBROSIS RESTRICTIONS

2014



2019



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FIBROSIS RESTRICTIONS AS OF 1/31/19

No Restrictions

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

Percentage of States | **75%**

Number of States | **39**

F1

Michigan

Percentage of States | **2%**

Number of States | **1**

F2

Alabama
Indiana
Iowa
Nebraska
Maryland
Oregon
West Virginia

Percentage of States | **13%**

Number of States | **7**

F3

Arkansas
Louisiana
Montana
South Dakota
Texas

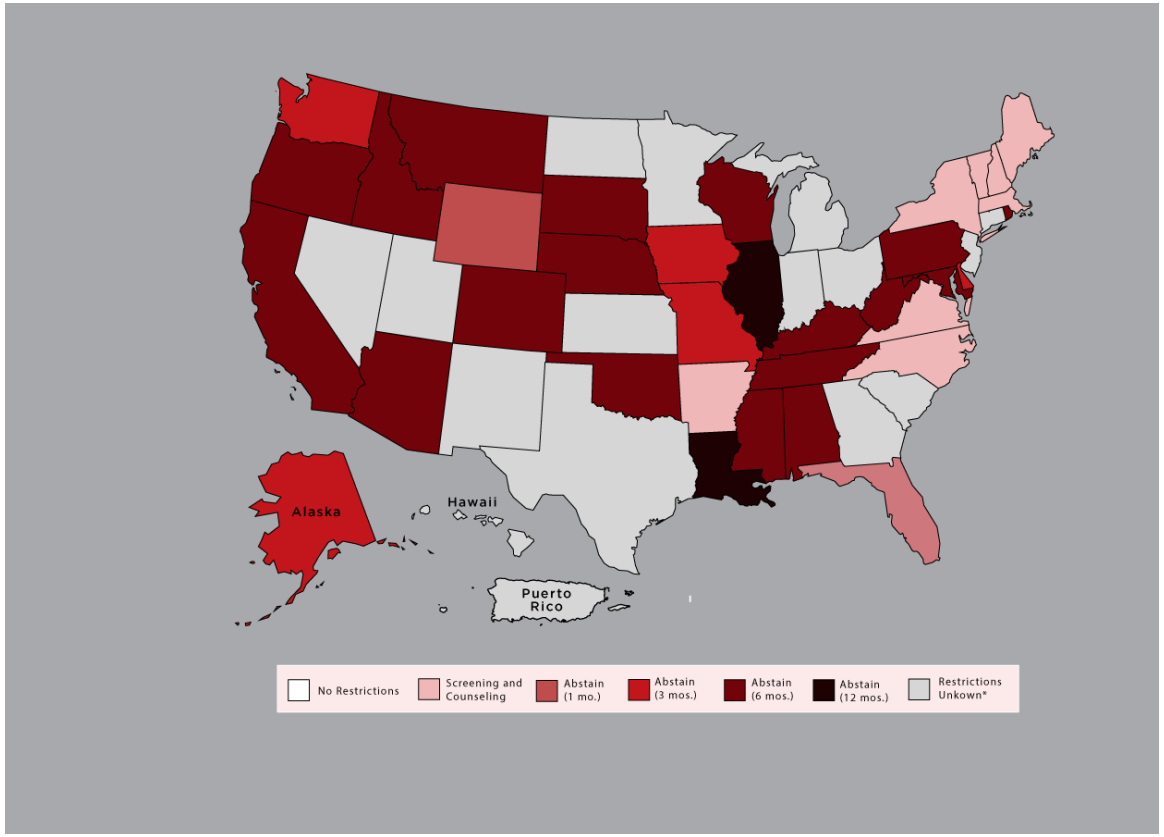
Percentage of States | **10%**

Number of States | **5**

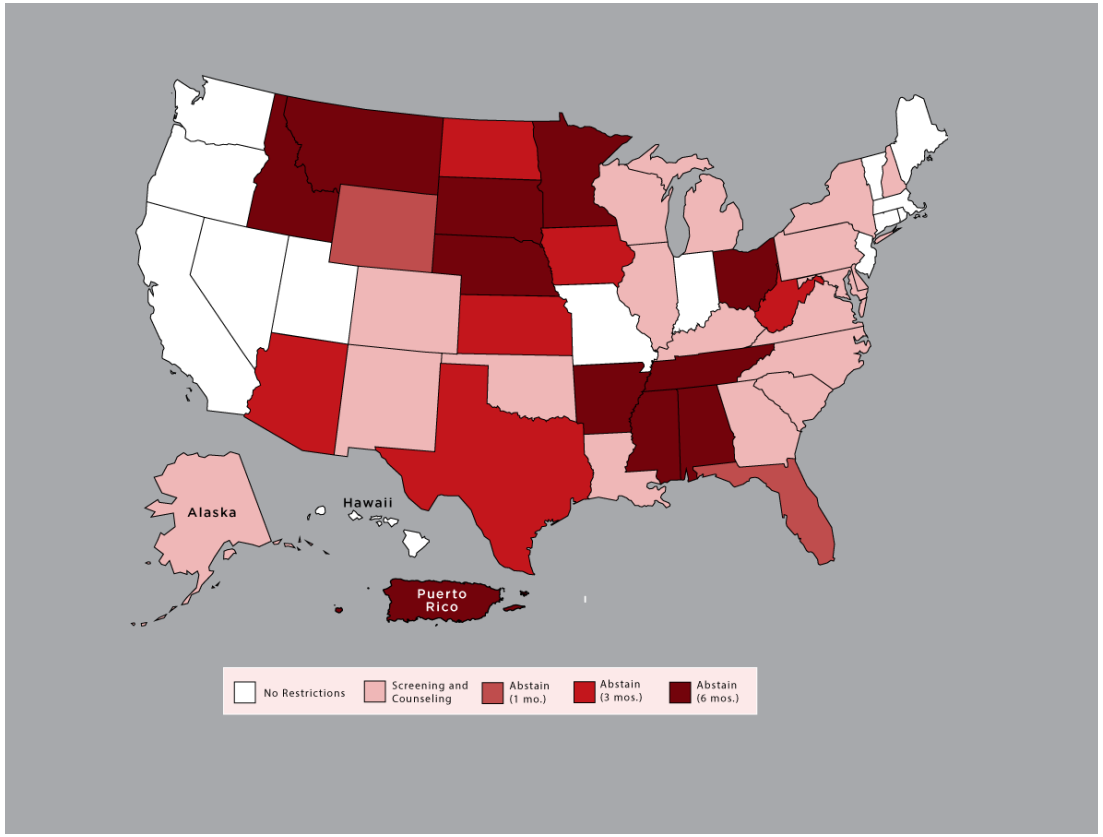
Bolded text indicates movement since October 2017

SOBRIETY RESTRICTIONS

2014



2019



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SOBRIETY RESTRICTIONS AS OF 1/31/19

No Restrictions

California
Connecticut
Hawaii
Indiana
Maine
Massachusetts
Missouri
Nevada
New Jersey
Oregon
Rhode Island
Utah
Vermont
Washington

Percentage of States | **27%**
Number of States | **14**

Screening and Counseling

Alaska
Colorado
Delaware
District of Columbia
Georgia
Illinois
Louisiana
Kentucky
Maryland
Michigan
New Hampshire
New Mexico
New York
North Carolina
Oklahoma
Pennsylvania
South Carolina
Virginia
Wisconsin

Percentage of States | **37%**
Number of States | **19**

1Month

Florida
Wyoming

Percentage of States | **3%**
Number of States | **2**

3 Months

Arizona
Iowa
Kansas
North Dakota
Texas
West Virginia

Percentage of States | **12%**
Number of States | **6**

6 Months

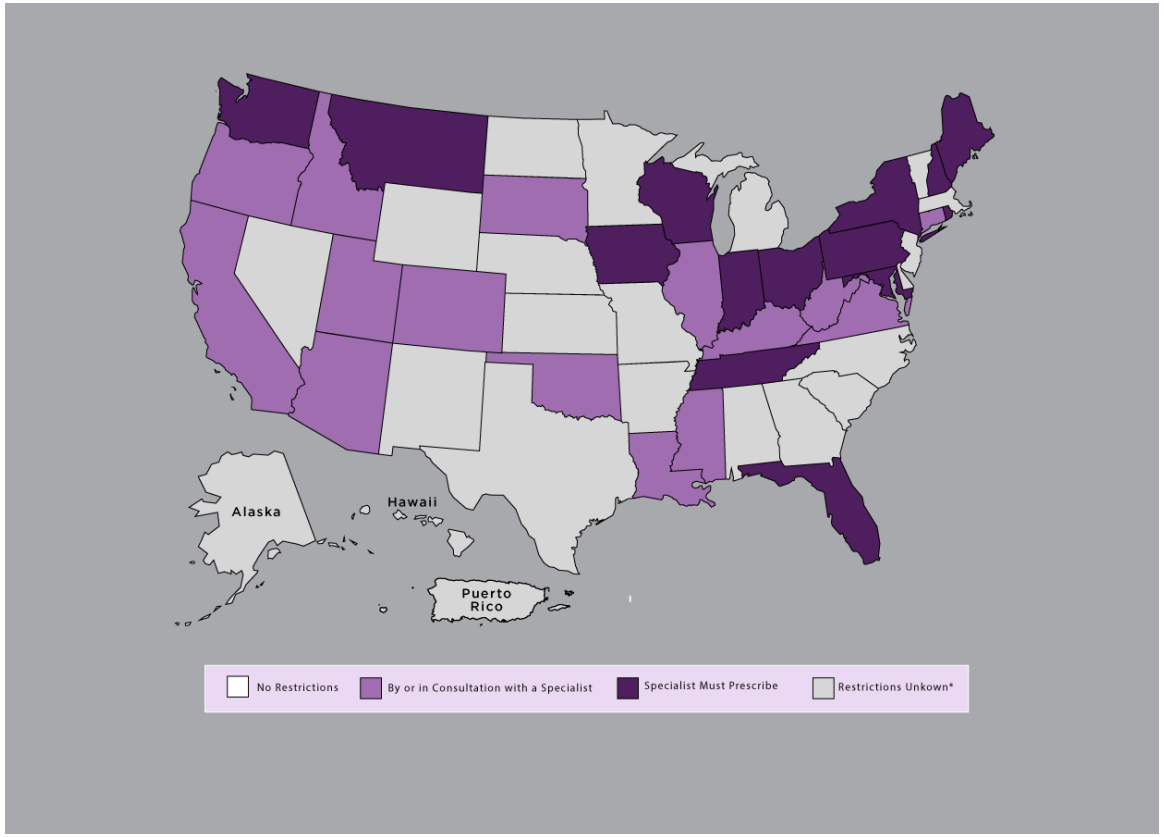
Alabama
Arkansas
Idaho
Minnesota
Mississippi
Montana
Nebraska
Ohio
Puerto Rico
South Dakota
Tennessee

Percentage of States | **21%**
Number of States | **11**

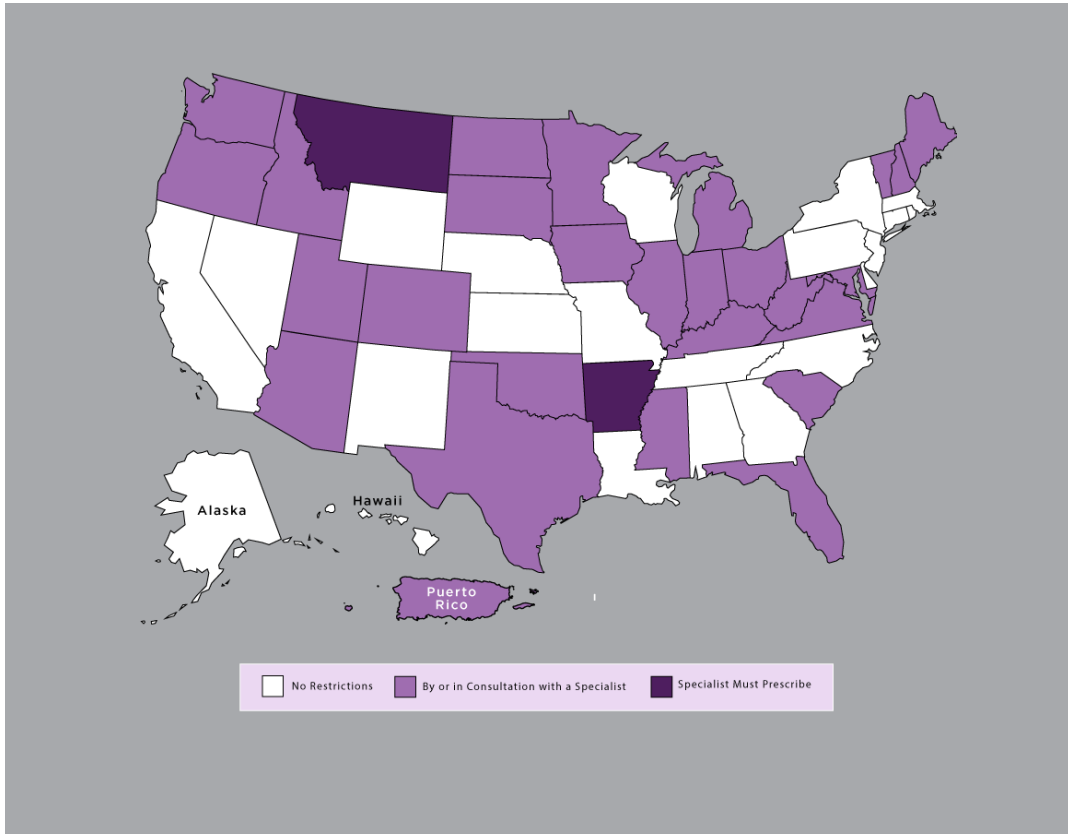
Bolded text indicates movement since October 2017

PRESCRIBER RESTRICTIONS

2014



2019



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PRESCRIBER RESTRICTIONS AS OF 1/31/19

No Restrictions

Alabama
Alaska
California
Connecticut
Delaware
Georgia
Hawaii
Kansas
Louisiana
Massachusetts
Missouri
Nebraska
Nevada
New Jersey
New Mexico
New York
North Carolina
Pennsylvania
Rhode Island
Tennessee
Wisconsin
Wyoming

Percentage of States | **42%**

Number of States | **22**

By or in Consultation

Arizona
Colorado
District of Columbia
Florida
Idaho
Illinois
Iowa
Indiana
Kentucky
Maine
Maryland
Michigan
Minnesota
Mississippi
New Hampshire
North Dakota
Ohio
Oklahoma
Oregon
Puerto Rico
South Carolina
South Dakota
Texas
Utah
Vermont
Virginia
Washington
West Virginia

Percentage of States | **54%**

Number of States | **28**

Specialist

Arkansas
Montana

Percentage of States | **4%**

Number of States | **2**

Bolded text indicates movement since October 2017

IT'S NOT JUST MEDICAID

Prisoner litigation: 8th Amendment class actions

- At least states 12: AL, CA, CO, FL, IN, MA, MN, MO, PA,TN, SC, VA
- January 2017: Strong decision in individual PA case brought by Mumia Abu Jamal; treatment ordered
- March 2018: Settlement in MA with restrictions reduced to F2 and 6-month screening cycle
- November 2018 – PA class settlement phasing in treatment without restrictions – follows strong court ruling early in case

COURTS CAN BE CONVINCED

Hoffer v. Jones

- "This Court will not tolerate further foot dragging"
- "Preventable deaths from HCV are occurring within the prison system"
- "Defendant has been deliberately indifferent to Plaintiffs' (and the class's) serious medical needs"
- "One can only wonder how long Defendant would have kicked the can down the road had Plaintiffs not filed this case."

Hoffer v. Jones, 290 F. Supp. 3d 1292 (N.D. Fla. 2017).

COURTS CAN REVERSE RESTRICTIVE TRENDS

Chimenti, et al. v. Wetzel

- "Defendants are deliberately refusing to treat for non-medical reasons, such as cost"
- "DOC Defendants are deliberately indifferent to the serious medical needs of inmates with chronic HCV"
- "Patients who have chronic HCV and whose Metavir scores are less than F2 have serious medical needs... and, if not treated with DAAs before their disease progresses, may suffer from liver inflammation, liver fibrosis, liver cancer and liver-related mortality"

Chimenti, et al. v. Wetzel, 2018 wl 3388305

PRIVATE-INSURER LITIGATION

- WA: Group Health, BridgeSpan and Regence Blue Cross all removed disease-severity restrictions after state court complaints filed
- CA: Anthem sued in May 2015; state policy was changed in Dec 2015
- NY: AG threatened litigation against 7 commercial insurers; 6 insurers immediately eliminated coverage restrictions
  - AG filed fraud and consumer-protection–based lawsuit against 1 holdout: Capital District Physicians' Health Plan settled shortly thereafter
- Nationwide class settlement by United Healthcare in 2016

Where We Go From Here

- Progress has been made in reducing access restrictions to HCV cure
- However, restrictions persist and many states continue to violate Medicaid law, CMS guidance, and clinical guidelines
- States are hiding behind cost, despite the approximate 75% reduction in cost over the past 3 years
- Stigma continues to drive access barriers: In what other disease would we withhold a cure that costs ~$20,000, or fail to treat due to alcohol or drug use?
- The law is clear and we will continue to with advocacy and litigation campaigns until all discriminatory HIC treatment access restrictions are eliminated

To reach the goal of eliminating HCV in the United States, Medicaid and all other insurers must end treatment-access restrictions

Removing Barriers: Necessary But Not Sufficient to Achieving HCV Elimination

- Making HCV elimination a priority in every city/state
- Create a central coordinating office at the highest level of city/state government
- Support for cross-sectional research to better understand incidence and prevalence
- Develop broad-based education and outreach campaigns to:
  - Expand access to testing
  - Expand access to a broad range of preventive measures
  - Building capacity to treat in primary care