HEPATITIS C
STATE OF MEDICAID ACCESS

April 26, 2023

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Disclosures

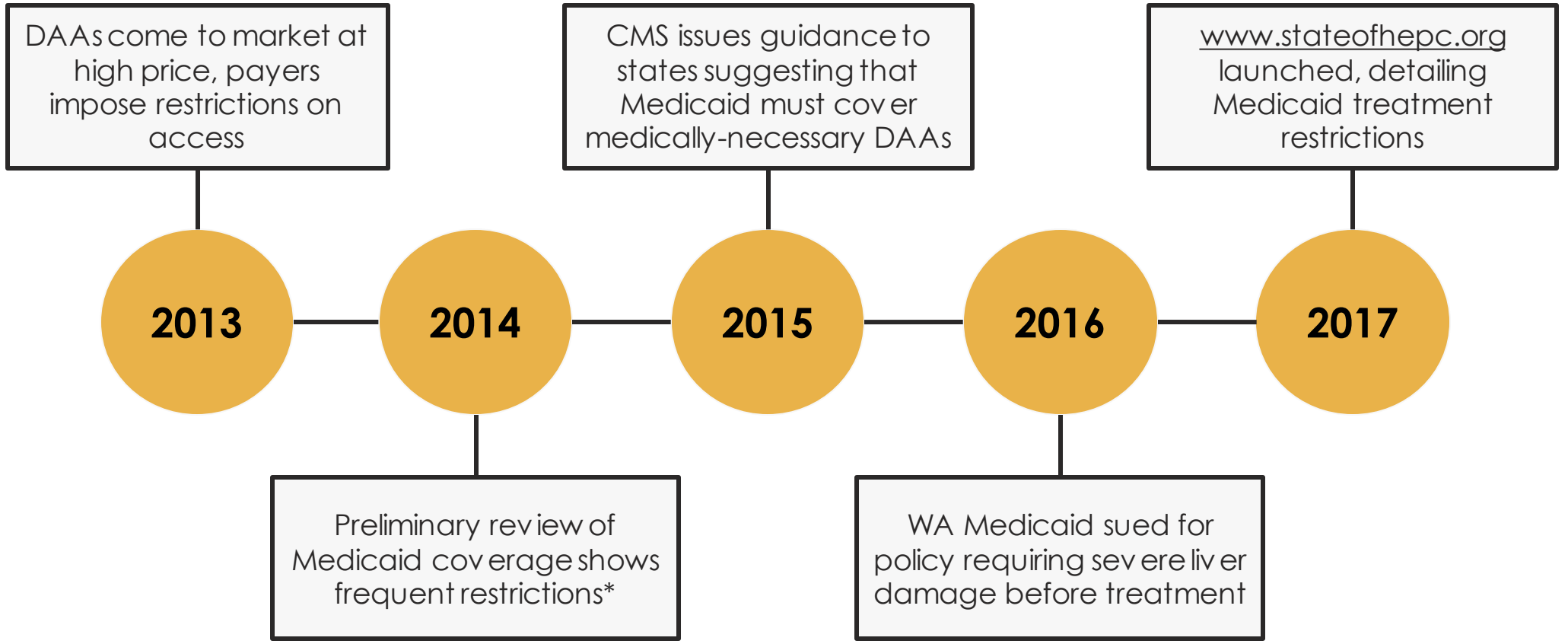
Hepatitis C: State of Medicaid Access is supported by AbbVie and Gilead Sciences. The methods, research, and conclusions of this project are those of the Center for Health Law and Policy Innovation of Harvard Law School and National Viral Hepatitis Roundtable and do not necessarily reflect the opinions of AbbVie or Gilead Sciences.

AGENDA

- Overview of *Hepatitis C: State of Medicaid Access*
- Why Treatment Restrictions Matter
- 2023 Findings & Trends in HCV Treatment Access
- Advocacy Opportunities & Key Takeaways
- Discussion & Q&A

Overview of *Hepatitis C: State of Medicaid Access*

History of HCV Treatment Access in Medicaid



*Barua S, Greenwald R, Grebely J, Dore GJ, Swan T, Taylor LE. Restrictions for medicaid reimbursement of sofosbuvir for the treatment of hepatitis c virus infection in the united states. Ann Intern Med. 2015;163(3):215-223.

Hepatitis C: State of Medicaid Access

- Launched in 2017 as a partnership between the Center for Health Law and Policy Innovation (CHLPI) and the National Viral Hepatitis Roundtable (NVHR)
- Documents the current state of Medicaid HCV treatment access across 52 jurisdictions, including state-by-state "report cards"
- Findings are based on publicly available documents, including published clinical criteria, prior authorization forms, meeting minutes, and press releases

CHLPI CENTER for HEALTH LAW and POLICY INNOVATION HARVARD LAW SCHOOL

NVHR National Viral Hepatitis Roundtable

Medicaid Treatment Access Restrictions

Historical Restrictions

Fibrosis

Substance Use

Prescriber

Managed Care

Added June 2022

- Prior Authorization
- Retreatment
- Additional Restrictions

Our Website Got a Makeover!

2023 NATIONAL SNAPSHOT REPORT

Since 2014, The Center for Health Law and Policy Innovation of Harvard Law School (CHLPI) and the National Viral Hepatitis Roundtable (NVHR) have fought to ensure that all people living with hepatitis C (HCV) are able to access treatment through our joint work on the *Hepatitis C: State of Medicaid Access* project.

We're pleased to report our collective advocacy over the last decade has been working. In particular, the ongoing publication of our *State of Medicaid Access* reports has successfully supported efforts to eliminate treatment restrictions across the nation. Since we began publishing annual reports in 2017, 21 states have removed prior authorization requirement for most patients, 33 have either eliminated or reduced their fibrosis restrictions, 37 have loosened their sobriety restrictions, and 34 have scaled back their prescriber restrictions.

We celebrate this significant wave of progress, but our work will not be done until the promise of an HCV cure is an accessible reality for all. It is in that spirit that we bring you our 2023 snapshot of Medicaid access. You can click of the categories below to jump to that topic or simply scroll to take it all in.

OVERALL GRADES

RESTRICTIONS: PRIOR AUTHORIZATION · FIBROSIS
SOBRIETY · PRESCRIBER · RETREATMENT · MANAGED CARE

PREVIOUS UPDATES

Compare this snapshot's findings with our previous updates:

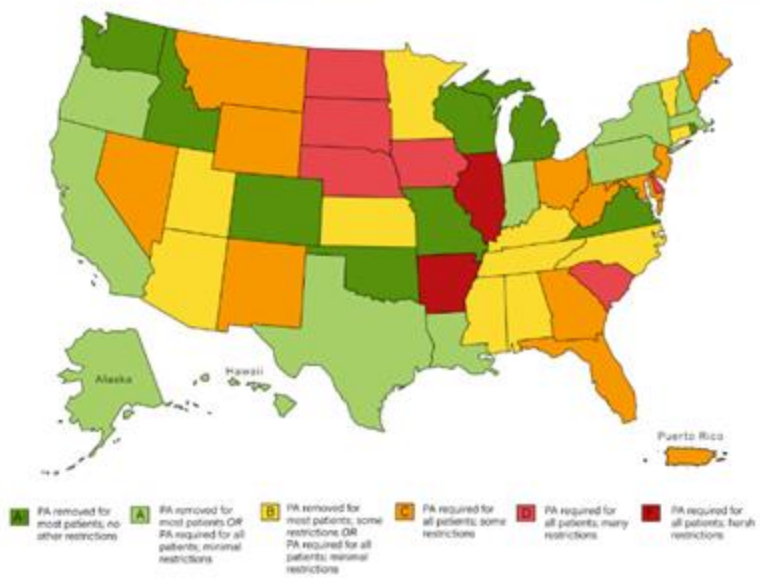
June 2022 | January 2022 | May 2021 | August 2020 | February 2020 | November 2019 | July 2019 | January 2019 | Original 2017 Report

Check out your state's most up-to-date report card and our latest national snapshot report at www.stateofhepc.org

OVERALL GRADES

HEPATITIS C
STATE OF MEDICAID ACCESS

OVERALL STATE GRADES
FEBRUARY 2023



A+ (9): Colorado, Idaho, Michigan, Missouri, Oklahoma, Rhode Island, Virginia, Washington, Wisconsin

A (12): Alaska, California, DC, Hawaii, Indiana, Louisiana, Massachusetts, New Hampshire, New York, Oregon, Pennsylvania, Texas,

B (11): Alabama, Arizona, Connecticut, Kansas, Kentucky, Minnesota, Mississippi, North Carolina, Tennessee, Utah, Vermont

C (12): Florida, Georgia, Maine, Maryland, Montana, Nevada, New Jersey, New Mexico, Ohio, Puerto Rico, West Virginia, Wyoming

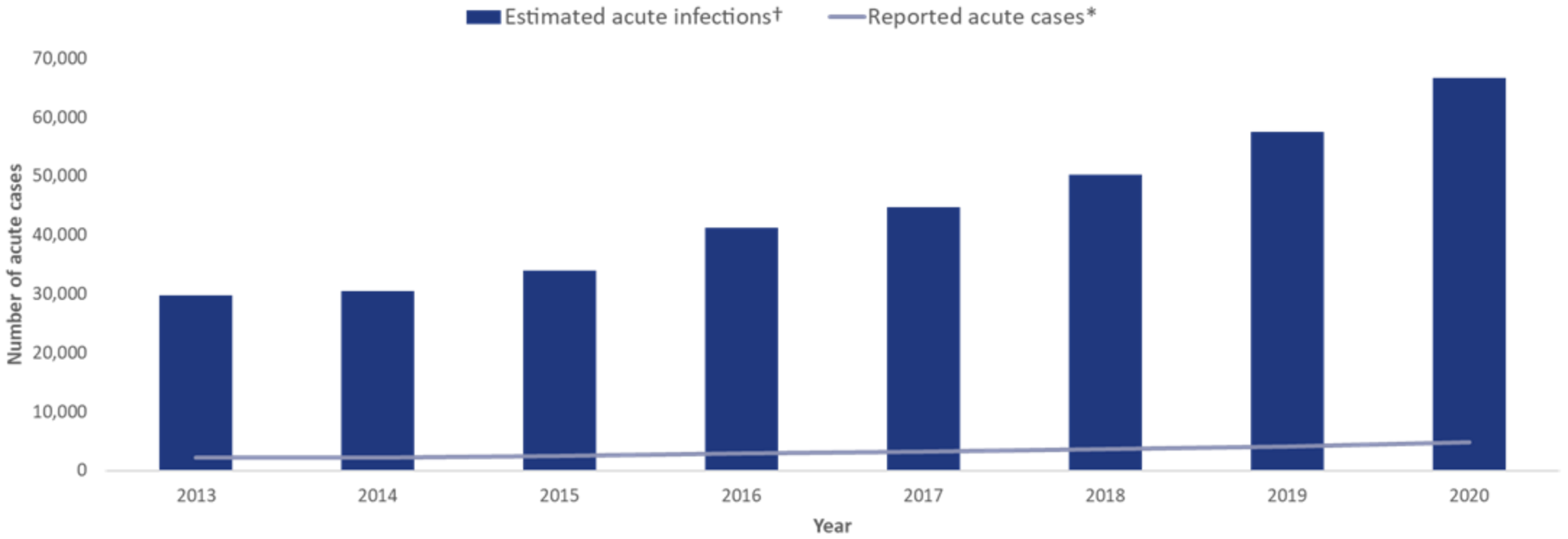
D (6): Delaware, Iowa, Nebraska, North Dakota, South Carolina, South Dakota

F (2): Arkansas, Illinois

Citation: Center for Health Law and Policy Innovation & National Viral Hepatitis Roundtable, Hepatitis C: State of Medicaid Access (2023), www.stateofhepc.org

Why Treatment Restrictions Matter

HCV Infections are Rising

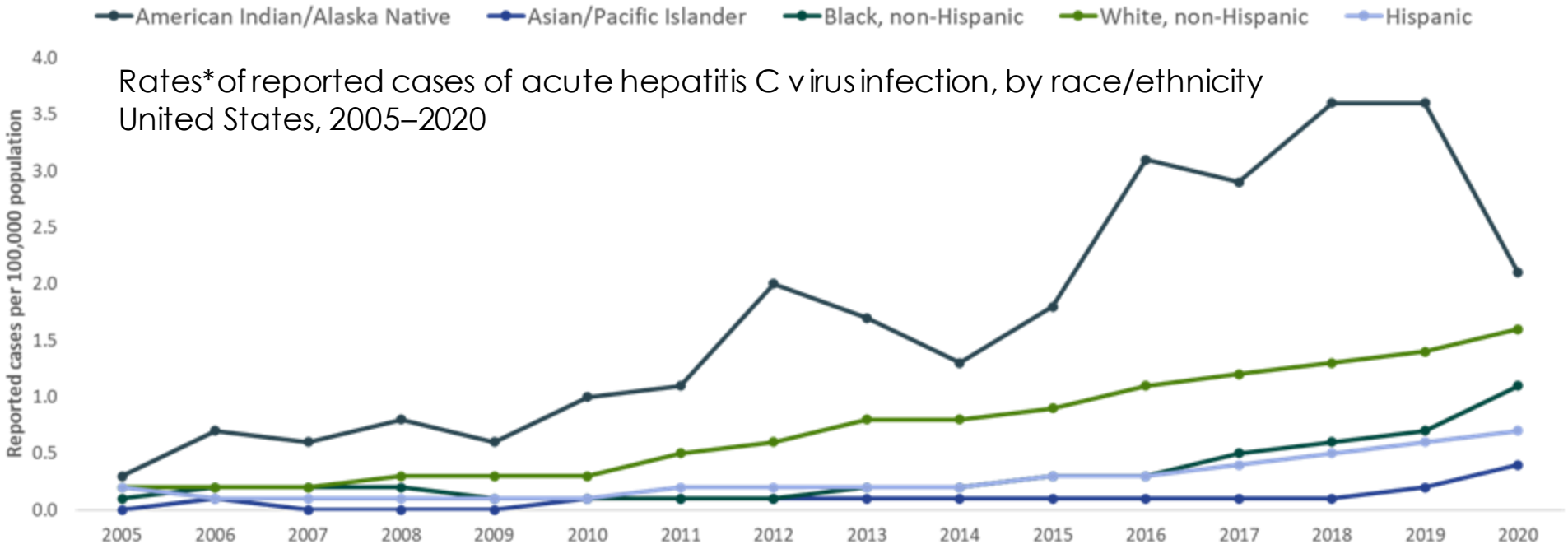


- The incidence rate of acute hepatitis C has more than doubled since 2013, and increased 15% from 2019.
- Persons aged 20-39 years had the highest incidence of acute hepatitis C.
- 66% of cases with risk information reported injection drug use.

Centers for Disease Control and Prevention. Viral Hepatitis Surveillance Report – United States, 2020. https://www.cdc.gov/hepatitis/statistics/2020surveillance/index.htm. Published September 2022. Accessed February 16, 2023.

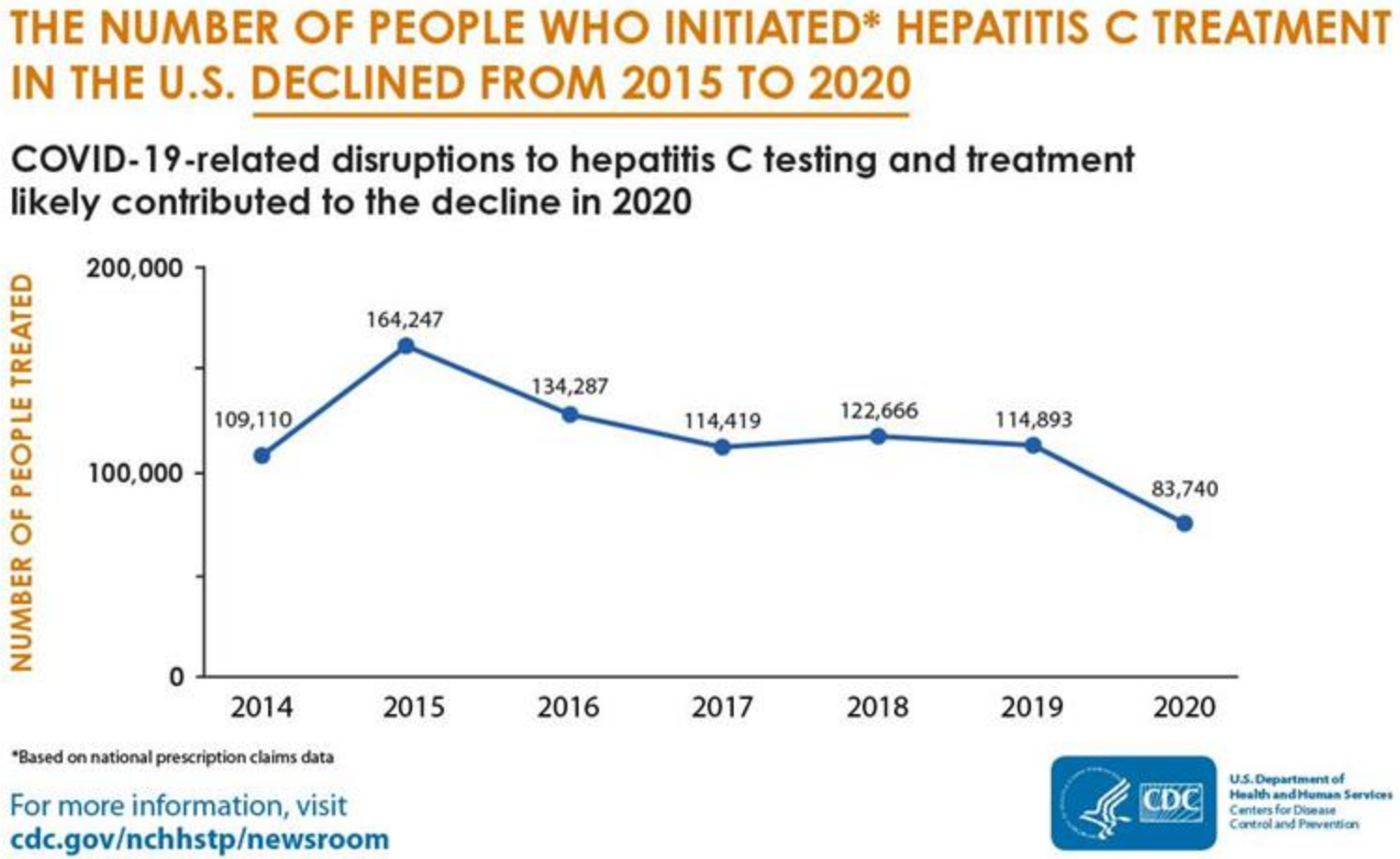
People of Color Have Worse HCV Outcomes

- Native Americans experience higher rates of acute HCV, and higher rates of HCV-related mortality, than any other racial/ethnic group
- Mortality rates are highest among Native American and Black people (3.2 times and 1.8 times, respectively) compared to white people



Centers for Disease Control and Prevention. Viral Hepatitis Surveillance Report – United States, 2020. https://www.cdc.gov/hepatitis/statistics/2020surveillance/index.htm. Published September 2022. Accessed February 16, 2023.

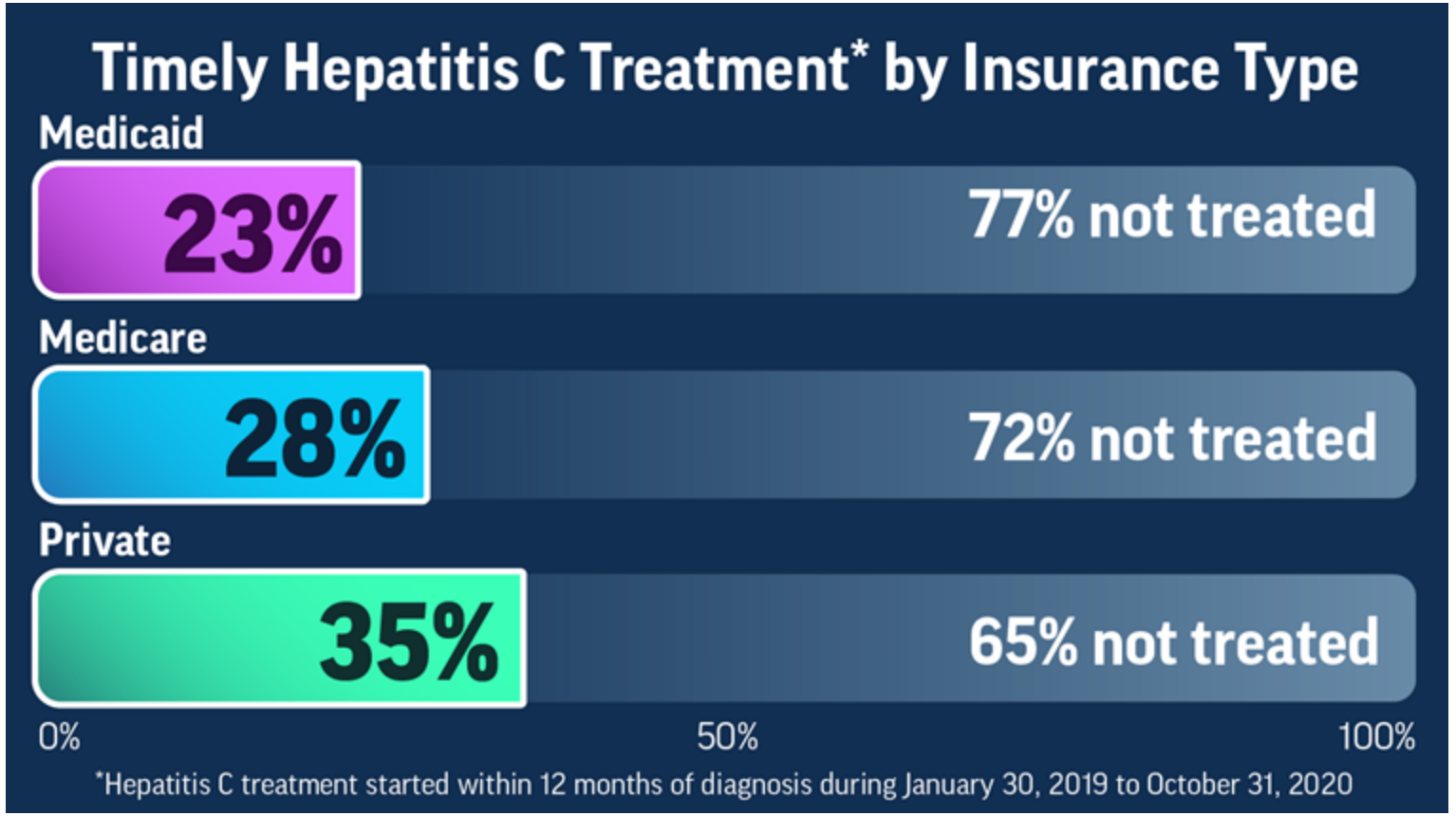
As HCV Cases Rise, Treatment Rates are Declining



- To eliminate hepatitis C, more than 260,000 people should be treated every year.
- The number of people treated was highest in 2015 and declined to its lowest level in 2020.

Eyasu H Teshale, MD, Henry Roberts, PhD, Neil Gupta, MD, MPH, Ruth Jiles, MS, MPH, PhD, Characteristics of persons treated for hepatitis C using national pharmacy claims data, United States, 2014–2020, Clinical Infectious Diseases, 2022;, ciac139, https://doi.org/10.1093/cid/ciac139

Only 1 in 3 of Insured Receive Timely HCV Treatment



Timely treatment rates drop to 1 in 4 among Medicaid Beneficiaries

Thompson WW, Symum H, Sandul A, et al. Vital Signs: Hepatitis C Treatment Among Insured Adults — United States, 2019–2020. MMWR Morb Mortal Wkly Rep 2022;71:1011-1017. DOI: http://dx.doi.org/10.15585/mmwr.mm7132e1.

HCV Treatment Access is a Health Equity Issue

- Certain communities are disproportionately impacted by the HCV epidemic and have poorer treatment outcomes, including:
  - Black communities and other communities of color;
  - Rural communities;
  - People who are unhoused or housing insecure;
  - People who use drugs; and
  - People who have a history of incarceration.
- Treatment access restrictions often **disproportionately restrict access** to these same communities, widening disparities in both health care access and health outcomes

Disparities are Widened by Prior Auth Requirements

Treatment access restrictions can widen already-existing disparities for groups that already experience disproportionate rates of infection

- People who use drugs are at higher risk for hepatitis C, but may be denied treatment in states that impose substance use restrictions
- People who are unhoused and without access to reliable transportation may have difficulting meeting prior authorization requirements, like submitting multiple rounds of lab work within a certain timeframe
- Providers who serve rural communities with low populations may face difficulty scheduling a specialist consultation, particularly if there are only a few specialists in network

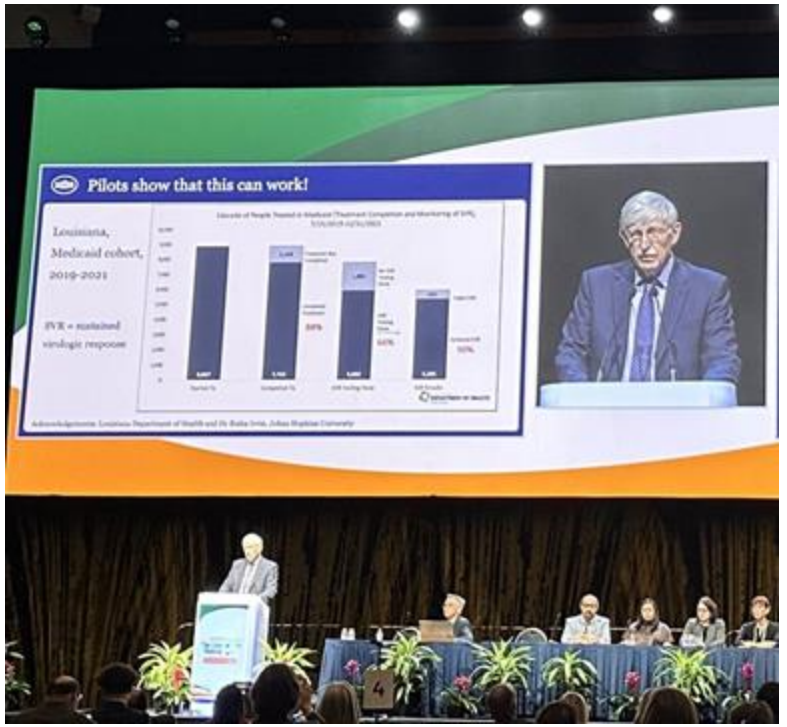
Federal HCV Elimination Initiative

- Dr. Francis Collins leading development of a proposal for a National HCV Elimination Program
- Early discussions include **financing strategies for direct-acting antivirals** and novel HCV diagnostics
- Funding not yet secured for program and program details not yet finalized

POLICY

Administration eyes national hepatitis C treatment plan

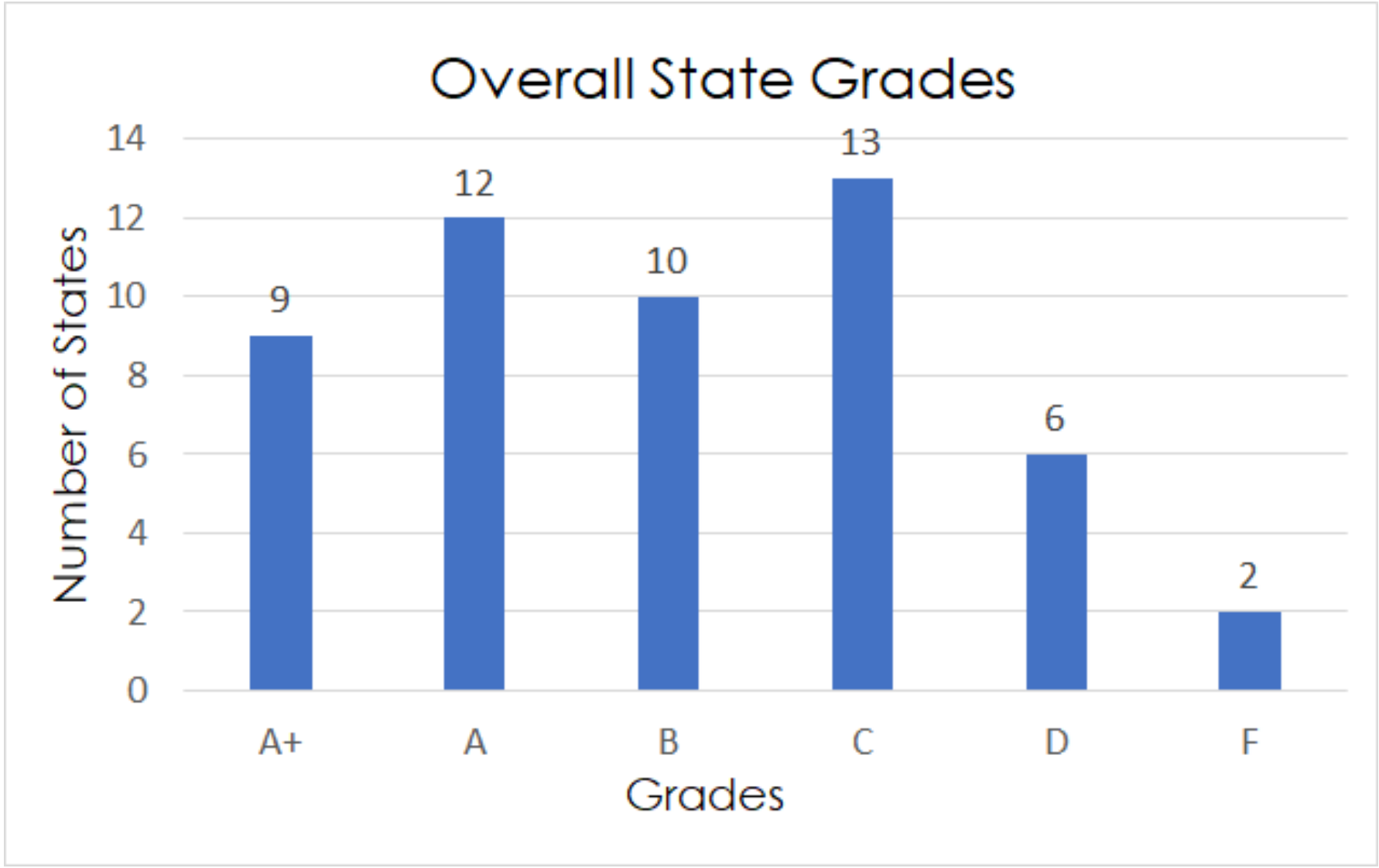
The plan would streamline testing and treatment and secure an agreement with drugmakers to bring down the cost of treatment of the disease, which has spiked during the pandemic



2023 Findings & Trends in HCV Treatment Access

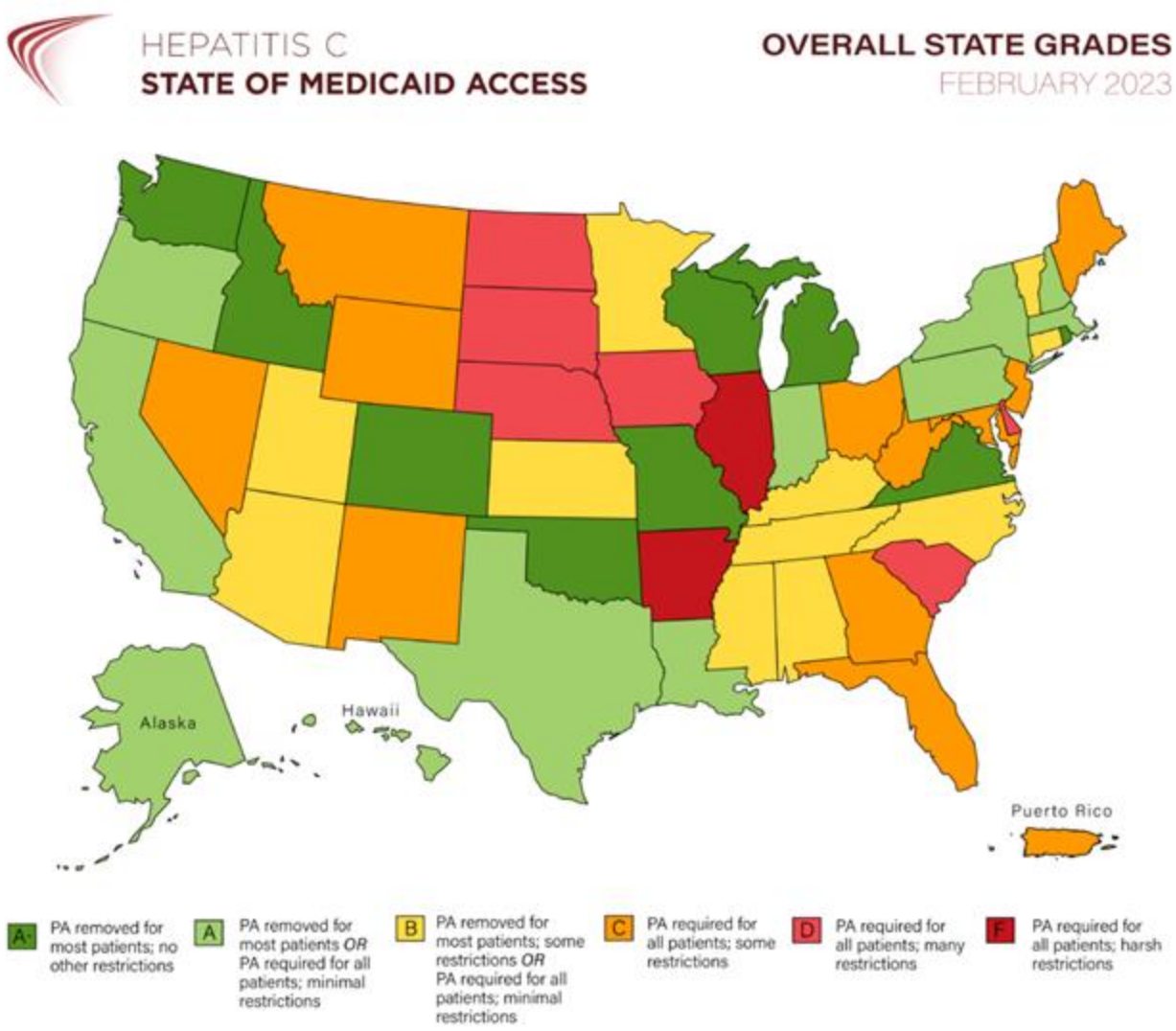
State Grading

A+	100
A	90-99
B	80-89
C	70-79
D	60-69
F	<60



Overall State Grades

Since 2017, 33 states either eliminated or reduced fibrosis restrictions, 36 loosened sobriety restrictions, and 35 scaled back prescriber restrictions.



Noteworthy Progress Since June 2022 Report

ALABAMA eliminated 6-month abstinence requirement following DOJ complaint

ARIZONA removed prior authorization for most patients, including prescriber restriction

COLORADO removed prior authorization for most patients, including retreatment restriction

DC removed prior authorization for most patients, including substance use and prescriber restrictions

MISSISSIPPI eliminated substance use and prescriber restrictions

OKLAHOMA removed prior authorization for most patients, including substance use and prescriber restrictions

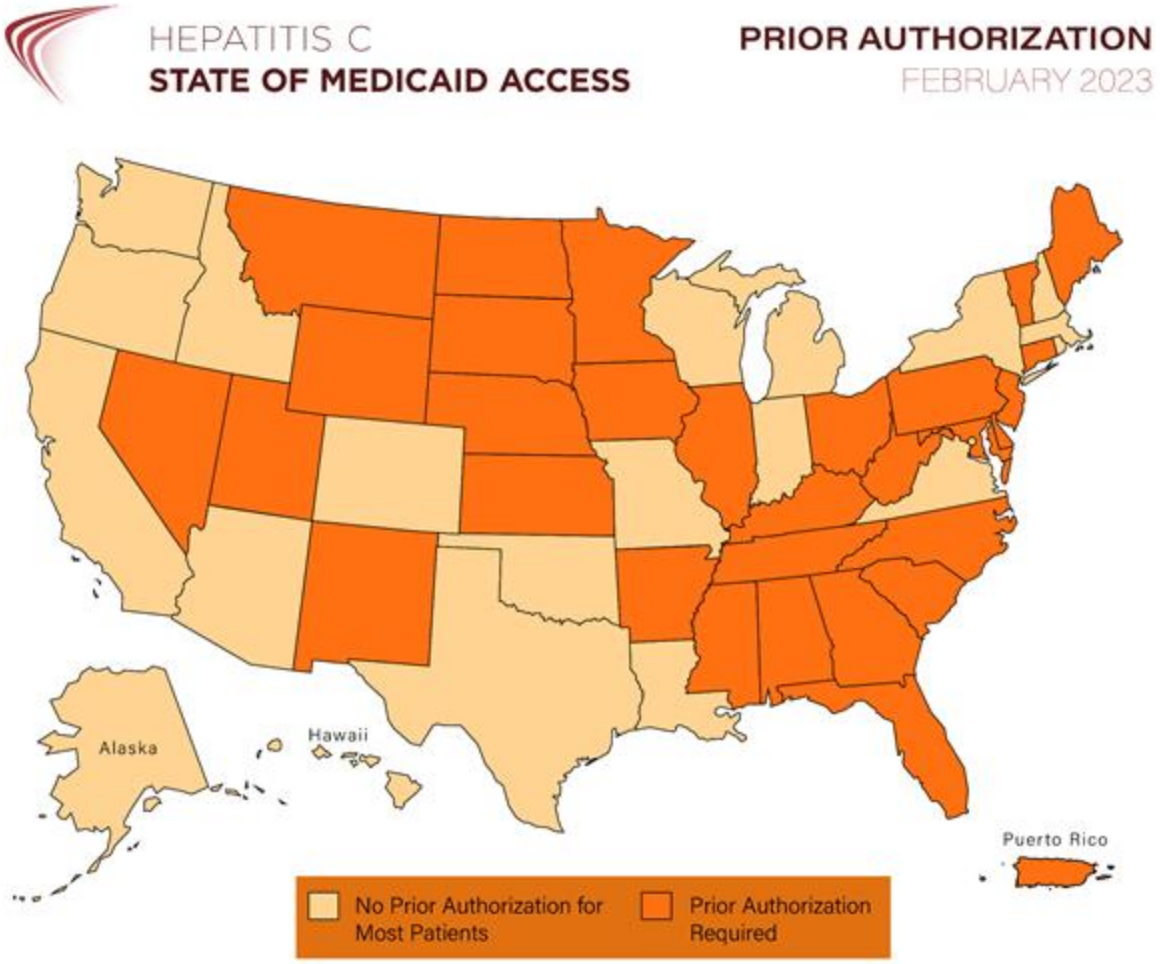
OREGON removed prior authorization for most patients, including retreatment restriction

TEXAS removed prior authorization for most patients, including substance use counseling restriction

- **21 states (40%)** have removed prior authorization for treatment-naive patients and/or preferred drug regimens, significantly reducing administrative barriers to care
- 7 of those states removed prior authorization after June 2022 report was published

Updates since February 2023

- Florida removed prior authorization by implementing SmartPA
- New Mexico and Pennsylvania may be next to remove PA



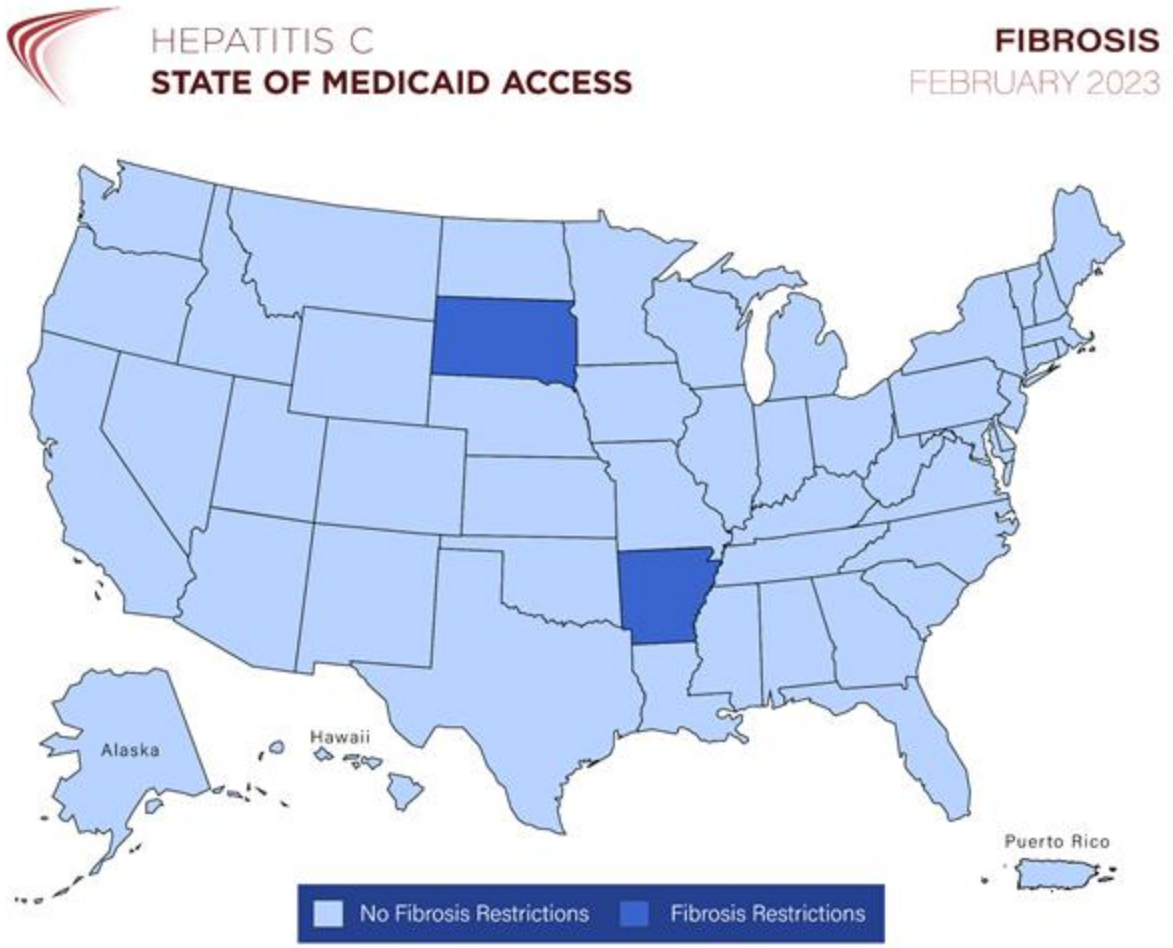
Prior Authorization

Fibrosis Restrictions

- **All but two states (Arkansas, South Dakota)** have removed restrictions based on liver damage (fibrosis)
- This is a significant change. In 2017, **34 states (65%)** imposed some kind of liver damage requirement

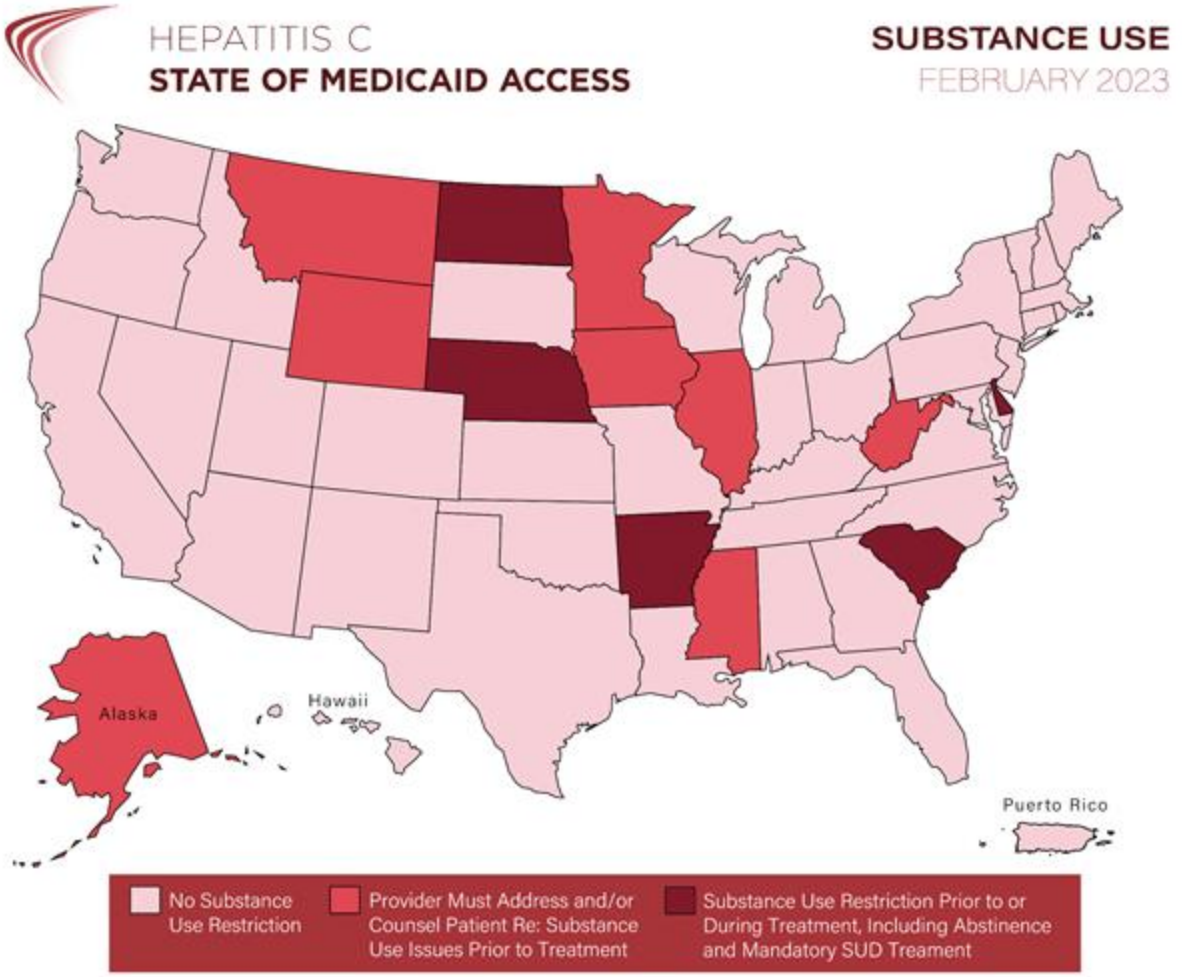
Updates since February 2023

- South Dakota removed fibrosis restriction as of April 1, 2023, leaving Arkansas as the only state that imposes a fibrosis restriction.



Substance Use Restrictions

- **5 states (10%)** require abstinence from alcohol/substances prior to or during treatment, including participation in a substance use treatment program
- **8 states (15%)** require a provider to counsel or address substance use issued prior to treatment
- **39 states (75%)** have no substance use restriction

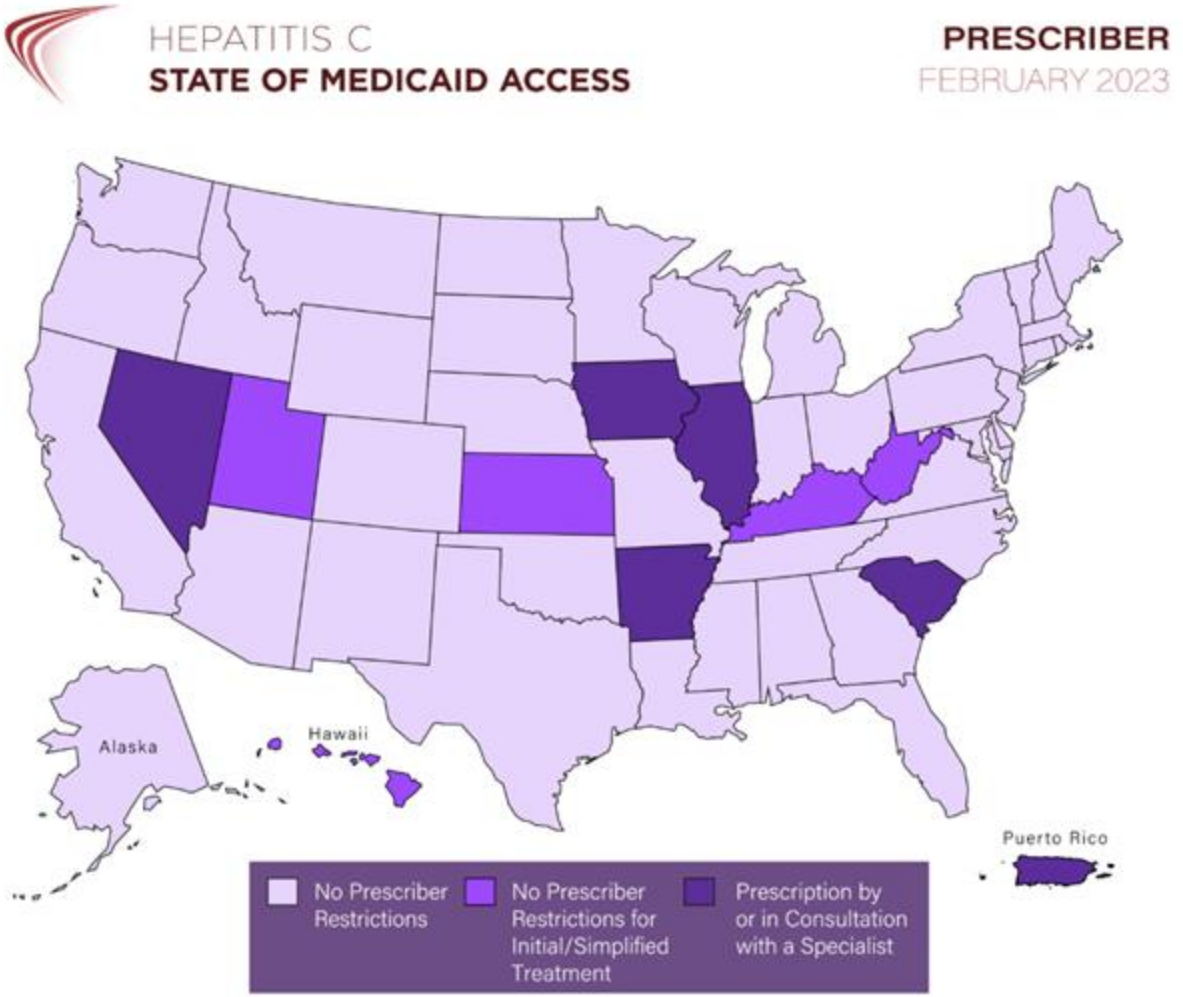


Updates since February 2023

- South Dakota removed substance use requirement as of April 1, 2023

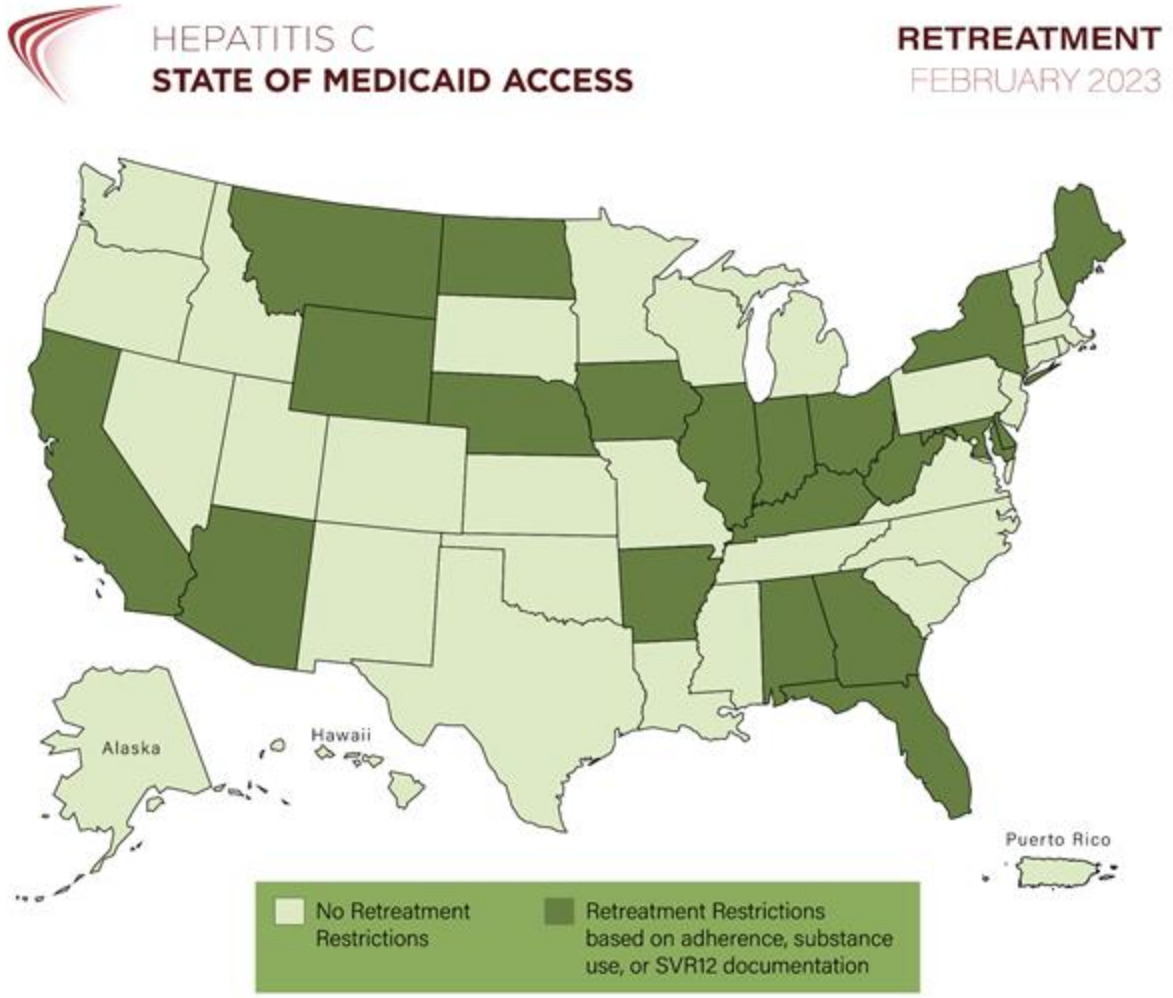
Prescriber Restrictions

- **6 states (12%)** impose prescriber restrictions for initial treatment:
  - **Arkansas** requires that the prescription written be a specialist; all other states require specialist consultation
  - **Puerto Rico** allows primary care physicians to prescribe only if they undergo additional training and certification



Retreatment Restrictions

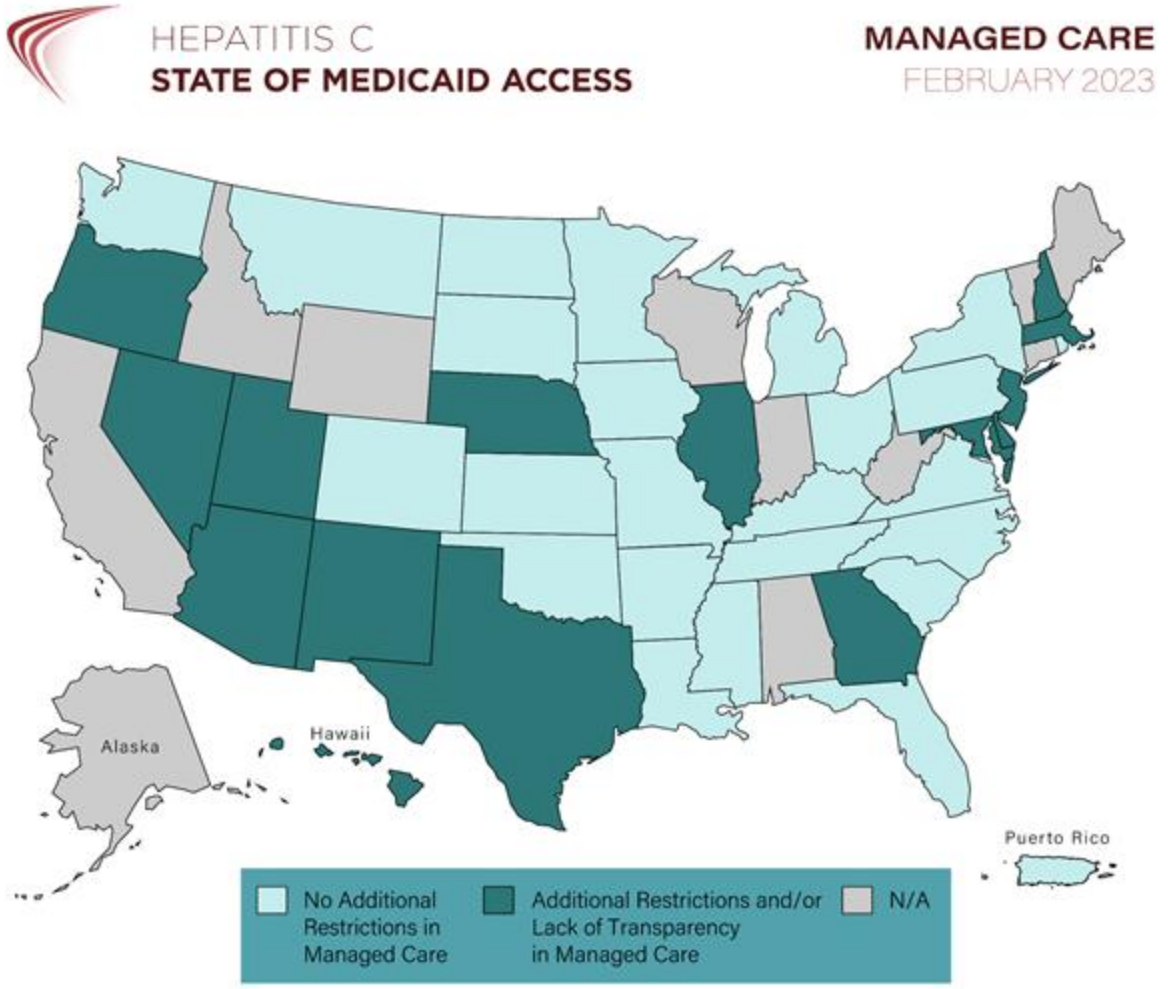
- **20 states (38%)** impose retreatment restrictions
- Such restrictions include lifetime restrictions on retreatment and policies that are otherwise more restrictive than those for treatment-naive patients (e.g., denying retreatment based on past treatment adherence, substance use, SVR12 documentation)



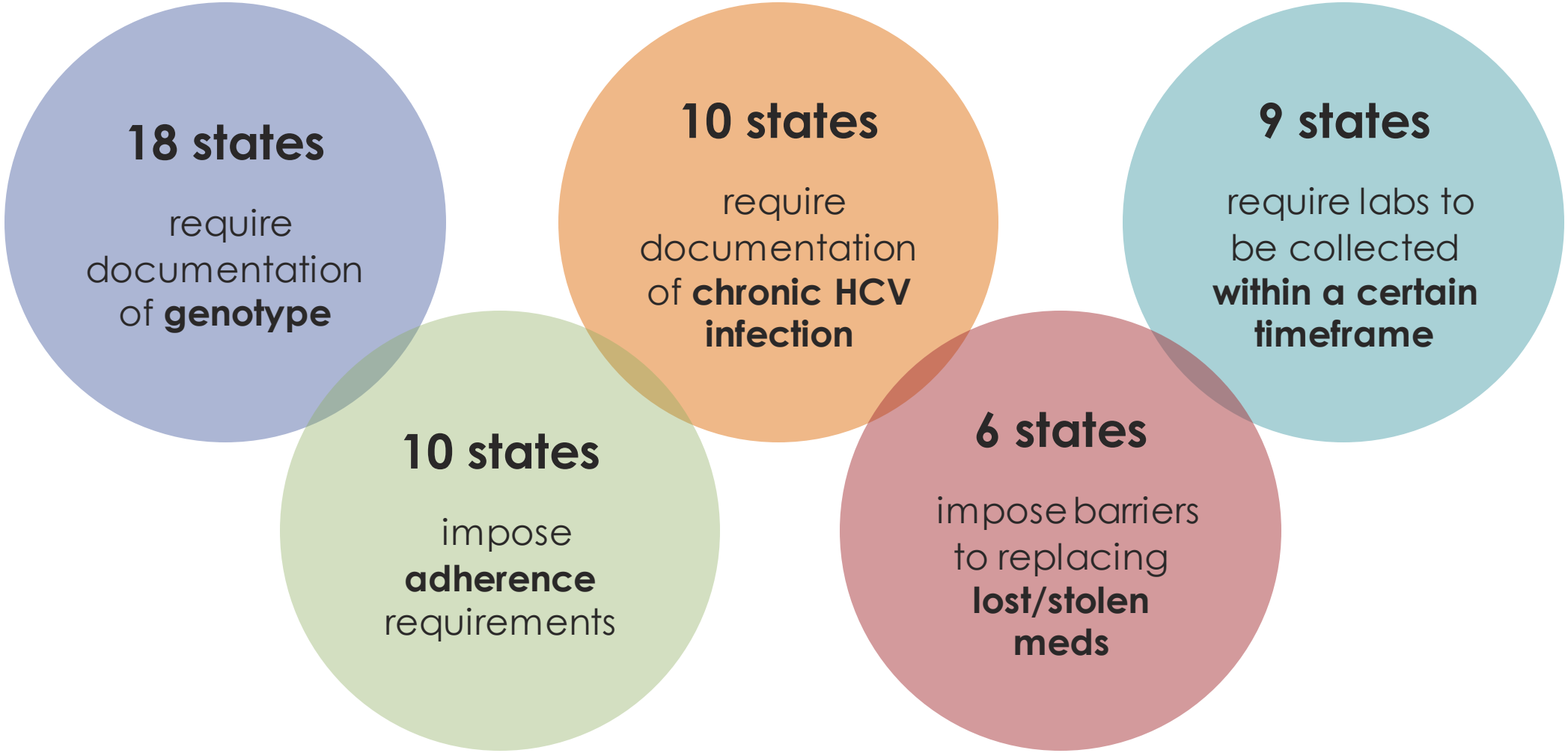
Access in Managed Care

- In states that operate managed care programs, **16 states** have at least one managed care organization (MCO) that imposes more stringent criteria to treatment access or does not provide publicly available HCV treatment criteria

Some states have strong FFS policies, but poor MCO enforcement (e.g., New Hampshire)



Additional Restrictions



Specialty Pharmacy Reinforces Barriers to Treatment

Challenges

- Mail order and lock-in requirements
- Dispensing limitations (often 30-days' supply)
  - Two states (Connecticut and Maine) have 14-day limits
- Specialty pharmacy processes vary by plan
  - Intake forms often mimic PA forms
  - Signature/phone call requirements are challenging for historically marginalized communities

Solutions

- Allow medication to be filled by non-specialty pharmacies
  - Louisiana and Virginia allow retail pharmacies to fill Rx
- Improve specialty pharmacy processes around communication and delivery
- Dispense full treatment course at treatment initiation
  - Colorado allows 90-day fills
- Engage pharmacy benefit managers about data requirements

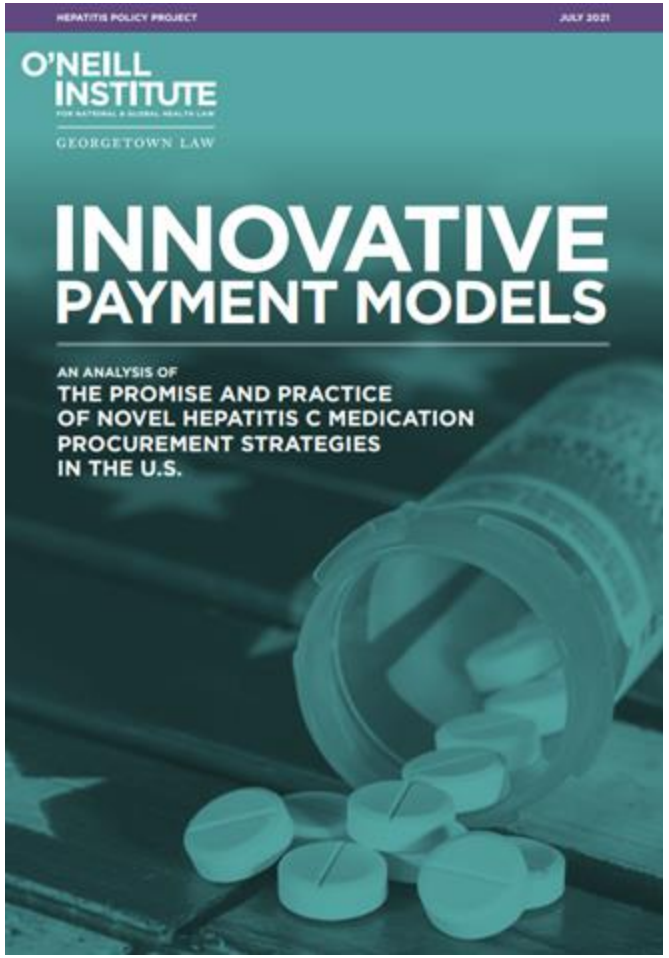
Innovative PA Mechanisms are on the Rise

- States are looking to automatic prior authorization processes referred to as Auto PA or SmartPA
- System automated criteria check for specific requirements (e.g., diagnosis, age, previous therapies, etc.). If all requirements are found, the claims will pay at the pharmacy counter without need of manual prior authorization submission.
- To date, **Indiana** and **Massachusetts** use these processes. **Florida** is in the process of implementing Auto PA.

Auto PA may be an alternative strategy in states that are hesitant to remove prior authorization altogether.

Growing # of States have Single Preferred Agent

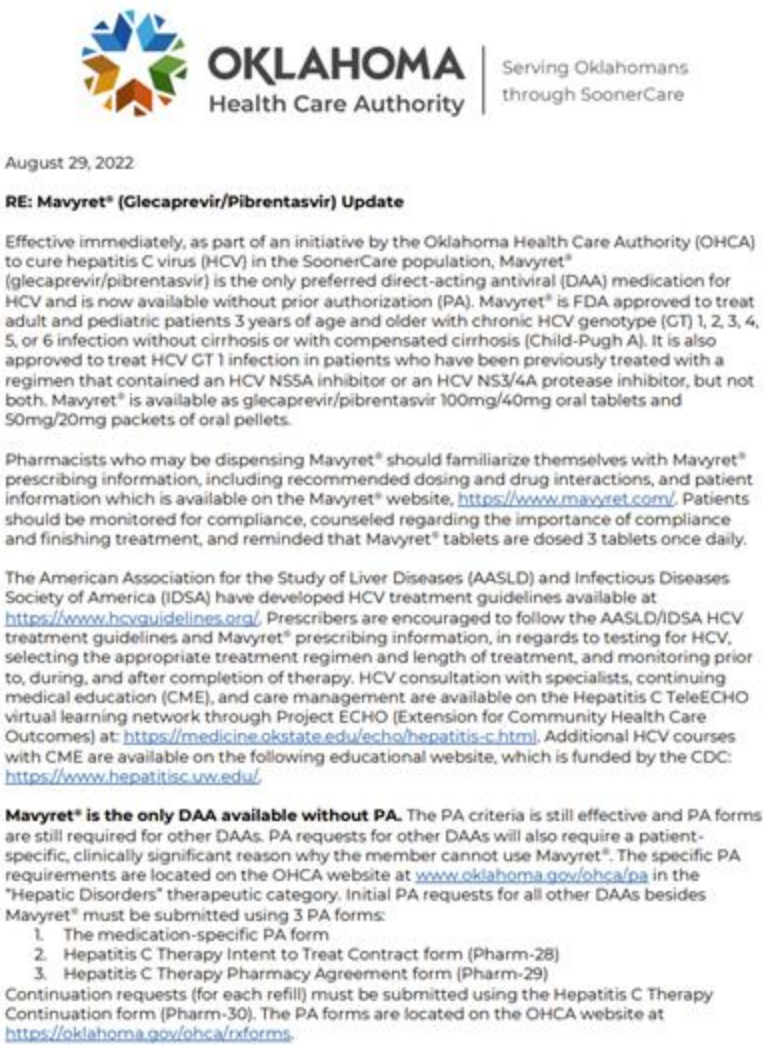
- 10 states have a **single** preferred agent (Mavyret **OR** generic Epclusa) on their Preferred Drug List
  - DC, Louisiana, Michigan, Minnesota, Missouri, Montana, Oklahoma, Puerto Rico, Texas, Washington
- 5 of these states use an innovative payment model (subscription model)
  - Louisiana, Michigan, Missouri, Texas, Washington
- Oklahoma appears to use an outcomes-based contract
- Other states may be purchasing through multi-state purchasing agreements



https://oneill.law.georgetown.edu/wp-content/uploads/2021/07/Innovative-Payment-Models.pdf

Policies Change, Awareness Lags

- When states change policies, patients and providers are often unaware
- States should send letters to providers and conduct outreach to patients who were previously diagnosed and may be untreated
- Clinics, medical societies & professional associations, provider training programs, community-based organizations, and coalitions can also be effective messengers



OKLAHOMA Health Care Authority | Serving Oklahomans through SoonerCare

August 29, 2022

RE: Mavyret® (Glecaprevir/Pibrentasvir) Update

Effective immediately, as part of an initiative by the Oklahoma Health Care Authority (OHCA) to cure hepatitis C virus (HCV) in the SoonerCare population, Mavyret® (glecaprevir/pibrentasvir) is the only preferred direct-acting antiviral (DAA) medication for HCV and is now available without prior authorization (PA). Mavyret® is FDA approved to treat adult and pediatric patients 3 years of age and older with chronic HCV genotype (GT) 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A). It is also approved to treat HCV GT 1 infection in patients who have been previously treated with a regimen that contained an HCV NS5A inhibitor or an HCV NS3/4A protease inhibitor, but not both. Mavyret® is available as glecaprevir/pibrentasvir 100mg/40mg oral tablets and 50mg/20mg packets of oral pellets.

Pharmacists who may be dispensing Mavyret® should familiarize themselves with Mavyret® prescribing information, including recommended dosing and drug interactions, and patient information which is available on the Mavyret® website, https://www.mavyret.com/. Patients should be monitored for compliance, counseled regarding the importance of compliance and finishing treatment, and reminded that Mavyret® tablets are dosed 3 tablets once daily.

The American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA) have developed HCV treatment guidelines available at https://www.hcvguidelines.org/. Prescribers are encouraged to follow the AASLD/IDSA HCV treatment guidelines and Mavyret® prescribing information, in regards to testing for HCV, selecting the appropriate treatment regimen and length of treatment, and monitoring prior to, during, and after completion of therapy. HCV consultation with specialists, continuing medical education (CME), and care management are available on the Hepatitis C TeleECHO virtual learning network through Project ECHO (Extension for Community Health Care Outcomes) at: https://medicine.okstate.edu/echo/hepatitis-c.html. Additional HCV courses with CME are available on the following educational website, which is funded by the CDC: https://www.hepatitisc.uw.edu/.

Mavyret® is the only DAA available without PA. The PA criteria is still effective and PA forms are still required for other DAAs. PA requests for other DAAs will also require a patient-specific, clinically significant reason why the member cannot use Mavyret®. The specific PA requirements are located on the OHCA website at www.oklahoma.gov/ohca/pa in the "Hepatic Disorders" therapeutic category. Initial PA requests for all other DAAs besides Mavyret® must be submitted using 3 PA forms:

1. The medication-specific PA form
2. Hepatitis C Therapy Intent to Treat Contract form (Pharm-28)
3. Hepatitis C Therapy Pharmacy Agreement form (Pharm-29)

Continuation requests (for each refill) must be submitted using the Hepatitis C Therapy Continuation form (Pharm-30). The PA forms are located on the OHCA website at https://oklahoma.gov/ohca/rxforms.

Opportunities, Advocacy, & Key Takeaways

Opportunities and Threats

Opportunities

- National HCV Elimination Program
- MINMON Study
- Treatment access in correctional facilities
  - California 1115 Waiver for Medicaid eligibility 90 days pre-release
- COVID-19 pandemic innovations (e.g., rapid diagnostics, telehealth)

Threats

- Public Health Emergency expiration
- Medicaid expansion holdout states
- Manufacturer restrictions on 340B Program
- Treatment access in Medicare & commercial insurance

Call to Action

- ***Patients***: Tell your story! Join our Voices4Hep Network & see our Prior Auth and Letter to the Editor toolkits
- ***Advocates***: Share your state's grade & call for action! Use social media & advocacy events to publicize the need for change
- ***Providers***: Use your voice! Make the case for removing burdensome barriers through written or oral testimony to your state Medicaid P&T Committee or Drug Utilization Review Board
- ***Viral Hepatitis Coordinators***: Link to elimination planning! Convene stakeholders in charting a path to full access to cure
- ***State Medicaid Officials***: Review and update your policies!
- ***CMS***: Issue updated guidance to State Medicaid Directors!

Key Takeaways

- Prior authorization removal offers an exciting opportunity for state Medicaid programs to increase HCV treatment access and advance health equity.

- Substantial progress has been made since 2017 in reducing the number of states that impose fibrosis, substance use, and prescriber restrictions on HCV treatment access.

- Many restrictions rooted in stigma and discrimination remain. Restrictions must be removed to eliminate HCV by 2030.

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