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and POLICY INNOVATION
HARVARD LAW SCHOOL



The State of Medicaid Access:

National Summary Report

June 28, 2018

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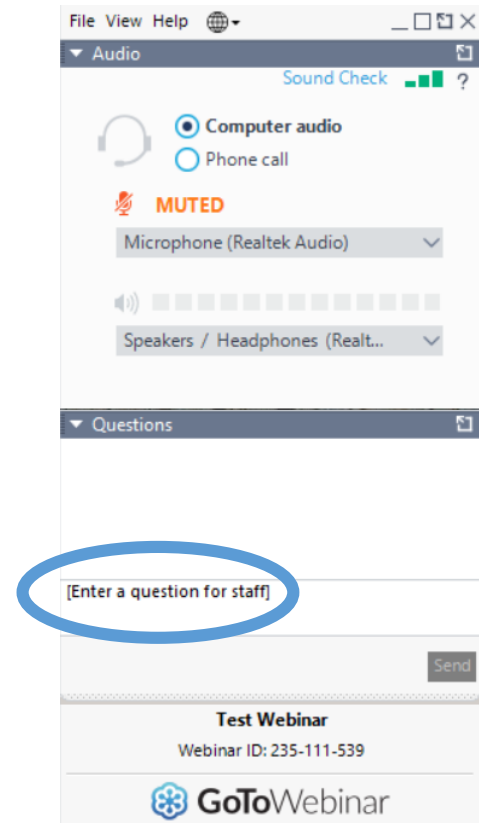
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Housekeeping: GoToWebinar

- Slides and a recording of the webinar will be sent to everyone who registered and posted on our website.
- Please use the question box to submit your questions and comments
- The Q&A session will follow the last presentation



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The Big Picture

- The advent of new treatments to combat HCV is a major development in treating the deadliest infectious disease in US.
- Unfortunately, despite the potential of curative medications, many state Medicaid programs limit access due to cost concerns.
- Limitations run counter to clear guidance from CMS and are in direct opposition to AASLD and IDSA treatment guidelines.
- Failure to provide appropriate access to HCV treatment threatens the health of millions of our most vulnerable residents in the US.

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The Research

- *Hepatitis C: The State of Medicaid Access*, updates and expands upon initial 2014 Medicaid fee-for-service (FFS) surveys, and documents the current state of Medicaid FFS and managed care organization (MCO) HCV treatment access currently.
- The preliminary report provides an evaluation of treatment access in each state's Medicaid program.
 - focusing on liver damage, sobriety, and prescriber restrictions
 - highlighting successes in access expansion as well as ongoing challenges since 2014
 - providing a first-time national assessment of Medicaid Managed Care Organization (MCO) coverage

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Methods

- Evaluated Medicaid reimbursement criteria for available DAAs for all 50 states, the District of Columbia and Puerto Rico.
- 2014 research from Annals of Internal Medicine survey.
- Ongoing research of state Medicaid reimbursement criteria from responses to survey sent to Medicaid officials, publically available Medicaid documents, or official press or media releases.
- Data were crosschecked by CHLPI and NVHR staff with differences resolved by consensus.
- Multiple MCOs may operate in a state, and restrictions on access to HCV treatment are expressed in a range.

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Key Findings

- Access to HCV treatment has improved, primarily in reduction/elimination of FFS liver disease or fibrosis restrictions.
- Access restrictions related to sobriety and prescriber limitations have decreased to a far lesser extent.
- While there are some MCOs with low levels of restrictions, many follow their states' fee-for-service (FFS) Medicaid restrictions, and others impose more onerous restrictions.
- Transparency has increased dramatically from 2014 to 2018.

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Report Card Comparison

Connecticut



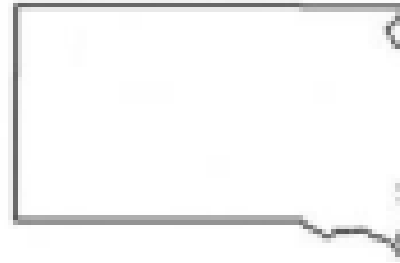
Liver Damage Minimum: None

Sobriety: None

Prescriber: None

Grade: **A+**

Montana



Liver Damage Minimum: F3

Sobriety: 6 Months

Prescriber: Specialist

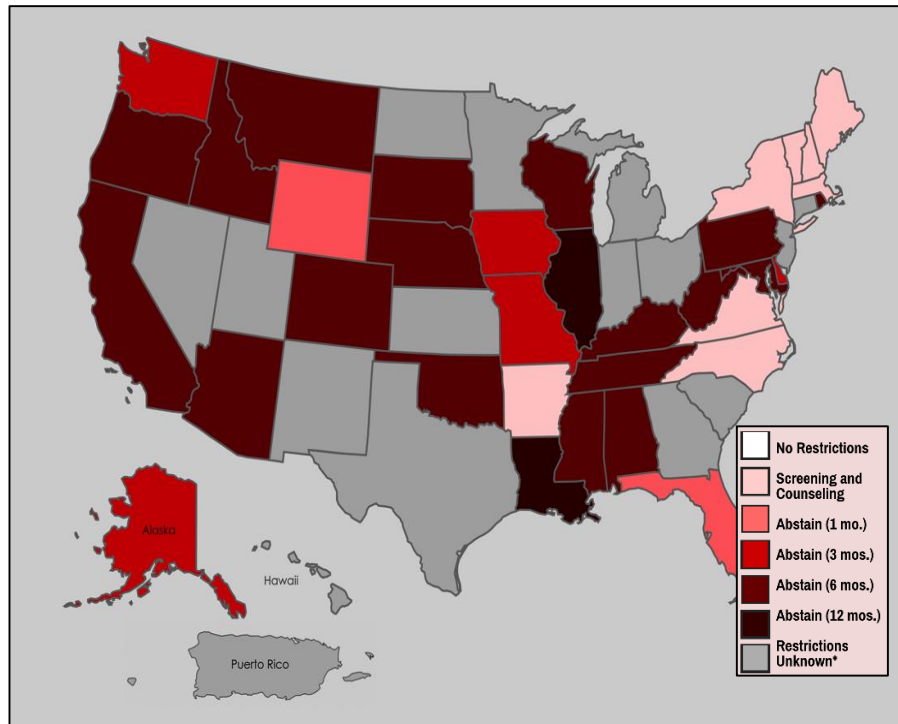
Grade: **F**

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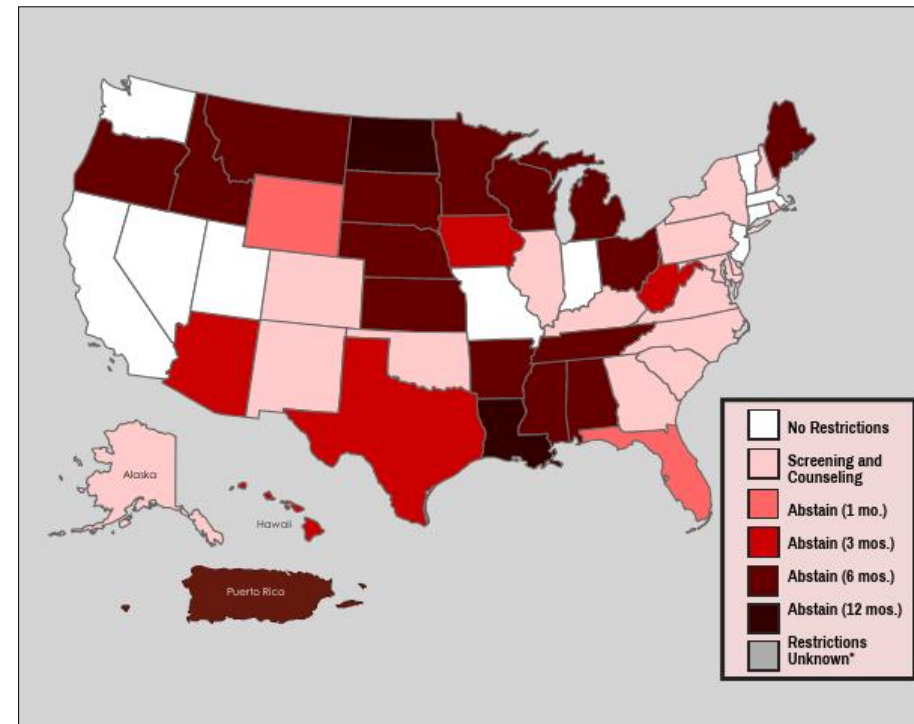
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Findings: Sobriety Restrictions

2014



2018

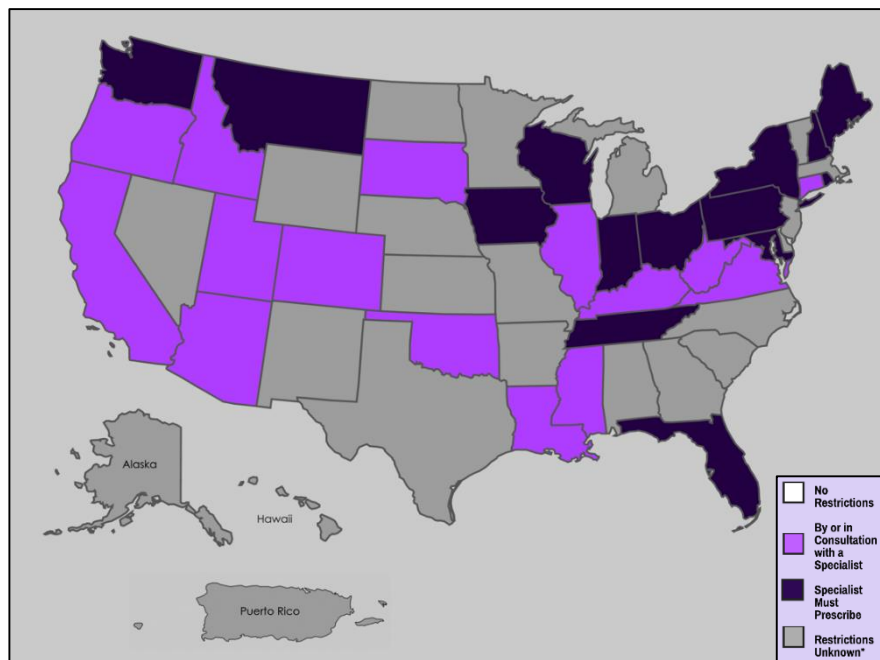


Data and figures presented here are current as of May 2018. CHLPI and NVHR at <https://stateofhepc.org/>.

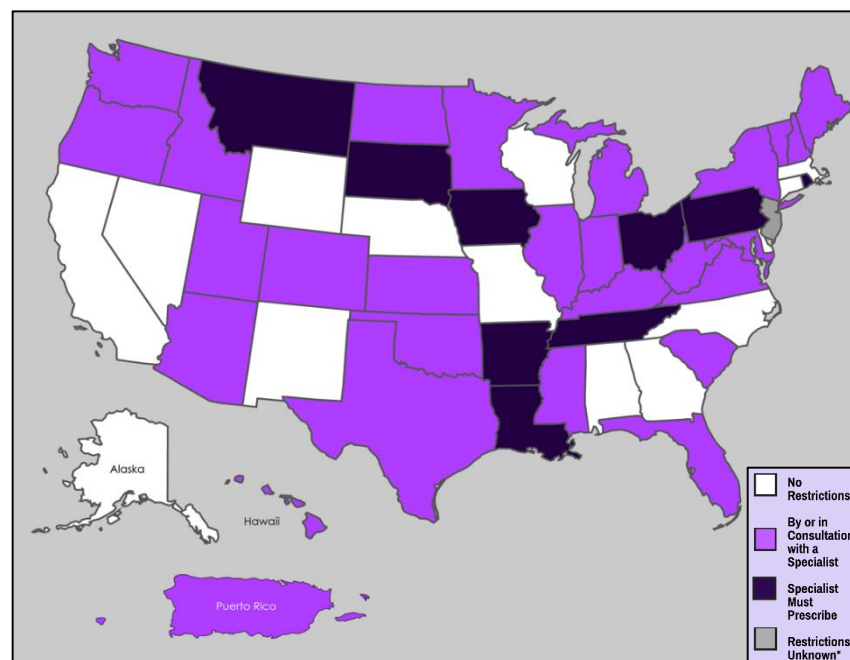
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Findings: Prescriber Restrictions

2014



2018



Data and figures presented here are current as of May 2018. CHLPI and NVHR at <https://stateofhepc.org/>.

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Findings: MCOs

Liver Damage	Sobriety	Prescriber
34%	28%	41%

- While most MCOs follow their state's FFS rules, some impose more restrictive treatment criteria
- 42 CFR § 438.210: “Each contract between a State and an MCO. . .must. . .[r]equire that. . .services. . .be furnished in **an amount, duration, and scope that is no less than the amount, duration, and scope for the same services furnished to beneficiaries under FFS Medicaid . . .**”

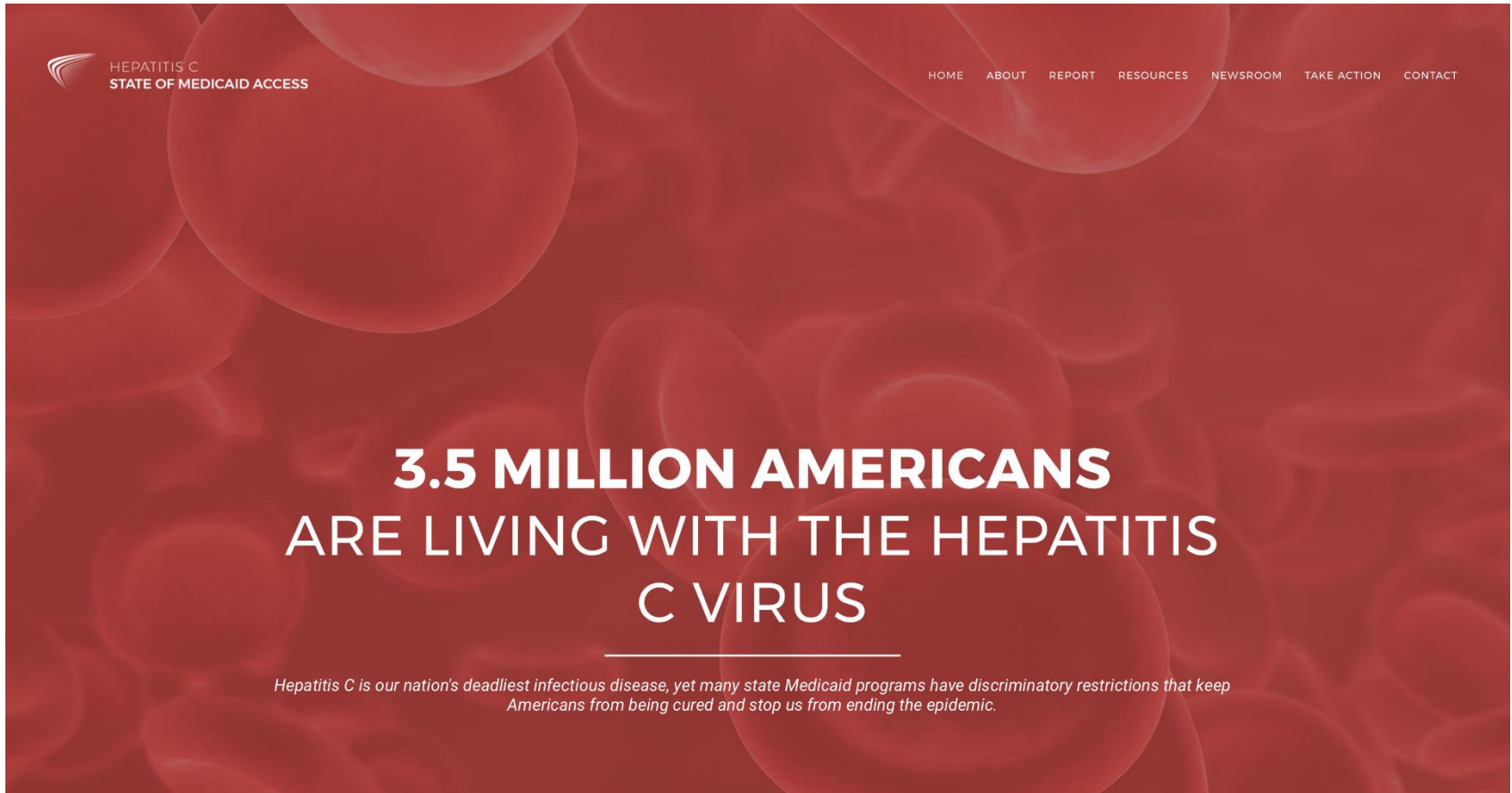
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Report Card Example

Go to:
stateofhepc.org

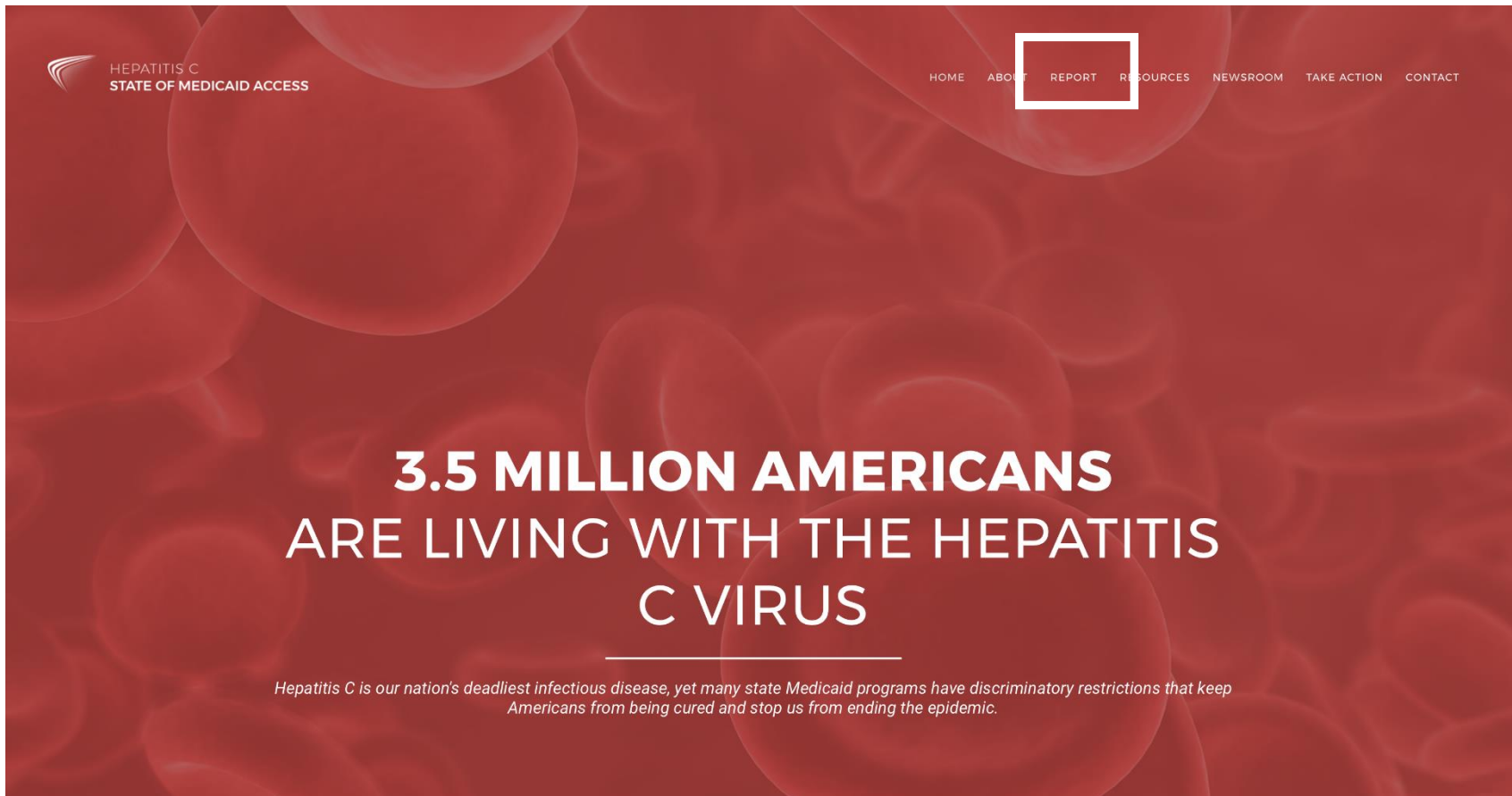
#StateofHepC

Report Card Example



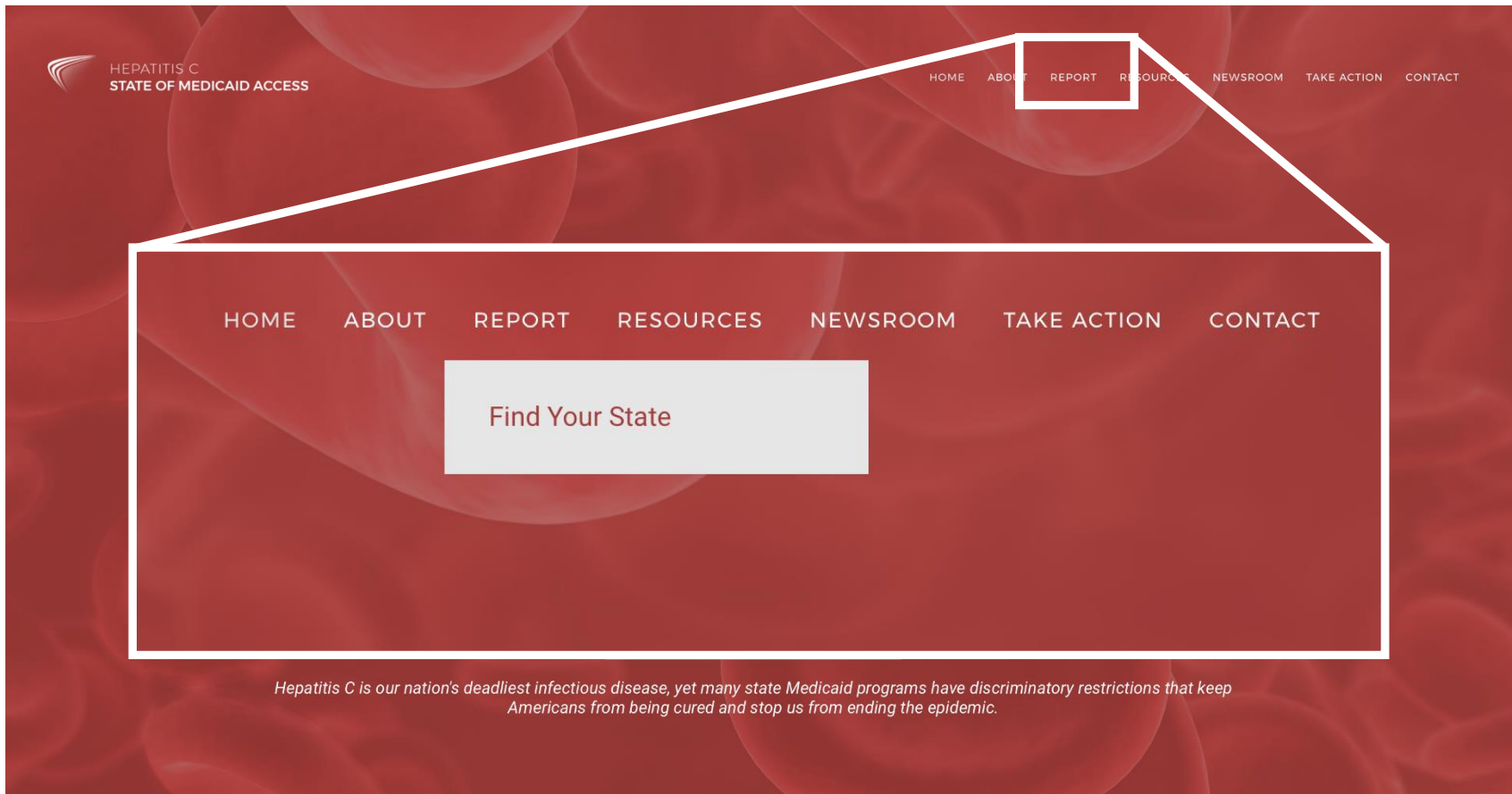
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Report Card Example



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Report Card Example



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Report Card Example

FIND YOUR STATE

A-H

I-L

M

N

O-S

T-W

Alabama

State of Hepatitis C Medicaid Access:

D+

—

LIVER DAMAGE RESTRICTIONS

Alabama requires at least moderate liver damage (F2 or greater).

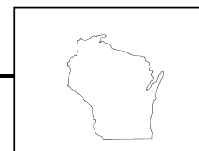
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Report Card Example

Hepatitis C: State of Medicaid Access Report Card

Wisconsin

Estimated Number of Individuals Living with Hepatitis C: 31,100¹



Grade	Summary
D+	<p>Liver Damage (Fibrosis) Restrictions: Fee-For-Service (FFS) and Managed Care Organizations (MCOs) do not have any liver damage restrictions.</p> <p>Sobriety Restrictions: FFS and MCOs require beneficiaries with a history of alcohol or substance use to be abstinent six months prior to and during treatment. A patient with a recent history of substance use must be an active participant in a treatment program.</p> <p>Prescriber Restrictions: FFS and MCOs do not have any prescriber requirements.</p> <p>Recommendations to Improve Patient Access:</p> <ul style="list-style-type: none">• Remove sobriety restrictions.• Maintain transparency regarding hepatitis C coverage criteria and continue to exclude prescriptions from MCO contracts to ensure requirements apply to all Medicaid beneficiaries. <p><i>Grade Rationale: Wisconsin recently removed liver damage and prescribing requirements. However, the state still imposes unacceptable sobriety (six months) restrictions. With these restrictions, many people with hepatitis C do not have access to treatment. In recognition of parity across FFS and MCOs and the removal of liver damage and prescriber requirements, a "plus" has been added to Wisconsin's D grade.</i></p>

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Report Card Example

Background

As of June 2017, Wisconsin had 1,039,204 individuals enrolled in Medicaid and Children's Health Insurance Program (CHIP).² ForwardHealth is the umbrella term used for all the health care and nutrition benefit programs offered through the Wisconsin Department of Health Services.³ The state operates a Fee-For-Service (FFS) program and contracts with Managed Care Organizations (MCOs), a program known as BadgerCare Plus.⁴ Sixty-seven percent participate in the MCO program and 33 percent in FFS.⁵ BadgerCare Plus was created to expand Medicaid coverage and since 2008 has expanded to include additional populations.⁶ Wisconsin contracts with 18 MCOs⁷; however, the state excludes most prescription medications—including hepatitis C medications—from BadgerCare Plus contracts. Wisconsin pays for drugs through the FFS program.⁸ FFS establishes the prior authorization (PA) coverage criteria and approves hepatitis C treatment.

State of Medicaid Hepatitis C Treatment Access

Wisconsin Medicaid has significantly improved access to hepatitis C medications by eliminating liver damage and prescriber requirements. Previously, the state required at least moderate liver damage (F2 or greater) and a prescription to be written by or in consultation with a specialist.⁹ In September 2017, Wisconsin removed all liver damage and prescriber criteria.¹⁰ The state requires a diagnosis of chronic hepatitis C.¹¹ Sobriety requirements remain unchanged. Patients with a history of alcohol or substance use must be abstinent for six months prior to and during treatment.¹²

Beneficiaries must be at least 18-years-old.¹³ The PA requires detailed clinical information be submitted including: a copy of current medical records, hepatitis C assessment and treatment plan, testing results with in the last six months (for albumin, complete blood count, international normalized ratio, liver function tests, and serum creatinine), the current medication list and current and past psychological history (including alcohol and substance use) provided by the primary care provider.¹⁴ Prescribers must also provide the date the beneficiary was diagnosed with hepatitis C, the likely source of infection as well as the patient's genotype and subtype.¹⁵ Initially, treatment is approved for eight weeks and may be renewed for up to twelve weeks if the HCV RNA level falls below 25 IU/mL.¹⁶ Additionally, "PA requests for hepatitis C agents included in drug class on the Preferred Drug List are approved as pharmacy provider-specific."¹⁷ For renewal, a copy of the patient's HCV RNA lab results must be submitted for treatment weeks four and 12.¹⁸ The preferred drugs are listed by genotype: Genotype 1 (Viekira XR, Viekira Pak, Zepatier); Genotype 2 & 3 (Epclusa); Genotype 4 (Technivie, Zepatier)¹⁹ PA requests for treatment due to reinfection will be denied.²⁰

Liver Damage (Fibrosis) Restrictions

Wisconsin Medicaid requires only a diagnosis of chronic hepatitis C and does not have liver damage requirements.²¹

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Report Card Example

Points of Contact for Questions & Concerns about Wisconsin's State of Medicaid Hepatitis C Access

Medicaid²⁵: Michael Heifetz, Medicaid Director, Department of Health Services, State of Wisconsin

One West Wilson Street, Room 350 PO Box 309, Madison, WI 53701-0309;

Telephone: (608) 266-5151; Email Address: michael.heifetz@dhs.wisconsin.gov

Drug Utilization Review (DUR) Board²⁶: Jacque Nash, Pharm D

Telephone: (334) 466-3057; Email Address: Jacqueline.nash@hidesigns.com

¹ Wisconsin State Profile, HepVu (Accessed July 2017): <https://hepvu.org/state/wisconsin/>

² Medicaid and CHIP in Wisconsin, By-State, Medicaid.gov (Accessed July 2017): <https://www.medicaid.gov/medicaid/by-state/stateprofile.html?state=wisconsin>

³ Information about Your Enrollment and Benefits, ForwardHealth, Wisconsin Department of Health Services, February 2017 (Accessed July 2017): <https://www.dhs.wisconsin.gov/publications/p0/p00079.pdf>

⁴ Share of Medicaid Population Covered Under Different Delivery Systems, Medicaid Managed Care Market Tracker, The Henry J. Kaiser Family Foundation, July 1, 2016 (Accessed: July 2017):

<http://www.kff.org/medicaid/state-indicator/share-of-medicaid-population-covered-under-different-delivery-systems/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>

⁵ Ibid. Share of Medicaid Population Covered Under Different Delivery Systems

⁶ Alexandra Gates and Robin Rudowitz, Wisconsin's BadgerCare Program and the ACA, The Henry J. Kaiser Family Foundation, Feb. 25, 2014: <http://kff.org/medicaid/fact-sheet/wisconsins-badgercare-program-and-the-aca/> (Accessed July 2017)

⁷ BadgerCare Plus Enrollment Data, Wisconsin Department of Health Services (Accessed July 2017): <https://www.dhs.wisconsin.gov/badgercareplus/enrolldata.htm>

⁸ Contract for BadgerCare Plus and/or Medicaid SSI, HMO Services between The HMO and The Wisconsin Department of Health Services, January 1, 2016 through December 31, 2017 (Access July 2017): <https://www.forwardhealth.wi.gov/WIPortal/content/Managed%20Care%20Organization/Providers/2016-2017HMOContract.pdf>; See also: Devon M. Herrick, Reforming Wisconsin's Medicaid Drug Program, National Center for Policy Analysis No. 139 February 19, 2014 (Accessed July 2017): <http://www.ncpa.org/pub/ib139>; See also: Molina Healthcare, Prescription Drugs What's Covered, MOLINAHEALTHCARE.COM <http://www.molinahealthcare.com/members/wi/en-US/hp/medicaid/ssiovw/coverd/Pages/presdrugs.aspx> (Accessed July 2017); Molina Healthcare, Member Handbook 2017 (Accessed July 2017): <http://www.molinahealthcare.com/members/wi/en-US/PDF/Medicaid/member-handbook.pdf>

⁹ Ibid. Prior Authorization Drug Attachment for Hepatitis C Agents, ForwardHealth

¹⁰ Pharmacy Published Policy Through September 30, 2017, Claims, Wisconsin Medicaid (Accessed October 2017): <https://www.forwardhealth.wi.gov/kw/archive/Pharmacy100217.pdf>

¹¹ Ibid. Pharmacy Published Policy Through September 30, 2017, Claims, Wisconsin Medicaid

¹² Ibid. Pharmacy Published Policy Through September 30, 2017, Claims, Wisconsin Medicaid

¹³ Ibid. Prior Authorization Drug Attachment for Hepatitis C Agents, ForwardHealth

¹⁴ Ibid. Prior Authorization Drug Attachment for Hepatitis C Agents, ForwardHealth

¹⁵ Ibid. Prior Authorization Drug Attachment for Hepatitis C Agents, ForwardHealth

¹⁶ Claims, Pharmacy, Wisconsin Medicaid, Published Policy through May 31, 2017 (Accessed June 2017): <https://www.forwardhealth.wi.gov/kw/archive/Pharmacy060117.pdf>

¹⁷ July 2017 Preferred Drug List Review and Other Pharmacy Policy Changes, ForwardHealth, No. 2017-17, Update: June 2017 (Accessed July 2017): <https://www.forwardhealth.wi.gov/kw/pdf/2017-17.pdf>

¹⁸ Claims, Pharmacy, Wisconsin Medicaid, Published Policy through May 31, 2017 (Accessed June 2017): <https://www.forwardhealth.wi.gov/kw/archive/Pharmacy060117.pdf>

¹⁹ Ibid. Pharmacy Published Policy Through September 30, 2017, Claims, Wisconsin Medicaid

²⁰ Ibid. Pharmacy Published Policy Through September 30, 2017, Claims, Wisconsin Medicaid

²¹ Ibid. Pharmacy Published Policy Through September 30, 2017, Claims, Wisconsin Medicaid

²² Prior Authorization Drug Attachment for Hepatitis C Agents, ForwardHealth, Division of Health Care Access and Services, Wisconsin (Version 01/2017): <https://www.dhs.wisconsin.gov/forms/f01247-0717.pdf> (Accessed July 2017); See also: Prior Authorization Drug Attachment for Hepatitis C Agents, Wisconsin Department of Health Services (Accessed July 2017): <https://www.dhs.wisconsin.gov/library/F-01247.htm>

²³ Ibid. Prior Authorization Drug Attachment for Hepatitis C Agents, ForwardHealth

²⁴ Ibid. Pharmacy Published Policy Through September 30, 2017, Claims, Wisconsin Medicaid

²⁵ Medicaid Directors, National Association of Medicaid Directors (Accessed July 2017): <http://medicaiddirectors.org/about/medicaid-directors/>

²⁶ Board Members, Wisconsin Drug Utilization Review Board, ForwardHealth (Accessed July 2017): <https://www.forwardhealth.wi.gov/wiportal/content/provider/medicaid/pharmacy/dur/members.htm> <https://www.forwardhealth.wi.gov/kw/archive/Pharmacy060117.pdf>

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Data for Advocacy

- Links to data sources in report cards for tracking drug coverage changes (in footnotes)
 - Evolving project capturing updates as they occur
- HCV report cards can be used to advocate for increased access to HCV drugs to state Medicaid directors
 - Contact info for each state Medicaid director and Drug Utilization Board chair is in the report card

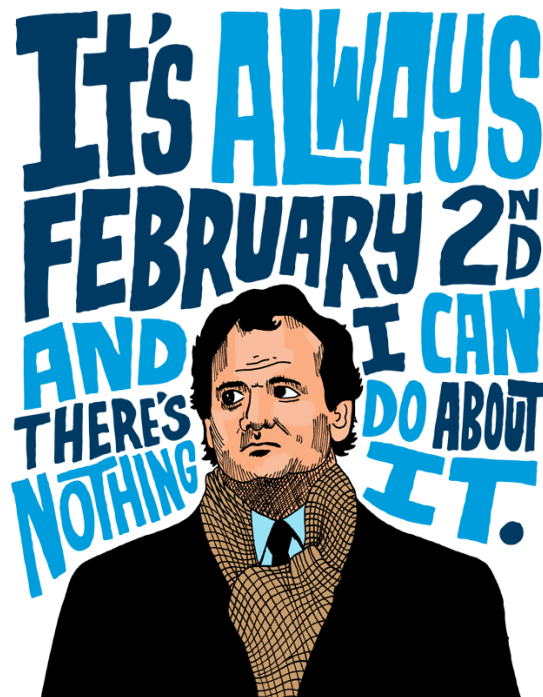
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Expanding Access to DAAs for People who are Medicaid Recipients in Rhode Island

Lynn E. Taylor, MD, FACP, FAASLD
Research Professor, University of Rhode Island
Director of HIV and Viral Hepatitis Services, CODAC Behavioral Health
www.RIDefeatsHepC.com
June 28, 2018



OR...Ending Hepatitis C Groundhog Day



Outline

- Discuss History of Rhode Island (RI) Medicaid Re: Access to Direct Acting Antiviral (DAA) Agents
- Review How NVHR's Report Card Impacted Advocacy
- Consider Role of Clinicians in Advocacy
- Report on New Policy Changes for RI

December 2013

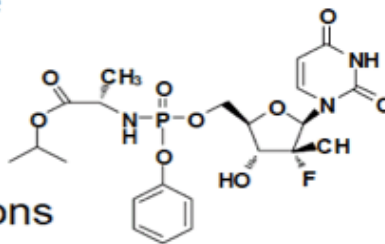


FIRST EVER Interferon-Free Therapy approved by FDA: Sofosbuvir

Nucleotide Analogue Inhibitor of HCV NS5B polymerase enzyme

Sofosbuvir (GS-7977)

- ◆ Potent HCV-specific nucleotide analog (chain terminator)
- ◆ Safe and well tolerated
 - Once daily, no food effect
 - No significant drug interactions
 - No safety signals in preclinical/clinical studies
- ◆ High barrier to resistance
 - No virologic breakthrough to date
- ◆ Pangenotypic antiviral effect



"historic"
"game-changer"
"miracle drug"

Medicaid and DAAs

- In U.S., disproportionate number of people living with HCV are of low-income.
- Most are eligible for HCV therapy reimbursement through Medicaid, the jointly-funded federal/state partnership that provides health insurance for low-income people meeting the program's eligibility criteria.
- Each state has wide discretion in administering its own Medicaid program. While this creates unique Medicaid programs in each state, there are some federal standards that states must follow. These include:
 - Covering all FDA-approved drugs, consistent with FDA labelling, whose manufacturers participate in Medicaid's prescription drug rebate program;
 - Not discriminating in drug coverage—a state “may not arbitrarily deny or reduce the amount, duration, or scope of a required service . . . to an otherwise eligible beneficiary solely because of the diagnosis, type of illness, or condition.”

What Happened with RI Medicaid and Sofosbuvir

Access after Dec 2013??

- NOTHING. No sofosbuvir access for months
- Medicaid: Meetings, meetings, more meetings...no sofosbuvir...Prior Authorization (PA) form being developed...months went by...HCV experts weighed in/reviewed PA drafts, provided input... science shared, reviewed evidence...no patients were treated...
- Meanwhile: started conferring with colleagues around U.S.; started investigating Medicaid response to FDA-approval sofosbuvir around U.S.
 - Barua S, Greenwald R, Grebely J, Dore GJ, Swan T

From: RN
Sent: Tuesday, July 08, 2014 3:38 PM
To: Taylor, Lynn E. MD



- “Had an unusual call today. X’s insurance called looking for information to ship meds out. Insurance asked if patient current substance user, I said no.
- Person wanted to know information like last tox screen, past substance use, made me uncomfortable, my response was to tell her that per my knowledge you had just spoken with medical director and medication was approved for 24 weeks, cited your note in EMR.
- I told her that she needed to speak with you for more information. I don’t understand why they would need that information.”

Sent: Tuesday, July 15, 2014 5:15 PM

To: Taylor, Lynn E. MD


- “Hi Lynn,
- Interesting follow up to the X situation from last week where apparently Y (RI Medicaid) was asking about X’s substance use etc.
- Got a phone call today from someone named Z (RI Medicaid) asking if we would send them over a copy of a urine tox screen on X and a letter signed by her saying that she no longer uses drugs! Can you believe it?!
- I tried to call him back but I get no answer or voice mail...odd. And, apparently he doesn’t know that his company has already approved X’s Ribavirin.”

Aug 14, 2014: RI Medicaid Prior Authorization

CLINICAL INFORMATION:

a. HEPATITIS C GENOTYPE _____ QUANTITATIVE VIRAL LOAD _____ DATE OF REPORT _____

b. CURRENT CLINICAL STATUS INCLUDING COMPENSATED/DECOMPENSATED LIVER DISEASE:

c. STAGE 3 OR 4 LIVER DISEASE CONFIRMED BY (PLEASE INDICATE QUANTITATIVE VALUE): 

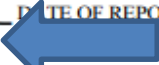
i. AST/PLATELET RATIO INDEX: _____ DATE OF REPORT _____

ii. FIBROSCAN: _____ DATE OF REPORT _____

iii. FIBROTEST: _____ DATE OF REPORT _____

iv. IMAGING STUDY (PLEASE SPECIFY AND ATTACH REPORT): _____
_____ DATE OF REPORT _____

v. LIVER BIOPSY RESULT: _____
_____ DATE OF REPORT _____

d. HISTORY OF SIGNIFICANT ALCOHOL OR INTRAVENOUS DRUG USE DISORDER:  YES ___ NO ___

a. IF YES, HAS PATIENT BEEN DRUG FREE FOR THE PAST SIX(6) MONTHS? YES ___ NO ___

b. OR, IS PATIENT PARTICIPATING IN AN ACTIVE MONITORING/THERAPEUTIC PROGRAM? brYES ___ NO ___

e. EVIDENCE OF HEPATOCELLULAR CARCINOMA: YES ___ NO ___

f. _____ YES ___ NO ___

g. _____ YES ___ NO ___

h. _____ YES ___ NO ___

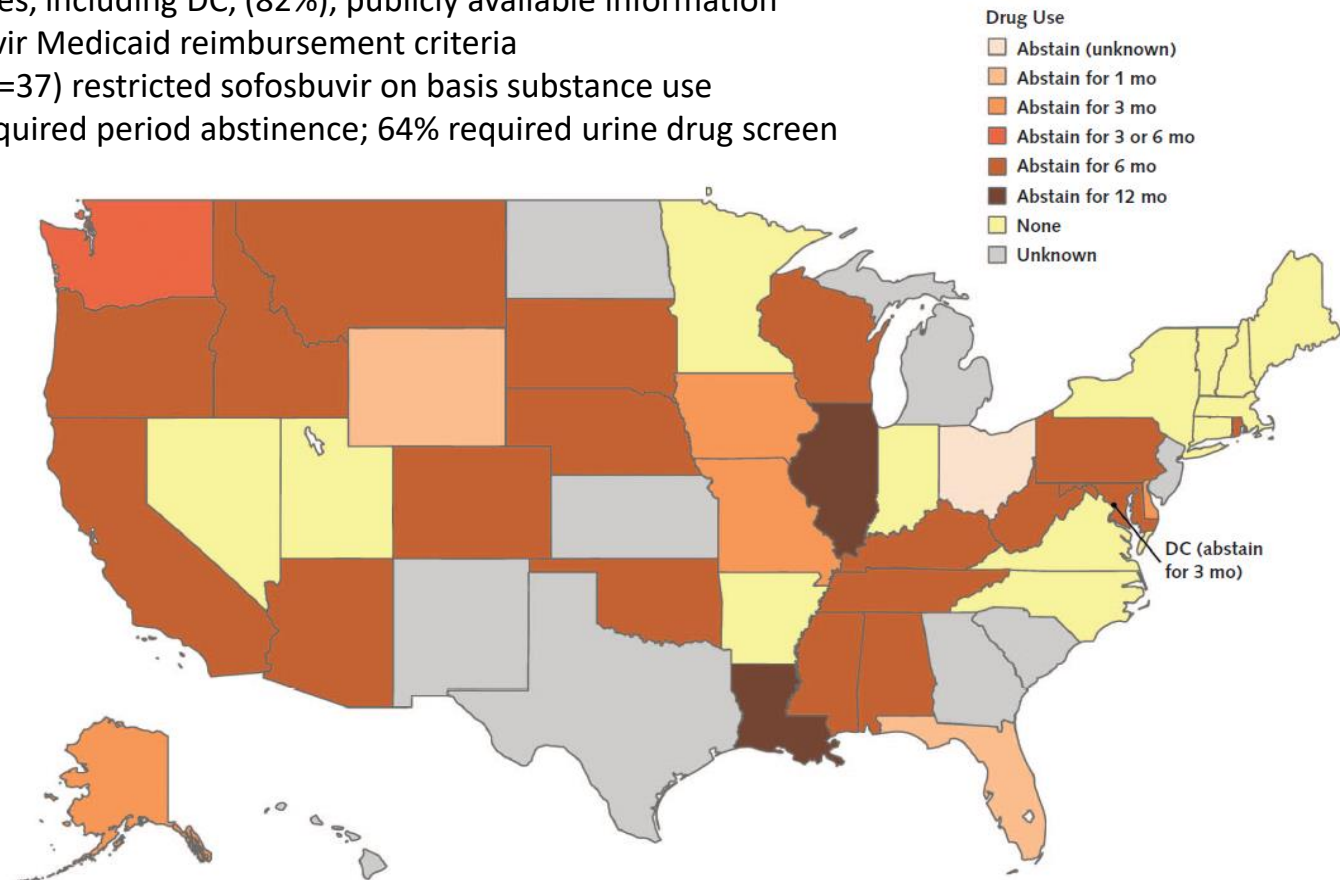
i. _____ YES ___ NO ___

Have you ever seen these questions when you prescribe treatment for HIV/AIDS, cancer, RA?

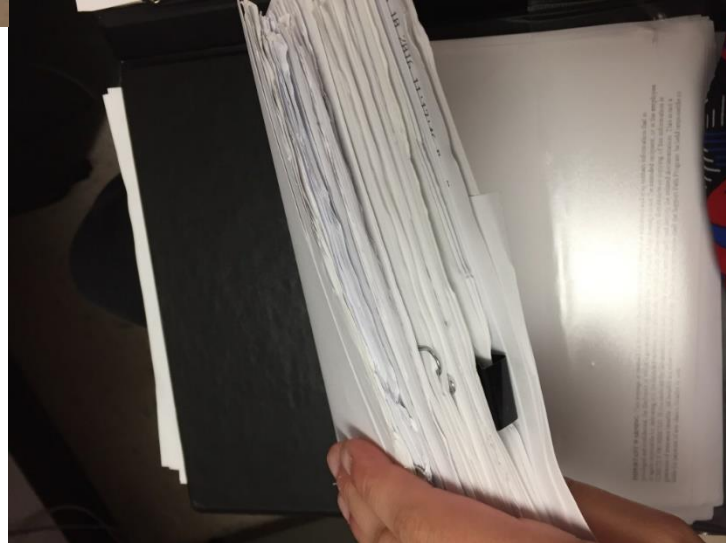
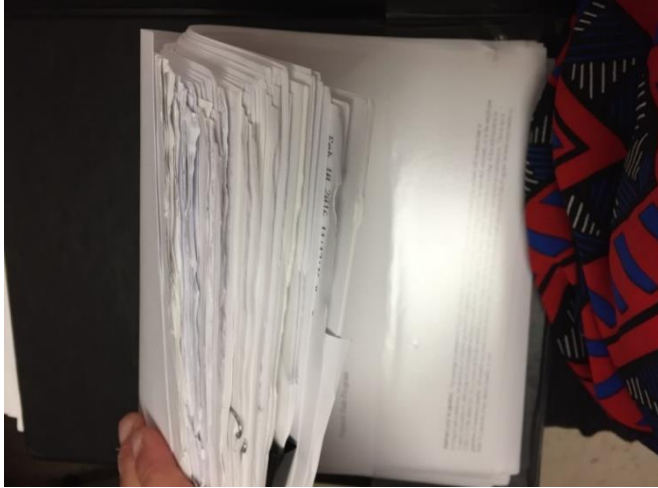
People who use drugs hold key to ending HCV epidemic

Sofosbuvir Medicaid restrictions in US: Illicit drug use

- 42 states, including DC, (82%), publicly available information sofosbuvir Medicaid reimbursement criteria
- 88% (n=37) restricted sofosbuvir on basis substance use
50% required period abstinence; 64% required urine drug screen



Appeals Documentation Examples: Each stack for 1 patient



RI Advocacy



- **RID Hep C** is a comprehensive program to:
 - Seek, treat, cure and eliminate HCV in Rhode Island.
 - Reduce illness, suffering and death due to HCV in RI.
 - Save money for RI and Rhode Islanders by enhancing proactive HCV care.
 - Bring resources into RI to help combat RI's HCV epidemic.
- **RID Hep C** priorities include:
 - Facilitating strategic HCV partnerships in RI and bringing HCV to the forefront of education and public health institutions.
 - Advocating to reduce the stigma and health care disparities associated with HCV.
 - Developing efficient, affordable and equitable community-based responses.
 - Keeping RI up to date with rapidly evolving best practices for implementing HCV diagnosis, evaluation and treatment.
 - Improving the capacity of RI's health systems to address HCV.
 - Utilizing innovations in health technology to enhance HCV prevention and diagnosis to cure in RI.
 - Developing on-site HCV care for high prevalence populations.
 - Fostering HCV research focused on enhancing care in RI.
 - Using RI's world-class arts community to engage people in the HCV field.

Kept the Pressure on 2013-2017...no progress re: restrictions

Hep C WaterFire: Annually for World Hepatitis Day



Meetings with

- RI Medicaid
- RI DOH
- National policy leaders
- HCV Advocacy group/diverse stakeholders

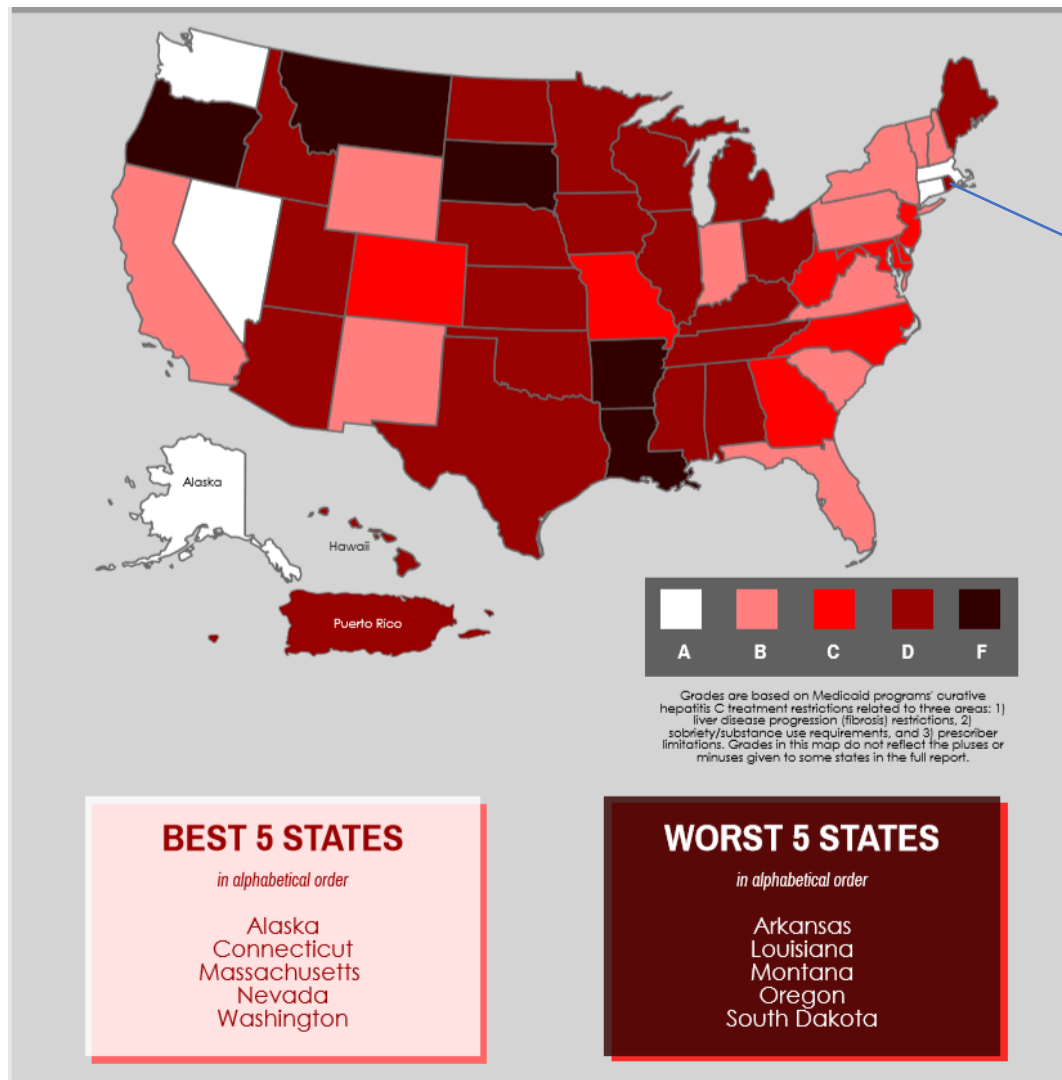


Hepatitis C: State of Medicaid Access Report Card

Updated November 2017

Rhode Island: Estimated Number of Individuals Living with Hepatitis C: 17,500

Grade	Summary
D-	<p>Liver Damage (Fibrosis) Restrictions: Fee-For-Service (FFS) requires at least moderate liver damage (F2 or greater) for patients co-infected with HIV and severe liver damage (F3 and above) for mono-infected patients. One Managed Care Organization (MCO), Neighborhood Health Plan, imposes the same liver damage requirements as FFS. One MCO, UnitedHealthcare Community Plan, requires severe liver damage (F3 or greater). One MCO, Tufts Health Plan, has unclear liver damage requirements.</p> <p>Sobriety Restrictions: FFS requires screening and concurrent alcohol and substance use counseling for beneficiaries actively using. One MCO, Tufts Health Plan, requires screening for active alcohol and substance use. One MCO, UnitedHealthcare Community Plan, imposes different sobriety requirements depending on which Medicaid program (Rite Care or Rhody Health Partners) a beneficiary is enrolled in (30 days abstinence or six months abstinence). One MCO, Neighborhood Health Plan, does not impose sobriety requirements.</p> <p>Prescriber Restrictions: FFS requires a specialist to prescribe and be approved by the Executive Office of Health & Human Services. One MCO, Neighborhood Health Plan, also requires the prescriber to be approved by the state. Two MCOs, UnitedHealthcare Community Plan and Tufts Health Plan, require a specialist to prescribe.</p> <p>Recommendations to Improve Patient Access:</p> <ul style="list-style-type: none"> Remove liver damage, sobriety and prescriber requirements. Ensure hepatitis C coverage parity across FFS and MCO programs and transparency regarding hepatitis C coverage guidelines. <p><i>Grade Rationale: Rhode Island's FFS and at least two MCO programs impose severe liver damage restrictions for mono-infected patients. Prescriptions must be written by a specialist. Additionally, one plan, UHC, imposes different sobriety requirements depending on which Medicaid program a beneficiary is enrolled in, with some beneficiaries required to have six months abstinence. With these restrictions, many people with hepatitis C do not have access to treatment. In reflection of Rhode Island not successfully eliminating six months' sobriety for all beneficiaries as well as the lack of parity between FFS and MCO programs, a "minus" has been added to the state's D grade.</i></p>



Rhode Island (D-)

Rhode Island Medicaid Restrictions



Early 2018: stakeholders told we could not discuss DAA restrictions at RI Hepatitis Advisory Committee meetings

Grade: D- PUBLICIZED this widely to shame RI

- RI Medicaid maintains liver damage, sobriety and prescriber restrictions that limit many people with HCV from accessing treatment.
- RI Medicaid requires at least moderate liver damage (fibrosis) of F2 or greater for patients co-infected with HIV and severe liver damage of F3 or greater for mono-infected patients.
- RI Medicaid fee-for-service requires screening and concurrent alcohol and substance use counseling for beneficiaries using drugs. One managed care organization requires screening, one requires an abstinence period and one does not impose sobriety restrictions.
- Fee-for-service and one managed care organization require a specialist to prescribe and be approved by the state. Two managed care organizations require a specialist to prescribe.

Physician Advocacy

- “Physicians and government have a responsibility to make sure that health policy is determined by the needs of the public, not the financial interests of rich organizations.”
- “Physicians have a duty to advocate for the best interests of patients, while controlling threats to public health is the purview of governments. Physicians and governments must take control of health policy and not let it be convulsed by power struggles between multibillion dollar entities.” Brian Edlin, MD, MPH
- Pay Gap in RI
 - Out of the 19 public companies that are based in or have significant operations within RI, 14 have CEOs with salaries at least 100 times larger than median salary of its employee base.
 - **CEO of UHC, David S. Wichmann: \$17,404,609/year compensation**
 - Median employee salary (employers were allowed to exclude some workers from the calculation): \$58,378
 - CEO-to-median ratio: 298 to 1
- CEO Pay:
 - **CEO of AbbVie (maker of glec/pib), Richard A. Gonzalez: \$19,128,539/yr compensation**
 - Median employee pay \$157,347

Access to treatment for HCV infection: time to put patients first. Edlin, B. *Lancet* 2016

Pay Gap Significant in RI, US. Providence Business News, June 2018 CEO Pay: The Rankings. NYT May 27, 2018

May 16, 2018: Demand Letter to RI Medicaid Issued

- Lawyers representing at least 1 RI Medicaid Recipient denied DAAs
 - Kevin Costello, Center for Health Law and Policy Innovation, Harvard Law School
 - Jennifer Wood, RI Center for Justice
 - Patrick T. Jones, Ralph L. Liguori, Jones Kelleher LLP
- If RI OHHS did not agree to remove the disease severity restrictions by June 15, policy would be challenged in court.
- Discussion of:
 - The Disease
 - OHHS's Exclusionary PA criteria
 - Fibrosis restrictions not holding up in court
 - OHHS Policy Violating Medicaid Act
 - Cost-Effectiveness
 - Conclusion

Rhode Island Policy Changes



- May 23, 2018: RI Medicaid announced restrictions would be lifted
- As of July 1, 2018
- **ALL restrictions**
 - Fibrosis
 - Substance Use
 - Prescriber Type

RI: Even without restrictions, PAs are burdensome

HCV medications are not available at local pharmacies. They are specialty medications. HCV medications must be requested directly through the patient's payer via a PA.

For all PAs: Fill out the form specific to the patient's payer. Dr. must review and sign all PAs prior to submission

- Patients with United Healthcare (UHC) and Tufts Public plan must sign a member consent form allowing for representation our staff to communicate on their behalf
- Send all relevant HCV labs + insurance card info requested by PAs (e.g. HCV viral load, genotype, liver panel, FibroTest, etc.). Fax forms and supporting clinical documentation to number indicated on PA. After a decision is rendered:
- If approved, work with nurse to help patient receive medication (they will either need home delivery or pick up at a pharmacy)
 - UHC members must coordinate home delivery of medication. This insurer will not delivery to pharmacy
- If denied, send appeal letter or request peer-to-peer review within 48 hours of denial for Dr. Taylor
 - There are templates of all kinds for appeal letters on our team's shared drive. If denied 2 or more times for Abbvie medications, apply to patient support program

I. RI Medicaid

- PA Requests <http://www.eohhs.ri.gov/Portals/0/Uploads/Documents/Pharmacy/PA22.pdf>. All PA requests must include a signed patient contract: <http://www.eohhs.ri.gov/Portals/0/Uploads/Documents/Pharmacy/PA22-PT.pdf>

A. Neighborhood Health Plan (NHP)

- Many patients have Medicaid managed plans through NHP of RI. Walgreens is Neighborhood's preferred pharmacy. PA form for DAAS: https://www.nhpri.org/Portals/0/Uploads/Documents/Prior_Authorization_Forms/HepC_Aug_2017-PA_FORM.pdf. NOTE: Walgreens pharmacists Carmen/Dave/Jen at Walgreens will submit the PA directly to NHP. Fax the PA to them at 401-781-4645. If you have questions about the PA request, you can always call them at contact information listed below.
- Appeals Process: Within 48 hours of a denial of the initial prior authorization, a peer-to-peer review can be done to expedite the appeals process. Peer-to-peer phone/physician advisor line: 401-459-6069. To follow-up on the status of an appeal, check with Carmen, Jennifer, or David

B. United Healthcare (UHC)

- Many patients have Medicaid managed plans through UHC. UHC does not have a preferred local pharmacy. They utilize a specialty pharmacy called BriovaRx.
- To appeal a denial from UHC: All members must fill out and sign a member consent form so clinical coordinator can contact UHC on their behalf. Form: https://www.uhccommunityplan.com/content/dam/communityplan/healthcareprofessionals/providerinformation/RI-Provider-Information/RI_Member_Consent_Form_Provider_Representation.pdf
 - Under 'Description of Services,' write down "Coordination of care for hepatitis C medications, appeals and prior authorizations, and coordinating medication delivery and shipment." Appeal Letters can be faxed to 1-800-757-2617
- All specialty medications (including all HCV DAAs and HBV medications) must be ordered and sent to patient's home addresses through BriovaRx Specialty Pharmacy.
 - *NOTE: You must manually call in refills every month to BriovaRx (THEY DO NOT HAVE AUTOMATIC REFILLS)!
- Patients must have additional signed member consent form for BriovaRx for medication delivery coordination services to be set up through clinic coordinator.
 - Form: https://uat.briovax.com/assets/pdf/BRX6719E_170316_FORM_AuthorizePHI_FINAL-Editable_.pdf

C. Tufts Health Public Plan For prior authorizations (says MA on top but this IS the correct form): <https://tuftshealthplan.com/documents/providers/forms/hepatitis-c-medication-request-form>

RI: Even without restrictions, PAs are burdensome

Non-Medicaid

1. Blue Cross Blue Shield of RI Utilizes a specialty pharmacy, Prime Therapeutics/AllianceRx. For PAs: First, fill out BCBS RI form or print here: <https://www.bcbsri.com/sites/default/files/forms/HepCPABForm.pdf>. Fax PA request to BCBS. If approved, contact Prime Therapeutics/AllianceRx to coordinate delivery of medication for patients

- *Note: For BCBS RI plans paid for by patients, co-pays for HCV medication will likely be high (\$100 or more). They do not allow coupon assistance after first refill.

2. Medicare: Medicare will cover medications for all patients. The preferred pharmacy is CarePlus CVS. Pharmacist Bridget will submit PA to BCBS once she receives everything from Dr. Taylor. She may send back a request for more information after the initial PA is submitted to her.

3. AIDS Drug Assistance Program (ADAP) For HIV co-infected patients ONLY. Steps: Be sure the patient either has ADAP or if not by calling P directly. Notify her while on the phone that you have a new patient who you would like to access DAAs through ADAP program. If patient is new to ADAP program, a new ADAP application must be completed (this step can be lengthy and requires proof of income and proof of residency from patients) ([Forms and Handouts\Prior Authorization Forms\ADAP Enrollment Form 3.2.18.pdf](#)). If this link does not work, the full application can be found on: www.eohhs.ri.gov/Consumer/Adults/RyanWhiteHIV/AIDS.aspx. If patient was *previously* an ADAP patient, they may only need a “recertification application.” That form can be found on: www.eohhs.ri.gov/Consumer/Adults/RyanWhiteHIV/AIDS.aspx. If patient is already enrolled in ADAP, complete ONLY the ADAP Prior Authorization Request Form ([Forms and Handouts\Prior Authorization Forms\ADAP Prior Authorization Request Form.pdf](#)). If this link does not work, the form is on our team shared drive

- Make sure that the patient has a HCV viral load within 3 months. Not clinically necessary as we know but ADAP requires this
- Email or phone P to let her know you have faxed the form/s and write “HEPATITIS C MEDICATION” on the top of whatever form you are faxing in. She will then get back to you about approval (takes 24-48 hours), issues, and if it’s an existing Medicaid patient, how she will turning the ADAP off/on for them to process the meds at the pharmacy. P will likely start an email chain with her team members and K, a pharmacist at RIH, regarding the approval of the patient’s medications through ADAP. K will process the prescription once the ADAP coverage is “turned on”. After the prescription and meds have been processed at the pharmacy, K will email that they are ready to be picked up
- Either the patient or clinical coordinator can pick up the prescription at RIH Pharmacy or have the medication transferred to Miriam Hospital. If clinical coordinator is picking up medication (usually easiest option for our patients), coordinator can ask for K at window or explain to pharmacist working that day that you are picking up HCV meds processed by K through ADAP. After picking up meds, bring *directly* to nurse at clinic for her to hold until patient sees doctor for treatment initiation visit. After patient or clinical coordinator picks up the medication, send an email to P and cc K that the medication was picked up. At that point, P will “turn off” the patient’s ADAP coverage and turn on their RI Medicaid once again
- Steps will be repeated for *each* refill for the patient’s medications. P will keep track of when refill is due for ADAP processing for all patients, but clinical coordinator should also keep record of when refills should be processed and picked up

4. Aetna: <http://www.aetna.com/pharmacy-insurance/healthcare-professional/documents/medicare-prior-auth-hepatitis-c.pdf>. Fax form and supporting clinical documents to: 1-800-408-2386.

5. Pharmaceutical Support Paths: In the event a patients’ insurance will not cover medication, we may go through these channels. The eligibility requirements change rapidly. Other companies may only offer co-pay assistance coupons (\$5).

- **Gilead:** only provides co-pay assistance coupons. Application can be found at: http://www.mysupportpath.com/~media/Files/mysupportpath.com/Support_Path_Intake_Form.pdf. Website: <http://www.mysupportpath.com/>
- **Abbvie:** patient assistance program will provide medication if approved. Call **1-877-628-9738** to request additional applications OR for any patient assistance program follow-up/updates on applications/medication delivery coordination. *NOTE: Mavyret PAP program requires a HCV RNA within 90 days. *NOTE: Abbvie requires that the patient speak directly to representative to authorize the release of the medication to be shipped. You cannot coordinate delivery for patients.

Acknowledge -- forced financially strapped
Medicaid program to pay more to pharmaceutical
companies already making large profits: need
pharma to reduce prices
Competition does not lower drug prices



- Several weeks ago, Donald Trump issued blueprint to bring down pharmaceutical prices
- Does not include plan, as in virtually every other nation, for government to regulate drug prices
 - Exists in countries with and without national health system
- Other countries conduct large-scale negotiations to set a national price or price ceiling that its government, hospitals or citizens will pay

National and Global Call for HCV Elimination by 2030

- ‘Some treatments are simply too important to public health to leave their distribution to the private interests vying against each other in the US healthcare system.’
- Breakthrough pharmaceuticals priced so that we cannot meet public health need.
- “Doctors can, and have, influenced drug prices.”
- Government action on medicines – legislation
 - Allow subset payers join together, commit to broad treatment strategy, lower prices (Ryan White ADAP)
 - Govt. purchase the meds (Vaccines for Children program)
 - Non-voluntary licensing: Govt. make DAAs without regard to pharma patents (anthrax/cipro)
- 2017 some states passed laws to restrain/impose transparency requirements on pharmaceutical prices
 - States serve as ‘laboratories of democracy’ for new challenges
- Act on synergy between opiate crisis and HCV epidemic
 - 5 new HCV infections for every OD

THINK BIG  WE DO™



HCV Clinicians Collaborating with Payers

- Share your understanding and concern about the budget impact of HCV treatments
- Efficacy and safety will not be compromised (non-negotiable)
- Express responsibility for our shared resources:
 - For reasonably equivalent treatment options, include cost as a factor
 - Optimize adherence and AE management
 - Prioritize reducing re-infection rates
 - Minimize other causes of liver damage such as alcohol

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Camilla S. Graham

IDSA/AASLD/IAS–USA HCV Guidance



HCV WaterFire: July 28, 2018



NVHR Advocacy Engagement

- Patient and Community Voices in the Media
 - Advocates can share their own stories and experiences and advocate for less restrictive HCV Medicaid policies by changing the conversation narrative. NVHR and CHLPI can provide support.
- Upcoming Patient Summit
 - Join the first NVHR national patient gathering in 2019 to address the need for greater patient engagement and leadership in the HCV field.
- Building Relationships with Allied Healthcare Providers
 - Clinical pharmacists and community pharmacies can expand hepatitis C awareness, vaccination, screening, linkage to care, and treatment.
 - NVHR presentations at conferences such as American Society of Addiction Medicine, National Correctional Health Conference, American Public Health Association, etc.

NVHR Clinician Advocacy

- NVHR HCV Treaters Advocacy Group

- A multidisciplinary group for clinicians sharing best practices for providing HCV treatment. The focus for 2018 is expanding treatment access in Medicaid programs.
- Activities include developing tools to track progress, identifying champions, and supporting clinicians in key states who wish to pursue further advocacy
- 30 minute calls, monthly every third Thursday, and/or email communication

- NVHR HCV Telehealth Group

- A multidisciplinary group working to share models and strategies around the use of telemedicine to improve access to HCV care, including expanding access where specialist restrictions remain.
- 30 minute calls, monthly

- Contact Tina Broder, NVHR Interim Executive Director, for more information tbroder@nvhr.org

NVHR HHS Sign-On Letter



May 3, 2018

Alex Azar, Secretary
The U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Azar:

We, the undersigned health care providers, write to alert your attention to a new report, Hepatitis C: The State of Medicaid Access, jointly published by the National Viral Hepatitis Roundtable (NVHR) and Harvard Law School's Center for Health Law Policy and Innovation (CHLPI). This report reveals that many Medicaid programs across the country impose discriminatory, unlawful restrictions that prevent Americans from being cured of the hepatitis C virus (HCV).

As you likely know, HCV kills about 20,000 Americans per year – more people than all 60 nationally notifiable infectious diseases combined. At least 3.5 million Americans are living with HCV, according to the most conservative estimates. The opioid crisis has rapidly fueled the spread of the virus; injection drug use is the cause of most new infections. From 2010 to 2015, the number of new HCV infections jumped nearly 300 percent. HCV is also the leading cause of liver cancer – the fastest-growing cause of cancer mortality in the U.S., killing twice as many Americans now than it did in the 1980s.

The good news is that a cure exists for HCV, making elimination of the virus as a public health threat possible. But contrary to clear guidance from the Centers for Medicare and Medicaid Services (CMS) cautioning states not to impose restrictions that were not medically necessary, most states limit access to the cure by imposing restrictions based on disease severity, sobriety, and/or prescriber type. Many programs even require patients to wait to be treated until they have advanced liver disease – which can cause liver cancer even after the patient is cured. Most jurisdictions mandate sobriety periods, despite unequivocal scientific evidence that the HCV cure is equally effective in people who use drugs and/or alcohol. These restrictions directly contradict the standard of care outlined in the treatment guidelines established by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA).

As providers, we are particularly troubled by these restrictions. If HCV is diagnosed and treated early, the progression to advanced liver disease as well as transmission to others can be prevented. Limiting treatment to those individuals with the most advanced disease not only puts individuals at risk for the development of advanced liver disease and higher risk of liver cancer, but also compromises public health. Furthermore, the sobriety requirement perpetuates the discrimination felt by people living with HCV as well as people who use drugs. The stigma surrounding alcohol and drug use often discourages 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 make it more difficult for providers to engage with a population especially at risk for HCV.

We urge HHS to do everything within its power to enforce the CMS guidance and ensure that all jurisdictions open access to HCV treatment for Medicaid beneficiaries without delay. If you have questions or concerns, please feel to contact Elizabeth Paukstis at epaukstis@nvhr.org. Thank you for your consideration.

NVHR Texas HHS Sign-On Letter

Texas Health and Human Services

<exact names to be added>

Dear xxxxxx,

We write to you as clinicians concerned about an ongoing serious health issue in Texas.

This letter is also submitted on behalf of the Alliance for Patient Access ("AfPA") and its Hepatitis Therapy Access Physicians Working Group ("Physicians Working Group"), and the National Viral Hepatitis Roundtable (NVHR).

AfPA is a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care. The Physicians Working Group is made up of leading practitioners from across the country and came together in 2014 to ensure the perspectives of hepatologists, gastroenterologists, infectious diseases specialists and other clinicians treating patients suffering from hepatitis, are shared with policymakers considering issues impacting access to hepatitis therapies.

NVHR is a national coalition of more than 500 members working together to eliminate hepatitis B and C in the United States. NVHR's vision is a healthier world without hepatitis B and C. NVHR is the largest national coalition of community-based organizations, advocates, healthcare providers, and government and industry partners working together to address hepatitis.

We write to encourage Texas Medicaid to reconsider the current prior authorization policies for the treatment of the hepatitis C virus (HCV). Specifically, the Texas Medicaid Program should reconsider its current prior authorization requirement of a Metavir Fibrosis Score of F3 or F4 for access to curative medical treatments. In effect, this requires patients to advance to liver disease before allowing them to be treated for their disease. In addition to this public health concern, this requirement also causes an undue economic burden to the health system.

The prior authorization policy should be revisited for three basic reasons:

First, and most importantly, the policy has no basis in sound medical practice and is in direct contradiction to the definitive guidelines for care developed by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America ("AASLD/IDSA Guidelines").

Second, as has been clearly articulated by CMS and demonstrated in numerous other states through expensive and needless litigation, the current prior authorization policy violates federal Medicaid law.

Finally, the directly stated assumptions in the state budget process which were the sole basis of support for the current prior authorization policies have turned out to be completely wrong.

We will discuss each in turn.

Prior Authorization -- Fibrosis Score

As physicians, we will address first the issue we feel should be dispositive of the discussion and the issue on which we have the most personal experience and expertise. The current prior authorization policy needlessly endangers patient health and needlessly endangers public health as well.

First, on the individual patient level, it appears to be the view of some that those with a fibrosis score below F3 have plenty of time before the disease has any impact on them or others. In short, these patients have time to wait. That is simply not the case for many reasons.

Setting aside the novel medical concept that an available treatment that can avoid physical damage to a patient should await the occurrence of the physical damage before allowing access to the treatment, liver fibrosis is not the sole complication of HCV. All of the following are also potential symptoms with HCV: fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, and joint pain. These potential physical manifestations are in addition to the patient knowingly living with a contagious condition of deadly potential – that can be cured.

The "it can wait" philosophy also ignores the reality that liver disease progression in HCV patients is not a predictable, straight-line event. It is recognized in this practice area that some patients do not progress while others rapidly develop significant fibrosis. While some of the factors that are related to rate of progression are known, there is no way to predict the progression rate for any particular patient. Also, the "it can wait" approach completely ignores the critical issue of hepatocellular cancer (HCC), which has the highest age-adjusted incidence in Texas. HCC rates continue to increase whereas other cancer rates are decreasing. HCV is the leading cause of HCC and the only proven method to effectively prevent HCC is to treat HCV. However, this treatment must occur at an early stage. The current Medicaid policy of waiting until patients have F3 and F4 puts them at risk for HCC. It is worth noting that the Cancer Prevention and Research Institute of Texas (CPRIT) – funded by state legislation to curb the incidence of cancers in Texas – has made HCC prevention a top priority. It would certainly seem that Medicaid should be aligned with that critical public health goal.

Second, the current prior authorization policy needlessly endangers public health. No matter what the rate of liver damage progression is or the presence of other symptoms and the day-to-day of living with a dangerous yet curable disease, the simple reality remains that the patient is contagious until cured. This involves all kinds of potential transfers of the disease, including potential vertical transmission to infants. Further, the extremely unfortunate and dangerous reality of the opioid crisis which our state and nation currently face makes the presence of contagious individuals all the more dangerous to the public health. This issue is becoming so acute that the National Academies of Science just held a two day seminar devoted to the topic:

<http://nationalacademies.org/hmd/Activities/PublicHealth/IntegratingInfectiousDiseaseConsiderations>

As physicians who see the medical impacts – both to individuals and the public health – of the current prior authorization policy up close every day, we urge you to bring the Medicaid policy into alignment with the accepted and definitive medical guidelines for treatment in this area.

Medicaid Law Requires Treatment

While we are not lawyers, we would ask that you consult with Medicaid law experts on the consistency between the current prior authorization policy and federal

Well over two years ago, CMS issued a letter to the states with a direct warning about prior authorization policies inconsistent with sound medical practice: <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/tx-releases/state-releases/state-rel-172.pdf>

Since that time, multiple states have found themselves defending expensive lawsuits because their prior authorization policies were in conflict with federal law. Universally, those suits have resulted in the states moving towards access policies more in line with sound medical practice.

Given CMS directly called this issue out to the states so long ago, one would suspect patience with Medicaid programs that have not moved into compliance is near an end with regulators and potential plaintiffs. We urge Texas not proceed down a route that will only result in funds wasted on expensive litigation when we should be treating patients and protecting the public health.

Prior Authorization Policy Directly Based On Flawed Assumptions

During the adoption process of the current Texas budget, in setting specific budget assumptions for the Medicaid program in general and hepatitis C treatment specifically, the Legislative Budget Board wrote the following:

*Similarly, advances in treatment for the hepatitis C virus (HCV) are resulting in increased costs for CMHC. Assuming the number of patients treated for HCV remains similar to previous years, **cost for the treatment of this population may increase as newer, more expensive therapies are approved.** In November 2015, CMHC implemented changes in treatment protocol in an effort to control costs associated with the development and availability of new HCV drugs by prioritizing patients for treatment based on severity of disease. CMHC updated its disease management guide for HCV, requiring that a patient meet certain advanced-stage clinical criteria before receiving treatment. This change in treatment protocol resulted in a decrease in the number of patients with HCV that receive treatment. For fiscal year 2016, CMHC provided treatment for 833 HCV patients at a drug cost of \$3.1 million, compared to 2,532 HCV patients for fiscal year 2015 at a drug cost of \$2.0 million. Changes such as this increased cost are considered by UTMB and TTHSC in the development of their estimate of upcoming resource needs.*

See Page 373-374 of the Legislative Budget Board Staff Reports (emphasis added): http://www.lbb.state.tx.us/documents/publications/staff_report/3729_lbb_staff_reports.pdf

In reality, the exact opposite has occurred versus what was assumed when the Medicaid budget was adopted. Since the above was written and the state's Medicaid budget was adopted based upon those assumptions, it is true that newer therapies have been introduced. However, the costs of those newer therapies are dramatically lower than the cost of the some of the previous therapies, and that has had the effect of lowering the cost of all therapies in this area (just as CMS correctly predicted in its 2015 letter to the states.)

While we must note as physicians we find the idea of utilizing prior authorizations as a fiscal rationing tool – unrelated to any legitimate medical considerations – as highly objectionable on many levels, the fiscal reality is clear that the budget assumption were wrong, and therefore the policies driven by those underlying assumption should be revisited.

Conclusion

On behalf of ourselves and other like-minded clinicians in Texas, the AfPA and its Hepatitis Therapy Access Physicians Working Group, and the NVHR, we urge you to seriously reconsider and revise the current prior authorization policy for treatment of hepatitis C in Texas. We thank you for your attention to these important issues and would be pleased to meet with you to discuss this matter further or provide any further information that may be useful.

Conclusion

- Progress has been made, yet too many restrictions remain.
- Use the resources available at www.stateofhepc.org to influence your state's Medicaid program.
- With the changing political environment, collaborative advocacy is more important than ever

#StateofHepC

Questions?

#StateofHepC



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