

Managed Care & HCV Treatment Access

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Prior Authorization & HCV Treatment

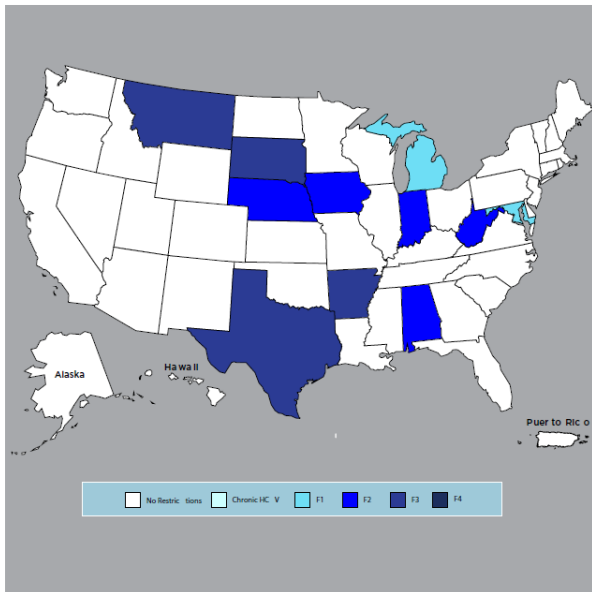
Prior authorization: Utilization management process used by some health insurance companies in the United States to determine if they will cover a prescribed procedure, service, or medication

When can states impose prior authorization criteria?

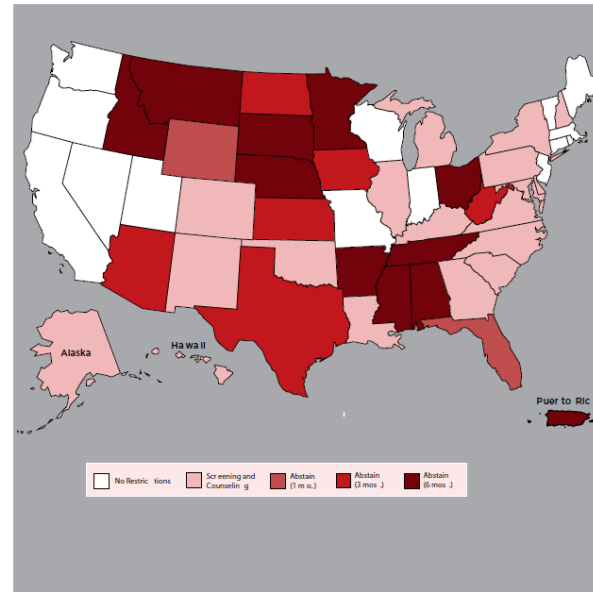
- If the prescribed use is not for a medically accepted indication
- If it does not have a therapeutic advantage over other drugs included in the formulary (*+publicly available written explanation for basis of exclusion*)

Tracking Medicaid HCV DAA Prior Authorization Criteria

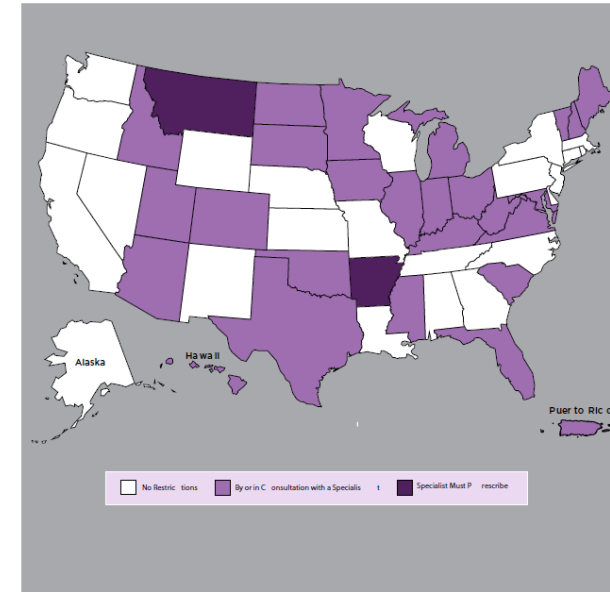
Liver Disease Severity



Substance Abstinence



Provider Specialty



For updates and details visit StateOfHepC.org

CMS Guidance is clear: Prior Authorization should not be used to ration hepatitis C treatment

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850



Center for Medicaid and CHIP Services

NOVEMBER 5, 2015

MEDICAID DRUG REBATE PROGRAM NOTICE

Release

“[T]he effect of (PA criteria) should not result in the denial of access to effective, clinically appropriate, and medically necessary treatments using DAA drugs for beneficiaries with chronic HCV infections.”

For State Technical Contacts

ASSURING MEDICAID BENEFICIARIES ACCESS TO HEPATITIS C (HCV) DRUGS

The Centers for Medicare & Medicaid Services (CMS) remains committed to Medicaid beneficiaries continuing to have access to needed prescribed medications, a commitment we know that states share. The purpose of this letter is to advise states on the coverage of Medicaid beneficiaries living with hepatitis C virus (HCV) infections. Specifically, this letter addresses utilization of the direct-acting antiviral (DAA) drugs approved by the Food and Drug Administration (FDA) for the treatment of chronic HCV infected patients.

Rules Regarding Medicaid Drug Coverage

Coverage of prescription drugs is an optional benefit in state Medicaid programs, though 50 states and the District of Columbia currently provide this benefit. States that provide assistance for covered outpatient drugs of manufacturers that have entered into, and have effect, rebate agreements described in section 1927(b) of the Social Security Act (the Act) under their Medicaid fee-for-service (FFS) programs or Medicaid managed care plans are required to comply with the requirements of section 1927(d)(1) and (2) of the Act.

“[T]he managed care plan may not use a standard for determining medical necessity that is more restrictive than is used in the state plan.”

Section 1927(d)(1) of the Act provides that a state may subject a covered outpatient drug to prior authorization, or exclude or otherwise restrict coverage of a covered outpatient drug if the prescribed use is not for a medically accepted indication as defined by section 1927(k)(6) of the Act, or the drug is included in the list of drugs or drug classes (or their medical uses) that may



The courts have supported this stance

Litigated Results

- Washington: BE vs Teeter (injunction granted; settlement approved, April 2017)
- Missouri: JEM vs Kinkade (policy reformed, November 2017)
- Michigan: JV vs Lyon (settlement reached, March 2018)
- Colorado: Ryan vs Birch (disease severity criteria removed and settlement pending, April 2018)

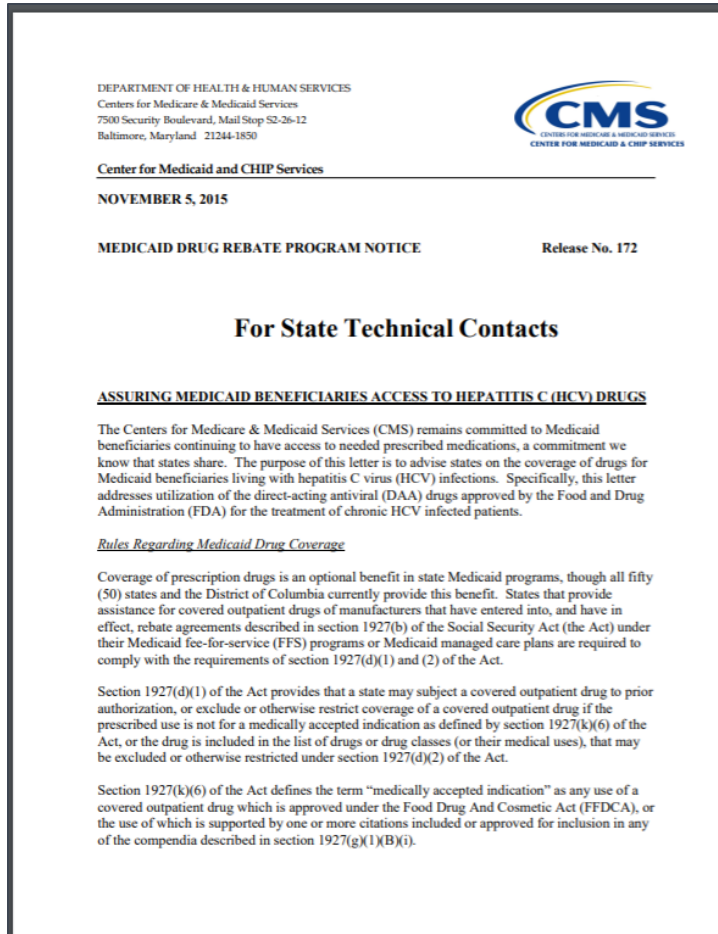
Pre-Litigation Settlements

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

Several pending cases in development!



States must track MCO practices to ensure enrollees in any MCO have equitable access to FFS



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 . . .”

“States are urged to carefully monitor the DAA HCV drug coverage policies of their MCOs to ensure enrollees have appropriate access.”

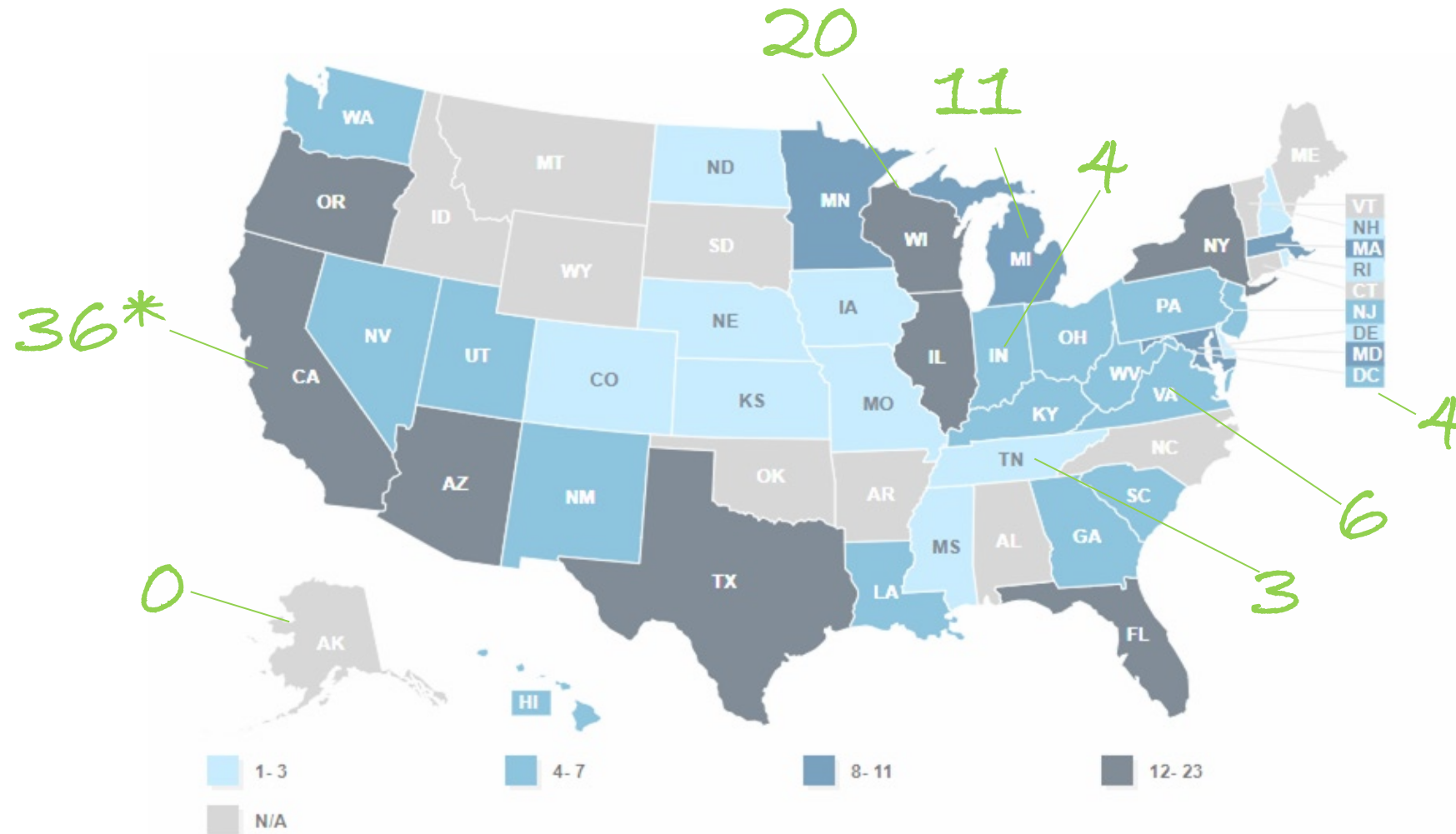
Managed Care Organization Accountability

Increasing MCO utilization by public payers makes tracking that much more important *and* difficult

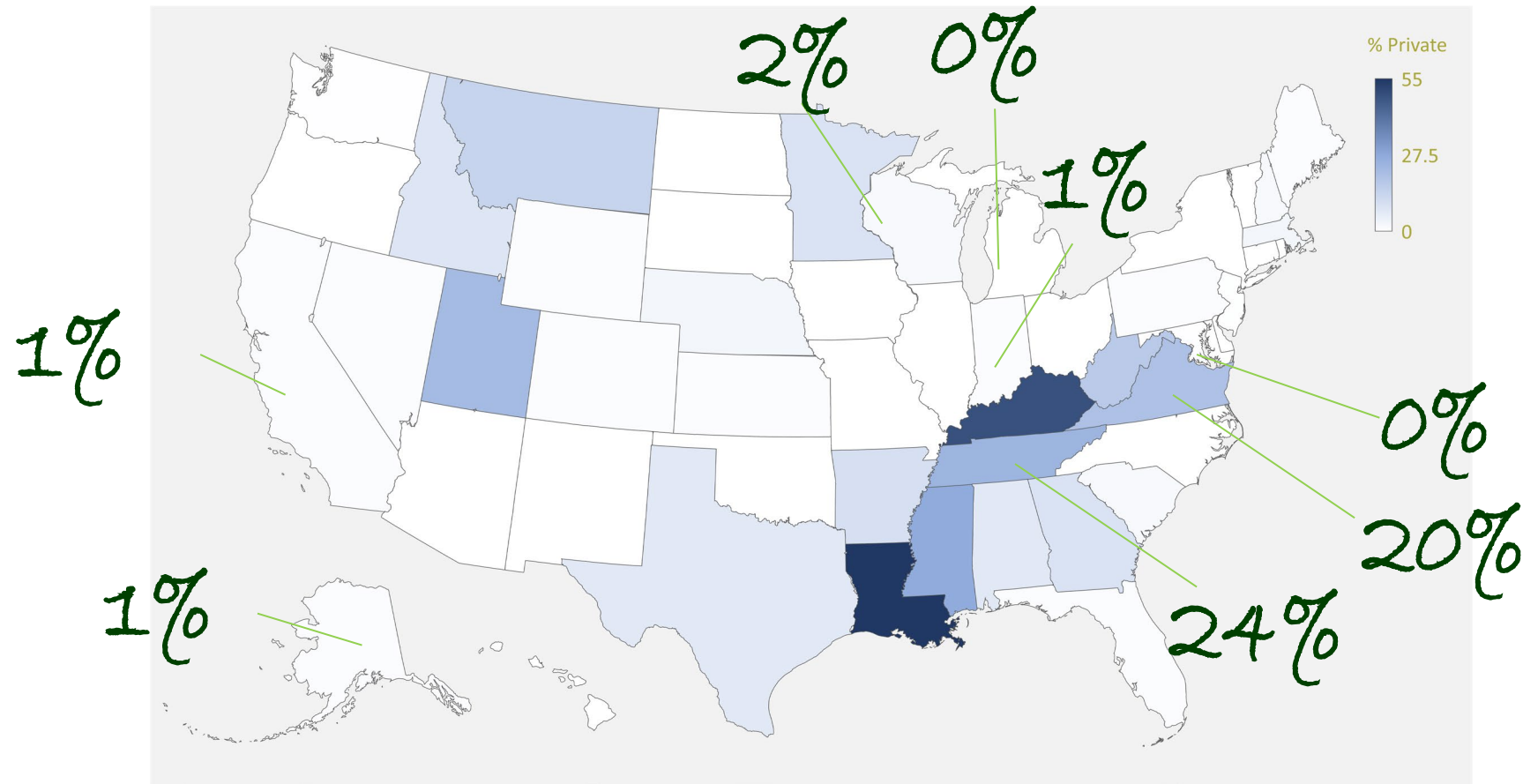
- **Medicaid**: 238 MCOs: 70% of Enrollees
- **Medicare**: 2,317 Medicare Advantage plans: 40% of enrollees
- **Correctional health**: 27 states; 8% of persons incarcerated in state and federal prisons

MCO's may have financial incentives (esp. in the short term) to deny care—the difference between capitated rate and actual spending creates profits, and for IPO's can spur investor activity.

Number of Medicaid MCOs by state



Proportion of incarcerated persons in private state prison facilities (2017)



Incarcerated persons have a constitutional right to HCV treatment

8th Amendment

Excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted.

Per the landmark Supreme Court case *Estelle v. Gamble*, this requires that all people who are incarcerated receive the medical standard of care for any condition.

Litigation for HCV Treatment in Correctional Facilities

Settled or Decided (4)	Ongoing (10)
<u>Colorado</u> : Aragon v. Raemisch	<u>Alabama</u> : Braggs v. Dunn
<u>Indiana</u> : Stafford et al v. Carter	<u>California</u> : Bayse et al v. California Dept of Corrections and Rehabilitation et al
<u>Massachusetts</u> : Paszko v. O'Brien	<u>Florida</u> : Hoffer v. Jones
<u>Pennsylvania</u> : Chimenti v. Pennsylvania Dept of Corrections	<u>Illinois</u> : Orr et al v. Eleya et al
	<u>Minnesota</u> : Ligons v. Minnesota Dept of Corrections
	<u>Missouri</u> : Postawko v. Missouri Dept of Corrections
	<u>North Carolina</u> : Buffkin v. Hooks
	<u>South Carolina</u> : Geissler v. Sterling
	<u>Tennessee</u> : Graham v. Parker
	<u>Virginia</u> : Riggleman v. Clarke

MCO Accountability–Payment Structure

DAA payment structure

- Paid by managed care
- Carved out of managed care
- Hybrid: paid by managed care, but state manages prior authorization process

How does this work with subscription model?

In Louisiana, DAAs are part of managed care capitated rates. The state has incentive to increase utilization due to subscription model, but MCOs don't. Louisiana created a risk corridor to mitigate risk and is closely monitoring utilization.


Managed Care HCV Treatment Access Monitoring

In partnership with CHLPI we are tracking MCO coverage restrictions, pharmacy benefit managers, and carveout strategies on a state-by-state basis.

Hepatitis C: State of Medicaid Access Report Card

Wisconsin

Estimated Number of Individuals Living with Hepatitis C: 28,500¹



Grade	Summary
A	<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 do not have any sobriety restrictions.</p> <p>Prescriber Restrictions: FFS and MCOs do not have any prescriber restrictions.</p> <p>Recommendations to Improve Patient Access:</p> <ul style="list-style-type: none"> Continue to provide access to hepatitis C treatment to all beneficiaries. Maintain coverage parity between FFS and MCOs. <p style="font-size: small; margin-top: 10px;"><i>Grade Rationale: Wisconsin has removed all coverage restrictions. Additionally, because the state carves prescription drug benefits out of MCO contracts, coverage access is uniform for all beneficiaries statewide.</i></p>

Background

As of May 2019, Wisconsin had 1,031,719 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 While Wisconsin contracts with MCOs to deliver most health services to its beneficiaries, the state excludes most prescription medications—including hepatitis C medications—from BadgerCare Plus contracts. Wisconsin pays for drugs through the FFS program.⁷ FFS establishes the prior authorization

MCO Accountability—strategies

- **Explicit language in contract (Medicaid DAA, Private Correctional Health Testing and Tx)**
- Transparency—require MCO's to make PA publicly available
- Beneficiary complaints (*make public to consumers*)
- Monitor denials (*encourage providers to prescribe and track denials, appeals processes, etc*)
- Monitor treatment rates (*claims data*)
- Other reporting processes and indicators (*new diagnoses; delays in care*)
- Compliance monitoring (review of final prior authorization criteria)

MCO Accountability—State & Federal Advocacy

- Engage patients and providers with state health insurance commissioners and governors
- Encourage CMS to implement punitive measures for states that fail to remove barriers to care
- Litigation
- Empower consumers with knowledge ahead of open-enrollment season
- Enact national and state legislation to further address the prior authorization process



Prior Authorization & HCV Treatment





Modern
Healthcare

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PAYMENT
August 13, 2019 04:18 PM

Hospitals call for overhauling Medicare Advantage prior authorization rules

SUSANNAH LUTHI  

 TWEET  SHARE  SHARE  EMAIL

Opportunity to address Medicaid and Correctional managed care?

H.R.3107 - Improving Seniors' Timely Access to Care Act of 2019

(1) use of prior authorization should be streamlined through electronic transmissions for coverage of covered services for individuals enrolled in federally funded programs such as Medicare, Medicaid, and federally contracted managed care plans to improve patient access to medically appropriate services and reduce administrative burden through automation informed by clinical decision support;

We are happy to work with state and federal partners to ensure equitable access to HCV care.

[NVHR.org](https://www.nvhr.org)



For questions contact:
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