

IMPROVING ACCESS TO CARE FOR HEPATITIS C TREATMENT



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Expert Consultation on the Evidence for Early
Hepatitis C Treatment in the United States
September 12, 2016

Overview

- **Context: The Need for Rights Enforcement**
- **Informal Enforcement**
- **Litigation**
- **Access as Step One – Next Steps**
- **Clinician's Perspective**



CONTEXT: THE NEED FOR HEALTH CARE RIGHTS ENFORCEMENT

The Access Landscape is Mixed

- Generalizations difficult
- Quickly Evolving
- Even Medicaid compilations are few and far between
 - Annals of Internal Medicine – Aug. 4, 2015 (2014 data)
 - OHSU – 50 state survey (Data from first week of May 2015).

ACCESS RESTRICTION TYPES

- Disease Severity
- Substance Abuse History
- Provider Type

COVERAGE WITHOUT REGARD TO DISEASE SEVERITY

- Medicaid (MA, CT, NY, ME, GA, WA, MS, NV, DE, FL)
 - Public Insurers: Medicare & Veterans' Administration
 - Major Commercial Insurers (Anthem, Aetna, United, Humana, Cigna)
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CONTEXT – PRICE

- Reported sticker price: \$84,000 (\$1k / pill x 12 weeks)
- Medicaid program discount: 23%, before supplemental, negotiated rebates.
- Best guess - \$20k - \$30k
- Medicaid price impact also must account for federal dollar contribution.
- WA 2016 Supplemental Budget Request
 - Requested ~\$77M of Medicaid budget (\$20M state portion) (25%)
 - Represented that this would treat 4700 enrollees
 - Math = \$16,450 per enrollee per treatment (State portion = ~\$4k)

INFORMAL ENFORCEMENT

CMS GUIDANCE

NOVEMBER 5, 2015

- Directed to State Technical Contacts
 - Explicitly couched in the posture of the Medicaid statute: States “are required to provide coverage for those covered outpatient drugs of manufacturers that have entered into, and have in effect, rebate agreements described in section 1927(b) of the Act, when such drugs are prescribed for medically accepted indications, including the new DAA HCV drugs.”
 - “CMS is concerned that some states are restricting access to DAA HCV drugs contrary to the statutory requirements . . . by imposing conditions for coverage that may unreasonably restrict access to these drugs. For example, several state Medicaid programs are limiting treatment to those beneficiaries whose extend of liver damages has progressed to [a] fibrosis score [of] F3.”
 - Other issues: Abstinence requirements, Prescriber-type restrictions and Medicaid managed care parity.
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STATE ADVOCACY

- Pharmacy & Therapeutics Committee
 - New York
 - Pennsylvania
 - Colorado
 - Oregon
- State Budgetary Issues
 - IL is *sui generis*.

DEMAND LETTERS

Examples

- **CT** - Feb. 2015 – New Haven Legal Assistance Ass'n & CT Legal Services
 - **MO** – Jan. 2016 – Legal Services of Eastern Missouri
 - **DE** - March 2016 – Center for Health Law & Policy Innovation at Harvard Law School, Tycko & Zavareei, and Community Legal Aid Society
 - **FL** - April 2016 - NHeLP, FL Legal Services & Legal Aid Society of Palm Beach County
 - **NY** – April 2016 – NY AG Schneiderman issues subpoenas to 7 major insurers.
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LITIGATION

LITIGATION AS LAST RESORT

- Medicaid Cases
 - **IN** – Nov. 2015 (*Jackson*)
 - **WA** – March 2016 (*B.E. v. Teeter*)
- Prisoner Litigation – 8th Amendment
 - **MA** – June 2015 (*Paszko*)
 - **PA** – June 2015 (*Chimenti*)
- Private Insurers
 - **WA** - GroupHealth, BridgeSpan and Regence Blue Cross all agree to remove disease severity restrictions after state ct complaints filed.
 - **CA** - Anthem sued in state court in May 2015 – policy was changed across states in December 2015.
 - **NY** - AG threatened litigation against 7 commercial insurers. Policies changed after investigation.
 - AG filed fraud and consumer-protection based lawsuit against lone holdout: Capital District Physicians' Health Plan. Settled with policy change shortly thereafter.

FEDERAL MEDICAID LAW

- Federal law requires each state’s Medicaid program to provide “**medically necessary**” care according to a state definition that must be approved by CMS. *See Beal v. Doe*, 432 U.S. 438, 444–45 (1977).
 - Typical definition includes services necessary for the prevention, diagnosis, or treatment of a physical or mental health condition, but provides allowances for state discretion on equally effective, cheaper care, and prohibitions on “convenience” care. Some definitions reference the clinical standard of care.
- Federal law allows states significant discretion in determining the **amount, duration and scope** of services to be provided. 42 C.F.R. § 440.230(b). Must **not be arbitrary**. 42 C.F.R. § 230(c).
- Policies must nevertheless be in the “**best interests**” of the recipients. 42 U.S.C. § 1396a(a)(19).
- Medical assistance must be furnished with “**reasonable promptness.**” 42 U.S.C. § 1396a(a)(8).
- Coverage must be **comparable** as between similarly-situated Medicaid enrollees. 42 U.S.C. § 1396a(a)(10)(B)(i) and (ii); 42 C.F.R. § 440.240.

TEETER CASE

Medical Necessity

- “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.”
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TEETER CASE (CONT)

Irreparable harm

- Deprivation of medically necessary care.
 - “Plaintiffs argue, persuasively, that without an injunction “they are at imminent risk of deteriorating health, liver damage and even death.”
 - Example of L.B. – missed treatment window during “observation period.”
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TEETER CASE (CONT)

Public Interest

- “[T]he 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.”
 - PI favors enforcement of existing law.
 - “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.”
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ACCESS AS STEP ONE – NEXT STEPS

DEFACTO BARRIERS

- Identifying those who will benefit - Outreach
- Engagement in Care
- Testing
- Prior Authorization process



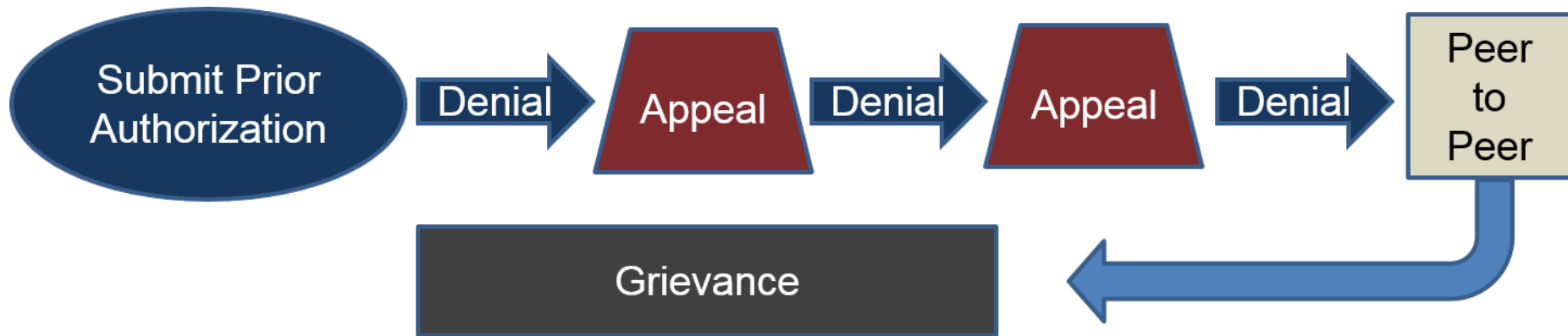
CLINICIAN'S PERSPECTIVE

ACCESS RESTRICTION TYPES

- Disease Severity
- Substance Abuse History
- Provider Type

UNWRITTEN BARRIERS

- Non standardized restriction criteria between payers
- Non standardized data requirements and prior authorization procedures
 - Expiration time on data from labs
- “Automated” systems, hold wait times
- Approximately 6-8 hrs of staff time per patient
- 1 to 4 months to go through the process



To be a DAA prescriber or not?

- Practice resources?
 - Keep up with changing payer specific restrictions and requirements
 - Prior authorization process
 - Support services in place for vulnerable patient populations
- Patient population?
 - Percentage of Cirrhotic vs noncirrhotic patients
 - Prevalence of comorbid addiction and active drug/alcohol use
- Patience, passion, purpose?
- Bottom Line: \$

Impact on Patient Care: First Visit

- Welcome
- History and Physical
- Patient Education
- Plan

Impact on Patient Care: First Visit

- Welcome
 - Assess insurance coverage
- History and Physical
 - Treatment history
 - Presence of extrahepatic manifestations
 - Family planning
 - Contraindications to ribavirin
 - Social history
 - Drug use, alcohol use

Impact on Patient Care: First Visit

- Patient Education
 - Payer specific restrictions
 - Process of obtaining approval
 - Set expectations
 - Harm reduction counseling
- Plan
 - Urine drug screen/ blood alcohol level (optimal timing)
 - Treatment for addiction
 - Labs and imaging as dictated by payer requirements
 - Treatment soon or wait based on likelihood of approval
 - Return visit/ ongoing engagement

WHEN INSURANCE WILL NOT COVER DRUGS

- Wait until patient qualifies
 - Sobriety
 - Worsening fibrosis
 - Take legal action
 - Apply to patient assistance programs to obtain free drug
 - There is only one company that does this currently
 - Financial information to qualify
 - Proof that patient does not qualify for insurance
 - Challenging to navigate
 - Wait for new drugs to be approved
 - No guarantee that those will be covered/ patient will qualify
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THE PROVIDER ADVOCATE

- Join or form a coalition
- Develop relationships with medical directors of managed care programs and become a resource
 - Insight and experiences from the field
 - Evidence based recommendations
 - Be a voice for the patients
- Provide expert testimony





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