

## Overcoming Injustice: A Roadmap to Improve Access to HCV Therapy for Our Medicaid

### Patients

A recent survey of state Medicaid programs by the Senate Finance committee revealed that of 68 million Medicaid enrollees in 44 states, nearly 700,000 are positive for the Hepatitis C virus (HCV).<sup>1</sup> The advent of new Direct-Acting Antivirals (DAAs) has not just given these patients treatment without the devastating side effects of interferon; it has given them the promise of a cure. However, as 88% of states have established and now implemented restrictive prior authorization policies regarding new DAAs in clear violation of federal mandate, the promise of a cure is one that the Medicaid system is not fulfilling.<sup>1,2</sup> As such, it has been left to doctors and advocates to stand up for the rights of these individuals in a fight not unlike that faced in the early years of the HIV crisis. We have seen that change is possible. What we are urging is that greater change will come from providers' willingness to serve as advocates.

It is important to note that coverage for outpatient prescription drugs within a Medicaid plan is not a requirement by federal or state mandate. Rather, it is a decision left entirely to each state. However, despite being optional, every state has chosen to participate in the Medicaid Drug Rebate Program and is therefore de facto bound and accountable to the regulations set forth in the Social Security Act, title XIX.<sup>3</sup> Hence, while prior authorization requirements are neither forbidden nor uncommon in state Medicaid plans, they *should* comply with federal regulations. As it stands now, with more than forty states having not only instituted restrictive prior authorization policies but also continuing those violations in direct defiance to Medicaid's November 2015 Medicaid Drug Rebate Program Notice, the joint Medicaid system shows a

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grave weakness in that it does very little to recognize and reprimand the blatant non-compliance of state partners.<sup>4</sup>

This perspectives piece addresses the common question of both doctors and advocates: What can I do right now to make a change? It so happens that we are not alone, not without cause, and not without a roadmap. There are at least ten states to which we can look for guidance in achieving greater access and the elimination of restrictions (see Table 1). Recent successes toward improved access to DAAs include advocacy driven demand letters, four class-action lawsuits, related investigations initiated by the State Attorney General toward private insurers, challenges to state prison systems, and recommendations by Drug Utilization Review boards. The arguments used in the above successes, some of which we review below, include one or more of three basic arguments: failure to provide care that is medically necessary, failure to provide care with reasonable promptness, and failure to provide comparable care.

### **Failure to Provide Care that is Medically Necessary**

The first argument, that of failure to provide medically necessary care, is found in Section 1927 of the Medicaid Act (specifically 42 U.S.C. 1396r-8) which discusses payments for covered outpatient drugs. In it lies the details upon which this legal claim is based. It states that:

A State may exclude or otherwise restrict coverage of a covered drug if –  
i) the prescribed use is not for a medically accepted indication<sup>5</sup>

Advocates in Connecticut, Washington, Indiana, Missouri, and Colorado each invoked violations of this section of the Medicaid Act in their petitions for change noting that allowed exceptions are expressly defined and clearly do not include indications for which a safe and effective (FDA approved) drug is medically necessary. State programs are under mandate by the Medicaid Act to cover participating drugs for their prescribed use when medically indicated and as stipulated in FDA approved labeling (noting of course that FDA approved labeling implies that the drug has already been determined safe and effective by the FDA.) There are a few enumerated exceptions

in the Act, but none of those exceptions apply to current circumstances. New Haven Legal Assistance Association, Inc. summarizes the mandate quite succinctly in their letter to the State of Connecticut's Commissioner of the Department of Social Services:

... under federal Medicaid law, notwithstanding cost, if a drug is FDA-approved, subject to a rebate agreement with the manufacturer, and not in one of the few categories in which a state is allowed to exclude coverage (for adults only, none of which are applicable here), the drug must be made available wherever medically necessary, although prior authorization may be imposed.<sup>6</sup>

The letter was so successful that within three months DAAs were listed on the State Medicaid's Preferred Drug List, and the prior authorization process was reviewed and restrictions loosened making DAAs "readily available" to all Connecticut Medicaid beneficiaries regardless of disease stage, substance abuse history, or specialty care.<sup>7</sup>

Medicaid beneficiaries and advocates in the state of Washington also relied on an argument citing denial of medically necessary care. In this instance, however, intervention from a Judge was necessary to bring about change. The federal court case of *B.E. et al v. Teeter* (2:16-cv-00227) resulted in the Honorable John C. Coughenour granting a preliminary injunction finding that the plaintiffs were likely to prove that the state's restrictions on DAAs were violating access requirements according to federal Medicaid policy. In his decision, Judge Coughenour states:

The extensive evidence provided by the plaintiffs and the lack of substantial counterevidence from the [Washington Health Care Authority] establishes that there is a consensus among medical experts and providers that the lifesaving DAAs are 'medically necessary' for all [Hepatitis C virus] infected persons, regardless of fibrosis score.<sup>8,9</sup>

In a summary with positive implications and a path for others fighting the same state imposed restrictive requirements, Judge Coughenour went on to argue that the "plaintiffs have adequately demonstrated that they are likely to prevail on their claim." Consequently, Washington state's Medicaid program now covers Hepatitis C treatment regardless of disease stage.

### **Failure to Provide Care with Reasonable Promptness**

The second argument, that of reasonable promptness, is found in 1396(a)(8) of the

Medicaid Act which states:

A State plan for medical assistance must provide that all individuals wishing to make application for medical assistance under the plan shall have opportunity to do so, and that such assistance shall be furnished with reasonable promptness to all eligible individuals;<sup>10</sup>

Advocates in Delaware, Connecticut, and most recently Colorado and Missouri, have used the argument that criteria stipulating fibrosis score or requiring advanced disease stage are a violation of federal law which requires reasonable promptness of care. HCV is a slowly progressing infection with more severe and life threatening symptoms sometimes taking decades to develop and occurring at unpredictable and variable rates. According to the plaintiffs, requiring patients to wait years while their disease progresses is not reasonable promptness. Prior Authorization criteria which limit DAAs to those patients with advanced stage liver disease are, in essence, requiring beneficiaries to wait for what the plaintiffs consider to be an unreasonable time span. Supporting their claim, the reasonable promptness argument maintains that if a drug made by a participating manufacturer is FDA approved and medically indicated, it should be furnished with reasonable promptness as stipulated in 1396(a)(8). State plans which require Metavir scores of F3 or F4 for authorization, as is the case with 26 states, may stand in possible violation of the Medicaid Act according to this argument.

In the case of Connecticut, advocacy groups and legal aid foundations sent coordinated letters to the Commissioner of the Department of Social Services.<sup>6, 11</sup> In a similar manner, Delaware beneficiaries worked with legal counsel to threaten the State with a class action lawsuit. In Delaware's demand letter dated March 28, 2016, attorneys for Tycko & Zavareei with representatives from both Community Legal Aid Society, Inc. and Harvard Law School's Center for Health Law & Policy Innovation argued on behalf of Medicaid beneficiaries that Delaware's

Medicaid Prior Authorization Conditions for HCV violate the Medicaid Act in at least three ways: medical necessity, reasonable promptness, and comparable care.<sup>12</sup> The demand letter included a copy of the State's required three-page Prior Authorization and Informed Consent document and CMS's November 2015 letter to all State Medicaid plans. With the violations carefully enumerated and CMS purportedly on their side, the plaintiffs requested that Delaware Medicaid remove its restrictions on DAA coverage by April 15, 2016. The letter was a success without court action and the State responded by placing DAAs on the Medicaid's Preferred Drug List as of July 1, 2016. In a similar, though partial, success, Colorado revised their prior authorization criteria in response to a legal threat from the ACLU and at the prompting of their state Drug Utilization Review board. Colorado's response was to reduce the minimum fibrosis score from F3 to F2 and remove fibrosis score requirements entirely for women planning to become pregnant within one year. These changes fell short of advocates' hopes and a class action suit was filed on September 19, 2016.

### **Failure to Provide Comparable Care**

The third argument, that of comparable care, is found in 1396(a)(10)(B)(i) of the Medicaid Act which states:

A State plan for medical assistance must provide that the medical assistance made available to any individual described in subparagraph (A) shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual

...<sup>10</sup>

In other words, a Medicaid plan may not automatically deny coverage to some beneficiaries when others with comparable needs are granted access. It is important to clarify that the argument of Comparable Care involves identifying a class individuals and comparing the medical assistance each receives relative to another in the same class. This particular argument rarely stands alone and is more often found as one of many arguments used in an advocate's efforts to improve access to HCV therapy.

Of the states reviewed, advocates in Florida, Delaware, Missouri, and Colorado argue that fibrosis score restrictions violate the comparable care provision by denying the cure to some Medicaid beneficiaries with Hepatitis C while granting it to others. Delaware utilizes this argument as the last of its three arguments and gives it the least attention. The letters written to Florida's State Medicaid plan were not readily available, but advocates' success in Florida is evidenced in the State Medicaid's revised Prior Authorization policy published on May 27, 2016:

The managed care plan's prior authorization criteria and protocols may not be more restrictive than that used by the Agency as indicated in the Florida Statutes, the Florida Administrative Code, the Medicaid State Plan, and those posted on the Agency's website. (Attachment II, Exhibit II-A, Section V.A. 1.a.(25)(d)<sup>1</sup>) Effective June 1, 2016, the Agency will be amending its posted drug criteria for all drugs for the treatment of hepatitis C to discontinue the requirement for evidence of hepatic fibrosis.<sup>13</sup>

Advocates in Missouri and Colorado use the Comparable Care argument to highlight the discriminatory nature of certain State Medicaid prior authorization requirements. Advocates in Missouri claim fibrosis score requirements are "discriminating among similarly situated Medicaid beneficiaries on the basis of categorical restrictions that are not based upon prevailing clinical standards."<sup>14</sup> Likewise, advocates in Colorado point out that "discriminating amongst similarly situated Medicaid individuals infected with the Hepatitis C Virus by denying treatment with DAAs to those with Metavir Scores of less than a specified minimum" is a violation of the Medicaid Act.<sup>15</sup>

The outcomes of the legal challenges in Missouri and Colorado have yet to be decided. However, as Delaware and Florida have seen progress utilizing the Comparable Care argument to obtain complete removal of fibrosis requirements, there is reason to believe these successes can be emulated.

### **Bridging the Gap**

In all the above cases, beneficiaries and providers were able to petition for positive

change regarding state violations of federal law. It should be noted that the full burden of lack of coverage does not fall solely upon the shoulders of state Medicaid plans. Budgetary constraints place most state plan administrators in the unenviable position of rationing care when needs far outweigh funds. When budgets are fixed, forced funding for Hepatitis C treatment means a reduction in funding devoted to other diseases and current programs. Cost basis, discount negotiations, and competitive pricing are beyond the scope of this paper but do exist as very real components of the landscape in which treatment and advocacy decisions are made. Our point here is that when this reality forces restrictions in violation of federal law, there are several specific steps physicians and advocates can take to further support the elimination of barriers to care.

- Write a letter to your state's Medicaid program using the examples of others as a guide. Local legal aid and advocacy groups may be able to help.
- Seek out and assist patients who are interested in filing claims with the state if they are denied.
- Apply for medications even when you know they will be denied. This is important in identifying patients who may want to file suit, and it helps compile accurate data regarding the number of applicants and denials.
- Include advocacy organizations in your practice either by direct participation or by linking your patients to these organizations.

We urge practitioners to continue to stay abreast of the ways in which their state may be violating federal law and to both keep informed of, and build off of, the successes of other advocates. Advocacy can take many forms and there is some debate that the physician's role for advocacy should not extend beyond the individual patient. Although some may feel that physician involvement in policy matters is beyond their specific role or purview, we argue that in this case, doing good for your patients can also mean doing something for the greater good as

well. When providers step up as advocates, they lend a strong voice opposing the injustice of the current Medicaid system's denial of access to Hepatitis C therapies.

Notwithstanding the recent successes, fifty percent of states with known prior authorization criteria still require a fibrosis score of F3 before treatment will be approved.<sup>16</sup>

There is no doubt that a huge disconnect remains between implementation at the state Medicaid program level and the mandates of federal law. It is the opinion of the authors of this article that a federally funded program similar to the Ryan White Care Act would best bridge this disconnect.<sup>17</sup> However, for now, letter writing and assisting patients who are interested in taking legal action seems to have the most momentum and may be the most accessible options to persuade states to lessen their current prior authorization restrictions. It is the hope of the authors that we have offered a sampling of arguments to use in writing your states and petitioning on behalf of Hepatitis C patients so that they may get the cure to which they are federally entitled.



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Table 1 Action Taken and Result by State					
State	Date of Initial Action	Type of Action	Argument	Section Violated	Result of Action
Connecticut <sup>6,7,11</sup>	2/19/2015	Letter to State Medicaid Office	Medically Necessary	42 U.S.C. 1396r-8(d)(1)(B)	All restrictions were lifted within 3 months
			Reasonable Promptness	42 USC 1396(a)(8)	
Delaware <sup>12</sup>	3/28/2016	Letter to State Medicaid Office threatening class action	Reasonable Promptness	42 USC 1396(a)(8)	Phasing in expanded access with all disease stage requirements removed by January 2018
			Comparable Care	42 USC 1396(a)(10)(B)(i)	
Washington <sup>8,9</sup>	5/31/2016	Federal Court Case of <i>B.E. et. al v. Teeter</i> - Later changed to a Class action	Medically Necessary	42 U.S.C. 1396r-8(d)(1)(B)	Judge ordered disease stage restrictions lifted. Other restrictions remain in place.
Florida <sup>12</sup>	04/2016	Letters to State Medicaid Office	Comparable Care	42 USC 1396(a)(10)(B)(i)	Removed disease stage requirements but Substance Use and Abuse requirements remain in place
New York <sup>20,21</sup>	03/02/2016	State Attorney General investigated private insurers	Medically Necessary	Varies by private insurance plan	Removed disease stage requirements, substance abuse limitations, and provider restrictions
Colorado <sup>19</sup>	07/2016	Letter to State Medicaid Office threatening class action and Recommendation from Drug Utilization Review board	Reasonable Promptness	42 USC 1396(a)(8)	Lessening of restrictions on disease stage and removal of fibrosis requirements for women planning to become pregnant
Colorado <sup>15</sup>	9/19/2016	Class action 1:16-cv-02353	Medical Necessity	42 U.S.C. 1396r-8(d)(1)(B)	Ongoing trial
			Reasonable Promptness	42 USC 1396(a)(8)	
			Comparable Care	42 USC 1396(a)(10)(B)(i)	
Indiana <sup>18</sup>	11/25/2015	Class action 1:15-cv-01874	Medical Necessity	42 U.S.C. 1396r-8(d)(1)(B)	Ongoing trial
Missouri <sup>14</sup>	10/18/2016	2:16-cv-04273	Medical Necessity	42 U.S.C. 1396r-8(d)(1)(B)	Ongoing trial
			Reasonable Promptness	42 USC 1396(a)(8)	
			Comparable Care	42 USC 1396(a)(10)(B)(i)	