UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

J.E.M., et al.,	)	
Plaintiffs,	)	
v.	)	
BRIAN KINKADE, et al.,	)	Case No. 16-04273-CV-C-NKL
Defendants.	)	

PLAINTIFFS' REPLY SUGGESTIONS IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

Defendants' authorization policies violate the Medicaid Act by denying Plaintiffs timely coverage of medically necessary Direct Acting Anti-viral (DAA) medications to treat their Hepatitis C Virus (HCV). Defendants' written policies clearly state that DAA treatment will not be approved for individuals with a fibrosis score below F3, or for those who are unable to submit three months of negative drug and alcohol screens. Defendants defend the policy while at the same time arguing that it is not always applied. Defendants maintain that they need not cover Plaintiffs' DAAs because they disagree with the established standard of care for HCV treatment. On the other hand, they argue, based on unspecified criteria, that exceptions are made for some individuals. Critically, Defendants never explain why the prevailing medical treatment that cures a symptomatic and life-threatening communicable disease—and for which there is no equally effective alternative medication—is not medically necessary until irreparable liver damage occurs. This Court should grant Plaintiffs' Motion for a Preliminary Injunction.

I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS

A. Plaintiffs are not making a reasonable standards claim.

Plaintiffs have established claims for relief under three separate provisions of the Medicaid Act, all of which are privately enforceable under 42 U.S.C. § 1983. Defendants throw

the Court a "red herring" by arguing that Plaintiffs cannot privately enforce Medicaid's "reasonable standards" provision, 42 U.S.C. § 1396a(a)(17). See Defendants' Suggestions ("Defs Sugg.") at 5-9. However, Plaintiffs have not made a reasonable standards claim, nor are they required to do so.[1] Plaintiffs appropriately make claims under a variety of theories that fit the facts of the case, and those claims must be judged on their own merit. Courts consistently hold Plaintiffs' actual claims are enforceable pursuant to § 1983.[2] This Court should readily dismiss Defendants' arguments concerning a claim that Plaintiffs have not made.

B. Plaintiffs are not challenging reasonable utilization and control procedures; rather, they challenge a policy that denies medically necessary treatment.

Defendants erroneously argue that limiting access to DAAs based on fibrosis score is a utilization control that they can implement under the Medicaid program. Defs Sugg. at 9-16. In guidance, the federal Medicaid agency, the Centers for Medicare & Medicaid Services (CMS), has acknowledged that states have the authority to establish appropriate utilization controls, such as preferred drug lists and use of a prior authorization process, but has also reminded states that such practices must ensure appropriate utilization. D. Ex. G. And as Defendants acknowledge, CMS has found that limiting treatment for HCV to only those beneficiaries whose liver damage has progressed to fibrosis score F3 and requiring a period of abstinence from drug and alcohol abuse are "unreasonable restrictions." Id.

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[1]Such challenges are typically brought under a variety of provisions of the Medicaid statute. See, e.g. Lankford v. Sherman, 451 F.3d 496 (8th Cir. 2006); Weaver v. Reagen, 886 F.2d 194 (8th Cir. 1989); Hiltibran v. Levy, 793 F. Supp. 2d 1108 (W.D. Mo. 2011); J.D. v. Sherman, No. 06-4153-CV-C-NKL, 2006 U.S. Dist. LEXIS 78446 (W.D. Mo 2006).

[2]See Pediatric Specialty Care, Inc. v. Ark. Dept. of Human Servs., 293 F.3d 472 (8th Cir. 2002) ((a)(10)(A) privately enforceable under § 1983); Unan v. Lyon, 2016 WL 107193 (E.D. Mi. Jan. 11, 2016) (same); Cruz v. Zucker, No. 14-cv-4456, 2015 WL 4548162 (S.D.N.Y. Jul. 29, 2015) ((a)(10)(B) privately enforceable under § 1983); Thoreson v. Palmer, No. C96–2051, 1997 WL 33558625 (N.D. Iowa 1997) (same); Romano v. Greenstein, 721 F.3d 373 (5th Cir. 2013) ((a)(8) enforceable under § 1983); White v. Martin, No. 02-4154-CV-C-NKL, 2002 WL 32596017 (W.D. Mo. Oct. 3, 2002) (same).

To be clear, Plaintiffs do not object to Missouri's process for developing a preferred drug list or its use of prior authorization. The problem is that Defendants' Preferred Drug List for HCV—specifically, the policy for determining whether prior authorization requests for DAAs can be approved—includes restrictive authorization criteria that limit access to medically necessary prescription drugs, in violation of the Medicaid Act. Plaintiffs' Memorandum in Support of Motion for Preliminary Injunction ("Plfs Memo") at 5-6 (citations therein); Defs Sugg. at 2; D. Ex. B.[3] In fact, Defendants' criteria for DAAs include two limitations that Defendants acknowledge CMS has deemed unreasonable: a limit on treatment for beneficiaries with a fibrosis score lower than F3 and a required three-month abstinence period before beneficiaries can initiate treatment.

C. Defendants' *post-hoc* rationalizations cannot justify policies and practices that limit treatment based on fibrosis score.

Defendants' published prior authorization policy blocks treatment for individuals who do not have a fibrosis score of F3 or higher. D. Ex. B; Plfs Memo at 5-6; P. Ex.7, 8, 9. They have previously acknowledged that limiting coverage based on fibrosis score is a cost-control aimed at limiting treatment to only the sickest patients. D. Ex. B; Plfs Memo at 5. In this case, Plaintiffs' providers were told *in writing* that treatment was denied because their fibrosis scores were too low. Plfs Memo at 5 (and citations therein). Nevertheless, Defendants argue that, in spite of their official policy, they have approved drugs for patients with lower fibrosis scores (including a handful of patients treated by Plaintiffs' experts). Defendants never articulate their standards for deviating from their official policies, instead claiming this deviation occurs on a "case-by-case

[3]None of the cases relied on by Plaintiffs attacked Missouri's method of establishing prior authorization criteria but those courts still struck down illegal policies and practices. See, e.g., Lankford v. Sherman, 451 F.3d 496 (8th Cir. 2006); Weaver v. Reagen, 886 F.2d 194 (8th Cir. 1989); Hiltibran v. Levy, 793 F. Supp. 2d 1108 (W.D. Mo. 2011).

basis." However, providing DAAs to some individuals with chronic HCV based on arbitrary criteria while leaving out others (including Plaintiffs) for whom such treatment is also medically necessary violates the Medicaid Act. See Plfs Memo at 9-20 (and citations therein).[4]

In B.E. v. Teeter, a federal court in Washington found likely violations of the same provisions at issue here, where defendants made DAAs available to HCV patients with fibrosis scores lower than F3 when they had other "concerning health factors." See B.E. v. Teeter, No. C16-227-JCC, 2016 WL 3033500, at *1, *3-*6 (W.D. Wash. May 27, 2016). Unlike the defendant in B.E., however, Defendants here do not allege that they cover DAAs for low fibrosis scores based on any specific conditions, just that they sometimes disregard the fibrosis requirement—evidently arbitrarily—to cover the DAAs. Nevertheless, they violate the Medicaid Act by approving medically necessary DAA treatment for some individuals with chronic HCV but not others.

At the same time that Defendants attempt to minimize the impact of their restrictive policy, they defend those restrictions. Defendants argue that they need not follow the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) guidelines for HCV treatment and that those guidelines are not the standard of care in the medical community.[5] This litigation position is misplaced and should be disregarded

[4]Defendants allege that their Clinical Consultant reviews requests that "do not meet the approval criteria." Defs Sugg. at 12. Defendants do not (and cannot) explain why DAAs are not medically necessary for Plaintiffs. The contemporaneous documents establish, however, that they were rejected based on their low fibrosis scores pursuant to Defendants' restrictive policy. Plfs Memo at 5. While Defendants' denial notices add that they found no comorbidities that speed up the progression of the disease (P.Ex.6), this is not part of their published authorization criteria nor do Defendants ever argue that it is a component of their policy. Not surprisingly, the pharmacy told JLM's provider that she was denied "due to low F-Score," that there were "no other options," and she "will need to advance to F3/F4 in order for MO Medicaid to approve her." Id.

[5]Of course if low fibrosis scores were not a barrier, there would be no reason for Defendants to attack the AASLD/IDSA guidelines.

by the Court. Prior to this lawsuit, Defendants stated that the MO HealthNet Division "agrees with the AASLD/IDSA recommendation that ALL patients should be treated" and "welcomes the opportunity for every HCV infected participant to have the chance to be 'cured.'" D. Ex. C (emphasis in original). The AASLD/IDSA guidelines were similarly referenced by CMS in instructing states that they must not deny coverage to DAAs based on restrictive fibrosis requirements.

Defendants simply cannot dispute the prevailing medical opinion as established by AASLD/IDSA and testified to by Plaintiffs' nationally recognized experts in Hepatology and Liver Disease: DAAs are the standard of care for chronic HCV irrespective of fibrosis score. Defendants' prior, forthright statement, which they admit was not intended to "constitute a legal defense of [their] authorization criteria," is entitled to more weight than the litigation position they have taken here. See D. Ex. C.[6]

Defendants also speculate that, because they "only" received 1200 prior authorization requests for DAAs, these medications must not be the standard of care. But it is impossible to tell how many beneficiaries with HCV have even seen a specialist (or are on a waiting list for one), how many are receiving any treatment at all relative to the number infected, and of those infected with HCV, whether their physicians have not requested treatment because they know it will likely be denied under Defendants' restrictive standards. Defendants' speculation is no substitute for expert opinion about the *actual* standard of care in the community of liver disease specialists

[6]Defendants' current position appears to have been fashioned solely for the purposes of this litigation. See Bowen v. Georgetown Univ. Hosp, 488 U.S. 204, 212-13 (1988) (rejecting counsel's *post-hoc* rationalizations for agency action); S. D. v. Hood, 391 F.3d 581, 601 (5th Cir. 2004) ("[I]f an agency's decision is to be sustained in the courts," it "must be upheld on the rationale set forth by the agency itself." *Post-hoc* explanations of counsel are "simply an inadequate basis" for "substantive review of an administrative decision") (emphasis added) (quoting Fort Stewart Schools v. FLRA, 495 U.S. 641, 651-52 (1990)).

with whom Defendants agreed just before this lawsuit was filed and which is similarly recognized by CMS, the federal Medicaid agency.

Defendants also attempt to dismiss the AASLD/IDSA guidelines based on a "disclaimer" that they are not intended to constitute a diagnosis, treatment or recommendation for a particular individual. Defendants leave out the very next sentence stating that the guidelines "should not be used in place of a visit, call, consultation or the advice of a physician or other qualified health care provider." See AASLD & IDSA, HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C (Feb. 2016), (http://www.hcvguidelines.org/full-report/website-policies) (last visited Nov. 30, 2016). Plaintiffs have never disputed that it is the responsibility of the individual's treating physician to determine whether a particular patient actually has chronic HCV, which DAAs should be prescribed, and whether the individual meets one of the rare circumstances in which DAAs should not be used. Bacon Decl. ¶ 12; Fleckenstein Decl. ¶ 4. The fact that a treating physician must make individualized determinations does not, however, render the guidelines meaningless. DAAs are still the standard of care for HCV patients, just as chemotherapy is medically appropriate for individuals with certain types of cancer without regard for whether the cancer has reached a more advanced stage. See B.E. at *4 (DAAs are considered the "standard of care" by the AASLD/IDSA and CMS). Here, both the guidance and the Plaintiffs' treating health care providers reach the same conclusion: DAAs are medically necessary to treat Plaintiffs' HCV. Only the Defendants' arbitrary authorization criteria lead to a different result. Defendants also fail in their efforts to distinguish Weaver. Defs Sugg. at 13-14.[7] Defendants minimize the point that a government official is overruling the

[7]Defendants mischaracterize Plaintiffs' argument as conflating FDA approval with medical necessity. Plaintiffs actually pointed out that Defendants have a legal obligation to cover nearly all FDA-approved medications in their Medicaid program. See 42 U.S.C. § 1396r-8. In their

medical judgment of Plaintiffs' treating providers. But the fact that Defendants' "Clinical Consultant" is a licensed pharmacist with a medical degree does not change the fact that the government is substituting its judgment for the established standard of care. See Weaver, 886 F.2d at 200 (restrictions on prescription drugs may not reject the "accumulated knowledge of the medical community"). In fact, Defendants argue that a government official should override the judgments of treating professionals who are HCV experts and actually have examined the Plaintiffs. See id. at 199 (determination of medical necessity "rests with the individual recipient's physician and not with clerical personnel or government officials"); Plfs Memo at 15.

Here, the prevailing community standard for HCV treatment is established by the AASLD/IDSA; this standard has been recognized by CMS and endorsed by the Defendants prior to this litigation. D. Ex. 3. Defendants have not offered any alternative standard for determining when treatment is medically necessary. See Defs Sugg. at 15 (asserting that "[t]he standard of care in Missouri is established within the medical community by other than just AASLD/IDSA guidelines," but failing to specify what other sources establish the standard of care). Moreover, Defendants do not offer a reason why such treatment is not "medically necessary" for the Plaintiffs other than the reasons offered at the time treatment was arbitrarily denied—that they did not meet the fibrosis score restrictions of Defendants' own policy.[8] The only logical conclusion is that any criteria Defendants employ to evaluate medical necessity for individuals

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opening brief, Plaintiffs note that Weaver acknowledges the Medicaid Act's mandate that states provide FDA-approved drugs to individual Medicaid beneficiaries when they are medically necessary for those individuals. See Plfs Memo at 15 (and citations therein).

[8]See note 4 supra. Defendants assert that they have never denied a request for HCV treatment based on a positive drug and alcohol screen—calling the three month abstinence period a "preference," rather than a requirement (Defs Sugg. at 12) but their written criteria belie this claim. "Positive alcohol and illicit drug urine screen (without current prescription)" is listed as a Denial Criteria for all DAAs. Plfs Memo at 20, n. 15 (and citations therein). This unnecessary barrier creates additional delay in receiving a coverage determination and exacerbates the "reasonable promptness" violation. Id.

who are not eligible under their published "Approval Criteria" for DAAs are completely arbitrary and not founded on any clinical basis. Defendants may not continue using these arbitrary criteria to deny medically necessary treatment.

D. Defendants fail to counter Plaintiffs' other arguments.

Defendants are unable to contradict Plaintiffs' comparability and reasonable promptness claims. Defs Sugg. at 16-18. Defendants argue that because they have approved requests for some individuals with fibrosis scores of less than F3, there is no comparability violation.[9] This argument fails, even assuming that Defendants sometimes approve DAAs for individuals not described in their published requirements. As noted earlier, Defendants do not allege which conditions might give rise to approval of DAA treatment, just that they have approved some individuals with low fibrosis scores. Defs Sugg. at 10-12, D. Ex. C. Defendants violate comparability by discriminating against Plaintiffs and other chronic HCV-infected individuals with lower fibrosis scores. See Weaver, 886 F.2d at 197-200 (finding comparability violation where Missouri limited Medicaid coverage of AZT to only those recipients with AIDS who met certain narrow medical criteria and denied the drug to other recipients whose physicians had prescribed it). Defendants' HCV policy similarly violates comparability by excluding certain Medicaid enrollees with HCV from medically necessary DAA treatment, while providing the treatment to other Medicaid enrollees with HCV.

Defendants also argue that Plaintiffs are not likely to succeed on their "reasonable promptness" claim because their treatment was denied altogether on medical necessity grounds

[9]Defendants misstate—without citation—the standard for establishing a comparability claim as requiring a showing that "a named plaintiff would be treated differently under MHC's policy than other Medicaid recipients with the same level of need." Defs Sugg. at 16. The correct standard asks whether a state has restricted services to some categorically needy individuals but not others. See, e.g., White v. Beal, 555 F.2d 1146 (3d Cir. 1977).

rather than delayed. Defs Sugg. at 17. However, this litigation position contradicts Defendants' earlier, more credible statements that they defer or delay treatment of individuals who do not meet fibrosis score requirements. D. Ex. C ("We therefore view the decision regarding metavir fibrosis score and access to treatment as a DEFERRAL rather than a DENIAL.") (emphasis in original). As stated in Plaintiffs' opening brief, deferring treatment until a patient reaches an advanced stage of liver disease is neither "reasonable" nor "prompt" service, and therefore, violates the Medicaid Act. Plfs Memo at 19-20 (and citations therein).

II. PLAINTIFFS MEET THE OTHER FACTORS FOR ISSUANCE OF A PRELIMINARY INJUNCTION

Plaintiffs have established that that they suffer irreparable harm from the denial of medically necessary services, that their harm outweighs any alleged harm to the State and that an injunction is in the public interest. Plfs Memo at 20-24. Without treatment, Plaintiffs suffer from a variety of symptoms and can transmit Hepatitis C to others. Id. at 21. Defendants respond that relief from this Court would require them to provide DAAs without regard to medical necessity. Plaintiffs in fact seek the opposite, they ask this Court to remove an arbitrary barrier—a fibrosis score of F3 or greater—to medically necessary treatment. This is the same kind of arbitrary barrier that this Court and many others have stricken. Id. at 9-20 (and cases cited therein). Defendants also suggest, without legal support, that Plaintiffs must demonstrate additional factors that could accelerate their liver disease in order to show irreparable harm. Defs Sugg. at 18-19. As Plaintiffs have already established, the denial of medically necessary, curative treatment is more than sufficient to show irreparable harm.

Moreover, Defendants deny any obligation to "provide general public health for the entire population." Defs Sugg. at 20. While Medicaid is undeniably an individual entitlement program, that does not mean that there is no public interest in curing beneficiaries of

communicable diseases. In fact, Congress has included a wide range of immunizations for children and adults as Medicaid services, in part to prevent the spread of contagious disease. See 42 U.S.C. § 1396d(a)(13)(B) (authorizing adult vaccines as Medicaid service); id. §§ 1396a(a)(43), 1396d(r)(1)(B)(iii) (establishing childhood immunizations as mandatory Medicaid service). There is no question that DAA treatment is necessary to prevent the spread of HCV, and preventing the spread of infectious disease is consistent with medical necessity. See Andrews v. Cervantes, 493 F.3d 1047, 1057 (9th Cir. 2007) (holding that the risk of a prisoner contracting Hepatitis C was an allegation that met the "imminent threat of serious physical injury" standard).

For the reasons expressed herein and in Plaintiffs' opening brief, this Court should grant Plaintiffs' Motion for Preliminary Relief.

Respectfully submitted,

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Dated December 2, 2016 ATTORNEYS FOR PLAINTIFFS

CERTIFICATE OF SERVICE

I hereby certify that on December 2, 2016, I electronically filed the foregoing with the clerk of the Court using the CM/ECF system which sent notification of such filing to the following counsel of record: Colleen Joern Vetter, Assistant Attorney General, P.O. Box. 861, St. Louis, MO 63101.

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