

**IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION**

J.E.M., et al.,)	
)	
Plaintiffs,)	
)	
v.)	Case No. 16-cv-04273-SRB
)	
)	
BRIAN KINKADE, in his official capacity)	
as Director of the Missouri Department of)	
Social Services, et al.,)	
)	
Defendants.)	

ORDER

Before the Court is Plaintiffs’ Motion for Preliminary Injunction. (Doc. #2). For the reasons stated below, the motion is granted in part.

Plaintiffs J.E.M. and J.L.M, Medicaid beneficiaries with Hepatitis C virus (“HCV”), seek a preliminary injunction against Defendant Brian Kinkade in his official capacity as Director of the Missouri Department of Social Services, and Joe Parks, M.D., in his official capacity as Director of the MO HealthNet Division, enjoining them from applying certain Hepatitis C drug-treatment policies and prior-authorization criteria that Plaintiffs argue exclude them from medically-necessary, direct-acting antiviral treatment (“DAAs”). With the Defendants’ agreement, the Court grants Plaintiffs’ request for a preliminary injunction prohibiting Defendants from requiring three months of negative drug and alcohol screens prior to submitting requests for DAA approval. The Court finds, however, that an evidentiary hearing is necessary before the Court can rule on the Plaintiffs’ request for a preliminary injunction prohibiting Defendants from applying policies and prior authorization criteria regarding fibrosis scores

because a material factual dispute exists regarding the medical necessity of treating all HCV patients with DAAs regardless of fibrosis score.

I. Procedural History

Plaintiffs are low-income Missouri Medicaid beneficiaries who are infected with HCV, a life-threatening, infectious, blood-borne disease. Defendants are officials who are in charge of the state's Medicaid program called MO HealthNet. Plaintiffs filed their Complaint on October 18, 2016, including three claims for relief: 1) a 42 U.S.C. § 1983 claim for failure to provide medically-necessary prescription drugs in violation of 42 U.S.C. §§ 1396a(a)(10)(A) and 1396d(a); 2) a 42 U.S.C. § 1983 claim for violation of the Medicaid Act's "comparability" requirement at 42 U.S.C. § 1396a(a)(10)(B); and 3) a 42 U.S.C. § 1983 claim for violation of the Medicaid Act's "reasonable promptness" requirement at 42 U.S.C. § 1396a(a)(8).¹ The case was originally assigned to Judge Nanette Laughrey.

Plaintiffs filed their Motion for Preliminary Injunction on October 18, 2016, and briefing was completed on December 2, 2016. On December 15, 2016, Judge Laughrey held a teleconference regarding scheduling related to the Motion for Preliminary Injunction. The Minute Entry states in part:

The parties presented argument on the need for an evidentiary hearing. Defendants argued an evidentiary hearing is required for the Court to determine the community standard of care for Hepatitis C treatment. Defendants also argued for an evidentiary hearing so that they can cross-examine Plaintiffs' experts on their opinions, which Defendants are challenging. Plaintiffs argued that no evidentiary hearing is required because all issues can be resolved on the law.

¹ Defendants filed a Motion to Dismiss on January 3, 2017, arguing that Plaintiffs' claims are not cognizable under 42 U.S.C. § 1983. The Court denied the Motion to Dismiss in a separate order.

(Doc. #28). Also on December 15, 2016, Judge Laughrey set the motion for oral argument, and the case was transferred to the undersigned Judge. Upon transfer, oral argument was re-set to coordinate with the Court's schedule. A motion hearing was held on January 6, 2017, during which the Court heard oral argument from both sides.

II. Legal Standard

“A plaintiff seeking a preliminary injunction must establish that (1) he is likely to succeed on the merits, (2) he is likely to suffer irreparable harm in the absence of preliminary relief, (3) the balance of equities tips in his favor, and (4) an injunction is in the public interest.” *Hiltibran v. Levy*, No. 10-CV-4185-NKL, 2010 WL 6825306, at *2 (W.D. Mo. Dec. 27, 2010) (citing *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 129 S.Ct. 365, 374 (2008); *Dataphase Sys., Inc. v. C.L. Sys., Inc.*, 640 F.2d 109, 113 (8th Cir. 1981)). “An evidentiary hearing is required prior to issuing a preliminary injunction only when a material factual controversy exists.” *United Healthcare Ins. Co. v. AdvancePCS*, 316 F.3d 737, 744 (8th Cir. 2002) (citing *Movie Sys., Inc. v. MAD Minneapolis Audio Distribs.*, 717 F.2d 427, 432 (8th Cir. 1983)).

III. Factual Background

Missouri participates in the federal Medicaid program and accepts federal matching funds for its program expenditures. Where a state accepts federal Medicaid funds, it must comply with federal Medicaid law. *See* 42 U.S.C. § 1396a. Missouri's Medicaid program provides health services only to the “categorically needy,” including Plaintiffs. 42 U.S.C. § 1396a(a)(10)(A); Mo. Rev. Stat. § 208.151. Missouri elects to provide prescription drug benefits to participants pursuant to Mo. Rev. Stat. § 208.152(7) and 13 C.S.R. 70-20.030.

Missouri has established a Preferred Drug List (PDL) and prior authorization program as a condition of coverage or payment for DAAs. To initiate the process, health care providers must submit a prior authorization request to MHD for DAAs for a Medicaid participant with HCV and provide sufficient information to satisfy the criteria associated with the drug requested. For all DAA requests, MO HealthNet's Approval Criteria require "negative urine alcohol and illicit drug screen results submitted for [the] most current 3 months[.]" (Doc. #22, Ex. B). Depending on the specific drug requested and HCV genotype, MO HealthNet's Approval Criteria require a fibrosis score of at least F2 or F3. *Id.* MO HealthNet's "Denial Criteria" include: "Positive alcohol and illicit drug urine screen[;]" "Metavir fibrosis score of less than F3 for genotypes 1, 2 or 4[;]" and "Metavir fibrosis score of less than F2 for genotype 3[.]" *Id.* A fibrosis score, indicated by F0 through F4, represents the amount of fibrosis or scarring of the liver. F0 indicates no fibrosis while F4 represents cirrhosis.

J.E.M.'s and J.L.M.'s health care providers prescribed DAA treatments to treat and potentially cure their chronic HCV. MO HealthNet denied Plaintiffs' requests for treatment at least in part because their fibrosis scores were lower than F3. J.E.M. received a letter stating, "MO HealthNet Division has denied the request because the information submitted did not meet the criteria established to obtain authorization for this drug." (Doc. #2-5, p. 4).

IV. Discussion

Plaintiffs' suit challenges MO HealthNet's Approval Criteria based on three months of negative urine alcohol and drug screens, and fibrosis score. Plaintiffs argue the challenged criteria have no impact on the medical necessity of DAAs for HCV patients, and by applying the criteria, Mo HealthNet is failing to provide medically-necessary prescription drugs in violation of 42 U.S.C. §§ 1396a(a)(10)(A) and 1396(d)(a). Plaintiffs further argue that application of the

challenged criteria violates the Medicaid Act's "comparability" requirement at 42 U.S.C. § 1396a(a)(10)(B) and "reasonable promptness" requirement at 42 U.S.C. § 1396a(a)(8).

A. Negative Alcohol and Drug Screens

As stated in their proposed order submitted to the Court, Defendants agree Plaintiffs are entitled to a preliminary injunction prohibiting the application of Mo HealthNet's Approval Criteria requiring three-months of negative alcohol and illicit drug screens before submission of a request for DAA treatment. Upon review of the parties' filings and evidence submitted in support, as well as the oral arguments made at the January 6 hearing, the Court finds Plaintiffs have established their right to a preliminary injunction on this point. Plaintiffs have established: 1) they are likely to succeed on the merits of this issue; 2) they are likely to suffer irreparable harm in the absence of preliminary relief; 3) the balance of equities tips in their favor; and 4) an injunction is in the public interest. *See Hiltibran*, 2010 WL 6825306, at *2 (citations omitted). Accordingly, the Court grants Plaintiffs' request for a preliminary injunction prohibiting Defendants from requiring three months of negative drug and alcohol screens prior to submitting requests for DAA approval.

B. Fibrosis Score

Upon review of the parties' filings and the evidence submitted in support, the Court finds that at least two, material, factual controversies exist requiring that the Court conduct an evidentiary hearing before issuing an order on this point. First, MO HealthNet's published Approval Criteria and corresponding Denial Criteria indicate that a health care provider's request for DAA treatment *will* be denied if the HCV patient's fibrosis score is below either F2 for genotype 3 or below F3 for genotypes 1, 2, and 4. In contrast, Defendants submitted evidence

through affidavit testimony that some patients with fibrosis scores below the published thresholds are approved for DAA treatment based on a case-by-case review that happens in response to every DAA prior authorization request submitted by a healthcare provider. (Doc. #22, Ex. D, ¶12). MO HealthNet's published criteria and Defendants' stated procedures are in conflict, and the Court finds an evidentiary hearing is required on this issue.

Second, in support of their argument that an HCV patient's fibrosis score has no impact on whether DAA treatment is medically necessary, Plaintiffs directed the Court to several pieces of persuasive evidentiary support, including: 1) their expert affidavits; 2) treatment guidelines issued by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America stating DAAs should not be reserved for only individuals with F3 or F4 fibrosis scores; and 3) the Centers for Medicare and Medicaid Services of the U.S. Department of Health and Human Services' Medicaid Drug Rebate Program Notice: Release No. 172 criticizing some states' practice of restricting DAA treatment based on fibrosis score. To counter Plaintiffs' evidence that medical necessity of DAA treatment is not related to fibrosis score, Defendants submitted their own experts' affidavits, one of whom opines, "There are many medically and clinically recognized and accepted contraindications to immediate and aggressive treatment. . . . Treating every diagnosis of HCV exposes the individual to the possibility of adverse effects or worse damage to bodily organs that may only show up years in the future." (Doc. #22, Ex. D, ¶19). The Court finds that Defendants' experts' affidavits are sufficient to create a factual controversy regarding the medical necessity of DAA treatment regardless of fibrosis score, requiring a hearing.

The Court informs the parties that based on the present record, it is inclined to grant Plaintiff's requested preliminary injunction preventing Defendants from considering an HCV

patient's fibrosis score in deciding whether to approve DAA treatment, particularly given that on-point, case-law precedent, although not binding on this Court, weighs in favor of the preliminary injunction. *See B.E. v. Teeter*, No. 16-227-JCC, 2016 WL 3033500 (W.D. Wash. May 27, 2016) (granting preliminary injunction prohibiting the Washington State Health Care Authority from considering fibrosis score in making DAA treatment decisions). However, given the Court's inclination to grant Plaintiffs' requested preliminary injunction on this issue as well as the fact that Defendants specifically requested an evidentiary hearing in order to be allowed an opportunity to cross-examine Plaintiffs' experts, the Court will conduct an evidentiary hearing before issuing its ruling.

V. Conclusion

Accordingly, it is hereby ORDERED:

- 1) Plaintiffs' Motion for Preliminary Injunction (Doc. #2) is granted in part;
- 2) The Court enters a preliminary injunction prohibiting Defendants from requiring three months of negative drug and alcohol screens prior to submitting requests for DAA approval;
- 3) Defendants are directed to file a status report with the Court regarding implementation of this injunction within thirty (30) days of the date of this Order; and
- 4) The Court will contact the parties to schedule an evidentiary hearing regarding Plaintiffs' request for a preliminary injunction prohibiting Defendants from considering an HCV patient's fibrosis score in deciding whether to approve or deny a healthcare provider's request for DAA treatment.

IT IS SO ORDERED.

Dated: February 2, 2017

/s/ Stephen R. Bough
STEPHEN R. BOUGH
UNITED STATES DISTRICT JUDGE