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

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

ORDER

Before the Court is Plaintiffs' Motion for Preliminary Injunction (Doc. #2) asking the Court to enjoin Defendant Jennifer Tidball, in her official capacity as Acting Director of the Missouri Department of Social Services, and Defendant Jay Ludlum, in his official capacity as Acting Director of MO HealthNet Division, from applying certain state-imposed, drug-treatment policies that deny some Medicaid beneficiaries with Hepatitis C virus the direct-acting antiviral treatment ("DAAs") prescribed by their doctors, at least in part, based on fibrosis score. Upon consideration of the record, including but not limited to the evidence submitted during the evidentiary hearing held on March 10, 2017, the motion is DENIED.

I. Procedural and Factual Background

Plaintiffs J.E.M. and J.L.M are Medicaid beneficiaries with Hepatitis C virus ("HCV"). Plaintiffs' Complaint includes 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).

The Court ruled previously on a portion of Plaintiffs' Motion for Preliminary Injunction. On February 2, 2017, the Court entered an order granting Plaintiffs' request for a preliminary injunction enjoining Defendants from requiring three months of negative drug and alcohol screens prior to submitting requests for DAA approval. At that time, the Court deferred its ruling on the fibrosis score issue. The Court stated, "The Court finds, however, that an evidentiary hearing is necessary before the Court can rule on 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." (Doc. #40, pp. 1-2).

An evidentiary hearing was held on March 10, 2017. Plaintiffs presented evidence through the testimony of Dr. Bruce R. Bacon, and Defendants presented evidence through the testimony of Dr. Ronald L. Koretz and Steven Michael Calloway, R.Ph. Dr. Bacon is a professor of internal medicine at St. Louis University and served previously as the director of the division of gastroenterology. Dr. Bacon is a high-volume provider who sees patients with all types of liver disease including HCV. Dr. Koretz is presently an Emeritus Professor of clinical medicine at David Geffen-UCLA School of Medicine, and up until his retirement in 2006, he served as the Chief of Gastroenterology at the Olive View-UCLA Medical Center. Stephen Michael Calloway is the Director of Pharmacy with Mo HealthNet and has held the job since January 2015. Both Plaintiffs and Defendants admitted new exhibits during the course of the evidentiary hearing. The Court has considered the entirety of the evidentiary record in reaching its decision that

Plaintiffs have not established their entitlement to a preliminary injunction prohibiting Defendants from considering fibrosis scores in deciding whether to approve DAA treatments.

a. HCV and Fibrosis Scores

HCV is a blood-borne virus that predominately affects the liver. Patients with HCV for more than six months are said to have chronic HCV. Patients with chronic HCV can progress to have cirrhosis of the liver or liver cancer, but not all patients with HCV will progress to that point. The parties presented conflicting evidence regarding the percentage of chronic HCV patients whose condition will progress to the point of cirrhosis or liver cancer. Dr. Bacon testified that 20% - 50% of chronic HCV patients will progress to end stage liver disease while Dr. Koretz testified the number is closer to 15%. Even so, all witnesses agreed that not all chronic HCV patients will progress, and it is impossible to predict which patients will progress, with the caveat that patients who consume alcohol or those with certain comorbidities such as HIV or co-infectional Hepatitis B are more likely to progress.

One symptom of HCV is fibrosis, the scarring of the liver caused by inflammation. The level of fibrosis is measured by a fibrosis score. The term "fibrosis score" as used throughout this Order refers to Metavir fibrosis score, one of the most commonly used scoring systems for measuring liver disease. A fibrosis score ranges from F0 (mild or no scarring) to F4 (significant liver damage/cirrhosis). The demarcation between fibrosis levels is not a bright line, but rather, progression is based on a continuum. HCV is divided into six distinct types, called genotypes.

The rate of progression varies, but on average it will take decades for an HCV patient to progress from F0 to F4. There is no strong correlation between fibrosis progression and symptoms. Some HCV patients with a low fibrosis score may have severe symptoms while other

patients with a higher fibrosis score may have no symptoms. Any cirrhosis of the liver is generally irreversible.

b. DAA Treatments

DAAs were first introduced in late 2013, and there are presently four or five different regimens available. Approximately 90%-95% of HCV patients who take DAAs will achieve a sustained virologic response ("SVR"), which refers to the lack of the virus in the patient's bloodstream during a three-month follow-up period after completion of a twelve-week treatment regimen. The primary side effects of DAAs include headache and fatigue, although one study showed that in a very few patients co-infected with Hepatitis B, DAA treatments caused an activation of their Hepatitis B.

Dr. Bacon referred to an SVR as a "cure" while Dr. Koretz challenged the use of the term. Dr. Koretz testified that patients think "cure" means the virus is gone, it will never come back, and any liver disease will not progress. However, Dr. Koretz testified SVR has not been shown to meet those criteria, in part because no long-term randomized studies have been conducted. Dr. Koretz testified that some studies have shown even in a patient who has achieved SVR, it is possible that HCV-RNA still exists in the peripheral mononuclear cells.

c. Evidence Regarding the Standard of Care

Dr. Bacon testified that treating all HCV patients with DAAs regardless of fibrosis score is the standard of care, at least amongst high-volume providers. Dr. Koretz countered that a more restrictive approach is the standard of care in many areas, and a restrictive approach is appropriate for two, primary reasons: 1) by treating all patients, even those at F0 or F1, you will

necessarily be treating patients whose fibrosis would never have progressed; and 2) the medical community does not yet know what kind of long-term side effects will occur.

Plaintiffs relied on the fact that in 2014, the American Association for the Study of Liver Disease (AASLD) and the Infectious Disease Society of America (IDSA) issued treatment guidelines stating that DAAs should not be reserved for only patients with fibrosis scores of F3 and F4. Dr. Koretz challenged the AASLD/IDSA guidelines on the grounds they were adopted by a panel whose member majority had conflicts of interest with the pharmaceutical industry. Plaintiffs also relied on the fact that the Medicare system no longer considers fibrosis scores in approving DAA treatments for Medicare recipients. Plaintiffs further relied on the November 5, 2015, release by the Centers for Medicare and Medicaid Services of the U.S. Department of Health and Human Services which states:

> CMS is concerned that some states are restricting access to DAA HCV drugs contrary to the statutory requirements in section 1927 of the Act 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 extent of liver damage has progressed to metavir fibrosis score F3, while a number of states are requiring matavir fibrosis scores of F4. . . .
>
> While states have the discretion to establish certain limitations on the coverage of these drugs, such as preferred drug lists and use of prior authorization processes, such practices must be consistent with the requirements of section 1927(d) of the Act to ensure appropriate utilization.
>
> As such, the effect of such limitations 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. States should, therefore, examine their drug benefits to ensure that limitations do not unreasonably restrict coverage of effective treatment using the new DAA HCV drugs.

(Doc. #2-13, pp. 2-3). Defendants argued Missouri's Approval/Denial criteria are in line with the CMS release because Missouri does not limit treatment to only HCV patients with a fibrosis

score of F3 or F4, but rather, as will be shown in part I.e. below, Missouri conducts an individualized review of every request for DAA treatment.

Defendants argued their policy is in line with the majority of state Medicaid systems. After the hearing and at the Court's request, Mr. Calloway compiled and submitted a chart showing the DAA treatment approval policy as it relates to fibrosis score for each state and the District of Columbia. Plaintiffs responded by submitting an affidavit of Kevin Costello, Litigation Director, Center for Health Law & Policy Innovation at Harvard Law School, which challenged four designations in Mr. Calloway's chart. Giving Plaintiffs the benefit of the doubt with respect to their challenges, the information shows fourteen states presently do not take fibrosis score into account in deciding whether to approve DAA treatment. Conversely, the information shows thirty-six states and the District of Columbia consider fibrosis score in some respect, although not all in the same way as Missouri, in deciding whether to approve DAA treatments.

d. Plaintiffs J.E.M. and J.L.M.

J.E.M.'s and J.L.M.'s doctors prescribed DAA treatment, which was denied by Mo HealthNet. At the time Mo HealthNet reviewed the prescriptions and prior authorization requests, J.E.M. had an F2 fibrosis score, and J.L.M. had an F0 fibrosis score. Neither J.E.M. nor J.L.M requested administrative review of the denials.

J.E.M. submitted an affidavit attesting that he has been a Missouri Medicaid recipient for four years due to his disabilities, including arthritis of the spine, pancreatitis, high blood pressure, and HCV. J.E.M. further attested that Hepatitis C has negatively affected his quality of life in that he is drained of all energy and in daily physical pain, and he is no longer able to participate in activities he once enjoyed. J.E.M. is fearful he will transmit the disease to friends

and family and takes extra precautions around his home as a result. J.E.M.'s father had HCV and died of liver cancer, and J.E.M. is fearful the same will happen to him.

J.L.M. submitted an affidavit attesting that she is a Missouri Medicaid recipient due to her disabilities, including fibromyalgia and Hepatitis C. J.L.M. further attested that her HCV has aggravated her fibromyalgia, and her body aches more. J.L.M. suffers anxiety as a result of her diagnosis. J.L.M. is also fearful she will transmit the disease to her family and takes extra precautions around her home as a result.

e. Current Missouri Approval/Denial Criteria for DAA Treatments

After the Court granted part of Plaintiffs' motion for preliminary injunction on February 2, 2017, but before the evidentiary hearing on March 10, 2017, MO HealthNet revised its DAA Preferred Drug List for DAAs and the associated Approval Criteria. (Doc. #51-1). The Approval Criteria now provide that DAAs will be approved for HCV patients with genotype 1, 2, or 4, who have a fibrosis score equal to or greater than F3 or who have a fibrosis score of F0-F2 with certain comorbidities. The Approval Criteria further provide that DAAs will be approved for HCV patients with genotype 3 who have a fibrosis score equal to or greater than F2 or who have a fibrosis score of F0-F1 with certain comorbidities. The corresponding Denial Criteria provide that DAAs will be denied to patients with either a "fibrosis score of less than F3 for genotypes 1, 2, or 4" or a "fibrosis score of less than F2 for genotype 3[.]" (Doc. #51-1, p. 8). A footnote applicable to both Denial Criteria states, "In addition to Metavir fibrosis score, Clinical Consultant will review all therapy requests for documentation of comorbidities that may result in approval." (Doc. #51-1, p. 8).

The previous version of the Approval Criteria and Denial Criteria provided that DAAs would only be approved for HCV patients with a fibrosis score of F3 or greater for genotypes 1,

2, or 4 or for HCV patients with a fibrosis score of F2 or greater for genotype 3. The previous version did not provide for individual consideration and did not allow for approval of DAAs for patients with lower fibrosis scores with comorbidities. Even though the prior criteria did not allow for individual considerations and on their face did not allow approval of DAA treatment for patients with a fibrosis score of less than F2 or F3 depending on genotype, Defendants submitted evidence that in practice an individual review was conducted for every DAA prior authorization request received and many were approved. The new criteria explicitly include this process.

f. Application of the Missouri Approval/Denial Criteria and Resulting Statistics

To obtain prior authorization for DAA treatment, a medical care provider must submit a request for Drug Prior Authorization to Mo HealthNet's Drug Help Desk. Each request is reviewed by a registered nurse to ensure the request includes all clinical data necessary to make a decision. Once all the necessary information is received, all requests are sent to Mo HealthNet employee Mark McBride Roaseau for a comprehensive review. Mr. Roaseau is a licensed pharmacist with a medical degree. Mr. Roaseau attested in his affidavit, "I consider all information when determining whether a prior authorization request should be approved or denied. Every decision is made individually on a case by case basis upon the latest medical information based upon generally accepted medical and pharmacy practice." (Doc. #22-4, ¶ 12).

Mo HealthNet estimates there are approximately 13,000 Missouri Medicaid patients with HCV. Since 2013, Mo HealthNet has received approximately 2,400 requests for pre-authorization of DAA treatment. Of those 2,400, approximately 56% have been approved. Of those approved, approximately 33% have been HCV patients with a fibrosis score below F3.

II. Legal Standard

"[W]hether a preliminary injunction should issue involves consideration of (1) the threat of irreparable harm to the movant; (2) the state of balance between this harm and the injury that granting the injunction will inflict on other parties litigant; (3) the probability the movant will succeed on the merits; and (4) the public interest." *Dataphase Sys., Inc. v. C.L. Sys., Inc.*, 640 F.2d 109, 113 (8th Cir. 1981)). "No one factor is dispositive of a request for injunction; the Court considers all the factors and decides whether on balance, they weigh towards granting the injunction." *Grasso Enters., LLC v. Express Scripts, Inc.*, No. 4:14CV1932-HEA, 2015 WL 10781579, at *2 (E.D. Mo. 2015) (citations and internal quotation marks omitted). "The most important of the *Dataphase* factors is the . . . likelihood of success on the merits." *Shrink Mo. Gov't. PAC v. Adams*, 151 F.3d 763, 764 (8th Cir. 1998).

"In seeking a mandatory injunction that disrupts the status quo, the [movant] must demonstrate not only that the four requirements for a preliminary injunction are met but also that they weigh heavily and compellingly in their favor." *Grasso Enters., LLC*, 2015 WL 10781579, at *2 (citations and internal quotation marks omitted). "In general, a mandatory preliminary injunction at the preliminary stage of the proceedings should be granted only in rare instances where the facts and law are clearly in favor of the moving party, especially if the grant of the temporary injunction would in effect give the plaintiffs the relief which they seek in the main case." *Jackson v. Conway*, 476 F. Supp. 896, 902 (E.D. Mo. 1979) (citations omitted).

III. Discussion

Plaintiffs ask the Court to impose a mandatory preliminary injunction prohibiting Defendants from considering fibrosis scores in deciding whether to approve DAA treatments for

Missouri Medicaid patients with HCV. At this stage in the proceeding and given the heightened standard applicable to a motion for a mandatory preliminary injunction, on balance, the preliminary injunction factors weigh against issuance of a preliminary injunction.

Likelihood of Success on the Merits

a. Count I – Violations of Medicaid Entitlement to Appropriate Amount, Duration, and Scope of Treatment

Missouri, like every other state, has opted to provide prescription drugs, an optional service category, as part of its Medicaid program. 42 U.S.C. § 1396d(a)(12); 13 C.S.R. 70-20.030. Because prescription drugs are covered Medicaid services, Defendants must ensure that they are available to Medicaid beneficiaries in "sufficient . . . amount, duration, and scope to reasonably achieve [the] purpose" of the covered service. 42 C.F.R. § 440.230(b); 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a). "While a state has discretion to determine the optional services in its Medicaid plan, a state's failure to provide Medicaid coverage for non-experimental, medically-necessary services within a covered Medicaid category is both per se unreasonable and inconsistent with the stated goals of Medicaid." *Lankford v. Sherman*, 451 F.3d 496, 511 (8th Cir. 2006). Accordingly, to succeed on the merits, Plaintiffs must prove that DAA treatments are medically necessary for all HCV patients regardless of fibrosis score.

Plaintiffs argue that the standard of care is to treat all HCV patients with DAAs regardless of fibrosis score. Plaintiffs rely on Dr. Bacon's testimony, the AASLD/IDSA guidelines, the CMS release, as well as the fact that other organizations such as Medicare and some state Medicaid programs do not consider fibrosis scores in deciding whether to approve DAA treatments. Defendants counter that a more restrictive approach is well within the standard of care for treating HCV patients. Defendants rely on Dr. Koretz's testimony, the fact that a majority of state Medicaid systems still consider fibrosis scores in some manner in deciding

whether to approve DAA treatments, and the fact that there are approximately 13,000 Missouri Medicaid patients with HCV but since 2013 only approximately 2,400 requests for DAA treatment approval have been submitted. Defendants also argue they are in compliance with the CMS release because they do not restrict DAA treatments to patients with a fibrosis score of F3 or F4, but rather, Defendants consider each and every request individually. Defendants further point out that approximately 33% of the approvals have been for patients with fibrosis scores lower than F3. Considering all of the evidence, the Court finds Plaintiffs have not shown they are likely to succeed on the merits to a degree necessary to justify the imposition of the mandatory preliminary injunction they seek.

Plaintiffs argue that the cases of *B.E. v. Teeter*, No. C16-227-JCC, 2016 WL 3033500 (W.D. Wash. May 27, 2016), and *Abu-Jamal, et al. v. Kerestes*, 3:15-CV-00967, 2016 WL 4574646 (M.D. Penn. Aug. 31, 2016), compel issuance of a preliminary injunction in this case. The Court disagrees. First, the cases are not binding authority on this Court. In addition, the cases were decided on very different evidentiary records than the one before the Court. The Court must base its decision in this case on consideration of the *Dataphase* factors in the context of the evidentiary record before it.

Plaintiffs also argue that *Weaver v. Reagan*, 886 F.2d 194, 199 (8th Cir. 1989), requires the finding that DAAs are medically-necessary treatment if a physician prescribes DAAs as has Plaintiffs' doctor, Dr. Bacon. Plaintiffs argue, "It is improper to interfere with a physician's judgment of medical necessity by limiting coverage of prescription drugs based on criteria that do not reflect current medical knowledge or practice." (Doc. #5, p. 20). The Court disagrees that a physician's prescription will always equate to medical necessity, regardless of the other facts at issue. While Plaintiffs were prescribed DAAs, as were approximately 2,400 other HCV

Missouri Medicaid beneficiaries, an overwhelming majority of Missouri Medicaid patients were not. In addition, *Weaver* is distinguishable on the fact. There the Court characterized the Medicaid rule at issue as constituting "an irrebutable presumption that AZT can never be medically necessary treatment for AIDS patients who have neither a history of PCP nor a CD4 count below 200." *Weaver*, 886 F.2d at 199. Here, Defendants conduct an individualized inquiry of every DAA authorization request, and of the prescriptions approved, approximately 33% have been for patients with fibrosis scores below F3.

b. Count II – Violations of Medicaid Comparability

The Medicaid Act requires that the "medical assistance made available to any [categorically needy] individual . . . shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual[.]" 42 U.S.C. § 1396a(a)(10)(B). 42 C.F.R. 440.240(a). Plaintiffs argue that because DAAs are medically necessary for all HCV patients and Defendants are not authorizing DAAs for all HCV patients, Defendants are violating this Medicaid provision. Defendants state, "[T]he Defendants are providing coverage not based on medical necessity—which is the same for all patients who contract Hepatitis C—but based on severity of liver damage." (Doc. #18, p. 23). Because the Court has already found that Plaintiffs failed to establish they are likely to succeed in proving DAAs are medically necessary for all patients regardless of fibrosis score to a degree necessary to justify imposition of a mandatory preliminary injunction, Plaintiffs' comparability argument fails for the same reasons.

c. Count III – Violations of Reasonable Promptness

The Medicaid Act states that covered services "shall be furnished with reasonable promptness to all eligible individuals." 42 U.S.C. § 1396a(a)(8). Plaintiffs argue Missouri's

Approval/Denial Criteria "leave[] Plaintiffs waiting for medically necessary covered prescription medications well beyond the timeframe for initiation of treatment recommended by their doctors and the professional standard of care[.]" (Doc. #5, p. 24). Again, because the Court has already found that Plaintiffs failed to establish they are likely to succeed in proving DAAs are medically necessary for all patients regardless of fibrosis score to a degree necessary to justify imposition of a mandatory preliminary injunction, Plaintiffs' reasonable promptness argument fails for the same reasons.

Likelihood of Irreparable Harm to Plaintiffs

Defendants presented evidence and Plaintiffs presented no contradictory evidence, that on average it takes several decades for HCV patients to progress from F0 to F4. The Court is mindful of and sympathetic toward the evidence regarding Plaintiffs' present physical and mental conditions. Plaintiffs argue, however, that the irreparable harm they will suffer is the likelihood of progression. Plaintiffs argue, "Without a preliminary injunction, the Plaintiffs will not receive the medical treatment that provides them the best chance to prevent their conditions from worsening." (Doc. #5, p. 26). The issue now, however, is what irreparable harm the Plaintiffs might suffer ***during the pendency of this case*** if Plaintiffs are not awarded the preliminary and extraordinary relief they seek. Plaintiffs presented no evidence that they are immediately at threat of progression. The pendency of this case through to completion will be but a short period of time relative to the amount of time it takes an HCV patient's fibrosis condition to progress. Accordingly, the Court finds Plaintiffs have not shown they are subject to an immediate and irreparable injury to the degree necessary to justify imposition of a mandatory preliminary injunction.

Balance of Equities and Public Interest

For all the same reasons already discussed, the Court finds the balance of equities favors Defendants. Given that Plaintiffs have not established they are likely to succeed on the merits to the degree necessary to justify imposition of a mandatory injunction and given the irreparable harm Plaintiffs argue will occur is not immediate, the potential consequences to Defendants of being forced to change their Medicaid DAA Approval/Denial Criteria at this early stage of the proceeding weighs in favor of denying the preliminary injunction. Finally, while the public interest in this issue is apparent given Missouri Medicaid estimates 13,000 of its beneficiaries have HCV, the weight of this consideration is not enough to tip the balance of the *Dataphase* factors in Plaintiffs' favor given the Court's findings in relation to the other factors.

IV. Conclusion

For the foregoing reasons, Plaintiffs' Motion for a Preliminary Injunction (Doc. #2) asking the Court to enjoin Defendants from considering Missouri Medicaid beneficiaries' fibrosis scores in deciding whether to approve DAA treatments, is denied.

IT IS SO ORDERED.

Dated: April 24, 2017

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