UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

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

DEFENDANTS' SUGGESTIONS IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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Plaintiffs J.E.M and J.L.M. cannot satisfy their burden of demonstrating that they are entitled to the "extraordinary and drastic remedy" of preliminary injunctive relief. *Munaf v. Green*, 553 U.S. 674, 689 (2008). Plaintiffs allege three claims for declaratory and injunctive relief against Defendants 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 (MHD), to enjoin them from applying MHD utilization control procedures established in 13 CSR 70-20.200 for the provision of direct-acting-antivirals (DAAs) for treatment of Hepatitis C Virus (HCV) infection, as authorized by 42 C.F.R. 440.230(d).

Plaintiffs cannot show they will likely succeed on the merits of their claims, that they will suffer irreparable harm in the absence of an injunction, that the balancing of the hardships weighs in their favor, or that an injunction is in the public interest. Plaintiff cannot carry their burden of demonstrating that they are entitled to injunctive relief, and their Motion for Preliminary Injunction should be denied.

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, known as MO HealthNet, provides health services only to the "categorically needy," including Plaintiffs. 42 U.S.C. § 1396a(a)(10)(A).

RSMo § 208.151. Missouri elects to provide prescription drug benefits to participants pursuant to RSMo § 208.152(7) and 13 CSR 70-20 – Pharmacy Program. See also, 42 C.F.R. 440.225 (2014). In accordance with section 1927(d)(5), 42 U.S.C. § 1396r-8, of the Social Security Act, Missouri has established a Preferred Drug List (PDL) and prior authorization program as a condition of coverage or payment for DAAs.

The Social Security Act ("the Act"), at 42 U.S.C. § 1396a(a)(17), "confers broad discretion to states to adopt standards for determining the extent of medical assistance, requiring only that such standards be 'reasonable' and 'consistent with the objectives' of the Act." *Beal v. Doe*, 432 U.S. 438, 444 (1977). An "agency may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures." 42 C.F.R. § 440.230(d) (2015). "In so doing, a state can review the medical necessity of treatment prescribed by a doctor on a case-by-case basis, and may present its own evidence of medical necessity in disputes between the state and Medicaid patients." *Moore v. Reese*, 637 F.3d 1220, 1255 (11th Cir. 2011) (citing *Rush v. Parham*, 625 F.2d 1150, 1155 (5th Cir. 1980)). This discretion is afforded because a participating state "is not required to fund desirable but medically unnecessary services requested by a Medicaid recipient's physician." *Id.* at 1244.

In keeping with these principles, Missouri, like any state electing to provide prescription drug benefits, has the authority to limit the coverage for those drugs under federal law. *See* 42 U.S.C. § 1396r-8(d) (2016). States are specifically allowed

to "subject to prior authorization *any* covered outpatient drug." *Id.* at (d)(1) (emphasis added). As such, and pursuant to this authority, the MO HealthNet program requires health care providers to complete a prior authorization process before a Medicaid recipient can receive certain identified prescription drugs. 13 CSR 70-20.200, .340(6) (Exhibit A).

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. *See* 13 CSR 70-20.340(6). The prior authorization criteria are enumerated in the Preferred Drug List—"a list of medications within a functional therapeutic class that are available via open access on the basis of supplemental rebate status and consideration of available evidence-based clinical review findings." 13 CSR 70-20.200(D) (Exhibit B, MHD Hepatitis C Preferred Drug List). The criteria are developed and maintained through the process outlined in MHD's rules, and include clinical review and recommendations by independent, subject matter experts within two distinct advisory boards—the MO HealthNet Drug Prior Authorization Committee and the Drug Utilization Review Board. 13 CSR 70-20.200(2), (7); RSMo § 208.175. (Exhibit C, June 23, 2016 MHD Letter).

Once a provider submits the request, the MHD Clinical Consultant, who is a licensed pharmacist with a medical degree, considers all information when determining whether to approve or deny. (Exhibit D, Roaseau Decl., ¶¶ 3, 12). Of 1,200 prior authorization requests for DAAs from October, 2014 through September,

2016, MHD approved 698, representing over 58% of all requests submitted. Of those approved requests, over 30% of those were submitted for participants with fibrosis scores below F3. (Exhibit E, Parks Decl., ¶ 9)(Exhibit F, MO HealthNet DAA Approvals).

Plaintiffs' medical providers submitted requests for DAAs to treat their HCV. Following individualized review of each Plaintiff's submission, MHD's Clinical Consultant denied the requests. Plaintiffs did not avail themselves of the procedures in place for administrative review of the decision and did not exhaust their administrative remedies. (Rouseau Decl., ¶¶ 25-35) The review procedures include a full administrative hearing process. RSMo § 208.080.

Plaintiffs filed their Complaint (Doc. 1) alleging MHD is excluding Medicaid participants from receiving medically necessary treatment as required by 42 U.S.C. §§ 1396a(a)(10)(A) and 1396d(a)(12), is violating Medicaid Act comparability requirements at 42 U.S.C. § 1396a(a)(10)(B)(i) by discriminating among similarly situated Medicaid beneficiaries on the basis of categorical restrictions that are not based upon prevailing clinical standards, and is violating the "reasonable promptness" requirement of the Act at 42 U.S.C. § 1396a(a)(8) by implementing a policy that *de facto* rations coverage for Medicaid enrollees seeking HCV treatment, thereby requiring Plaintiffs and those like them to wait until they have developed severe liver damage before receiving medically necessary treatment. (Doc. 1, ¶¶ 83, 85, 87). Plaintiffs filed this Motion for Preliminary Injunction (Doc. 5) with their Complaint.

STANDARD OF REVIEW FOR INJUNCTIVE RELIEF

A plaintiff seeking a preliminary injunction must show that (1) he is likely to succeed on the merits of his claims; (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. *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); Dataphase Sys., Inc. v. C.L. Sys., Inc., 640 F.2d 109, 113 (8th Cir. 1981). The Court "must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief." *Winter*, 555 U.S. at 24. Injunctive relief is never awarded as a matter of right. *Id.*

ARGUMENT

I. Plaintiffs will not likely succeed on the merits of their claims.

A. There is no individualized federal right to reasonable Medicaid standards enforceable under 42 U.S.C. § 1983.

Medicaid "confers broad discretion on the States to adopt standards for determining the extent of medical assistance" that will be provided through the Medicaid programs. *Beal v. Doe,* 432 U.S. 438, 444 (1977). Plaintiffs assert three claims under 42 U.S.C. § 1983, that MHD is violating the Act by denying Medicaid participants medically necessary treatment, violating the comparability requirements provision, and violating the reasonable promptness provision. (Doc. 1, ¶ 83, 85, 87). 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(12), 1396a(10)(B)(1), and 1396a(a)(8). However, the crux of all three of Plaintiffs' claim is methodology—DAAs are medically necessary for all participants diagnosed with HCV, thus according to MHD's published prior authorization criteria, which appear to restrict

DAAs to those participants with fibrosis scores of F3 or F4, some participants must wait until their liver disease has progressed to the level of F3 to receive DAAs.

The State "may place *appropriate limits* on a service based on such criteria as *medical necessity* or on *utilization control* procedures." 42 C.F.R. § 440.230(d) (emphasis added). Consequently, MHD may lawfully establish utilization control procedures to review and determine appropriate uses of medication. "[I]t is hardly inconsistent with the objectives of the [Medicaid] Act for a State to refuse to fund unnecessary though perhaps desirable medical services." *Beal*, 432 U.S. at 444-45. The express purpose of the Act was to enable states to provide health care to the needy "as far as practicable under the conditions in such State…." 42 U.S.C. § 1396.

Accordingly, such a challenge must be brought under the Act's reasonable-standards requirement at 42 U.S.C. § 1396a(a)(17) (requiring participating states to "include reasonable standards . . . for determining eligibility for and *the extent of medical assistance* under the plan which (A) are consistent with the objectives of this title . . . .") (emphasis added). It follows then that Plaintiffs' claims for relief actually arise as § 1983 challenges to an alleged violation of § 1396a(a)(17).

To enforce a federal statute under § 1983, Plaintiff "must assert the violation of a federal right, not merely a violation of federal law." *Blessing v. Freestone*, 520 U.S. 329, 340 (1997) (citing *Golden State Transit Corp. v. Los Angeles*, 493 U.S. 103 (1989)); *accord Gonzaga Univ. v. Doe*, 536 U.S. 273, 282 (2002). A three-part test determines whether this legislation creates a right of action under 42 U.S.C. § 1983: (1) Congress intended the statutory provision in question to benefit Plaintiffs; (2)

the asserted right is not so vague and amorphous that its enforcement would strain judicial competence; and (3) the provision clearly imposes a mandatory obligation upon the states. *Lankford v. Sherman*, 451 F.3d 496, 508 (8th Cir. 2006) (citing *Blessing*, 520 U.S. at 340-41). Failure to satisfy any one of the three prongs renders a federal statute unenforceable under § 1983. *Gonzaga,* 536 U.S. at 284. See also: *Armstrong vs. Exceptional Child Ctr., Inc.,* 135 S.Ct 1378 (2015) (no private right of action in federal court for Medicaid provider to challenge rates); *Midwest Foster Care and Adoption Ass'n vs. Kinkade*, 712 F3d 1190 (8th Cir. 2013) (no private right of action for foster parents to challenge Missouri's maintenance payment rates). See also, *In re Pharmaceutical Industry Average Wholesale Price Litigation vs. Abbott Laboratories,* 339 F.Supp.2d 165 (USDC Mass 2004) (no private remedy under 42 USC § 1396r-8 for county payor for Medicaid drugs against pharmaceutical companies which allegedly filed false price reports with the federal government).

Here, § 1396a(a)(17)—the proper provision under which all three of Plaintiffs' § 1983 claims arise—ultimately fails under the *Blessing* test. First, Congress did not intend that § 1396a(a)(17) benefit Plaintiff. Under *Blessing*, not only must Congress intend that a statute confer such a benefit, but it must explicitly state as much by using "rights-creating language" that clearly imparts an "individual entitlement" and have an "unmistakable focus on the benefited class." *Gonzaga*, 536 U.S. at 287. The Eighth Circuit found Congress had no such intent when it enacted § 1396a(a)(17); this "statutory language [is] insufficient to evince a congressional intent to create individually-enforceable federal rights." *Lankford*, 451 F.3d at 509.

And, "[e]ven if the statute referenced the individuals it benefitted, the right it would create is too vague and amorphous for judicial enforcement." *Id*. (citing *Watson v. Weeks*, 436 F.3d 1152, 1162-63 (9th Cir. 2006); "Congress provided no meaningful instruction for the interpretation of 'reasonable standards' in terms of medical need."). According to the Eighth Circuit, "[t]he only guidance Congress provides in the reasonable-standards provision is that the state establish standards 'consistent with [Medicaid] objectives' – an inadequate guidepost for judicial enforcement." *Id*. Instead, § 1396a(a)(17) "sets forth only broad, general goals, which the states have broad discretion to implement." *Id*.

Finally, none of the sections of the Act Plaintiffs rely on either expressly or by implication impose a "mandatory obligation" for the state to pay for DAAs, or even a specific drug or class of drugs without any restriction. Instead, states are authorized to elect to establish a prior authorization program, and Missouri has elected to do so. 42 U.S.C. §1396r-8(d). 13 CSR 70-20.200; RSMo § 208.175. Plaintiffs' argument that MHD has failed to approve medications their physician determined to be "medically necessary" with "reasonable promptness" fails the *Blessing* analysis because it impermissibly ignores the whole statutory scheme of the Act as it applies to the utilization of prescription drugs and the "contract" between the United States and a participating state expenses in implementing the Medicaid program are reimbursed. *Armstrong vs. Exceptional Child Ctr., Inc.,* 135 S.Ct 1378, 1387 (2015)(Spending clause legislation is "much in the nature of a contract". … "More fundamentally, however, the modern jurisprudence permitting intended

beneficiaries to sue does not generally apply to contracts between a private party and the government, …much less to contracts between two governments."). Federal law has properly left these complex determinations to be made by the administrative branch of the government and to the states, and has not provided a private remedy to individual Medicaid participants in the federal courts.

Consequently, 42 U.S.C. § 1396a(a)(17) fails under all three prongs of the *Blessing* test and Plaintiffs' claims are unenforceable under 42 U.S.C. § 1983.

B. MHD's utilization controls comply with federal law.

The November 2015, Centers for Medicare & Medicaid Services (CMS) Medicaid Drug Rebate Program Notice (Release No.172) entitled "Assuring Medicaid Participants Access to Hepatitis C (HCV) Drugs" reminds states of their legal obligation under Medicaid to pay for drugs that are both covered and medically necessary. "While states have the discretion to establish certain limitations on the coverage of DAAs, 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. … States should examine their drug benefits to ensure that limitations do not unreasonably restrict coverage of effective treatment using the new DAA HCV." (Exhibit G, CMS November 2015 Notice, p. 3.) CMS identified unreasonable restrictions to access to DAAs as limiting treatment to those participants whose extent of liver damage has progressed to metavir fibrosis score F3, requiring a period of abstinence from drug and alcohol abuse, and requiring prescribers be a specific provider.

Missouri law establishes a rigorous process for the development and implementation of prior authorization requirements for drugs such as DAAs. 13 CSR 70-20.200. MHD's limitations are consistent with the requirements of section 1927(d) of the Medicaid Act, ensure appropriate utilization, and are not unreasonable restrictions as defined by CMS in its November 2015 Notice. MHD's Preferred Drug List and prior authorization criteria provide for individual review for *all* participants requesting treatment of HCV with DAAs; MHD approves prior authorization requests at all levels of fibrosis score, from F0 to F4[1]. (Ex. F). Of the 698 participants approved for DAAs from October, 2014-September, 2016, over 30% had fibrosis scores of less than F3. *Id*.

Moreover, Plaintiffs' reliance on expert declarations from Dr. Bacon, Dr. Fleckenstein, and Nurse Practitioner Campbell is misplaced. Dr. Bacon and Dr. Fleckenstein both testified to this Court (pursuant to 28 U.S.C. § 1746) that MHD restricts access to treatment based on the participant's fibrosis score, specifically to F3 for patients with genotypes 1, 2 and 4 and to F2 for genotype 3. (Doc. 2-3, ¶ 19; Doc. 2-4, ¶ 6, ¶ 10). In fact, MHD statistics show Dr. Bacon, Dr. Fleckenstein, and Nurse Practitioner Campbell have submitted prior authorization requests for DAAs for MO HealthNet participants with fibrosis scores of F0, F1, and F2 and have received MHD approval. Since January of 2015, Dr. Bacon has received 7

[1] CMS explains the metavir scoring system is used to assess inflammation and fibrosis by histopathological evaluation of liver biopsy of patients with heapatitis C. The stages, indicated by F0 through F4, represent the amount of fibrosis or scarring of the liver. F0 indicates no fibrosis while F4 represents cirrhosis, a chronic degenerative liver disease state in which normal liver cells are damaged and are then replaced by scar tissue. (CMS exhibit at 2).

approvals, Dr. Fleckenstein has received 9 approvals, and Nurse Campbell has received 7 approvals. (Exhibit H, chart of approvals below F3 for Dr. Bacon, Nurse Practitioner Campbell, and Dr. Fleckenstein since January 2015).

Although Plaintiffs argue MHD's utilization control procedures allow for no exceptions, Plaintiffs' experts are aware that MHD performs individualized review on a case-by-case basis, sometimes requests other information, clarification, or switch to another DAA, and will approve requests for prior authorization when the treatment is effective, clinically appropriate, and medically necessary at any fibrosis score, from F0 to F4. This practice is consistent with 13 CSR 70-20.340(6) which directs providers, for those patients who do not meet the system approval criteria, to contact the Drug Prior Authorization Hotline to initiate a review or use the CyberAccess tool to electronically initiate an edit override review. Plaintiffs' experts are aware that MHD's utilization criteria are not a barrier to treatment for participants with low fibrosis scores, despite their testimony otherwise to this Court. Thus, Plaintiffs' experts know the evidence of their own practice will show MHD's policy does not require participants with HCV to experience significant damage to the liver before they may receive DAAs when those drugs are medically necessary for individual participants.

Similarly, MHD does not unreasonably restrict access to DAAs by requesting information regarding participant's drug and alcohol use. MHD engages in a comprehensive individualized review of each request for prior authorization of treatment for HCV with DAAs by a Missouri licensed pharmacist with a medical

degree. While MHD prefers 3 months of negative alcohol and drug screens before a request is submitted, MHD does not require it when the delay could be a factor in successful treatment. (Roaseau Decl., ¶ 16). MHD has never denied a request based on positive alcohol and drug screens but asks the provider to address the issue with the patient. *Id*.

Plaintiffs rely extensively on *Weaver v. Reagen,* 886 F.2d 194 (8th Cir. 1989) to argue MHD must approve DAAs for all participants diagnosed with HCV. In *Weaver* the court found Missouri's Medicaid rule constituted an irrebuttable presumption that AZT could never be medically necessary treatment for AIDS patients who had neither a history of PCP nor a CD4 count below 200. *Id*. at 199. Missouri's rule was found arbitrary and capricious as Missouri made no provision for providing medication for AIDS patients who did not meet the restrictive diagnosis criteria in Missouri's regulation. *Id*.

Here, MHD's utilization control procedures regarding DAAs are rigorous, extensive, and regularly reviewed. 13 CSR 70-20.200, RSMo § 208.175. MHD's prior authorization process specifically provides for individualized review by the MHD Clinical Consultant of all requests which do not meet approval criteria.13 CSR 70-20.340(6). DAAs are not arbitrarily restricted to participants with fibrosis scores of at least F3; evidence shows more than one-third of DAA since October of 2014 were for participants with fibrosis scores below F3. (Ex. F). Plaintiffs' experts know MHD utilization control procedures do not restrict DAAs to HCV by participant's fibrosis scores, yet have stated to this Court under oath that they do.

MHD's utilization control procedures for treatment of HCV with DAAs is not arbitrary or capricious and these facts are clearly distinguishable from those in *Weaver*.

Plaintiffs also make an interesting argument, that "DAA drugs are FDA-approved as medically necessary for HCV patients," in light of *Weaver*. (Doc. 5, p. 15). In *Weaver,* Missouri relied on the FDA's approval process as determinable of medical necessity, a position the court soundly rejected. "[T]he FDA new drug approval process is intended to ensure that drugs meet certain statutory standards for safety and effectiveness, manufacturing and controls, and labeling, 21 C.F.R. § 314.105(c) (1988), and to ensure that manufacturers market their drugs only for those indications for which the drug sponsor has demonstrated "substantial evidence" of effectiveness." *Weaver*, 886 F.2d at 198; 21 C.F.R. § 314.126. Plaintiffs' suggestion here that FDA approval for DAAs means they are medically necessary for all HCV participants is not supported by law.

Finally, Plaintiffs assert treatment of all participants with HCV at all stages of fibrosis with DAAs is the standard of care in the community, relying on treatment guidelines approved by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America (AASLD/IDSA). (Doc. 5, p. 8). Plaintiff argues determination of medical necessity rests with the participant's provider, so MHD's denial of DAAs for Plaintiffs improperly contradicts the provider's judgments which are based on established standards of medical necessity. (Doc. 5, p. 20). Nowhere in 42 U.S.C. §1396r-8 in particular and the

Social Security Act in general is the provider named as the sole arbiter of medical necessity. And, the state "may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures." 42 C.F.R. § 440.230(d).

In *Weaver* the court cited *Pinneke v. Preisser*, 623 F.2d 546 (8th Cir. 1980), in stating "[t]he decision of whether or not certain treatment or a particular type of surgery is 'medically necessary' rests with the individual recipient's physician and not with clerical personnel or government officials." 886 F.2d at 199 (citing 623 F.2d at 550). Here, all requests for prior authorization for DAAs are not reviewed by clerical personnel, they are reviewed by the MHD Clinical Consultant, a Missouri licensed pharmacist with a medical degree, who has reviewed every prior authorization request since DAAs became available in 2013. (Roaseau Decl. ¶ 3). The degree of medical necessity is considered carefully as part of an individualized review that takes into consideration all of the participant's information in light of MHD's criteria.

Moreover, since *Pinneke* and *Weaver*, the Eighth Circuit decided *Smith v. Rasmussen*, 249 F.3d 755 (8th Cir. 2001). There the court noted its presumption in favor of the medical judgment of the attending physician in determining the medical necessity of treatment, but "[a]t the same time, 'Medicaid was … designed … to provide the largest number of necessary medical services to the greatest number of needy people. … The Act 'confers broad discretion on the States to adopt standards for determining the extent of medical assistance,' … The Act and its

regulations both protect and limit the states' discretion.'" *Id*. at 759. There the court contrasted its holding in *Pinneke*, where it ordered medical treatment because denial of funding was based on a non-medical presumption not promulgated through a proper rule-making process and so was arbitrary, with the current matter, were the court recognized the denial of services was not arbitrary where the [state Medicaid agency] followed a rulemaking process and considered the knowledge of the medical community. *Id*. at 760. The court acknowledged some limitations of medically necessary services have been permitted as reasonable. *Ellis v. Patterson*, 859 F.2d 52 (8th Cir. 1988), *Alexander v. Choate*, 469 U.S. 287 (1985). *Id*. at 759.

The standard of care in Missouri is established within the medical community by other than just AASLD/IDSA guidelines. In fact, the AASLD/IDSA website posts a disclaimer stating "[n]othing contained at HCVguidelines.org is intended to constitute a specific medical diagnosis, treatment, or recommendation. … nor should it be relied on to suggest a course of treatment for a particular individual.[2] AASLD/IDSA rightly acknowledges that DAA treatment should be considered on an individualized basis, inconsistent with Plaintiffs emphasis in this motion that all HCV should be treated the same. A standard of medical care reflects the community of physicians and their decisions. MHD has over 13,000 participants diagnosed with HCV. MHD received 1,200 requests for DAAs since 2014. (Parks Decl., ¶ 9; Ex. F). Missouri physicians are not prescribing DAAs for all

[2] http://www.hcvguidelines.org/full-report/website-policies (last visited 11/20/16).

participants with HCV, based on their individual determinations of medical necessity. (Parks Decl., ¶ 16).

MHD is in compliance with the requirements stated for provision of outpatient prescription drugs pursuant to 42 U.S.C. § 1396r-8(k)(6). Plaintiffs cannot prove MHD wrongfully denies HCV treatment by arbitrarily and capriciously applying its utilization control practices to unreasonably restrict DAA treatment to participants with fibrosis scores less than F3. Plaintiffs will not likely succeed on the merits of their claims.

C. MHD's utilization control procedures comply with the comparability requirement.

42 U.S.C. § 1396a(a)(10)(B)(i) requires that the "amount, duration and scope" of medical assistance available to one recipient of Medicaid services be comparable to the "amount, duration and scope" of assistance available to other recipients. To prevail, Plaintiffs must show that a named plaintiff would be treated differently under MHD's policy than other Medicaid recipients with the same level of need.

As stated above, MHD's approval criteria are applied on an individualized basis, taking all information regarding each participant into consideration, reviewed by MHD's Clinical Consultant who is a licensed pharmacist with a medical degree. Furthermore, Plaintiffs claims are premised on its argument that MHD unreasonably restricts access to DAAs to participants with fibrosis scores F3 and above. As explained above, and as is evident from participants whose requests have been approved with fibrosis scores less than F3, MHD meets the

comparability requirement.

MHD's policy is need-based and accordingly comports with the comparability requirement under 42 U.S.C. § 1396a(a)(10)(B)(i). Plaintiffs are unlikely to succeed on the merits of their "comparability" claim.

D. MHD's utilization control procedures comply with federal law regarding reasonable promptness.

The state must "provide that . . . medical assistance . . . shall be furnished with reasonable promptness to all eligible individuals." 42 U.S.C. § 1396a(a)(8). Plaintiffs argue MHD is violating this "reasonable promptness" standard because Plaintiffs have been denied treatment with DAAs, thus will be subject to excessive delays and unreasonable deferrals.

If a requested service is denied by the state because it is not medically necessary, the state is not obligated to provide it at any time, much less within a certain time period. 42 C.F.R. § 440.230(c)(2). Plaintiffs do not cite to any authority that indicates otherwise. In fact, the case relied upon by Plaintiffs to support their argument, *Allen v. Mansour*, 681 F. Supp. 1232 (E.D. Michigan 1986), makes no reference to 42 U.S.C. § 1396a(a)(8) or to "reasonable promptness." Here, Plaintiffs J.E.M. and J.L.M.'s requests for DAAs have been denied based on an individualized medical necessity determination made by MHD's Clinical Consultant based upon prior authorization criteria. (Roaseau Decl. ¶¶ 25-35). Neither Plaintiff contacted MHD despite J.E.M.'s letter and the information available on MHD's website

inviting contact if a participant disagrees with a prescription denial.[3] MHD is under no obligation to provide J.L.M. and J.E.M. with a drug that has been denied because of lack of medical necessity. Thus, Plaintiffs are unlikely to succeed on the merits of their "reasonable promptness" claim.

II. Plaintiffs are not likely to suffer irreparable harm

Plaintiffs have not met their burden of proving they are likely to suffer irreparable harm in the absence of injunctive relief. Plaintiffs seeking preliminary relief are required to demonstrate that irreparable injury is likely in the absence of an injunction, not merely speculation. *Winter*, 555 U.S. at 7. Plaintiffs claim that without a preliminary enjoining MHD from applying its utilization control procedures for DAAs, they will not receive medical treatment that gives them the best chance to prevent their HCV from worsening. (Doc. 5, p. 26).

Plaintiffs' experts stated Plaintiffs are at risk of irreparable damage to their livers. (Doc. 5, p. 26). At the same time, the AASLD/IDSA guidelines state: [f]ibrosis progression is variable across different patient populations as well as within the same individual over time. Many of the components that determine fibrosis progression and development of cirrhosis in an individual are unknown. However, certain factors, such as coinfection with HIV or hepatitis B virus (HBV) and prevalent coexistent liver diseases (eg, nonalcoholic steatohepatitis [NASH]),

[3] If a provider feels the call center determination was clinically unsound they are encouraged to contact the Pharmacy and Clinical Services Unit clinical staff at 573-751-6963. If there is still disagreement, the participant has a right to appeal the determination through the Fair Hearings Process. http://dss.mo.gov/mhd/faq/pages/faqpdl.htm (last visited 11/20/16).

are well-recognized contributors to accelerated fibrosis progression." (Doc. 2-3, p.163). Plaintiffs' experts have not suggested Plaintiffs are at a greater risk for rapidly progressive fibrosis and cirrhosis. If Plaintiffs' providers believe their condition has changed in any way, they are aware they can submit a prior authorization request which will be individually reviewed based upon all relevant criteria for approval even if Plaintiffs' fibrosis score does not increase. Presuming no further requests have been submitted for J.E.M. (since July) or J.L.M. (since August), their condition has not progressed.

Although denial of medically necessary services could be evidence of irreparable harm, Plaintiffs have not been denied necessary medical care. Plaintiffs cannot demonstrate that their claim of irreparable harm is anything more than speculative. Plaintiffs have not met their burden of showing irreparable harm.

III. The balance of equities tip toward MHD and an injunction is not in the public interest

Plaintiffs have not met their burden of proving the balance of equities or the public interest tip in their favor. MHD's utilization control procedures comply with federal law. 42 U.S.C. §1396r-8, 13 CSR 70-20.200, RSMo § 208.175. Requiring MHD to approve requests for prior authorization without applying the criteria and an individualized review would cause MHD to violate the federal law it is currently in compliance with. The utilization control framework established by Congress cannot be ignored by MHD without great risk to Missouri's contract with the United States to provide Medicaid benefits to all participants within the state.

Plaintiffs imply that MHD has an obligation to pay for DAAs for all participants with HCV, regardless of medical necessity, because DAAs will eradicate HCV. Medicaid was enacted as an individual benefit for eligible individuals and does not provide statutory authority to provide general public health for the entire population. Plaintiffs' argument also assumes that providing DAAs to all Medicaid participants is in the best interest of the public health, which may or may not be true.

Plaintiffs have not met their burden of proving the balance of equities or the public interest tip in their favor.

VI. CONCLUSION

For the reasons discussed above, the Court should deny Plaintiffs' Motion for Preliminary Injunction. However, in the alternative, if the Court were inclined to entertain a preliminary injunction, it should be granted within the framework of the Social Security Act and be consistent with the "contract" between the state and the United States that gives broad authority to the state Medicaid agency to establish prior authorization and reasonable utilization control procedures to determine when the use of DAA's is medically necessary. MHD respectfully requests any injunction be limited to requiring review of policy governing DAAs utilizing its prior authorization and drug utilization procedures in light of the Court's findings.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing was filed electronically with the Clerk of Court on November 21, 2016 to be served by operation of the Court's electronic filing system upon all parties.

/s/ Colleen Joern Vetter
COLLEEN JOERN VETTER
Assistant Attorney General