UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

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

SUGGESTIONS IN SUPPORT OF
DEFENDANTS' MOTION TO DISMISS

Plaintiffs request this Court to issue a judgment declaring that 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), must relinquish MHD's right to develop and apply utilization control procedures as established in 13 CSR 70-20.200 for the provision of direct-acting-antivirals (DAAs) for treatment of Hepatitis C Virus (HCV) infection in Missouri Medicaid beneficiaries, as authorized by 42 C.F.R. 440.230(d). Instead, Plaintiffs' request this Court to declare that MHD must allow the American Association for the Study of Liver Diseases / Infectious Disease Society of America (AASLD/IDSA) and each beneficiary's medical provider to dictate the medical treatment MHD must

provide.

Plaintiffs' complaint fails to state a claim for which relief may be granted as there is no individualized federal right to reasonable Medicaid standards enforceable under 42 U.S.C. § 1983. Consequently, the Court should dismiss this claim in its entirety.

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).

Thus, 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). 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.

Plaintiffs' medical providers submitted prior authorization requests for DAAs to treat their HCV. (Doc. 1, ¶¶ 57, 68-69). MHD denied those requests. (Doc. 1, ¶¶ 58, 71). Plaintiffs filed a motion for preliminary injunction (Doc. 5) and this Complaint. (Doc. 1).

ARGUMENT

I. 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' claims is methodology, i.e. that 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.

Plaintiffs allege that MHD, in developing its criteria, violates federal law because those criteria are not consistent with AASLD/ISDA Treatment Guidelines. Such claim is, at its essence, a claim that MHD violates 42 U.S.C. § 1396a(a)(17). Plaintiffs' Request for Relief (Doc. 1 at 17-18) makes clear that, although Counts I – III specify certain statutory violations, their claim is ultimately a reasonable standards claim. They request the Court issue a judgment declaring that MHD must revise its criteria for determining whether Medicaid beneficiaries qualify for DAAs to be consistent with current AASLD/ISDA Treatment Guidelines; even though doing so violates all federal and state laws MHD must follow in developing its criteria.

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 v. 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 v. Kinkade*, 712 F.3d 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, Plaintiff's claims under § 1396a(a)(17)—the proper provision under which all three of Plaintiffs' § 1983 claims arise—ultimately fail 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.

Further, the medical necessity, comparability and reasonable promptness determinations cannot be made in isolation from the federal and state statutory and regulatory scheme as a whole, including prior authorization programs, that were created to govern the payment for outpatient drugs to balance all of the competing factors such as the needs of

patients, the advancement of medical science and the excessive costs that the United States and the states have shouldered to pay for these very expensive drugs. 42 U.S.C. §1396r-8; RSMo § 208.175; 13 CSR 70-20.200. As the United States District Court for the District of Columbia recently reasoned in a somewhat similar context "[s]imply put, just because a Medicaid recipient is entitled to coverage of prescription drugs in general does not mean that he is entitled to receive any drug under the sun. … To the contrary, the term 'covered services' means those services that are covered by Medicaid, which drugs are circumscribed by the limits that D.C. has lawfully imposed." *N.B. vs. District of Columbia*, 34 F. Supp.3d 146,154 (DCDC 2014) (emphasis in original).

Thus, Plaintiff's claims fail under all three prongs of the *Blessing* test and are unenforceable under 42 U.S.C. § 1983. Consequently, this Court should dismiss Plaintiffs' Complaint against Defendants in its entirety.

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 January 3, 2017 to be served by operation of the Court's electronic filing system upon all parties.

/s/ Colleen Joern Vetter
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