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.	)	

REPLY IN SUPPORT OF
DEFENDANTS' MOTION TO DISMISS

The Court should reject Plaintiffs' challenge to the State's prior authorization criteria as part of its utilization control process because a reasonable standards claim is not privately enforceable under 42 U.S.C. § 1983.

Plaintiffs claim they "have not challenged Defendants' entire [utilization control] process as legally deficient, but have taken issue with one instance where the process has apparently failed, resulting in illegal criteria applied to limit access to medically necessary prescription drugs." (Doc. 37 at 4). In a footnote, Plaintiffs state: "[c]ontrary to Defendants' arguments, Plaintiffs do not argue that they are entitled to "any drug under the sun" (Defs. Sugg. at 10). Rather, they argue that the law requires Defendants to cover drugs that are medically necessary as determined by their treating

physicians consistent with prevailing community standards, and which will cure a life-threatening disease. See Weaver v. Reagen, 886 F.2d 194, 199-200 (8th Cir. 1989)." (Doc. 37, fn. 3).

Weaver supports the State's argument that this is a reasonable standards claim and is not privately enforceable. The Eighth Circuit Court stated in *Weaver* that, "the state's plan for determining eligibility for medical assistance must be 'reasonable' and 'consistent with the objectives' of the Act. *Beal v. Doe,* 432 U.S. 438, 444, 97 S.Ct. 2366, 2371, 53 L.Ed.2d 464 (1977) (**quoting 42 U.S.C. § 1396a(a)(17)**). This provision has been interpreted to require that a state Medicaid plan provide treatment that is deemed "medically necessary" in order to comport with the objectives of the Act." *Weaver*, 886 F.2d at 198 (emphasis added). Here, Plaintiffs' have declared they have no problem with the States' utilization control process, just that the extensive review procedure the State follows according to federal and state law has reached a flawed result, that the prescription drugs their providers consider "medically necessary" have not been approved by the State.

However, *Weaver* does not support Plaintiffs argument that the Court should decide what prescription drugs are "medically necessary" and must be paid by the State through its Medicaid plan, as it did in *Weaver*, because 42 U.S.C. § 1396r-8, governing such State plans, was established after *Weaver* was decided in 1989.

"Prior to 1990, the Medicaid statute did not specifically address outpatient prescription drug coverage." *Pharmaceutical Research and Mfrs. of America v. Walsh*, 538 U.S. 644, 651 (2003). "The Secretary's [Secretary of Health and Human Services] regulations and guidelines 'set upper limits on each State's aggregate expenditures for drugs.' " *Id*. Some states designed and administered their own formularies and other states employed prior authorization programs with approval of the Secretary. *Id*. "These programs were not specifically governed by any federal law or regulations, but rather were made part of the State Medicaid plans and approved by the Secretary because they aided in controlling Medicaid costs." *Id*.

In 1990, Congress created the outpatient prescription drug rebate program at 42 U.S.C. 1396r-8 by amendment in the Omnibus Budget Reconciliation Act of 1990. *Walsh*, 538 U.S. at 652. The new drug program in the Medicaid Act imposed a general requirement that drug companies must enter into agreements to provide rebates on their Medicaid sales of outpatient prescription drugs and states must provide coverage, and allowed states to require approval of the drug before it is dispensed by prior authorization. 42 U.S.C. 1396r-8.

"Prior authorization is, by definition, a procedural obstacle to Medicaid beneficiaries' access to medically necessary prescription drugs covered under the Medicaid program. It nevertheless may serve a Medicaid purpose by

'safeguard[ing] against unnecessary utilization and assur[ing] that payments are consistent with efficiency, economy and quality of care. H.R.Rep. No. 101-881, p. 98 (1990), U.S.Code Cong. & Admin.News 1990, pp. 2017, 2110. A State accordingly may impose prior authorization to reduce Medicaid costs." *Walsh*, 538 U.S. at 685 (2003)(Justice O'Connor concurrence in part and dissent in part on other grounds).

Moreover, according to 42 U.S.C. § 1396a(a)(54), "a State plan for medical assistance must … in the case of a State plan that provides medical assistance for covered outpatient drugs (as defined in section 1396r-8(k) of this title), comply with the applicable requirements of section 1396r-8 of this title." According to the requirements of 42 U.S.C. § 1396r-8, the State: "shall provide … for a drug use review program … in order to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results."[1] 42 U.S.C. § 1396r-8(g)(1)(A).

Plaintiffs are asking this Court to declare that the State's prior authorization criteria are wrong, certain covered outpatient drugs are "medically necessary" for them, and then compel the State to disregard the many requirements in 42 U.S.C. § 1396r-8, RSMo § 208.175, and 13 CSR 70-

[1] This regulation requires the State to consider not just medical necessity, but also to monitor drug use risks such as those reported on January 25, 2017 suggesting direct-acting antiviral drugs to treat Hepatitis C may result in liver damage rather than benefit in some patients. See, www.ismp.org/QuarterWatch/pdfs/2016Q2.pdf

20.200 and simply approve those prescriptions. Thus, regardless what sections of the Medicaid Act Plaintiffs cite in bringing their claims for relief, Plaintiffs are asking the Court to enforce 42 U.S.C. § 1396a(a)(17), the "reasonable standards" provision which has been interpreted to require that a state Medicaid plan provide "medically necessary" treatment in order to comport with the objectives of the Act. *Weaver*, 886 F.2d at198.

Plaintiffs' claims fail because there is no individualized federal right to reasonable Medicaid standards enforceable under 42 U.S.C. § 1983. *See, Lankford v. Sherman*, 451 F.3d 496, 508 (8th Cir. 2006).

Further, the medical necessity, comparability and reasonable promptness claims Plaintiffs assert in this action regarding covered outpatient drugs cannot be considered in isolation from the federal and state statutory and regulatory scheme as a whole, including prior authorization programs, established by Congress in 1990 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.

Thus, Plaintiff's claims fail as they 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 27, 2017 to be served by operation of the Court's electronic filing system upon all parties.

/s/ Colleen Joern Vetter
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