UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

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

REPLY IN SUPPORT OF DEFENDANTS' MOTION
TO DISMISS PLAINTIFFS' AMENDED COMPLAINT

Before the Court is Defendants' (MHD's) Motion to Dismiss Plaintiffs' Amended Complaint (Doc. 71). For the reasons stated below in this Reply in Support, this Court should dismiss Counts I, II, III, IV, and VI.

A. Plaintiffs have failed to demonstrate their claims are individually enforceable under § 1983.

MHD's motion should be granted because Plaintiffs have failed to demonstrate that their claims are individually enforceable under § 1983:

> Even if a plaintiff demonstrates that a federal statute creates an individual right, there is only a rebuttable presumption that the right is enforceable under § 1983. Because our inquiry focuses on congressional intent, dismissal is proper if Congress "specifically foreclosed a remedy under § 1983. Congress may do so expressly, by forbidding recourse to § 1983 in the statute itself, or impliedly, by creating a comprehensive enforcement scheme that is incompatible with individual enforcement under § 1983.

Blessing v. Freestone, 520 U.S. 329, 341 (1997) (citations omitted). MHD argued in its dismissal motion that 42 U.S.C. § 1396r-8 includes a comprehensive enforcement

scheme incompatible with individual enforcement under § 1983 that would, in fact, run counter to the specific obligations MHD has to CMS and pharmaceutical manufacturers as set out in § 1396r-8. Plaintiffs failed to address this argument.

Instead, Plaintiffs cited the Court's prior order in response to a prior motion to dismiss the original complaint. There, the Court noted "Defendants do not argue that Plaintiffs' service availability, comparability, and reasonable promptness claims are not privately enforceable under 42 U.S.C. § 1983. As a result the Court need not address the issue." (Doc. 31 , p. 5). In the instant motion to dismiss Plaintiffs' Amended Complaint, MDH has expressly argued Plaintiffs' service availability, comparability, and reasonable promptness claims are not privately enforceable under 42 U.S.C. § 1983. However, Plaintiffs fail to address the rebuttable presumption that those rights are enforceable in this case.

Plaintiffs claim a right to service availability, comparability, and reasonable promptness enforceable under § 1983 – but for what benefit? Plaintiffs specify they are being excluded from medically necessary treatment as required by the service availability, comparability, and reasonable promptness provisions of 42.U.S.C. 1396a ***and*** 42 U.S.C. § 1396d(a)(12). (Doc. 71, ¶¶ 105, 107, 109). The prescription drug benefit in 42 U.S.C. § 1396d(a)(12) is the specific benefit Plaintiffs claim they are being excluded from. Plaintiffs claim they are being excluded from that benefit because MHD has established approval criteria according to § 1396r-8 which Plaintiffs do not meet. MHD is required to comply with § 1396r-8 according to 42 U.S.C. § 1396a(a)(54). (Doc. 71, ¶¶ 24, 26). Thus, Plaintiffs' claims for benefits are

premised upon the three sections pertaining to prescription drugs, 42 U.S.C. § 1396d(a)(12), § 1396a(a)(54), and § 1396r-8; Plaintiffs cannot expect the Court to consider one provision regarding prescription drug benefits and ignore the two others.

Section 1396a(a)(54) requires that "a State plan that provides medical assistance for covered out-patient drugs (as defined in section 1396r-8(k)) [must] comply with the applicable requirements of section 1396r-8 of this title." 42 U.S.C. § 1396a(a)(54). "This language does not bespeak Congress' intent to create a federal right. It does not contain any 'rights-creating' language that gives rise to an enforceable right. It speaks only to the states in terms of how their rebate plans must comply with the Medicaid Drug Rebate Program's requirements in Section 1396r-8." *Health Sci. Funding, LLC v. The New Jersey Dep't of Health & Human Services*, 658 Fed. Appx. 139, 141–42 (3d Cir. 2016). While the plaintiff in this Third Circuit case was a drug manufacturer, the same is true as applied to an individual; there is no rights-creating language in the statute that gives Plaintiffs an enforceable right. A statute does not grant a privately enforceable right simply because a plaintiff may "fall[ ] within the general zone of interest that the statute is intended to protect." *Gonzaga Univ. v. Doe*, 536 U.S. 273, 284 (2002). It will only confer a federal right when "its text [is] 'phrased in terms of the person benefitted."' *Id*. The Court in *Blessing* also rejected a plaintiff's § 1983 claim because the statutory provision at issue focused on the state rather than benefits conferred on the plaintiff. 520 U.S. at 340–44.

None of the cases Plaintiffs cite address the threshold question whether Plaintiffs are entitled to bring their claim for prescription drug benefits as a private right of action enforceable under § 1983 in response to MHD's argument in its Motion to Dismiss Plaintiffs' Amended Complaint.

The only new case Plaintiffs cite regarding a prescription drug benefit is mentioned in a footnote stating "[t]he Medicaid Act does not authorize a state to use a "prior authorization program to *deny* coverage for a covered drug; it can only *condition* reimbursement upon a prescribing doctor first calling a state pharmacist to obtain approval for the drug. *Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1330 (S.D. Fla. 2006)." (Doc. 84, fn. 4). However, there the court dealt only with the question whether the disputed drug uses were for medically accepted indications, and did not address the question whether there exists an individually enforceable right of action regarding prescription drug benefits. Moreover, in a footnote in that case, the court includes this language from § 1396r-8 which supports a state's decision to deny a prescription that is not medically necessary:

> States are required to implement drug use review programs in order to assure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results. § 1396r–8(g)(1). These drug use review programs "assess data on drug use against predetermined standards, consistent with" the drug compendia listed in § 1396r–8(g)(1)(B)(i) and peer-reviewed medical literature. § 1396r–8(g)(1)(B). These programs must (a) prospectively review drug therapy before prescriptions are filled or delivered to Medicaid recipients, and (b) retrospectively "identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists and [Medicaid recipients], or associated with specific drugs ...." §§ 1396r–8(g)(2)(A) & (B).

Edmonds, 417 F. Supp. 2d at 1330 fn. 5. The holding regarding drug use for

medically indicated accepted indications in *Edmonds* is not relevant here. Plaintiffs' suggestion that *Edmonds* stands for the proposition that a state cannot deny a prescription according to 1396r-8 is not supported.

Plaintiffs are not eligible for the prescription drug benefit they seek because they do not meet the prior authorization approval criteria. After a mandated review before a prescription is filled to assure it is clinically appropriate, medically necessary, and not adverse, a prescription that does not meet those requriements would not be filled, consistent with "the objectives of the [Medicaid] Act for a State to refuse to fund unnecessary though perhaps desirable medical services." *Beal v. Doe*, 432 U.S. 438, 444-45 (1977).

Edmonds is cited in *In re Plavix Mktg., Sales Practices & Products Liab. Litig.,* 123 F. Supp. 3d 584 (D.N.J. 2015), another case discussing restrictions on prescription drug coverage. That court found:

> there is no dispute that federal law permits states to place reasonable restrictions on prescription drugs covered by Medicaid. 42 U.S.C. §§ 1396r–8(d)(1), (5); 42 C.F.R. § 440.230(d); *NB v. District of Columbia,* 34 F.Supp.3d 146, 153 (D.D.C.2014), *rev. on other grounds, NB v. District of Columbia,* 794 F.3d 31 (D.C.Cir.2015). However, "[a] State plan for medical assistance must ... include reasonable standards ... for determining eligibility for and the extent of medical assistance under the plan ... which are consistent with the objectives of this subchapter [of Medicaid]," 42 U.S.C. § 1396a(a)(17), and the implementing regulation requiring that each provided service, including prescription drugs, "must be sufficient in amount, duration, and scope to reasonably achieve its purpose." 42 C.F.R. § 440.230(b); *Detgen v. Janek,* 752 F.3d 627, 631 (5th Cir.2014). That requirement has been interpreted by the Supreme Court to include certain reasonable restrictions relating to costs, *see* [*Pharm. Research & Mfrs. of Am. v. Walsh,* 538 U.S. 644, 666, (2003)] and *Beal[],* 432 U.S. 438, 444 [], albeit budgetary considerations cannot be "the conclusive factor in decisions regarding Medicaid." *Arkansas Med. Soc., Inc. v. Reynolds,* 6 F.3d 519, 531 (8th

> Cir.1993); *Bontrager v. Indiana Family & Soc. Servs. Admin.,* 697 F.3d 604, 611 (7th Cir.2012); *Tallahassee Mem'l Reg'l Med. Ctr. v. Cook,* 109 F.3d 693, 704 (11th Cir.1997).

In re Plavix Mktg., 123 F. Supp. 3d at 610. This case is no more relevant than *Edmonds* on the issue of whether Plaintiffs' claims are enforceable under § 1983, except to demonstrate the proper scope of inquiry this Court should consider regarding Plaintiffs' claim that MHD's prior approval criteria violate their rights to prescription drug benefits because they do not qualify for them. The alleged violation is related to MHD's approval criteria, which Plaintiffs' consider unreasonable, but are not individually enforceable under 42 U.S.C. § 1396a(a)(17). Claims for reasonable standards in prior approval criteria will 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).

Instead of arguing that 42 U.S.C. § 1396d(a)(12), § 1396a(a)(54) and § 1396r-8 create an individually enforceable right under § 1983, Plaintiffs assert only that they are allowed to bring their claims as they choose. Again, Plaintiffs chose to assert a claim for prescription drug benefits. They have not addressed the rebuttable presumption that their right to those benefits is enforceable under § 1983 and MHD has explained that it is not considering the regulatory framework established in 1396r-8 that allows and requires a state to determine when and whether prescriptions may be filled, reviewable only by the Secretary of Health and Human Services. See, Pe*nnhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 28 (1981). Plaintiffs' claims for service availability, comparability, and promptness,

although applicable to other benefits in other circumstances, are not enforceable here, where prescription drug benefits are subject to the regulatory framework created by Congress in § 1396r-8. See, *Blessing*, 520 U.S. at 340–44.

Plaintiffs have failed to demonstrate their claims are individually enforceable under § 1983. Accordingly, this Court should find Plaintiffs' Counts I, II, III, and IV fail to state a claim as a matter of law and must be dismissed.

B. Plaintiffs failed to demonstrate their claim alleged in Count IV is individually enforceable under § 1983.

Plaintiffs failed to cite any case involving Medicaid benefits to support its argument that the Court can require state agencies to promulgate substantive standards where plaintiffs allege those standards are lacking as not "ascertainable." Plaintiffs' argument is that one critical part of Defendants' criteria for DAAs lacks an ascertainable standard, specifically the criteria that allows coverage for individuals with "Metavir fibrosis scores F0-F2 with certain comorbidities." (Doc. 84, p. 6-7).

Plaintiffs admit "the standard for determining whether there is a violation of the Fourteenth Amendment is the 'absence of any ascertainable standards for inclusion and inclusion.' *Smith v. Goguen*, 415 U.S. 566, 578 (1974)." (Doc. 84, p. 6).[1] Plaintiffs cite MHD's criteria, thus admitting there is written criteria, then attempt to explain the criteria is insufficient. "The mere fact that written regulations do not

[1] Plaintiffs' citation to L.S. by & Through Ron S. v. Delta, No. 5:11-CV-354-FL, 2012 WL 12911052, at *4 (E.D.N.C. Mar. 29, 2012) is relevant only to Plaintiffs' Count V as it addresses information in a notice after a state action.

cover every contingency does not rise to the level of a constitutional violation. Substantive due process does not command an agency to promulgate a Napoleonic Code. At most, [plaintiff] was entitled to have his eligibility determination made pursuant to a written, ascertainable standard. *Hobbs ex rel. Hobbs v. Zenderman*, 579 F.3d 1171, 1187 (10th Cir. 2009).

Here, MHD's approval criteria provide specific information relating to DAAs, including that the "Clinical Consultant will review all therapy requests for documentation of comorbidities that may result in approval." (Doc. 84, p. 7). This is not a class action. Plaintiffs' requests for DAAs were submitted by their medical providers. Each Medicaid participant has a unique medical condition; MHD could not list all conditions which may result in approval for DAAs for every participant. Knowing that the Clinical Consultant will review documented comorbidities, Plaintiffs' medical providers are directed to submit documentation of that patient's conditions which could result in approval for DAAs. Plaintiffs have not alleged their medical providers were not allowed to submit such documentation. Moreover, when a request for a prescription drug benefit is denied, every Medicaid participant is informed how to request a State Fair Hearing, which will result in another review, safeguarding against denial by mistake. (Doc. 2, p. 273).

Again, Plaintiffs challenge MHD's prior approval criteria in the guise of a Fourteenth Amendment claim for "reasonable, ascertainable, non-arbitrary standards and procedures for determining eligibility for and the extent of medical assistance" (Doc. 71, ¶ 111), a challenge which cannot be sustained as a private

right of action. See, *Gonzaga,* 536 U.S. at 284; *Lankford*, 451 F.3d at 509.

Due process is violated when a state agency has no standards for inclusion and exclusion. Here, as MHD has established prior approval criteria for participants with HCV, Plaintiffs can prove no violation of the Fourteenth Amendment. Accordingly, this Court should find Plaintiffs' Count IV fails to state a claim as a matter of law and must be dismissed.

C. Plaintiffs failed to demonstrate a claim for relief under the ADA.

Again, Plaintiffs cannot show they are discriminated against because of their disability, they can only show that they fail to meet approval criteria for DAAs – which is an issue of *eligibility*, not *disability*. Where § 1396r-8 requires MHD to assure prescriptions are clinically appropriate, medically necessary, and not adverse in effect, then MHD's decision to deny DAAs to Plaintiffs after applying prior approval criteria means their prescriptions did not meet those qualifications.[2] That decision is a medical treatment decision; prescription drugs must be medically necessary in order for MHD to be reimbursed by the federal Medicaid program. § 1396r-8; *Beal*, 432 U.S. at 444-45.

"A claim based upon improper medical treatment decision may not be brought pursuant to either the ADA or the Rehabilitation Act. *See McElroy v. Patient Selection Comm. of Neb. Med. Center,* No. 07–3877, —— Fed.Appx. ——, ——, 2009

[2] Which means Plaintiffs are not qualified for DAA treatment despite their insistence that they are because they are diagnosed with chronic HCV and their treating physicians have prescribed DAAs. In asserting this position Plaintiffs ask the Court to ignore § 1396r-8 which it cannot in this claim for prescription drugs.

WL 50176, at *1 (8th Cir. Jan. 9, 2009) (per curiam) ("[A] medical-treatment decision, such as the one at issue here, cannot be the basis for an ADA Title III claim...."); *Burger v. Bloomberg,* 418 F.3d 882, 883 (8th Cir.2005) (per curiam) ("[A] lawsuit under the Rehab Act or the Americans with Disabilities Act (ADA) cannot be based on medical treatment decisions...") (adopting the positions of *Schiavo ex rel. Schindler v. Schiavo,* 403 F.3d 1289, 1294 (11th Cir.2005) and *Fitzgerald v. Corr. Corp. of Am.,* 403 F.3d 1134, 1144 (10th Cir.2005))." *Shelton v. Arkansas Dept. of Human Services*, 677 F.3d 837, 843 (8th Cir. 2012).

Plaintiffs incorrectly cite *Postawko v. Mo. Dep't of Corr.*, 2017 U.S. Dist. LEXIS 71715, at *13 (W.D. Mo. May 11, 2017), and another district court case[3] as though they are relevant and controlling authority. They are not.

Plaintiffs' claim for "reasonable modifications" (Doc. 71, ¶ 118) is, again, a challenge to MHD's utilization control procedures, specifically prior authorization criteria, used to manage prescription drug coverage, which it is entitled and obligated to do pursuant to 42 U.S.C. § 1396r-8. Plaintiffs ask the Court to make a medical treatment decision using the vehicle of the ADA, which this Court cannot do. Consequently, Count VI should be dismissed for failure to state a claim as a matter of law.

Conclusion

Defendants respectfully request this Court dismiss Plaintiffs' Counts I, II, III, IV, and VI, pursuant to Fed. R. Civ. P. 12(b)(6).

[3] *McNally v. Prison Health Services*, 46 F. Supp. 2d 49 (D. Me. 1999).

Respectfully submitted,

JOSHUA D. HAWLEY
Missouri Attorney General

/s/ Colleen Joern Vetter
COLLEEN JOERN VETTER
Assistant Attorney General
Missouri Bar No. 38353MO
P.O. Box 861
St. Louis, MO 63101
Telephone: (314) 340-7861
Fax: (314) 340-7029
Colleen.Vetter@ago.mo.gov

Attorneys for Defendants

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing was filed electronically with the Clerk of Court on July 17, 2017 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