UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

J.E.M., *et al*.,	)	
Plaintiffs,	)	
v.	)	Case No. 16-04273-CV-C-SRB
	)	
CORSI and LUDLAM,	)	
	)	
Defendants.	)	

PLAINTIFFS' SUGGESTIONS IN OPPOSITION OF DEFENDANTS' MOTION TO DISMISS

Plaintiffs are low-income Missouri Medicaid beneficiaries infected with Hepatitis C, a contagious and life-threatening disease. Recent pharmaceutical breakthroughs have resulted in a cure for their condition—direct-acting antiviral (DAA) medications, but Defendants deny this curative treatment to Plaintiffs, contrary to prevailing clinical guidelines and the standard of care. Plaintiffs seek to enforce the federal Medicaid Act against Defendants pursuant to 42 U.S.C. § 1983, alleging that Defendants' policies violate three separate Medicaid Act provisions: service availability, comparability, and reasonable promptness. Plaintiffs' amended complaint also alleges violations of the Americans with Disabilities Act and the Fourteenth Amendment to the United States Constitution.

Defendants have moved to dismiss, contending that Plaintiffs are really relying on another Medicaid provision that is not cause of action in their complaint and that may or may not be privately enforceable. This is the same argument that they made before, citing other statutes, and that the Court has already rejected. As the Court already found, this argument ignores the basic rules on pleading—the plaintiffs control the complaint and, as a result, get to choose which claims for relief they raise. The Court should deny Defendants' motion.

Standard of Review

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)). Here, Plaintiffs' complaint contains factual allegations that support Plaintiffs' claims for relief under the service availability (42 U.S.C. § 1396a(a)(10)(A)), comparability (§ 1396a(a)(10)(B)), and reasonable promptness (§ 1396a(a)(8)) provisions of the Medicaid Act. Defendants' only argument for dismissal is that Plaintiffs' claims are not privately enforceable under § 1983. This argument is not supported by law or cases, as established below. Defendants also erroneously argue that Plaintiffs' Americans with Disabilities Act and ascertainable standards claims (based on the Due Process Clause of the Fourteenth Amendment) should be dismissed.

I. THE COURT SHOULD NOT DISMISS PLAINTIFFS' CLAIMS AS UNENFORCEABLE UNDER 42 U.S.C. § 1396r-8.

A. Plaintiffs may choose their causes of action and have chosen not to claim relief under the 42 U.S.C. § 1396r-8.

Defendants argue that Plaintiffs' complaint must be dismissed because they are really seeking to enforce the "prior authorization" and "drug rebate" provision of the Medicaid Act, 42 U.S.C. § 1396r-8, and that provision is not privately enforceable.[1] (Defendants' Suggestions in Support of Defendants' Motion to Dismiss (Defs' Sugg.) pp. 6-12.) Plaintiffs' complaint contains no claim for relief under that provision. Plaintiffs simply have not raised the claim Defendants seek to refute.

[1] While irrelevant here, no court has held that 1396r-8 cannot be enforced by a beneficiary under § 1983. The Supreme Court held that a health care provider could not enforce related provisions governing drug pricing against drug manufacturers. See Astra v. Santa Clara County, 563 U.S. 110, 121 (2011). However, the Court subsequently broadly restricted providers' ability to enforce Medicaid Act provisions noting that Medicaid was enacted to benefit low-income individuals, not providers. See Armstrong v. Exceptional Child, 135 S.Ct. 1378, 1387 (2015).

Defendants cite no support for their contention that Plaintiffs must bring a 1396r-8 claim simply because Plaintiffs make allegations that could theoretically support such a claim. Nor could they cite any such authority. Plaintiffs' citation to other statutory provisions, including 1396r-8, to explain Medicaid background and to flesh out their claims does not require them to enforce those other statutory provisions. This discussion in the complaint does not "convert" their enforceable claims into another type of claim that—conveniently for Defendants—may or may not be privately enforced. O.B. v. Norwood, 170 F. Supp. 3d 1186, 1193 (N.D. Ill.), aff'd, 838 F.3d 837 (7th Cir. 2016).[2] As Plaintiffs have noted previously, it is quite common for multiple claims to arise from one set of illegal actions. The fact that the legal and factual issues in a case are interrelated does not mean that the Defendants get to decide which claims apply. [3]

It is well-settled that plaintiffs may choose their causes of action. See, e.g., Lowe v. Bateman, 586 F. Supp. 528, 531 (W.D. Mo. 1984). Here, Plaintiffs have exercised their choice and have not included a 1396r-8 claim. The Court should hold that Plaintiffs' allegations about Defendants' restrictive prior authorization criteria in support of their Medicaid Act claims do not convert them to a claim under § 1396r-8 of the Medicaid Act, which may or may not be enforceable under § 1983. Plaintiffs have brought claims under a variety of theories that fit the facts of the case, and those claims must be judged on their own merit.

Notably, Defendants' argument merely repackages the argument that this Court *already* rejected when Defendants tried to convert Plaintiffs' claims into a "reasonable standards" theory.

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[2] Logically, Defendants' proposition cannot be true—it would serve to prevent plaintiffs from citing other, related, statutory provisions to support their claims under a privately enforceable statutory provision, since any such citations could convert their claims from enforceable to unenforceable. See O.B., 170 F. Supp. 3d at 1193.

[3] For example, in Lankford v. Sherman, 451 F3d 496 (8th Cir. 2006), the Eighth Circuit considered both an enforceable comparability claim, and an unenforceable "reasonable standards" claim. The fact that the Plaintiffs alleged unreasonable conduct did not convert the comparability claim into a "reasonable standards" claim.

This Court appropriately denied Defendants' first Motion to Dismiss, stating that "[t]he Court agrees with Plaintiffs that they are the "masters of their complaint" and may choose their causes of action. (Doc. #41, p. 3 quoting Johnson v. MFA Petroleum Co., 701 F.3d 243, 247 (8th Cir.2012) (stating plaintiff may avoid federal jurisdiction by choosing to allege only state-law).)

Defendants also appear to argue that Plaintiffs cannot prevail on their claims because these claims are somehow precluded by the drug prior authorization statute. While these arguments are misplaced because they go to the merits of the case, they also do *not* establish that Plaintiffs' chosen claims are unenforceable. For example, Defendants argue that Plaintiffs cannot prevail under 42 U.S.C. § 1396a(a)(10)(A) because 1396r-8 allows them to impose the medically unsupported restrictions that plaintiffs challenge. The prior authorization provision allows no such *unbridled* authority for states to limit access to medications. Rather, any limits must comport with the very provisions of the Medicaid Act that Plaintiffs seek to enforce. For example, CMS specifically noted that states cannot rely on these provisions to "unreasonably restrict access to [DAAs]." (Doc. 2-13). Among such unreasonable restrictions are policies that limit treatment based on fibrosis scores of F3 or above, like those at issue in the instant case. Id.[4] In any event, while Defendants' "prior authorization" argument is erroneous on the *merits*, it also does not convert Plaintiffs' § 1396a(a)(10) claim into a claim based on § 1396r-8.

Similarly, Defendants erroneously argue that Plaintiffs cannot challenge discrimination among beneficiaries with HCV under the "comparability" provision and therefore Plaintiffs must make an unenforceable 1396r-8 challenge. Defs' Sugg. at pp. 14-15. As noted previously,

[4] Defendants erroneously assert that their limitations on treatment of HCV drugs are "expressly allowed" by 42 U.S.C. § 1396r-8. Defs' Sugg. p.14. The 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." Edmunds v. Levine, 417 F. Supp. 2d 1323, 1329 (S.D. Fla 2006).

Defendants have no authority to discriminate among categorically needy beneficiaries based on arbitrary factors. See, e.g., Weaver v. Reagen, 886 F.2d at 197-200; B.E. v. Teeter, No. C16-227-JCC, 2016 WL 3033500, at *1, *3-*6 (W.D. Wash. May 27, 2016) and cases cited in Plaintiffs' prior memoranda. (Doc # 5 pp. 16-18.)[5] Regardless, this merits-based argument does not convert Plaintiffs' comparability claim into a claim under 1396r-8.

Defendants further allege that the drug prior authorization and rebate provisions authorize the ongoing deferral of treatment pending escalation of liver damage so that Plaintiffs cannot prevail on "reasonable promptness." While this argument is also flawed, it is an argument about the *merits*—it does not permit Defendants to *select* causes of action for the Plaintiffs.

Plaintiffs' actual claims are all privately enforceable. (Doc. # 37, pp. 5-9, Doc. #24, p.2, n.2) As this Court has already recognized, "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) Plaintiffs bring the same three enforceable Medicaid claims that they brought in their initial complaint. Nothing has changed since the original filing regarding these claims and thus the result must be the same: Plaintiffs may choose their claims and Defendants' Motion to Dismiss must be denied.

B. Plaintiffs have established an ascertainable standards claim.

Defendants include the ascertainable standards claim as part of their argument that the claim should be dismissed as unenforceable under Section 1983. (Def. Sugg. p. 12.) Plaintiffs' "ascertainable standards" claim is not a Medicaid claim but a due process claim under the Fourteenth Amendment, which is clearly enforceable under Section 1983. Defendants seem to

[5] Defendants attempt to distinguish Weaver is equally misplaced. Defs' Sugg., pg. 11 n.4. The enactment of 1396r-8 while allowing for drug rebates and prior authorization did not abrogate States' duty to comply with comparability requirements in their prescription drug programs or to provide medically necessary treatment, as noted in the applicable CMS guidance. (Doc. # 2-13).

argue that Plaintiffs' ascertainable standards claim is *really* a claim under the Medicaid Act's prescription drug (42 U.S.C. § 1396r-8) or reasonable standards (*id*. § 1396a(a)(17)) provisions and is therefore not privately enforceable. Defs' Sugg., p. 17. Again, Plaintiffs are the "masters of their complaint" and may choose their claims.[6] Johnson, 701 F.3d at 247. That Plaintiffs stated their claim using some of the same words that are in the Act does not convert it from a constitutional claim to a Medicaid Act claim. Defendants do not challenge the enforceability of this claim under the Fourteenth Amendment. Defs' Sugg., p. 17. The claim is enforceable.[7]

Defendants' arguments as to the substance of Plaintiffs' ascertainable standards claims are equally meritless. Defendants are correct that the standard for determining whether there is a violation of the Fourteenth Amendment is the "absence of any ascertainable standard for inclusion and exclusion." Smith v. Goguen, 415 U.S. 566, 578 (1974). Due Process affords this protection in public benefits programs where there is "the possibility for honest error or irritable misjudgment," such that the recipient who is denied a benefit must be afforded "a chance, if he so desires, to be *fully informed* of the case against him so that he may contest its basis and produce evidence in rebuttal." Goldberg v. Kelly, 397 U.S. 254, 266 (1970) (emphasis added).

Defendants argue that their Prior Authorization criteria for DAAs are sufficiently ascertainable because the criteria are eight pages long. Defs' Sugg., p. 18. Plaintiffs' argument, however, 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

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[6] Notably, Defendants also do not challenge Plaintiffs' fifth cause of action under the Due Process clause of the Fourteenth Amendment to the U.S. Constitution.

[7] Despite Defendants' argument to the contrary, the Supreme Court recently made clear that Plaintiffs' failure to explicitly invoke § 1983 in their complaint is not a fatal flaw. Johnson v. City of Shelby, Miss., 135 S. Ct. 346, 346 (2014) ("[N]o heightened pleading rule requires plaintiffs seeking damages for violations of constitutional rights to invoke § 1983 expressly in order to state a claim."). If the Court is inclined to dismiss this claim for failing to request relief under § 1983, Plaintiffs respectfully request leave to amend their complaint.

scores F0-F2 with *certain* comorbidities," and states that "Clinical Consultant will review all therapy requests for documentation of comorbidities that may result in approval" (Doc 56-8, pp. 4-8 (emphasis added)). Defendants' criteria provide no definition or clarity as to which diseases qualify individuals with Metavir fibrosis scores F0-F2 for coverage of DAA treatment or what documentation of those diseases is required. Furthermore, Defendants have issued no external guidance or regulations that specify what types of comorbidities qualify. As it stands, the phrase "comorbidities" is used twice in the document and is otherwise left undefined and unexplained, meaning that those who have Hepatitis C with a score below F3 and another chronic condition are left to guess whether they will qualify for treatment or not. Defendants have failed to provide any way for these individuals or their treating providers to determine whether they are included or excluded from receiving coverage for DAA medications from MO HealthNet, or to contest a denial of DAA treatment. See Goldberg, 397 U.S. at 266.

Recently, the Eastern District of North Carolina found that plaintiffs were likely to succeed on an ascertainable standards claim where defendants determined eligibility for certain services using a computer program that scored plaintiffs' need for services, and notified them of the amount of services they would receive based on the score but failed to inform consumers how to "understand the score, [and] how the score was reached." L.S. by & through Ron S. v. Delia, No. 5:11-CV-354-FL, 2012 WL 12911052, at *14 (E.D.N.C. Mar. 29, 2012). Similarly, in this case, Plaintiffs do not have information to help them understand which comorbidities qualify individuals with a score of F0-F2 for DAA treatment, or how to document those comorbidities to Defendants' satisfaction. One person might guess that people with diabetes will qualify, but another may disagree—if a person with diabetes requests DAA treatment with a document confirming the diabetes diagnosis, and Defendants deny the request it will be impossible for the

person to know whether the denial is an appropriate application of Defendants' rules, whether the documentation provided was insufficient, or whether there was a mistake. Plaintiffs have shown that Defendants' criteria for DAA treatment for those with a fibrosis score lower than F3 is "so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application." Connally v. Gen. Const. Co., 269 U.S. 385, 391 (1926).

This vague standard unfairly distributes the balance of power in favor of the Defendants versus the low-income Medicaid beneficiary with disabilities, allowing the Defendants complete discretion as to which consumers they wish to favor with DAA treatment through a decided lack of transparency. Because of these deficiencies, Plaintiffs have pled a claim for relief under the Fourteenth Amendment of the U.S. Constitution.

II. PLAINTIFFS HAVE STATED A CLAIM FOR RELIEF UNDER THE AMERICANS WITH DISABILITIES ACT.

Defendants argue that Plaintiffs' Americans with Disabilities Act (ADA) claim is *really* a Medicaid comparability claim, which itself is really a claim under the 1396r-8, which is not privately enforceable. Defs' Sugg., p. 18. For the reasons set forth above, this argument does not hold water. Further, Defendants do not suggest that the ADA may not be privately enforced.

Defendants' attempts to attack the substance of Plaintiffs' ADA claim also fail. To state a discrimination claim under the ADA, Plaintiffs must establish that 1) they are people with disabilities under the ADA, 2) they are otherwise qualified for treatment, and 3) they were excluded from treatment due to discrimination based upon their disability—here, because of the *severity* of their disability. See Randolph v. Rodgers, 170 F.3d 850, 858 (8th Cir. 1999). Plaintiffs have met all three prongs of this test.

First, Plaintiffs have established that they qualify as people with disabilities under the ADA. Each has Hepatitis C, a disease that significantly limits major life activities including their ability to reproduce. (Doc 67-1, ¶¶1, 6-8, 117)

Second, Plaintiffs have shown that they are otherwise qualified for DAA treatment. All have diagnoses of Hepatitis C, and all have been prescribed DAAs by their treating physicians to cure their Hepatitis C. Defendants have alleged no reason for denial beyond its policy to withhold treatment from HCV patients with low fibrosis scores and no qualifying comorbidities. This distinction is arbitrary and unsupported by clinical rationale.

Third, Plaintiffs were excluded from treatment because of their disability; specifically because of the severity of their disability. Defendants argue that Plaintiffs asserted no distinction between services provided to those who have disabilities and those who are not. This is true. Plaintiffs' amended complaint alleges Defendants' policy treats Plaintiffs "differently than *other qualified people with disabilities*, based solely on the *severity* of their disability." (Doc 67-1, ¶118,). (emphasis added).) This discrimination among different groups of people with disabilities is just as objectionable under the ADA as discrimination between people with and without disabilities. See 28 C.F.R. § 35.130(b)(1)(iv) (A public entity may not "provide different or separate aids, benefits, or services to individuals with disabilities *or to any class of individuals* with disabilities than is provided to others") (emphasis added); Hahn ex rel. Barta v. Linn Cty., IA, 130 F. Supp. 2d 1036, 1055 (N.D. Iowa 2001) ("Mr. Hanh can set forth a claim of discrimination even if it is only between members of his protected class, namely, the disabled.")

Further, Defendants' refusal to provide DAAs to Plaintiffs was not a medical treatment decision, but an application of a blanket policy that systematically screens out a specific subclass of people with disabilities: individuals with Hepatitis C who have low F scores and no qualifying

comorbidities. Defendants rely on the same misinterpretation of Burger's "medical treatment decisions" that this Court recently rejected in Postawko v. Mo. Dep't of Corr., 2017 U.S. Dist. LEXIS 71715, at *13 (W.D. Mo. May 11, 2017) ("Defendants' authorities involve situations where individual plaintiffs simply disagreed with medical treatment decisions and did not challenge a prison's general policy or custom, as Plaintiffs do here."). As in Postawko, Plaintiffs here do not allege malpractice as the basis of their ADA claim. In fact, Plaintiffs allege that their treating physicians made the decision to prescribe a cure to their disabling condition, and the state has denied them access to that cure as a matter of a policy. See, e.g., McNally v. Prison Health Services, 46 F. Supp. 2d 49 (D. Me. 1999) (HIV-positive plaintiff stated an ADA claim because his prison was discriminating "not by providing him with inadequate care, but by denying him immediate access to prescribed medications, a service provided to detainees in need of prescriptions for other illnesses"). Plaintiffs have stated a claim for relief under the ADA.

Conclusion

For the reasons expressed herein, this Court should deny Defendants' Motion to Dismiss.

Respectfully submitted,

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Dated July 3, 2017 ATTORNEYS FOR PLAINTIFFS

CERTIFICATE OF SERVICE

I hereby certify that on July 3, 2017, I electronically filed the foregoing with the clerk of the Court using the CM/ECF system which sent notification of such filing to the following counsel of record: Colleen Joern Vetter, Assistant Attorney General, P.O. Box. 861, St. Louis, MO 63101.

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