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.,	)	ORAL ARGUMENT REQUESTED
	)	
Defendants.	)	

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

Respectfully submitted,

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

I. Background

Plaintiffs J.E.M., J.L.M, and H.L.O., Missouri Medicaid beneficiaries with Hepatitis C virus ("HCV") ("Plaintiffs") bring this suit against Defendant Steven Corsi[1], in his official capacity as Director of the Missouri Department of Social Services, and Jay Ludlam, in his official capacity as Acting Director of the MO HealthNet Division (MHD), alleging MHD is denying medically-necessary, direct-acting antiviral treatment (DAAs) to Plaintiffs in violation of the Medicaid Act.

Plaintiffs' suit challenges MHD's published approval criteria for HCV

[1] Steven Corsi began his new position as Director of the Missouri Department of Social Services on June 19, 2017 and thus is substituted for Jennifer Tidball by consent of the parties.

requiring a fibrosis score of at least F2 or F3 depending on the patient's genotype. Plaintiffs acknowledge the approval criteria permit exceptions to its fibrosis score requirement, but claim the exceptions are not stated or explained. Plaintiffs argue the challenged criteria have no impact on the medical necessity of DAAs for HCV patients, and by applying the criteria, MHD is failing to provide medically-necessary prescription drugs. Plaintiffs also claim MHD's notice of denial of DAAs is insufficient under the Act. And finally, Plaintiffs claim MHD's denial of DAAs to them is deliberate discrimination against them due to their disability as having HCV.

Plaintiffs' Amended Complaint includes six claims for relief: 1) a 42 U.S.C. § 1983 claim for failure to provide medically necessary prescription drugs in violation of 42 U.S.C. §§ 1396a(a)(10)(A) and 1396(d)(a); 2) a 42 U.S.C. § 1983 claim for violation of the Medicaid Act's "comparability" requirement at 42 U.S.C. § 1396a(a)(10)(B); 3) a 42 U.S.C. § 1983 claim for violation of the Medicaid Act's "reasonable promptness" requirement at 42 U.S.C. § 1396a(a)(8); 4) a claim for "ascertainable standards" in violation of the Due Process Clause of the Fourteenth Amendment[2]; 5) a 42 U.S.C. § 1983 claim for violation of Plaintiffs' due process rights under the Medicaid Act's 42 U.S.C. § 1396a(a)(3) and the Due Process Clause of the Fourteenth Amendment to the U.S. Constitution; and 6) a claim for violation

[2] Although Plaintiffs cite to the Fourteenth Amendment as legal grounds for their claim at Count IV, 42 U.S.C. § 1396a(a)(17) states in relevant part: A State plan for medical assistance must ... 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 subchapter, ..." (words in bold are the same as those in Plaintiffs' Complaint at ¶¶ 37, 111).

of the Americans with Disabilities Act (ADA), 42 U.S.C. § 12131-12134 and its implementing regulations.

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

II. Legal Standard

Pursuant to Fed. R. Civ. P. 12(b)(6), a claim may be dismissed for "failure to state a claim upon which relief can be granted." The Court must consider all facts alleged in the Complaint as true when considering a motion to dismiss. See *Data Mfg., Inc. v. United Parcel Service, Inc.*, 557 F.3d 849, 851 (8th Cir. 2009) (noting "[t]he factual allegations of a complaint are assumed true and construed in favor of the plaintiff, even if it strikes a savvy judge that actual proof of those facts is improbable"). "To survive a motion to dismiss [for failure to state a claim], 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 *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)) (internal citations omitted); *Zink v. Lombardi*, 783 F.3d 1089, 1098 (8th Cir. 2015). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678; *Ash v. Anderson Merchs., LLC*, No. 14–3258, 2015 WL 4978701, at *1 (8th Cir. 2015).

III. Statements of Fact

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 provides health services only to the "categorically needy," including Plaintiffs. 42 U.S.C. § 1396a(a)(10)(A); Mo. Rev. Stat. § 208.151. Missouri elects to provide prescription drug benefits to participants. Mo. Rev. Stat. § 208.152(7); 13 C.S.R. 70-20.030; 42 U.S.C. § 1396a(a)(54).

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 beneficiary 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.

Depending on the specific drug requested and HCV genotype, MHD's approval criteria require a fibrosis score of at least F2 or F3 (Doc. 71, ¶ 47[3]), or documentation of a comorbidity that may result in approval. (Doc. 71, ¶¶ 49, 99). A fibrosis score, indicated by F0 through F4, represents the amount of fibrosis or scarring of the liver. F0 indicates no fibrosis while F4 represents cirrhosis. Plaintiffs' health care providers prescribed DAA treatments to treat and potentially cure their chronic HCV. MHD denied Plaintiffs' requests for treatment at least in part because their fibrosis scores were lower than F3. Plaintiff J.E.M. received a letter stating, "MO HealthNet Division has denied the request because the information submitted did not meet the criteria established to obtain authorization for this drug." (Doc. 71, ¶ 72). Plaintiff H.L.O.'s doctor received a notice that "the patient does not meet MO HealthNet's criteria." (Doc. 71, ¶ 96).

[3] http://dss.mo.gov/mhd/cs/pharmacy/pdf/herpatitis-c-therapy.pdf is the correct citation to the revised criteria.

IV. Argument

A. Plaintiffs cannot assert a § 1983 private right of action to challenge MHD's compliance with 42 U.S.C. § 1396r-8.

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. *Pharmaceutical Research and Mfrs. of America v. Walsh*, 538 U.S. 644, 651-52 (2003). The covered drug program imposes 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. This regulation allows states to establish utilization control procedures that require approval of prescriptions for the drug by prior authorization before it is dispensed. 42 U.S.C. 1396r-8(d)(5).

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." 42 U.S.C. § 1396r-8(g)(1)(A).

MHD publishes its approval criteria for DAAs; a medical provider submits a prescription for a patient diagnosed with HCV and a clinical consultant reviews the request to determine whether the prescription is appropriate, medically necessary,

and not likely to result in adverse medical results. The Centers for Medicare & Medicaid Services ("CMS") has noted that states have the discretion to establish utilization controls on the coverage of DAAs, such as preferred drug lists and use of prior authorization processes, the practices must be consistent with the Act, and states' "limitations should not result in the denial of access to effective, clinically appropriate, and medically necessary treatments using DAAs." (Doc. 71, ¶ 27).

"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." *Walsh,* 538 U.S. at 685 (Justice O'Connor concurrence in part and dissent in part on other grounds). States are allowed to limit a prescription drug benefit to those who need it most while conserving state resources. *Id.* ("A State accordingly may impose prior authorization to reduce Medicaid costs.").

Plaintiffs' claims in Counts I, II, III and IV, that they are entitled to treatment with DAAs and MHD is violating the Medicaid Act by not approving their request for them, all stem from the same alleged root cause – that application of MHD's approval criteria established as a utilization control procedure, both allowed and required by 42 U.S.C. § 1396r-8, deprive them of their right to desired Medicaid benefits.

"Although [the Medicaid Act] does not require States to provide funding for all medical treatment falling within ... categories [of medical services], it does require that state Medicaid plans establish 'reasonable standards ... for determining ... the extent of medical assistance under the plan which ... are consistent with the objectives of [the Medicaid Act].' " *Beal v. Doe*, 432 U.S. 438, 441 (1977) (quoting 42 U.S.C. § 1396a(a)(17) (1970)). Regarding the particular medical assistance at issue here, covered outpatient drugs, the Medicaid Act at 42 U.S.C. § 1396a(a)(54) requires that MHD's plan for medical assistance must comply with § 1396r-8. Thus, Plaintiffs' claims all challenge MHD's compliance with the requirements of § 1396r-, and whether MHD's plan establishes reasonable standards for compliance.

The Supreme Court has interpreted § 1983 to create a cause of action only for violations of federal laws that "manifest [ ] an unambiguous intent to confer individual rights." *Gonzaga Univ. v. Doe*, 536 U.S. 273, 280 (2002). Federal laws that merely set standards on the basis of which states may receive federal funding, for example, but that do not create specific rights for individuals, are not enforceable by a civil action under § 1983. *Id.* at 283.

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 the 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 v. Freestone*, 520 U.S. 329, 340 (1997)). 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).

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. Accord, *Davis v. Shah*, 821 F.3d 231 (2nd Cir. 2016); *Watson v. Weeks*, 436 F.3d 1152, 1162 (9th Cir. 2006); *Hobbs ex rel. Hobbs v. Zenderman*, 579 F.3d 1171, 1182 (10th Cir. 2009). The Act's reasonable standards provision addresses a state's general administrative duties under the Act, rather than defining individual beneficiaries' entitlements under that program, so does not contain the type of rights-creating language necessary to confer a private cause of action. *Lankford*, 451 F.3d at 509, See also, *Armstrong,* 135 S.Ct. at 1387.

Similarly, 42 U.S.C. § 1396r-8, enacted as part of Congress' Omnibus Reconciliation Act in 1990, addressing rebate agreements amongst the Secretary of Health and Human Services, drug manufacturers, and states, is not enforceable by

a civil action under § 1983. The legislation gives states permission to create Drug Utilization Review (DUR) boards and preferred drug lists (PDLs) to manage state specific drug purchasing. The rebate agreement includes permissible restrictions on provision of covered drugs through the states' establishment of utilization control procedures including prior authorization requiring approval before prescription drugs are covered and paid for. § 1396r-8(d).

As such, the statute is in the nature of a contract regarding payment for and utilization of prescription drugs ("Spending Clause legislation"). "[T]he 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." *Armstrong,* 135 S.Ct at 1387. 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.

Plaintiffs cannot demonstrate an unambiguous intent to confer an individual right to prescription drug benefits or a judicial remedy to satisfy the *Blessing* test within § 1396r-8. When the statute references the states' obligation to assure that prescriptions are appropriate, medically necessary, and effective, the statue sets out regulations concerning limitations, restrictions, and reviews of prescriptions to screen for potential drug therapy problems, fraud, abuse, gross overuse, and inappropriate or medically unnecessary care. § 1396r-8(g). Prior authorization is acknowledged as a procedural obstacle to Medicaid beneficiaries' access to

prescription drug benefits. *Walsh*, 538 U.S. at 685. The agreement amongst HHS, the manufacturers, and the states may benefit individuals in a vague and amorphous way, but not sufficient for judicial enforcement. See, *Lankford*, 451 F.3d at 509. When Congress enacted 42 U.S.C. § 1396r-8, there was no congressional intent expressed within the legislation to create individually-enforceable federal rights or remedies.

"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*, 520 U.S. at 341. MHD is required by § 1396a(a)(54) to comply with § 1396r-8. Section 1396r-8 is a comprehensive enforcement scheme for coverage of prescription drug benefits which impliedly eliminates a private right of action under § 1983 in this case. Thus, the question whether MHD is in compliance with 42 U.S.C. § 1396r-8, enacted pursuant to Congressional spending power, is not addressed through a private right of action but rather an action by the federal government to terminate the funds provided to the state.[4] See, *Lankford*, 451 F.3d at 508.

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[4] Plaintiffs' reliance on *Weaver v. Reagen*, 886 F.2d 194 (8th Cir. 1989), is misplaced as Weaver is distinguishable as a matter of law in that the legislation at issue, 42 U.S.C. § 1396a(a)(54) requiring compliance with § 1396r-8, enacted as part of the Omnibus Budget Reconciliation Act of 1990, introduced a uniform regulatory framework not previously applied to states in regard to prescription drug coverage under the Medicaid Act.

Furthermore, the covered outpatient drug program is optional and therefore not mandatory, as required to satisfy the third prong under *Blessing*. According to 42 U.S.C. § 1396r-8 the "mandatory" requirement to receive the federal funds is that the state must enter into a state plan with HHS that is satisfactory to HHS. The state plan gives flexibility to the state and federal government to allow states to administer programs. Section 1396r-8 allows the state plan to establish the regulatory framework within which to determine clinical appropriateness, medical necessity, and effectiveness; the federal statute does not impose specific standards regarding those determinations.

For these reasons, 42 U.S.C. § 1396r-8 does not meet any of the three prongs of the *Blessing* test and does not confer upon Plaintiffs a private right of action enforceable under § 1983.

Considered through the prism of Plaintiffs' overall complaint, that MHD's prior approval criteria improperly exclude Plaintiffs from obtaining requested DAAs, Plaintiffs' Counts I, II, III, and IV regarding availability, comparability, reasonable promptness, and ascertainable standards are not enforceable under § 1983. Plaintiffs' claims for relief, asserted under 42 U.S.C. §§ 1396a(a)(10)(A), 1396(d)(a), 1396a(a)(10)(B), 1396a(a)(8), 1396a(a)(17), and the Fourteenth Amendment cannot be divorced from 42 U.S.C. §§ 1396da(a)(54) and 1396r-8 regarding specific regulation for covered outpatient drugs.

1. Count I should be dismissed as a matter of law.

Count I asserts a claim denominated "Violations of Medicaid Entitlement to Appropriate Amount, Duration, and Scope of Treatment," and states that Plaintiffs are being excluded from medically necessary treatment as required by both 42 U.S.C. § 1396a(a)(10)(A) and 42 U.S.C. § 1396d(a)(12). (Doc. 71, ¶ 105). Plaintiffs assert in the body of the complaint that "medical assistance" is defined in § 1396a(a)(10)(A) as "payment of part or all of the cost of … care and services" and Missouri has chosen to provide prescription drugs pursuant to § 1396d(a)(12). (Doc. 71, ¶¶ 22-23). Plaintiff alleges in Count I that, pursuant to these two provisions of the Act, MHD is violating their right to payment for prescription drug coverage.

However, the source of Plaintiffs' claim cannot be isolated to those two provisions because prescription drugs are addressed further in the Act and in Plaintiffs' complaint. Within the body of the complaint, Plaintiffs also correctly cite § 1396da(a)(54) wherein the Act "requires states' coverage of prescription drugs to comply with the requirements of 42 U.S.C. § 1396r-8" (Doc. 71, ¶ 24), acknowledge states can impose utilization review "techniques" on drugs pursuant to § 1396r-8(d)(5) (Doc. 71, ¶ 26), and note that CMS recognizes prior authorization can limit approval for DAAs (Doc. 71, ¶ 27). Thus, Plaintiffs' claim that MHD violates the Act at § 1396a(a)(10)(A) and § 1396d(a)(12) is necessarily constrained by the other sections of the Act pertaining to prescription drug coverage, and particularly by the congressional intent evinced in 42 U.S.C. § 1396r-8, which does not establish a private right of action. See, *Gonzaga,* 536 U.S. at 284.

Moreover, the effect of 42 U.S.C. § 1396r-8 is directly counter to a claim brought for violation of an entitlement to amount, duration, and scope of treatment pursuant to § 1396a(a)(10)(A). Those limitations are expressly allowed by § 1396r-8 for MHD's coverage of outpatient drugs.

Count I, although asserted pursuant to 42 U.S.C. § 1396a(a)(10)(A) and 42 U.S.C. § 1396d(a)(12), is necessarily an attempt to assert a private right of action regarding how MHD manages its prescription drug benefits, and is not sufficient to state a claim for relief. Consequently, Count I should be dismissed as a matter of law.

2. Count II should be dismissed as a matter of law.

Plaintiffs' Count II fails to state a claim for relief for the same reasons. Plaintiffs' Count II asserts MHD discriminates among similarly situated Medicaid beneficiaries (those who are diagnosed with HCV) on the basis of prior authorization approval criteria in violation of 42 U.S.C. § 1396a(a)(10)(B)(i). (Doc. 71, ¶ 107). Again, utilization control procedures which include prior authorization are a legally sanctioned method to implement federal law to provide access to prescription drugs when they are medically necessary, appropriate, and effective.

A claim that some Medicaid beneficiaries with HCV meet the approval criteria to obtain coverage for DAAs and others do not is not a proper basis for a "comparability" challenge. Plaintiffs must identify similarly situated beneficiaries – others who do not meet approval criteria – who are treated differently than them – receiving DAAs from MHD – to make an actionable claim. Those facts are not

asserted here. Instead Plaintiffs argue MHD discriminates against them, as Medicaid beneficiaries diagnosed with HCV, by approving DAAs for others diagnosed with HCV but not them, based on a specified amount of impairment. This distinction in treatment is allowed. 42 U.S.C. § 1396r-8; *White v. Beal*, 555 F.2d 1146, 1152 (3rd Cir. 1977).

Plaintiffs' challenge to that alleged discrimination regarding who receives coverage for outpatient drugs, alleging approval criteria are not based on certain standards (Doc. 71, ¶ 107), is necessarily 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. As explained above, such a challenge cannot be sustained as a private right of action. See, *Gonzaga,* 536 U.S. at 284.

Plaintiffs' claim for violation of 42 U.S.C. § 1396a(a)(10)(B)(i) must be considered in light of §§ 1396a(a)(54) and 1396r-8 and thus Plaintiffs cannot assert a private right of action under § 1983. Consequently, Count II should be dismissed for failure to state a claim as a matter of law.

3. Count III should be dismissed as a matter of law.

Plaintiffs' Count III fails to state a claim for relief for the same reasons. Plaintiffs' Count III asserts MHD's prior authorization approval criteria require them to wait for treatment in violation of 42 U.S.C. § 1396a(a)(8). (Doc. 71, ¶ 109). Prior authorization is a legally sanctioned method for determining which Medicaid beneficiaries receive approval for certain covered outpatient drugs. Plaintiffs have

not suggested that they are barred from submitting a future request when their request could result in approval. Moreover, Plaintiffs must meet the approval criteria in order to enforce § 1396a(a)(8) as a private right of action where the state plan allows MHD to limit access to covered outpatient drugs by establishing utilization control procedures. See, *Bertrand ex rel. Bertrand v. Maram*, 495 F.3d 452, 457 (7th Cir. 2007).

Plaintiffs' argument that MHD improperly denies their request for coverage for outpatient drugs when they do not meet approval criteria because they must wait until they do meet approval criteria (Doc. 71, ¶ 109) 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. As explained above, such a challenge cannot be sustained as a private right of action. See, *Gonzaga,* 536 U.S. at 284.

Plaintiffs' claim for violation of 42 U.S.C. § 1396a(a)(8) must be considered in light of §§ 1396a(a)(54) and 1396r-8 and thus Plaintiffs cannot assert a private right of action under § 1983. Consequently, Count III should be dismissed for failure to state a claim as a matter of law.

4. Count IV should be dismissed as a matter of law.

Plaintiffs' Count IV asserts a violation of the Fourteenth Amendment but is denominated a claim for "Ascertainable Standards" and uses the same words as those in 42 U.S.C. § 1396a(a)(17). The claim does not allege relief pursuant to 42 U.S.C. § 1983. However, in that the language used explicitly asserts a private right

of action pursuant to § 1983, the claim for "reasonable, ascertainable, non-arbitrary standards and procedures for determining eligibility for and the extent of medical assistance provided (Doc. 71, ¶ 111) 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. As explained above, such a challenge cannot be sustained as a private right of action. See, *Gonzaga,* 536 U.S. at 284; *Lankford*, 451 F.3d at 509.

Plaintiffs' claim for violation of 42 U.S.C. § § 1396a(a)(17) must be considered in light of §§ 1396a(a)(54) and 1396r-8 and thus Plaintiffs cannot assert a private right of action under § 1983. Consequently, Count IV should be dismissed for failure to state a claim as a matter of law.

If, however, Plaintiffs are alleging a Fourteenth Amendment claim for procedural due process, in that MHD's approval criteria for DAAs are deficient because they are "vague, subjective, arbitrary and secret," then the due process claim fails as well, even if Plaintiffs had properly asserted it as a § 1983. It is an "absence of *any* ascertainable standard for inclusion and exclusion" that offends the Due Process Clause. *Smith v. Goguen,* 415 U.S. 566, 578 (1974) (emphasis added); see also, *Hobbs ex rel. Hobbs v. Zenderman*, 579 F.3d 1171, 1185 (10th Cir. 2009) (courts have found benefits determinations to be insufficiently guided by standards only when agencies acted absent any ascertainable limit on eligibility).

Here, Plaintiffs refer the Court to MHD's approval criteria stating, "Defendants have adopted coverage criteria with respect to when and under what

conditions it will approve Harvoni and other similar DAAs for coverage under Missouri's Medicaid program that are more restrictive that the national standards of care." (Doc. 71, § 45). This description alone is sufficient to satisfy the Court that MHD has ascertainable standards; Plaintiffs' cannot state a claim that MHD acts with no ascertainable standards where the cited webpage references an 8 page document. *Id.* Again, Count IV should be dismissed for failure to state a claim as a matter of law.

B. Plaintiffs' claim under the ADA fails as a matter of law.

Plaintiffs' Count VI asserts a claim under the ADA, alleging Plaintiffs are treated differently than similarly situated people with the same disability (HCV) and request "reasonable modifications be made to state programs to avoid discrimination on the basis of disability." (Doc. 71, ¶ 118). This claim is essentially the same as the "comparability" claim, using the ADA as a vehicle to bring the claim, while requesting the same relief. For the reasons stated above in regard to Counts I, II, III, and IV, the claim asserted is necessarily 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, and must be dismissed.

In 2005, the Eighth Circuit conclusively established that ADA claims cannot be based on medical treatment decisions. See *Burger v. Bloomberg*, 418 F.3d 882, 883 (8th Cir. 2005) ("We agree with two other circuits that have recently concluded

that a lawsuit under the Rehab Act or the Americans with Disabilities Act . . . cannot be based on medical treatment decisions."). Courts have rejected attempts to secure a certain level of care from the state under the ADA because it is not a court's role "to determine what Medicaid benefits a state must provide." *Rodriguez v. City of New York*, 197 F.3d 611, 618 (2d Cir. 1999). See, *Alexander v. Choate*, 469 U.S. 287, 303 (1985) (holding that Medicaid "benefits" under the Rehabilitation Act [and hence ADA] are "the individual services offered" not the "amorphous objective of 'adequate health care' ").

Plaintiffs allege MHD discriminates against them because the state allocates limited resources among disabled individuals through utilization control procedures required by 42 U.S.C. §§ 1396a(a)(54) and 1396r-8. To make a claim under Title II of the ADA, a plaintiff must show (1) he is a person with a disability as defined by statute; (2) he is otherwise qualified for the benefit in question and (3) he was excluded from the benefit due to discrimination based upon disability. *Randolph v. Rodgers*, 170 F.3d 850, 858 (8th Cir. 1999). Here, 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*. They allege no impermissible distinction between services provided to those who are disabled and those who are not. Plaintiffs allege MHD must "make reasonable modifications to policies, practices, and procedures" (Doc. 71, ¶ 41) to accomplish Plaintiffs' purpose – approval criteria they will meet for coverage of DAAs – because they do not meet such criteria currently. But Medicaid programs

do not guarantee that each recipient will receive that level of health care precisely tailored to his or her particular needs. *Alexander*, 469 U.S. at 287.

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.

IV. Conclusion

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

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 June 20, 2017 to be served by operation of the Court's electronic filing system upon all parties.

/s/ Colleen Joern Vetter
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Assistant Attorney General