UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

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

DEFENDANTS' SUGGESTIONS IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT

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STATEMENT OF UNCONTROVERTED MATERIAL FACTS

Pursuant to L.R. 56.1, the following uncontested material facts support Defendants' Motion for Summary Judgment:

The FDA approves Mavyret as a breakthrough therapy to treat HCV.

1. The development of direct-acting antiviral drugs ("DAAs") to treat the Hepatitis C virus ("HCV") is rapidly evolving. This evolution includes recent approvals of new breakthrough therapy DAA drugs to treat HCV. (Ex. A1 to Callaway Declaration; Ex. C, Dr. Bacon testimony, Mar. 10, 2017 Evid. Hearing Trans. 71:2-10; Ex. D, Mark Roaseau Dep., 75:12-76:9).

2. On August 3, 2017, after this litigation was filed, MO HealthNet Division ("MHD") was notified that the U.S. Food and Drug Administration ("FDA") approved the drug Mavyret to treat HCV. (Ex. A, Calloway Dec., ¶5).

3. The FDA granted Mavyret "breakthrough therapy" status. (Ex. B, Roaseau Dec., ¶16).

4. "Breakthrough therapy" is an FDA designation used on drugs with significant clinical advantages subject to a shorter administrative review process by the FDA. (Dr. Bacon testimony, Mar. 10, 2017 Evid. Hearing Trans. 71:2-10).

5. Mavyret is available for qualifying MHD beneficiaries for whom an 8-week, 12-week, or 16-week treatment cycle is clinically appropriate. (Ex. A1 to Calloway Dec.).

6. Prior to the FDA's approval of Mavyret, there were no agents on the preferred drug list indicated for an 8-week treatment cycle. (Ex. A3 to Calloway Dec., preferred drug list updated February 24, 2017; (Ex. B, Roaseau Dec., ¶17).

7. Mavyret was approved by the FDA to treat patients having any of six recognized genotypes of HCV (genotypes 1, 2, 3, 4, 5, and 6), without cirrhosis or with mild (compensated) cirrhosis (Child-Pugh A). (Ex. B, Roaseau Dec., ¶16).

8. Mavyret is also indicated for the treatment of adult patients with HCV genotype-1 infection, who have been previously treated with an HCV regimen containing an HCV NS5A inhibitor or an NS4/4A protease inhibitor, but not both. (Ex. B, Roaseau Dec., ¶16).

9. Mavyret was introduced to the market at costs significantly below the costs of other DAAs approved to treat HCV. (Ex. B, Roaseau Dec., ¶17).

The FDA approves Vosevi as a breakthrough therapy to treat HCV.

10. On July 18, 2017, after this litigation was filed, after this litigation was filed, MHD was notified that the FDA approved the drug Mavyret to treat HCV. (Ex. B, Roaseau Dec., ¶14).

11. The FDA granted Vosevi "breakthrough therapy" status. (Ex. B, Roaseau Dec., ¶15).

12. Vosevi is available for qualifying MHD beneficiaries for whom a 12-week treatment cycle is clinically appropriate. (Ex. A1 to Calloway Dec.; (Ex. B, Roaseau Dec., ¶15).

13. Vosevi was approved by the FDA to treat patients with any of six recognized genotypes of HCV (genotypes 1, 2, 3, 4, 5, and 6), who do not have cirrhosis or who have mild (compensated) cirrhosis (Child-Pugh A), and who have been previously treated with an HCV regimen containing an NS5A inhibitor. (Ex. B, Roaseau Dec., ¶15).

MO HealthNet adds Mavyret and Vosevi to its preferred drug list.

14. On September 21, 2017, MO HealthNet Division ("MHD") issued a Preferred Drug List Criteria Proposal for therapy for patients with HCV. (Ex. A, Calloway Dec., ¶6; Ex. A1 to Calloway Dec.; Ex. B, Roaseau Dec., ¶18).

15. The availability of new DAAs like Mavyret and Vosevi prompted, in part, MHD to issue the proposal. (Ex. A, Calloway Dec., ¶6; Ex. A1 to Callway Dec.).

16. This proposal makes various changes to MHD's prior authorization review and approval process for HCV therapy. (Ex. A, Calloway Dec., ¶6; Compare Ex. A1 to Calloway Dec. *with* Ex. A2 to Calloway Dec.).

17. These changes include additions of Mavyret and Vosevi to Missouri's preferred drug list for HCV therapy and modifications to criteria considered by MHD in reviewing and approving DAAs for patients diagnosed with HCV. (Ex. A1 to Calloway Dec.).

18. Prior to the criteria change, Zepatier was the only DAA placed on the preferred drug list for treatment for HCV, and was available for qualifying MHD beneficiaries for whom a 12-week or 16-week treatment cycle is clinically appropriate. (Ex. A2 and A3 to Calloway Dec.).

19. Zepatier is approved by the FDA to treat patients with only certain genotypes of HCV (genotypes 1 through 4), who do not have cirrhosis or who have mild (compensated) cirrhosis (Child-Pugh A). (Ex. B, Roaseau Dec., ¶25).

20. Zepatier remains available on the preferred drug list for qualifying patients for whom a 12-week or 16-week treatment cycle is clinically appropriate. (Ex. A1 to Calloway Dec.).

Under MO HealthNet's new criteria, DAAs are available regardless of fibrosis score.

21. Under the new prior authorization criteria, a patient diagnosed with HCV who has a physician recommendation for HCV treatment may be approved by MHD for treatment with DAAs regardless of the patient's Metavir fibrosis score. (Ex. B, Roaseau Dec., ¶26).

22. The Metavir fibrosis scores is a system for evaluating the level of fibrosis in a patient's liver. The Metavir fibrosis score ranges from F0 through F4. A Metavir fibrosis score

of F0 indicates that the patient does not have fibrosis of the liver. On the other end of the spectrum, a Metavir fibrosis score of F4 indicates that the patient has cirrhosis of the liver. (Ex. B, Roaseau Dec., ¶27).

23. Under the prior criteria, a patient's Metavir fibrosis score was considered by MHD in conjunction with other criteria to include, but not be limited to a patient's other diseases (co-morbidities) to determine appropriateness of treatment. (Ex. B, Roaseau Dec., ¶31; Ex. D, Mark Roaseau Dep., 18:9-21:13).

24. Under the new criteria, the Metavir fibrosis score is used by MHD *only* as a measure of scarring and progression of the disease of the liver in order to approve which *type* of DAA may be appropriate for a particular patient. (Ex. B, Roaseau Dec., ¶32 ,33).

25. Under the new criteria, all patients over the age of 18 diagnosed with HCV will be approved for treatment with a DAA medication. (Ex. B, Roaseau Dec., ¶32 ,33).

26. Under the new criteria, beneficiaries are required to submit a fibrosis score in the MHD prior authorization to insure the specific drug approved for treatment is appropriate based upon FDA approved prescribing information. (Ex. B, Roaseau Dec., ¶21).

MO HealthNet's new criteria proposal was developed relying on AASLD guidelines on consideration of fibrosis score.

27. The criteria proposal dated September 21, 2017, was presented to MHD's Drug Prior Authorization Committee ("PA Committee") on September 21, 2017. (Ex. A, Calloway Dec., ¶7; Ex. B, Roaseau Dec., ¶19).

28. At the September 21, 2017, meeting, the PA Committee voted unanimously to recommend that MHD implement the new criteria. (Ex. A, Calloway Dec., ¶7; Ex. A4 to Calloway Dec.).

29. The criteria proposal was presented to MHD's Drug Utilization Review Board ("DUR Board") on October 18, 2017. (Ex. A, Calloway Dec., ¶8; Ex. B, Roaseau Dec., ¶21; Ex. B4 to Roaseau Dec.).

30. At the October 18, 2017, meeting, the DUR Board voted unanimously to recommend that MHD implement the new criteria. (Ex. A, Calloway Dec., ¶8; Ex. B4 to Roaseau Dec.).

31. The new criteria became effective on November 1, 2017. (Ex. A, Calloway Dec., ¶9; Ex. A1 to Calloway Dec.; Ex. B, Roaseau Dec., ¶21; Ex. B1 to Roaseau Dec.).

32. MHD's change to the former criteria was prompted, in part, due to the changing marketplace for DAA treatment for HCV including the introduction of Mavyret and Vosevi. (Ex. A, Calloway Dec., ¶6; Ex. A1 to Callway Dec.).

33. MHD's referred to and relied on, in part, AASLD/IDSA's guidelines regarding the consideration of fibrosis scores in evaluating and approving DAA treatment for patients with HCV. (Ex. B1 to Roaseau Dec. and Ex. A1 to Calloway Dec., *see* citing reference number 1).

MO HealthNet eliminates requirements that a provider submit evidence that a patient has abstained from alcohol or illicit drugs.

34. Under the prior policy, MHD generally required that providers submit clinical evidence of three months of negative urine and drug screens for alcohol or illicit drug abuse for a patient, though that requirement could be waived in some circumstances. (Ex. B, Roaseau Dec., ¶24; Ex. B2 to Roaseau Dec.).

35. As of February 24, 2017, MHD no longer requests or requires clinical evidence of urine and drug screens for alcohol or illicit drug abuse when reviewing a prior authorization request for HCV treatment. (Ex. B, Roaseau Dec., ¶24).

36. Each Plaintiff in this case has been sent a notice informing them of the change to

MHD's prior authorization criteria, of the change to the preferred drug list, and that they have the ability to apply for DAA treatment under the new criteria. (Ex. B, Roaseau Dec., ¶36; Ex. B6 and B7 to Roaseau Dec.).

SUMMARY OF THE ARGUMENT

Defendants Steve Corsi, named in his official capacity as Acting Director of the Missouri Department of Social Services, and Jennifer Tidball, named in her official capacity as Acting Director of the MO HealthNet Division, move for summary judgment on all of Plaintiffs' claims. No genuine issues of material fact remain, and given recent developments outside this litigation, the case is moot.

Effective November 1, 2017, MO HealthNet Division ("MHD") has implemented a modified preferred drug list and prior authorization criteria as a condition for approval of coverage or payment for DAAs for Medicaid recipients diagnosed with HCV. This criteria change was prompted by the FDA's recent approval of two new DAAs to treat HCV, which dramatically changes the type and cost of treatment options for HCV. Significantly, FDA approval of the new DAAs for treatment of every HCV genotype has prompted MHD to include these DAAs as preferred drugs and to update approval criteria, thereby changing the former criteria that Plaintiffs claim operated as a *de facto* cut-off to exclude DAA treatment based on a patient's fibrosis score. Under the new criteria, a patient's fibrosis score is not determinative—either by itself or in conjunction with other health indicators—on whether DAAs will be approved to treat a patient's HCV.

The rapidly evolving HCV treatment market and resulting change to MHD's prior authorization criteria moots this case. The criteria that Plaintiffs sought to be changed was, in fact, changed through MHD's regular and ongoing review. That criteria change obviates virtually all of Plaintiffs' requested declaratory and injunctive relief, and they no longer can meet their burden to prove a live case or controversy under Article III. In addition or in the alternative, this Court should exercise its inherent discretion to declare the case moot under the prudential mootness doctrine because the changing circumstances of this case eliminates the need for an adjudication on the merits.

To the extent the Court decides that this case is not moot under either theory, Plaintiffs do not have a private right of action to bring their case in federal court as a matter of law. In light of the Eighth Circuit's recent decision in *Does v. Gillespie*, 867 F.3d 1034 (8th Cir. 2017), this Court should reexamine its prior orders denying Defendants' motions to dismiss raising the private right of action argument. Finally, by refusing to appeal their denials of benefits, Plaintiffs have not exhausted their adequate administrative and state-court remedies, and so this Court should abstain from exercising jurisdiction under the *Younger* doctrine.

For each of these reasons, Defendants are entitled to summary judgment.

ARGUMENT

Standard of Review

Summary judgment is appropriate if the facts, viewed in the light most favorable to the non-moving party, show "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *Anda v. Wickes Furniture Co., Inc.*, 517 F.3d 526, 531 (8th Cir. 2008). A summary judgment motion is not disfavored under the law, as it allows for a "just, speedy and inexpensive determination of [the] action." *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986). In moving for summary judgment, the defendants do not bear the burden of coming forward with evidence negating the plaintiff's claims. *Id.* at 323. Rather, a defendant may discharge its burden under Rule 56 by pointing out to the Court that there is an absence of evidence to support the plaintiff's case. *Id.* at 325. Summary judgment is particularly appropriate when, as here, the unresolved issues are primarily legal rather than factual and where the plaintiff has failed to establish a factual dispute on an essential element of his case. *Id.* at 531; *see also Uhl v. Swanstrom*, 79 F.3d 751, 754 (8th Cir. 1996).

I. Plaintiffs' claims for injunctive and declaratory relief are moot under Article III and must be dismissed.

Plaintiffs' Amended Complaint alleges six counts against Defendants and ultimately seeks declaratory relief, injunctive relief, and attorneys' fees. As a threshold matter, Defendants maintain that MHD's former prior authorization policy—the "allegedly unlawful conduct"—was clinically appropriate and consistent with federal law's grant of discretion to states to "subject to prior authorization *any* covered outpatient drug." 42 U.S.C. § 1396r-8(d) (emphasis added); *see also* 42 U.S.C. § 1396a(a)(17). "A State accordingly may impose prior authorization to reduce Medicaid costs." *Pharmaceutical Research and Mfrs. of America v. Walsh*, 538 U.S. 644, 651-52 (2003) (O'Connor, J., concurring in part, dissenting in part). Missouri's Medicaid regulations specifically allow for the consideration of costs in developing a state Medicaid plan consistent with federal law. 13 CSR 70-20.200(4) ("When implementing [prior authorization criteria], Missouri-specific data shall include the consideration of use and cost data, pharmacoeconomic information and prudent utilization of state funds, and shall include medical and clinical criteria."). Plaintiffs have not challenged Missouri's Medicaid regulations. And, in any event, Defendants' former criteria never treated a patient's fibrosis score as outcome-determinative in deciding whether to approve DAA treatment for HCV, given that all reviews are conducted individually and take into account many variables. But given that these are fact-bound issues that Plaintiffs have contested throughout litigation, Defendants expressly reserve the right to defend the case at trial in the event that the Court denies this motion for summary judgment.

But this case should never go to trial, because even if Plaintiffs were to prevail on the merits of their claims, any relief the Court might grant would be *at minimum* duplicative in light of the recent change in DAA market conditions leading to FDA's new approval of DAAs to treat HCVs and the resulting change in MHD prior authorization criteria. Because there is no effectual relief that the Court can grant Plaintiffs, this case is moot. "The exercise of judicial

power under Art. III of the Constitution depends on the existence of a case or controversy." *Ringo v. Lombardi*, 677 F.3d 793, 796 (8th Cir. 2012). "[A]n actual controversy must be extant at all stages of review, not merely at the time the complaint is filed." *Id.* (alteration in original). Therefore, "[w]hen a case . . . no longer presents an actual, ongoing case or controversy, the case is moot and the federal court no longer has jurisdiction to hear it." *Neighborhood Transp. Network, Inc. v. Pena*, 42 F.3d 1169, 1172 (8th Cir. 1994).

"[P]laintiffs must allege personal injury fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief." *Phelps–Roper v. City of Manchester, Mo.*, 697 F.3d 678, 687 (8th Cir. 2012) (internal quotation marks and citation omitted). If a plaintiff's rights would not be affected by the requested relief, thus making it impossible for the court to grant effectual relief, there is no case or controversy for the court to adjudicate. *See Knox v. Serv. Employees Int'l Union, Local 1000*, 567 U.S. 298, 307 (2012). Events that occur after a lawsuit was filed can serve to moot a case. *See McCarthy v. Ozark Sch. Dist.*, 359 F.3d 1029, 1035 (8th Cir. 2004) (state legislature's change in the law after commencement of litigation mooted schoolchildren's religious-belief exemption under a mandatory immunization statute); *Smith v. Hundley*, 190 F.3d 852, 855 (8th Cir. 1999) (holding that an inmate's claims for declaratory and injunctive relief to improve conditions within the prison were rendered moot when he was transferred to a different facility and was no longer subject to those conditions).

The changing market conditions due to the FDA's approval of new DAAs to treat HCV and the ensuing modification to MHD's criteria for prior authorization are textbook examples of intervening events that moot a case, because Plaintiffs are "no longer in need of any protection from the challenged practice." *Camreta v. Greene*, 563 U.S. 692, 711 (2011). Plaintiffs had claimed that MHD's former prior authorization criteria excluded DAA coverage for patients with fibrosis scores of F0, F1 and F2 with genotypes 1, 2, and 4, fibrosis scores of F0 and for HCV

genotype 3. (Amd. Compl., ¶ 47). Assuming this were true for purposes of this motion, MHD's new criteria as recommended and approved by the PA Committee and DUR Board expressly eliminates consideration of a patient's fibrosis score as a denial criteria for a prior authorization request for HCV treatment. Ex. A5 to Calloway Declaration; Ex. B5 to Roaseau Declaration. In other words, if a physician recommends DAA treatment for HCV, under the new criteria a specific fibrosis score is not a threshold marker for approving or denying DAA treatment. Ex. A5 to Calloway Declaration; Exhibit B5 to Roaseau Declaration. . And a large portion of the relief sought by Plaintiffs is equitable in nature, which, if granted, would require Defendants to develop new criteria consistent with AASLD/IDSA Treatment Guidelines. However, MHD actually relied on these guidelines in developing the new criteria. *See* Ex. A1 to Calloway Dec.; Exhibit B1 to Roaseau Dec.

MHD's change to the prior authorization criteria is akin to cases where courts have found mootness based on postcommencement changes in legislation and administrative regulations. *See Burke v. Barnes*, 479 U.S. 361, 363 (1987) (mootness based on expiration of statute after litigation began); *McCarthy*, 359 F.3d at 1035-36 (mootness found where intervening legislative change "eliminate[s] the need for court action"); *Gulf of Maine Fisherman's All. v. Daley*, 292 F.3d 84, 88 (1st Cir. 2002) ("The promulgation of new regulations and amendment of old regulations are among such intervening events as can moot a challenge to the regulation in its original form."). Issuing new prior authorization criteria is a lengthy process that includes *two* public bodies charged with developing clinical criteria based on peer-reviewed medical literature—the PA Committee and the DUR Board. *See* 13 CSR 70-20.200(2). Similar to the process for administrative rulemaking, the PA Committee is required to publish notice of its meetings and criteria considered for change, hold a public hearing on the proposed change, and accept public comments. 13 CSR 70-20.200(6). And after the PA Committee issues a recommendation, the DUR Board must consider the recommendation and choose whether to

approve it, and the body may accept public comment. 13 CSR 70-20.200(7). That process was followed in issuing the new criteria. *See Ex. A,* Calloway Dec., ¶ 10; Ex. B. Roaseau Dec., ¶ 10.

Moreover, though exceptions to the mootness doctrine exist, none of those exceptions preclude mootness here. "When a law has been amended or repealed, actions seeking declaratory or injunctive relief for earlier versions are generally moot unless the problems 'are capable of repetition yet evad[ing] review.'" *Phelps-Roper*, 697 F.3d at 687 (citing *McCarthy*, 359 F.3d at 1036). "One condition that must exist before this exception applies is a reasonable expectation that the same complaining party will be subject to the same action again." *McCarthy*, 359 F.3d at 1036 (internal citations and quotations omitted). There is not a reasonable expectation that Plaintiffs will, in fact, be subject to the same review criteria given the new universe of HCV treatment options and changes to MHD's prior authorization criteria. In fact, the FDA granted Mavyret and Vosevi "breakthrough status," and Mavyret was introduced to the market at a fraction of the cost of existing DAAs. *See* Ex. B, Roaseau Dec., ¶¶ 15 and 16. These changes are not temporal; rather, they represent fundamental shifts in a rapidly evolving market leading to responsive changes in public policy. It would be speculative for Plaintiffs to suggest that they would be subject to the same prior authorization criteria in place when the lawsuit was filed, and it would cut against powerful and deep-seated economic trends to suggest that the DAA treatment market will devolve to become as inflexible as it had been. *See id.* (rejecting as speculative a claim that the legislature might repeal a statute absent court order); *see also Brown v. Buhman*, 822 F.3d 1151, 1170 (10th Cir. 2016) (county prosecutor's policy change after lawsuit was filed rendered case moot, and there was no credible threat that the prosecutor would resurrect the former policy).

Moreover, the "voluntary cessation" doctrine does not defeat mootness, as that doctrine is just a "specialized form" of the general exception just discussed. *McCarthy*, 359 F.3d at 1036. Underpinning the voluntary cessation rule is a concern that the "defendant [will] engage in

unlawful conduct, stop when sued to have the case declared moot, then pick up where he left off, repeating this cycle until he achieves all his unlawful ends." *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013). As such, "the question the voluntary cessation doctrine [poses is]: Could the allegedly wrongful behavior reasonably be expected to recur?" *Id.* at 92.

But just because it is the defendants—as parties to a lawsuit—who ceased the challenged conduct, this does not necessarily imply that they will revert back to that conduct. This is especially true where, as here, the rapidly-evolving market conditions that led the FDA to approve new breakthrough DAA drugs to be introduced into the market prompted MHD's change in the prior authorization criteria. Again, where the challenged conduct was changed by legislation or by administrative regulations—a direct parallel to MHD's change to prior authorization criteria—courts regularly find it unlikely that the challenged conduct will recur. *See McCarthy*, 359 F.3d at 1036; *see also Buhman*, 822 F.3d at 1170 (governmental policy change rendered case moot).

In addition, a party's historical conduct in reverting to unlawful policies as soon as litigation concludes, in an attempt to evade jurisdiction on mootness grounds, can indicate a likelihood of the party continuing the challenged conduct. *See Mesquite v. Aladdin's Castle, Inc.*, 455 U.S. 283, 289 (1982) (declining to find mootness when city had previously repealed and later reenacted the same objectionable language in a statute in response to a state court judgment). Plaintiffs have not made a showing that MHD has historically engaged in similar jurisdiction-evading conduct by changing prior authorization criteria and adding new medications to the preferred drug list, nor can they. To that end, MHD employees have expressly concluded that its comprehensive review and subsequent criteria changes would have occurred regardless of any litigation. This is because these changes were in reaction to the financial and clinical opportunities created following FDA approval of two, new DAAs prompting increased treatment resources and competition to renegotiate supplemental rebates by drug

distributors. (Calloway Dec., ¶¶ 5-7). In the face of the rapidly evolving market and new and less expensive DAAs to treat HCV—such as Mavyret—it is not likely that MHD will revert back to its former prior authorization criteria and preferred drug list. *See* Ex. B, Calloway Dec. ¶¶5-7. Indeed, the more likely course is for MHD to continue to make DAAs available as the cost of those drugs inevitably comes down and their availability increases.

In fact, the scope of the new policy changes is arguably greater than what Plaintiffs had requested as relief. The preferred drug list for DAA treatment for HCV has expanded with the addition of Mavyret. Mavyret has an 8-week treatment cycle, whereas before there were no agents on the preferred drug list with a treatment cycle less than 12 weeks. Plaintiffs effectively have "relief greater than that requested in the present litigation." *McCarthy*, 359 F.3d at 1036 (finding mootness where the state "acted quickly for the benefit of the Schoolchildren and other citizens."). "Most cases that deny mootness following government officials' voluntary cessation rely on clear showings of reluctant submission by governmental actors and a desire to return to the old ways." *Buhman*, 822 F.3d at 1167 (10th Cir. 2016) (internal citations, quotations, and brackets omitted). MHD's mission is to provide medical assistance on behalf of needy persons. *See* § 208.001.2, RSMo. Plaintiffs can make no showing that MHD's policy change is a case of reluctant submission masking a desire to return to old ways. And the changing market conditions for DAA therapy for HCV and MHD's new prior authorization policy mean that Plaintiffs can access *at least* the same level of practical relief sought in their lawsuit.

Finally, Plaintiffs' request for attorneys' fees and costs cannot "save the case from mootness" when declaratory and injunctive claims no longer present a live case or controversy. *Hechenberger v. W. Elec. Co., Inc.*, 742 F.2d 453, 455 n.5 (8th Cir. 1984); *see also Lewis v. Continental Bank Corp.*, 494 U.S. 472, 480 (1990) ("This interest in attorney's fees is, of course, insufficient to create an Article III case or controversy where none exists on the merits.").

The Plaintiffs can submit a new request for prior authorization for treatment of their HCV with DAAs. It will be reviewed under the new criteria and in the context of a preferred drug list that has expanded treatment options. At this point, Plaintiffs no longer have a personal stake in the outcome of this case because the Court cannot grant any effectual relief.

II. In the alternative, this Court should exercise its inherent discretion to declare the case prudentially moot based on intervening changes in circumstances.

Even if this Court were to determine that there is still a live case or controversy under Article III, the significant change in market conditions for DAA therapy and subsequent change in MHD's prior authorization criteria supports declaring the case moot under the prudential mootness doctrine. Under this doctrine, "if a court has jurisdiction under Article III to decide a case, prudential concerns may militate against the use of judicial power," and "the court should treat the case as moot for prudential reasons." *Ali v. Cangemi*, 419 F.3d 722, 724 (8th Cir. 2005). Where "common sense or equitable considerations" justify "a decision not to decide a case on the merits." *In re AOV Indus., Inc.*, 792 F.2d 1140, 1147 (D.C. Cir. 1986); *see also Flast v. Cohen*, 392 U.S. 83, 97 (1968) (court may refuse to issue a decision on the merits of a case "confessedly within the Court's jurisdiction" given "policy rather than purely constitutional considerations."). Prudential mootness is often exercised in cases seeking "declaratory and injunctive relief if the controversy is so attenuated that considerations of prudence and comity for coordinate branches of government counsel the court to stay its hand, and to withhold relief it has the power to grant." *Chamber of Commerce v. U.S. Dep't of Energy*, 627 F.2d 289, 291 (D.C.Cir. 1980) (internal quotations omitted).

Resolving this case on the merits would require this Court to make detailed factual findings about the standard of care for treating HCV in a rapidly-evolving field. *See FSLIC v. Locke*, 718 F. Supp. 573 (W.D. Tex. 1989) (exercising prudential mootness because a resolution on the merits would "require enormous expenditures of time and resources by all the parties . . .

and by the Courts, but will serve no practical purpose."). This is not necessary given that MHD has modified its prior authorization criteria and added new drugs to the preferred drug list in response to market conditions. The Court cannot grant any meaningful relief. *See Quintero Cmty. Ass'n, Inc. v. Hillcrest Bank*, 2014 WL 1687165, at *5–6 (W.D. Mo. Apr. 29, 2014) (exercising prudential mootness where intervening changes resulted in the Court's inability to grant meaningful relief).

In addition, if the Court were to grant Plaintiffs' requested relief—which Defendants maintain has already been provided—the Court would effectively be ordering class-wide relief for all Medicaid beneficiaries, even though Plaintiffs expressly declined to bring their suit as a class action. Plaintiffs, as individual Medicaid beneficiaries, can submit a new prior authorization request for DAA treatment for HCV under the new criteria. Going to trial and adjudicating the case on the merits would be an unnecessary expenditure of judicial resources.

For these reasons, the Court should exercise its inherent discretion to declare the case prudentially moot.

III. Plaintiffs do not have a private right of action to enforce the Medicaid provisions of the Social Security Act under § 1983.

Defendants have previously asserted in their Motions to Dismiss that this case should be dismissed because Plaintiffs lack a private right of action under 42 U.S.C. § 1983 to enforce certain provisions of the Social Security Act (the "Act"). Three counts in Plaintiffs' amended Complaint—Counts I, II, and III—assert various violations of the Act, using § 1983 as a vehicle to bring those claims. For purposes of preservation, Defendants raise those arguments in this summary judgment motion. Critically, this Court should revisit the issue in light of the Eighth Circuit's recent decision in *Does v. Gillespie*, 867 F.3d 1034 (8th Cir. 2017), which was issued after the Court's denial of Defendants' second dismissal motion.

In August, the Eighth Circuit issued new authority that thoroughly discussed private rights of action in the context of § 1983 lawsuits. In *Gillespie*, Medicaid recipients brought a § 1983 suit against the Arkansas Medicaid agency alleging that the agency violated their rights under the Act to choose a certain healthcare provider. The Eighth Circuit held that Congress did not intend the Act to create an enforceable right. Just because the Act might ultimately provide benefits to healthcare recipients, that is not enough to create a right of action in the federal courts. *Id.* at 2039-40. The alleged "right" in that case was asserted under 42 U.S.C. § 1396a(23), which closely parallels the theory of alleged "rights" Plaintiffs assert here under 42 U.S.C. § 1396a(a). In light of *Gillespie*, this Court should reexamine its prior orders denying Defendants' dismissal orders and conclude that Plaintiffs do not have a private right of action.

As Defendants have previously argued, 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). Under the Act and its regulations, state Medicaid agencies have substantial discretion to "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). 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. States are specifically allowed to "subject to prior authorization any covered outpatient drug." 42 U.S.C. § 1396r-8(d)(1).

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; *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).

Simply put, Plaintiffs cannot satisfy any of these criteria. As to the first factor, "anything short of an unambiguously conferred right' does not support an individual right of action under section 1983." *Lankford*, 451 F.3d at 508. "[T]he typical remedy for state noncompliance with federally imposed conditions is not a private cause of action for noncompliance but rather action by the Federal Government to terminate funds to the State." *Gonzaga*, 536 U.S. at 280 (citations and quotations omitted). As will be discussed in Section IV below, courts in the Eighth Circuit have held that available administrative or state-court vehicle for bringing a claim evidences a lack of an unambiguously conferred right under the first *Blessing* factor. *See Midwest Foster Care & Adoption Ass'n v. Kinkade*, 712 F.3d 1190 at 1202 (8th Cir. 2013); *see also Hudson v. Campbell*, 663 F.3d 985, 988 (8th Cir. 2011) (discussing remedies for Missouri Medicaid beneficiaries other than a federal § 1983 lawsuit). There is no individual rights-creating language in the various provisions of § 1396a(a) pursuant to which Plaintiffs brought this lawsuit. The proper enforcement mechanism is federal withholding of money to the states. Like Missouri's Adoption Assistance and Child Welfare Act program at issue in *Midwest Foster Care & Adoption Ass'n*, violations of the federal Medicaid Act trigger funding prohibitions. That federal-state statutory relationship was enough to preclude a private right of action in *Midwest Foster Care & Adoption Ass'n*, and it applies directly to preclude a private right of action here. The entire statutory scheme of the Medicaid program is a "contract" between the United States

and a participating state to implement the federal Medicaid program. Where a state accepts federal Medicaid funds it must comply with federal Medicaid law. *See* 42 U.S.C. § 1396a; *see also Armstrong vs. Exceptional Child Ctr., Inc.*, 135 S.Ct 1378, 1387 (2015) In light of this authority and the nature of the federal-state Medicaid partnership, Plaintiffs cannot show that the statutes under which they bring their action was intended to benefit them.

As for the second *Blessing* factor, even if federal Medicaid statutes did grant Plaintiffs did have a right to bring this action in federal court, that right would be "too vague and amorphous for judicial enforcement." *Lankford*, 451 F.3d at 509. Section 1396a(a), which is the source of Plaintiffs' allegations in Counts I through III of their Amended Complaint, "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); § 208.175, RSMo; 13 CSR 70-20.200. 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. *See Exceptional Child Ctr., Inc.*, 135 S.Ct at 1387 (2015) ("More fundamentally, however, the modern jurisprudence permitting intended beneficiaries to sue does not generally apply to contracts between . . . contracts between two governments.") (citations and quotations omitted). Federal law has properly left these complex determinations to be made by the administrative branch of the government and to the states, and it has not provided a private remedy to individual Medicaid participants in the federal courts.

Because Plaintiffs have failed to prove that they have a private right of action to enforce the medical necessity, comparability and reasonable promptness provisions of the Act through a § 1983 lawsuit, Defendants are entitled to summary judgment on Counts I through III of Plaintiffs' Amended Complaint.

IV. Plaintiffs have not exhausted their administrative or state-court remedies.

Missouri's Medicaid statutes provide recourse for Plaintiffs' that they have not yet exhausted. The federal Act provides that Medicaid benefit eligibility determination is made at the state or local level. 42 U.S.C. § 1396a(a)(5). Section 208.080.1 of the Missouri Revised Statutes authorizes MHD beneficiaries to appeal denials of benefits to the Director of the MHD. And after that, any beneficiary may contest that division in Missouri Circuit Court. § 208.100.1, RSMo. Here, neither Plaintiff has taken advantage of these administrative or state-court remedies. Instead of appealing their denial of benefits to the MHD Director, Plaintiffs filed a federal lawsuit.

Federal case law is clear that in § 1983 actions seeking declaratory and injunctive relief, *Younger* abstention divests the court of jurisdiction when there is an ongoing state judicial proceeding, important state interests are implicated, and adequate state remedies exist. *Middlesex Cnty. Ethics Comm. v. Garden State Bar Ass'n*, 457 U.S. 423, 432 (1982) (interpreting *Younger v. Harris*, 401 U.S. 37 (1971)). The doctrine also applies even when a state proceeding has not yet begun, because "a party cannot avoid *Younger* by choosing not to pursue available state appellate remedies." *Alleghany Corp. v. McCartney*, 896 F.2d 1138, 1144 (8th Cir. 1990).

The Eighth Circuit has spoken to this issue in a virtually identical context as the case here, holding that "Missouri law provides for administrative, circuit court, and appellate review of Medicaid eligibility decisions, *see* Mo.Rev.Stat. §§ 208.080, 208.100, and 208.110, remedies that [plaintiff] has not yet exhausted, and thus [plaintiff's] underlying state proceeding is ongoing." *Hudson v. Campbell*, 663 F.3d 985 (8th Cir. 2011). In *Hudson*, the plaintiff brought

declaratory and injunctive relief claims under § 1983 alleging that the Missouri Department of Social Services wrongfully denied her claim for Medicaid benefits due to assets exceeding the qualification threshold. *Id.* at 986. The plaintiff started the administrative appeals process but withdrew her request. *Id.* The Eighth Circuit reasoned that because Missouri has an important state interest in its Medicaid program, an avenue to appeal denials was provided by state law, and the proceeding was ongoing because she did not finish pursuing the administrative process, "Missouri law [therefore] provides for administrative, circuit court, and appellate review of Medicaid eligibility decisions, an appellate process that would allow [plaintiff] to raise her due process claims in the Missouri courts. *Id.* at 989.

Applying *Hudson* to the facts here, the case expressly instructs that Plaintiffs have not exhausted their available administrative and state-court remedies. This Court should therefore abstain from adjudicating Plaintiffs' claims for declaratory and injunctive relief under *Younger*.

CONCLUSION

For the reasons stated herein, Defendants respectfully request that the Court grant summary judgment in their favor and dismiss all of Plaintiffs' claims against them.

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 November 2, 2017 to be served by operation of the Court's electronic filing system upon all parties.

/s/ Michael Quinlan
Michael Quinlan