UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

J.E.M., J.L.M.
Plaintiffs,
v.
BRIAN KINKADE, in his official capacity as Director of the Missouri Department of Social Services; and JOE PARKS, M.D., in his official capacity as Director of the MO HealthNet Division,
Defendants.

Case No. 2:16-cv-04273 NKL

PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

Joel Ferber # 35165
Jamie L. Rodriguez # 64323
Legal Services of Eastern Missouri
4232 Forest Park Avenue
St. Louis, Missouri 63108
(314) 534-4200 telephone
(314) 534-1028 facsimile
jdferber@lsem.org
jlrodriguez@lsem.org

John J. Ammann # 34308
Saint Louis University Legal Clinic
321 N. Spring Street
St. Louis, Missouri 63108
(314) 977-2778 telephone
(314) 977-1180 facsimile
ammanjj@slu.edu

Abigail K. Coursolle
M. Jane Perkins
National Health Law Program, Inc.
3701 Wilshire Blvd, Suite #750
Los Angeles, CA 90010
(310) 204-6010, ext. 107 telephone
(213) 368-0774 facsimile
coursolle@health.law.org
perkins@healthlaw.org

ATTORNEYS FOR PLAINTIFFS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

FEDERAL STATUTES

STATE STATUTES

FEDERAL REGULATIONS

STATE REGULATIONS

OTHER AUTHORITIES

Plaintiffs are low-income Missouri Medicaid beneficiaries who are infected with the Hepatitis C Virus or HCV, a dangerous infectious disease infecting thousands of Missourians. Left untreated, the virus can result in significant liver deterioration and cause cirrhosis, liver cancer, the need for a liver transplant, or other serious and sometimes fatal consequences. Plaintiffs' treating providers have prescribed Direct-Acting Antivirals (DAAs), which can *cure* their chronic Hepatitis C, but the treatment is being denied by the Missouri Medicaid program, also known as "MO HealthNet." Defendants restrict access to DAAs based on a scoring system that limits treatment to those in the advanced stages of liver disease. These restrictions violate the standard of care for Hepatitis C treatment and the Medicaid Act by restricting Plaintiffs' access to medically necessary treatment. Plaintiffs ask this Court to enjoin the Missouri Department of Social Services from continuing to deny these life-saving medications to Plaintiffs and to cease enforcement of their illegal practices.

STATEMENT OF FACTS

Hepatitis C and DAAs

HCV is a chronic, life-threatening, communicable, blood-borne viral disease. Approximately 3.5 to 5 million individuals in the United States are living with HCV, accounting for over 1% of the population. The Missouri Department of Social Services estimates that 13,000 Missouri Medicaid beneficiaries are infected with HCV. Ex. 1. In addition to the baseline manifestation of chronic inflammation throughout the body, HCV can lead to severe liver damage, infections, liver cancer, and death. Bacon Decl. (Ex. 2.) ¶¶ 6, 14-17, 19, 25. Approximately 19,000 people in the United States die each year due to liver disease caused by HCV. CENTERS FOR DISEASE CONTROL, *Hepatitis C FAQs for*

the Public, http://www.cdc.gov/hepatitis/hcv/cfaq.htm (last visited 8/3/16). These figures likely underestimate the impact of HCV due to underreporting on death certificates. STAFF OF S. COMM ON FINANCE, 114TH CONG., *The Price of Sovaldi and Its Impact on the U.S. Health Care System*, at 5 (Comm, Print Dec. 2015). Even before the advanced stages of the disease, HCV can cause heart attacks, fatigue, joint pain, depression, sore muscles, and arthritis. Bacon Decl. ¶ 19. Statistics from the Centers for Disease Control and Prevention indicate that up to 70% of those with HCV will develop chronic liver disease; 20%, cirrhosis; and 5%, liver cancer. HCV is the leading indication for liver transplants in the United States. CENTERS FOR DISEASE CONTROL, *Hepatitis C FAQs for the Public*, http://www.cdc.gov/hepatitis/hcv/cfaq.htm (last visited 8/3/16).

One symptom of HCV is fibrosis, the scarring of the liver caused by inflammation. The level of fibrosis is an indication of the progression of HCV, which is measured by a fibrosis score.[1] This score ranges from F0 (mild scarring or scarring absent) to F4 (significant liver damage; cirrhosis). Bacon Decl. ¶ 7. HCV is divided into six distinct types, called genotypes. Genotype 1 is the most common type of Hepatitis C in the United States.

Until DAAs were approved, the standard of care for the treatment of HCV was a three-drug treatment containing boceprevir, interferon and ribavirin. Id. at ¶ 9. The treatment provided, at most, a 70% cure rate and was accompanied by significant side effects such as anemia, insomnia, anxiety, depression, nausea, bone pain, muscle pain, joint pain, memory loss, and death. Id.

On November 22, 2013, the FDA approved a new DAA treatment for HCV: a

[11] The fibrosis score is sometimes referred to as the Metavir fibrosis score. Metavir is the name of one of the most commonly used scoring system for measuring liver disease. See Ex. 1 (citing AASLD Guidelines, infra).

single pill containing simeprevir sold by Janssen Pharmaceutical under the trade name Olysio. The FDA designated Olysio as a "breakthrough treatment" because it showed potential to provide a substantial improvement over existing therapies. Since approving Olysio, the FDA has approved seven other breakthrough DAA treatments for HCV: Sovaldi, Harvoni, Viekira Pak, Daklinza, Technivie, Zepatier, and Epclusa. All of the current DAA treatments for HCV approved by the FDA since November 2013 were granted breakthrough status by the FDA. Clinical studies of each DAA treatment have found that the treatment cures the disease in more than 90% to 95% of cases. Id. at ¶¶ 11, 14, 21.

DAA treatments are recommended for nearly all patients with HCV, without regard to fibrosis score. Id. at ¶¶12, 13. DAAs are the standard of medical care for the treatment of HCV. Id. at ¶12, 14; Fleckenstein Decl. (Ex. 3) ¶ 3. Treatment guidelines approved by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America ("AASLD/IDSA") confirm that DAAs should ***not*** be reserved for only individuals with fibrosis scores of F3 and F4. See AASLD/IDSA, *Recommendations for Testing, Managing, and Treating Hepatitis C*, http://hcvguidelines.org/sites/default/files/HCV-Guidance_July_2016_b.pdf (last accessed 8/3/16); Bacon Decl. ¶¶ 13-15. Rather, the standard of care is to treat all patients with chronic HCV infection (infection lasting longer than six months), except those with short life expectancies. AASLD/IDSA guidelines; Bacon Decl. ¶¶ 12, 14. Treating HCV patients at **all** stages of fibrosis is the standard of care in the community. Bacon Decl. ¶ 12; see also Fleckenstein Decl. ¶¶ 4-6.

There is no equally effective alternative medication or medical intervention.

Bacon Decl. ¶¶ 14-15. Fleckenstein Decl. ¶ 15. Without treatment, Medicaid enrollees infected with chronic HCV will never rid themselves of the inflammatory disease, placing these individuals at significantly higher risk for liver disease, liver cancer, and death. Bacon Decl. ¶¶ 14-19; Fleckenstein Decl. ¶ 15.

As noted, HCV is a communicable disease. The CDC lists people known to be at increased risk for HCV infection, including health care workers who may encounter needle-sticks involving HCV-positive blood and infants born to HCV-positive mothers. See CENTERS FOR DISEASE CONTROL, *Hepatitis C FAQs for the Public*, http://www.cdc.gov/hepatitis/hcv/cfaq.htm (last visited 8/3/16). Missouri's policy of restricting DAAs ignores the public health risks associated with not curing HCV. Bacon Decl. ¶¶ 4, 23.

Plaintiffs J.E.M. and J.L.M.

Plaintiff J.E.M. is enrolled in MO HealthNet and he has been diagnosed with Hepatitis C for approximately five years. J.E.M. Decl. (Ex. 4) ¶¶ 4-5. Because of his Hepatitis C, J.E.M. has experienced a significant decrease in energy and motivation, and he experiences constant back pain. Id. at ¶ 6. Plaintiff J.L.M. is also enrolled in MO HealthNet and she was diagnosed with Hepatitis C in April of this year. J.L.M. Decl. (Ex. 5) ¶¶ 3-4. J.L.M.'s fibromyalgia and anxiety have worsened due to her Hepatitis C, and she experiences frequent pain and fatigue. Id. at ¶ 5. Both Plaintiffs are concerned about the possibility of infecting others, especially their loved ones, and take daily precautions to ensure that they do not spread the disease. For example, J.L.M. bleaches the bathroom after shaving her legs, and J.E.M. hides his toothbrush when his girlfriend's toddler visits his home. Id. at ¶ 12; J.E.M. Decl. ¶ 11. Their doctors prescribed DAA treatments to treat

and potentially *cure* J.E.M. and J.L.M.'s chronic Hepatitis C, but MO HealthNet denied Plaintiffs' requests for treatment because their fibrosis scores were lower than F3. J.E.M. Decl. ¶¶ 9-10; J.L.M. Decl. ¶¶ 9-10; Campbell Decl. (Ex. 6) ¶¶ 8-10; Bacon Decl. ¶ 25. J.E.M.'s father recently passed away due to his Hepatitis C, and resulting liver cancer. J.E.M. Decl. ¶ 11. Having watched his father die as a result of the disease, J.E.M. feels hopeless and anxious about the impact that Hepatitis C will have on his life and health. Id. at ¶¶ 11-12.

Missouri's Hepatitis C Drug Treatment Policy

Missouri has published authorization and denial criteria for coverage determinations for Hepatitis C antiviral drugs. The denial criteria list having a fibrosis score of less than F3 for genotypes 1, 2, and 4 and a score of less than F2 for genotype 3. MO HEALTHNET, *Missouri Pharmacy Program- Preferred Drug List*, http://dss.mo.gov/mhd/cs/pharmacy/pdf/hepatitis-c-therapy.pdf (revised 10/01/2015); Ex. 7. Pursuant to these policies, Plaintiffs were denied access to DAA treatment. Restricting DAA treatments to only the most advanced stage of chronic liver disease means that patients with early stage disease must wait until their conditions worsen before they can get treatment. The Department of Social Services described its current policy in budget documents as follows: "To control appropriate cost and assure appropriate treatment of Hepatitis C, including Solvaldi MHD uses the following 'evidence-based' criteria: **only treating the sickest patients**-confirming the level of disease via biopsy, fibroscan or other diagnostic testing…" Ex. 8, at 31 (emphasis added).

In spite of the above-stated policy rationale, the MO HealthNet Division subsequently informed Plaintiffs' counsel that it "agrees with the AASLD/IDSA

recommendation that ALL patients should be treated" but it "PRIORITIZES access to treatment" for Hepatitis C patients who it believes "most urgently need it" rather than provide it to all patients for whom such treatment is medically necessary. Ex. 1 (caps in original). Defendants also informed Plaintiffs' counsel that it "view[s] the decision regarding metavir fibrosis score and access to treatment as a DEFERRAL rather than a DENIAL." Id. (caps in original). However, Plaintiffs were never told that their treatment was being deferred; rather, they were denied the DAAs prescribed by their treating physicians.

Defendants report that they have approved "some participants" for coverage of DAAs with fibrosis scores of less than F3/F4 based on other specifics of their condition. Ex. 1. However, the Defendants' published prior authorization criteria do not reflect this practice nor have they have published any criteria for case-by-case decisions.[2] Defendants' policies do not include any factors under which individuals with fibrosis scores of less than F3 would qualify for coverage of DAAs.

Defendants prioritize treatment for Hepatitis C patients who they believe "most urgently need it" rather than provide it to all patients for whom such treatment is medically necessary.[3] Plaintiffs were denied DAAs because they did not have fibrosis scores of F3 or greater.[4] A low fibrosis score is not an acceptable medical reason for denying access to medically necessary DAAs.

---

[2] A decision tree used by MO HealthNet staff leaves no room for ambiguity. For the drug Viekira Pak, the tree diagram asks "Is the patient's fibrosis score ≥ F3?" If the answer is no, the diagram instructs staff to issue a denial. Ex. 9.

[3] For example, in August 2016, Defendants approved 38 prior authorization requests and denied 34 requests for DAA treatment for individuals with Hepatitis C. Ex. 10. In May 2016, 59 requests were approved while 73 were denied. Ex. 11.

[4] Plaintiffs' providers were informed: "Patient does not meet MO HealthNet's criteria for a fibrosis score of F3 or greater." Campbell Decl. ¶¶ 8, 10, and Att. B, C, D, E.

BACKGROUND ON THE MEDICAID PROGRAM

Congress created the Medicaid program in 1965 by adding Title XIX to the Social Security Act, 42 U.S.C. §§ 1396-1396w-2 (hereinafter "the Act"). State participation in Medicaid is optional. However, a state that chooses to participate, and thereby receive federal matching funds for program expenditures, "must comply with requirements imposed both by the Act itself and by the Secretary of Health and Human Services." Schweiker v. Gray Panthers, 453 U.S. 34, 37 (1981); see also Lankford v. Sherman, 451 F.3d 496, 504 (8th Cir. 2006); Weaver v. Reagen, 886 F.2d 194, 197 (8th Cir. 1989).

Missouri participates in the Medicaid program. The federal government pays 63.21 cents of every dollar spent on Medicaid services in Missouri. 80 Fed. Reg. 73,779.

Medicaid is not available to everyone who is poor. Rather, it only covers certain groups of needy individuals. See 42 U.S.C. § 1396a(a)(10)(A). Missouri must cover some of the groups listed in § (10)(A) and has the option to cover additional groups. The groups that a state must cover, referred to in Medicaid parlance as the "categorically needy," include individuals who are aged, blind, or disabled; working disabled individuals; and children and pregnant women who meet federal poverty level standards. Id. at § 1396a(a)(10)(A)(i). In Missouri, all Medicaid recipients are "categorically needy." Lankford, 451 F.3d at 504.

The Medicaid Act requires participating states to cover some services and allows states to cover others. See 42 U.S.C. §§ 1396a(a)(10), 1396d(a). Optional service categories include "prescribed drugs." 42 U.S.C. § 1396d(a)(12). Like every other state, Missouri has opted to cover prescription drugs in its Medicaid program. 13 C.S.R. 70-20.030. Because Missouri has chosen to provide this service, it is "bound to act in

compliance with the Act and the applicable regulations in the implementation of those services . . . ." Weaver, 886 F.2d at 197; see also McNeil-Terry v. Roling, 142 S.W.3d 828, 833 (Mo. App. 2004); Meyers v. Reagen, 776 F.2d 241, 243 (8th Cir. 1985) (when a state chose to offer an optional service, it "bound itself to act in compliance with Title XIX of the Social Security Act and the applicable regulations in the implementation of those services."). Moreover, Missouri must comply with the requirements of 42 U.S.C. § 1396r–8(k) for payment of covered outpatient drugs. See 42 U.S.C. § 1396a(a)(54). State Medicaid Plans are required to provide coverage for any outpatient drug which has U.S. Food and Drug Administration (FDA) approval when the manufacturer of the drug has entered into a rebate agreement with the U.S. Secretary of Health and Human Services (as all of the DAA manufacturers have done).[5]

ARGUMENT

I. STANDARD FOR PRELIMINARY RELIEF

Injunctive relief is "an equitable remedy shaped to right an ongoing wrong." Kohl v. Woodhaven Learning Ctr., 865 F.2d 930, 934 (8th Cir. 1989). There are four factors that this Court must consider in determining whether to grant preliminary relief: "(1) the probability of success on the merits, (2) the threat of irreparable harm to the movant, (3) the balance between the harm and the injury that granting the injunction will inflict on other interested parties, and (4) the public interest." Lankford, 451 F.3d at 503 (citing Dataphase Sys. v. C L Sys., Inc., 640 F.2d 109, 114 (8th Cir. 1981)). Plaintiffs meet all these factors.

[5]Limited exceptions exist but they are not relevant in this case. Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 652 (2003); 42 U.S.C. §§ 1396r-8(a)(1), 1396r-8(d)(B), 1396r-8(k)(2)(A),(6).

II. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS OF THEIR CLAIMS

A. Missouri Likely Violates The Medicaid Act By Failing To Make Medically Necessary Medical Assistance Available To Plaintiffs.

The Medicaid Act requires the State to make "medical assistance" available to eligible individuals. 42 U.S.C. § 1396a(a)(10)(A). This "medical assistance" includes both required and optional services. See McNeil-Terry, 142 S.W.3d at 833. Missouri covers prescription drugs as "medical assistance" in its Medicaid program.

Because prescription drugs are covered Medicaid services, the Defendants must ensure that they are available to Medicaid beneficiaries in "sufficient . . . amount, duration, and scope to reasonably achieve [the] purpose" of the covered service. 42 C.F.R. § 440.230(b); 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a); see also Weaver, 886 F.2d at 197. The cases have interpreted these provisions to "prohibit . . . states from denying coverage of 'medically necessary' services that fall under a category covered in their Medicaid plans." Alvarez v. Betlach, 572 Fed. Appx. 519, 521 (9th Cir. 2014); see also Bontrager v. Ind. Family & Soc. Servs. Admin., 829 F. Supp. 2d 688, 695-700 (N.D. Ind. 2011) (and citations therein), aff'd, 697 F.3d 604, 608 (7th Cir. 2012) (State must cover medically necessary treatments within Medicaid service categories (e.g., dental services) to comply with 42 U.S.C. § 1396a(a)(10)(A)); Dexter v. Kirschner, 984 F.2d 979, 983 (9th Cir. 1992) (requiring state to provide "*medically necessary* inpatient hospital and physician's services for eligible persons" under 42 U.S.C. § 1396a(a)(10)(A)) (emphasis in original). This interpretation is consistent with a primary objective of Medicaid, which, as noted by the Supreme Court, is "to furnish medical assistance to individuals whose income and resources are insufficient to meet the costs of **necessary** medical services,"

Beal v. Doe, 432 U.S. 438, 444-45 (1977), 42 U.S.C. § 1396-1 (emphasis added). Since Beal, courts, including the Eighth Circuit, have thus held uniformly that such "medically necessary" services must be covered. See, e.g., Lankford, 451 F.3d at 511 ("[A] state's failure to provide Medicaid coverage for non-experimental, medically-necessary services within a covered Medicaid category is both per se unreasonable and inconsistent with the stated goals of Medicaid."); Pinneke v. Preisser, 623 F.2d 546, 549 (8th Cir. 1980) (holding the Medicaid Act requires the provision of "medical assistance" to categorically needy persons when "medically necessary"); Weaver, 886 F.2d at 198 (citing Beal and requiring the State of Missouri to provide treatment that is "deemed 'medically necessary' in order to comport with the objectives of the Act").

This Court similarly found that the purpose of Medicaid *as stated in the Act* is to provide medical treatment to needy persons whose income and resources are insufficient to meet the cost of "necessary medical services." Hiltibran v. Levy, No. 10-4185-CV-C-NKL, 2010 WL 6825306, at *3 (W.D. Mo. Dec. 27, 2010) (emphasis added). In Hiltibran, this Court found that these same Defendants violated 42 U.S.C. § 1396a(a)(10)(A) when they limited the scope of medically necessary "home health" services. Id. at *4, same case, 793 F. Supp. 2d 1108, 1115 (W.D. Mo. 2011). Accordingly, the Defendants must provide Medicaid coverage for all medically necessary prescription drugs. Because DAA drugs are FDA-approved as medically necessary for HCV patients, Missouri's policy—which prevents Plaintiffs and others with Hepatitis C from receiving antiviral medications until they have already suffered serious, and irreversible liver damage—violates federal Medicaid law.

In the vast majority of cases, DAAs *cure* Hepatitis C. In so doing, the drugs prevent significant liver deterioration and potentially cirrhosis, liver cancer, the need for a liver transplant, or even death. By its terms, Missouri's policy requires patients to experience significant—and irreversible—damage to the liver before they may receive DAAs; but, given the efficacy of these drugs, this damage is unnecessary and entirely preventable. Notably, national guidelines for the testing, management, and treatment of Hepatitis C, published in a joint statement by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA), state that DAAs are recommended for all patients except for those with short life expectancies that cannot be remediated by treating Hepatitis C, by transplantation, or by other directed therapy. Bacon Decl. ¶¶ 12, 14; see also AASLD/IDSA, *Recommendations for Testing, Managing, and Treating Hepatitis C*, http://www.hcvguidelines.org (last visited Aug. 3, 2016). Moreover, the Centers for Medicare and Medicaid Services of the U.S. Department of Health and Human Services ("CMS") has emphatically rejected restrictions similar to those imposed by Missouri:

> CMS is concerned that some states are restricting access to DAA [that is, direct acting antiviral] HCV drugs contrary to the statutory requirements in section 1927 of the [Medicaid] Act [codified at 42 U.S.C. § 1396r-8] by imposing conditions for coverage that may unreasonably restrict access to these drugs. For example, several state Medicaid programs are limiting treatment to those beneficiaries whose extent of liver damage has progressed to metavir fibrosis score F3, while a number of states are requiring metavir fibrosis scores of F4.
>
> While states have the discretion to establish certain limitations on the coverage of these drugs, such as preferred drug lists and use of prior authorization processes, such practices must be consistent with requirements of section 1927(d) of the Act to ensure appropriate utilization.

> As such, the effect of such limitations should not result in the denial of access to effective, clinically appropriate, and medically necessary treatments using DAA drugs for beneficiaries with chronic HCV infections. States should, therefore, examine their drug benefits to ensure that limitations do not unreasonably restrict coverage of effective treatment using the new DAA HCV drugs.

U.S. Dep't of Health & Human Servs., Ctrs. for Medicare & Medicaid Servs., Medicaid Drug Rebate Program Notice: Release No. 172, *Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Medications*, Nov. 5, 2015 (Ex. 12), at 2-3 (emphasis added).[6] This statement of the federal agency responsible for administering the Medicaid program is, at the very least, entitled to "respectful consideration" under Skidmore v. Swift & Co., 323 U.S. 134 (1944), and U.S. v. Mead Corp., 533 U.S. 218 (2001).[7]

---

[6] CMS HCV guidance is available at: https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-172.pdf.

[7] Defendants' restrictions on access to a "prescribed drug" as that term is used in 42 U.S.C. § 1396d(a)(12) violates federal Medicaid law which specifies only four circumstances under which a state "may exclude or otherwise restrict coverage" of an outpatient drug (none of which are applicable here):

i) The prescribed use is not for a "medically accepted indication;"
ii) The drug is contained in a specified list of drugs subject to restriction, see U.S.C. § 1396r-8(d)(2);
iii) The drug is subject to restrictions "pursuant to an agreement between a manufacturer and a State authorized by the Secretary;" or
iv) The State has excluded coverage of the drug from its formulary established pursuant to 42 U.S.C. § 1396r-8(d)(4).

42 U.S.C. § 1396r-8(d)(1)(B). Harvoni and DAAs clearly are not excludable. First, the prescribed use of the drug has been approved by the FDA, and thus, the drug is being used for a "medically accepted indication." See 42 U.S.C. § 1396r-8(k)(6); U.S. Food and Drug Administration, *FDA approves first combination pill to treat hepatitis C*, Oct. 10, 2014, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm418365.htm (last visited July. 11, 2016). Second, the DAAs clearly are not included in the list of drugs that may be restricted pursuant to 42 U.S.C. § 1396r-8(d)(2). Third, as is evident from the federal government's criticism of restrictions on Harvoni similar (or identical) to Missouri's, these restrictions are not made pursuant to an agreement between the manufacturer and the State that has been approved by the federal government. And fourth, as is evident from the fact that the drug is provided to persons who have already

Given the effectiveness of DAAs, the United States Department of Veterans Affairs has dropped fibrosis score requirements as a prerequisite for Hepatitis C coverage.[8] Similarly, other states and private insurers have eliminated fibrosis scores as a barrier to treatment.[9] Among the state Medicaid programs that have dropped fibrosis score limits are Delaware, Florida, Massachusetts, New York, and Connecticut.[10] In addition, major private insurers such as United Health have also dropped fibrosis score limitations on DAAs.[11] And as already noted, the Missouri Medicaid Agency (MO

---

suffered severe liver damage, Hepatitis C drugs are included in Missouri's drug formulary.

[8]See Judith Graham, *VA Extends New Hepatitis C Drugs to All Veterans in its Health System*, The Journal of the American Medical Association, September 6, 2016 (Ex. 13); U.S. Dep't of Veterans Affairs, *VA Expands Hepatitis C Drug Treatment*, March 9, 2016 (News Release) (available at http://va.gov/opa/pressrel/pressrelease.cfm?id=2762) (VA funding treatment "regardless of the stage of the patient's liver disease").

[9] Judith Graham, *Medicaid, Private Insurers Begin to Lift Curbs on Pricey Hepatitis C drugs*, Kaiser Health News, July 5, 2016; Centers for Medicare and Medicaid Services, *Expansion of Hepatitis C Drug Coverage in Massachusetts (News Release)*, June 30, 2016 (available at http://www.hhs.gov/hepatitis/blog/2016/07/01/expansion-of-hepatitis-c-drug-coverage-in-massachusetts.html) ("Massachusetts joins other states including Delaware and Florida that have recently implemented or announced plans to enhance access to these important medications."); Don Sapatikin, *Delaware will treat all Medicaid patients with Hepatitis C*, Philly.com, June 9, 2016 (available at http://articles.philly.com/2016-06-09/news/73647247_1_medicaid-patients-hepatitis-c-state-medicaid-program); Jen Rini, *State Changes Hep C Medication Guidelines, Avoids Lawsuit*, June 1, 2016, Delaware On-Line (available at http://www.delawareonline.com/story/news/health/2016/06/07/state-changes-hep-c-medication-guidelines-avoids-lawsuit/85554396/); Daniela Altimari, *State Moves to Make Costly Hepatitis C Drugs More Accessible to Medicaid Patients*, Hartford Courant May 15, 2015 (available at http://www.courant.com/politics/hc-sovaldi-more-accessible-0516-20150515-story.html); Claire Hughes, *New York Medicaid to cover Hepatitis C treatment*, Times-Union, April 27, 2016 (available at http://www.timesunion.com/local/article/Patient-group-presses-state-for-increased-7378967.php).

[10] Id.

[11]Celia Ampel, *United Health Expands Hepatitis C Drug Coverage to Settle National Class Action*, Daily Business Review, September 12, 2016 (available at http://www.dailybusinessreview.com/id=1202767146286/United-Health-Expands-Hepatitis-C-Drug-Coverage-to-Settle-National-Class-Action)

HealthNet) "agrees with the AASLD/IDSA recommendation that ALL patients should be treated." Ex. 1 (caps in original).

Defendants claim to use "evidence-based" criteria of "only treating the sickest patients - confirming the level of disease via biopsy, fibroscan or other diagnostic testing . . . " Ex. 8, at 31. However, the Medicaid Act pins the evidentiary base to the medically accepted indications for outpatient prescription drugs pursuant to 42 U.S.C. § 1396r-8(k)(6), specifically here, FDA-approved uses which are not limited based on fibrosis score.

As already noted, Defendants arbitrarily limit Hepatitis C treatment based on cost-driven criteria other than medical necessity, thereby preventing individuals from receiving early intervention that will most likely cure their infection (and, thus, prevent the infection from spreading). This leaves J.E.M., J.L.M., and others like them to suffer symptoms and complications of Hepatitis C including anxiety, pain, and fatigue, for months or years. J.E.M. Decl. ¶ 6; J.L.M. Decl. ¶ 5. Despite their treating providers' recommendation that they receive curative treatment, MO HealthNet requires Plaintiffs and others to experience irreversible organ damage before it will authorize DAA drugs. See Bacon Decl. ¶¶ 15, 19, 25. The Eighth Circuit has previously rejected such restrictions on prescription drugs that "reflect . . . inadequate solicitude for the applicant's diagnosed condition, the treatment prescribed by the applicant's physicians, and the **accumulated knowledge of the medical community**." Weaver, 886 F.2d at 200 (quoting Pinneke, 623 F.2d at 546 (emphasis added)). Missouri's severe limitations on treatment contradict clearly established medical standards for treatment of Hepatitis C. See B.E. v. Teeter, No. C16-227-JCC, 2016 WL 3033500, at *4 (W.D. Wash. May 27,

2016) (finding that Washington's use of the same policy at issue here likely violated the Medicaid Act because it deprived Medicaid enrollees access to life-saving drugs in situations where it is "medically necessary," and noting that DAAs are considered the "standard of care" by the AASLD/IDSA and acknowledging CMS's rejection of such restrictive policies).

Finally, the Eighth Circuit has also held that the determination of medical necessity "rests with the individual recipient's physician and not with clerical personnel or government officials." Weaver, 886 F.2d at 199; Pinneke, 623 F.2d at 550; J.D. v. Sherman, No. 06-4153-CV-C-NKL, 2006 U.S. Dist. LEXIS 78446, at *10 (W.D. Mo 2006). It is improper to interfere with a physician's judgment of medical necessity by limiting coverage of prescription drugs based on criteria that do not reflect current medical knowledge or practice. Weaver, 886 F.2d at 197. Indeed, failing to provide DAAs to HCV-infected individuals pending further organ damage is "unethical" and may even "constitute medical malpractice." Bacon Decl. ¶ 15. Missouri's severe limitations on treatment improperly contradict the judgments of Plaintiffs' treating physician which are based on established standards of medical necessity for treatment of Hepatitis C.[12] Bacon Decl. ¶¶ 12-15, 19, 25.

[12] Defendants' authorization criteria also create an illegal irrebuttable presumption that antiviral drugs are *never* medically necessary for Medicaid recipients with Hepatitis C who have not reached an advanced stage of liver disease—an approach that has been rejected by the Eighth Circuit. In Weaver, the Eighth Circuit struck down a Missouri policy creating "an irrebuttable presumption that AZT can never be medically necessary treatment for AIDS patients" who did not meet specified diagnostic criteria. 886 F.2d at 199; see also Hiltibran, 2010 WL 6825306 at *3. Defendants' authorization criteria similarly presume that DAAs are never medically necessary, in violation of the Medicaid Act. While Defendants may argue that, on occasion, they have approved an authorization for Heptatitis C drugs when the fibrosis requirement was not met, their written policy allows for **no** exceptions. Nor were Plaintiffs offered any opportunity to receive these drugs without meeting the fibrosis requirement.

B. Defendants' Policies Likely Violate The Comparability Requirement Of The Medicaid Act.

The Medicaid Act's "comparability" requirement requires that the "medical assistance made available to any [categorically needy] individual . . . shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual." 42 U.S.C. § 1396a(a)(10)(B); 42 C.F.R. § 440.240(a) (stating that the services available to categorically needy individuals must be "equal in amount, duration, and scope").

The courts have repeatedly interpreted this statue to prevent states from restricting services to some categorically needy individuals but not others. For example, in White v. Beal, 555 F.2d 1146 (3d Cir. 1977), the Third Circuit Court of Appeals enjoined a Pennsylvania policy that covered eyeglasses for categorically needy individuals with pathologic need but not for those with ordinary refractive errors. While the state contended that limited resources justified the restrictive policy, the court enjoined it, in part, because "all persons within a given category must be treated equally." Id. at 1149. Similarly, in Sobky v. Smoley, 855 F. Supp. 1123 (E.D. Cal. 1994), the court enjoined a state policy that covered methadone maintenance for some categorically needy but not others. Stating that "§ 1396a(a)(10)(B) creates an equality principle by which all categorically needy individuals must receive medical assistance which is no less than that provided to any other categorically or medically needy individual," Id. at 1139, the Court held that "[b]y denying the same service to the categorically needy members of the plaintiff class that is received by other categorically needy persons . . . the State violates

§ 1396a(a)(10)(B)." Id. at 1140.[13]

In V.L. v. Wagner, the court found that, "[t]he use of numerical ranks and FI Scores to determine eligibility for IHSS services likely violates the comparability requirement because neither reasonably measures the individual need of a disabled or elderly person for a particular service." 669 F. Supp. 2d 1106, 1115 (N.D. Cal. 2009). Similarly, in this case the fibrosis scores do not reflect the medical need for DAA treatments. All patients with chronic HCV infections, including the Plaintiffs, require DAAs based on medical necessity regardless of the ranking of their liver damage. Bacon Decl. ¶¶ 12-15, 25; Campbell Decl. ¶¶ 12, 13. Moreover, the Second Circuit recently struck down a State restriction denying access to services based on the "nature of their medical conditions," thus providing some categorically needy individuals less medical assistance than was available to others with the same level of medical need. See Davis v. Shah, 821 F.3d 231, 256-59 (2d Cir. 2016). These restrictions, like the ones challenged here, violated the "plain text of § 1396a(a)(10)(B)(i) and § 440.240(b), denying categorically needy individuals comparable access to equally necessary medical services." Id. at 259.

[13] See also, e.g., Rodriguez v. City of N.Y., 197 F.3d 611, 615 (2d Cir. 1999) (noting that "states may not provide benefits to some categorically needy individuals but not to others [since Section 1396a(a)(10)(B)] . . . precludes states from discriminating against or among the categorically needy"); Parry v. Crawford, 990 F. Supp. 1250, 1257 (D. Nev. 1998) (noting state flexibility in operating the Medicaid program, but finding the state violated the comparability requirement when it excluded an entire class of categorically needy individuals from a service that it covered for other categorically needy individuals); DeLuca v. Hammons, 927 F. Supp. 132 (S.D.N.Y. 1996) (finding violation where state regulation limited number of home care hours that could be allocated to some categorically needy individuals but not others); Hodecker v. Blum, 525 F. Supp. 867, 872 (N.D.N.Y. 1981) ("Neither the benevolent purpose of the budgeting practice, nor the regulations relied upon by the State Commissioner . . . could have rendered lawful the violations of the statutory provisions regarding comparability.").

Most relevant here, the Eighth Circuit invalidated a Missouri regulation that limited Medicaid coverage of the drug AZT to only those recipients with AIDS who met certain narrow medical criteria and thereby denied the drug to other recipients whose physicians had also prescribed it as medically necessary treatment. Weaver, 886 F.2d at 197-200. The Court affirmed the district court's finding that the regulation violated the comparability requirement. 701 F. Supp. 717, 719, 726 (W.D. Mo. 1988), aff'd as modified, 886 F.2d at 194. The illegal policy in that case restricted treatment for AIDS to patients who were extremely immunocompromised or were suffering from an opportunistic fungal infection. Similarly, in this case, the limitation on availability of life-saving Hepatitis C drugs to only those individuals who meet narrow diagnostic criteria not based on medical necessity violates the comparability requirement. Defendants' policy runs afoul of the comparability requirement by excluding certain Medicaid enrollees with HCV from medically necessary DAA treatment, while providing the same treatment to other Medicaid enrollees with HCV.[14]

In sum, the Defendants are providing coverage not based on medical necessity—which is the same for all patients who contract Hepatitis C—but based on severity of liver damage. "By definition, such a selective distribution of medical assistance offers an unequal 'scope' of benefits to individuals within the categorically needy class, violating the plain language of § 1396a(a)(10)(B)(i) and § 440.240(b)." Davis, 821 F.3d at 256.

[14] The federal district court in Washington found the state Medicaid director likely violated the comparability requirement when it provided Hepatitis drugs to some Medicaid recipients but not to others based on fibrosis score. Because that court already found a violation of medical necessity requirements, it did not elaborate on comparability violations. B.E., supra, 2016 WL 3033500 at *5.

C. Plaintiffs Are Likely To Succeed On The Merits Of Their Reasonable Promptness Claim.

The Medicaid Act requires that covered services be furnished with "reasonable promptness to all eligible individuals." See 42 U.S.C. § 1396a(a)(8). Lengthy wait times for medically necessary treatment have been held by courts to be "unreasonable." See, e.g., Allen v. Mansour, 681 F. Supp. 1232 (E.D. Mich. 1986); Sobky, 855 F. Supp. at 1148 ("[T]he Medicaid Act's reasonable promptness requirement, set forth at § 1396a(a)(8), prohibits states from responding to budgetary constraints in such a way as to cause otherwise eligible recipients to be placed on waiting lists for treatment."). In Allen, the court found a two-year abstinence waiting period for a liver transplant was unreasonable because the waiting period was not imposed based upon clinical evidence. 681 F. Supp. at 1238. Instead, the waiting period impermissibly excluded a large group of Medicaid beneficiaries from ever getting the transplants they needed to survive. Id. Similarly here, Missouri's policy (which Defendants characterize as "deferral" of treatment) imposes an unreasonable delay on the provision of medically necessary treatment. The policy places Plaintiffs in a period of limbo, during which they are left to suffer through the progressive symptoms and effects of their disease, including pain, fatigue, and anxiety. J.E.M. Decl. ¶ 6; J.L.M. Decl. ¶ 5. The policy leaves Plaintiffs waiting for medically necessary covered prescription medications well beyond the timeframe for initiation of treatment recommended by their doctors and the professional standard of care, including quite possibly for years or forever. In this case, Defendants' "deferral significantly increases the risk of death from cancer or liver failure, as well as the likelihood that the patient may eventually require a liver transplant." Bacon Decl. ¶

15.[15] In identical circumstances, a federal district court found that the State of Washington likely violated the reasonable promptness requirement when it similarly delayed treatment until Plaintiffs reached an advanced stage of liver disease. B.E., 2016 WL 3033500 at *5.

These excessive delays and deferrals are unreasonable and are not prompt. Thus, Plaintiffs are likely to succeed on the merits of their "reasonable promptness" claim.

III. THE PLAINTIFFS ARE SUFFERING IRREPARABLE HARM AS A RESULT OF THE DEFENDANTS' FAILURE TO COVER HEPATITIS C DRUG THERAPIES

It is well settled that a denial of Medicaid benefits constitutes irreparable harm. See, e.g., Kai v. Ross, 336 F.3d 650, 656 (8th Cir. 2003) (danger to Plaintiffs' health gives them a strong argument of irreparable injury); Henderson v. Bodine Aluminum, Inc., 70 F.3d 958, 961 (8th Cir. 1995) ("It is hard to imagine a greater harm than losing a chance for potentially life-saving medical treatment.").

Plaintiffs are infected with Hepatitis C. Chronic Hepatitis C is the leading cause of liver cirrhosis and liver cancer. CENTERS FOR DISEASE CONTROL, *Viral Hepatitis – Hepatitis C Information*, http://www.cdc.gov/hepatitis/hcv/cfaq.htm (last accessed July 11, 2016). An estimated 19,000 people die from this disease every year. Id. Without a preliminary injunction, the Plaintiffs will not receive the medical treatment that provides

[15]On top of this "deferral," Defendants add even more delay by requiring Plaintiffs and others to submit to at least three months of unnecessary "abstinence" testing before they will even *consider* a request for approval of an antiviral drug for Hepatitis C. Bacon Decl, ¶ 22; Fleckenstein Decl. ¶¶ 7-10; J.L.M. Dec.¶ 8, J.E.M. Dec. ¶ 8. Such unnecessary drug testing unreasonably delays treatment and violates the standard of care for the prescription of medically necessary antiviral medications. Bacon Decl., ¶ 22.

them the best chance to prevent their conditions from worsening. There is no other remedy that would adequately prevent this harm.[16]

Dr. Bruce Bacon, co-director of the Abdominal Transplant Program at Saint Louis University Hospital and a nationwide expert on Hepatitis C, and Dr. Jaquelyn Fleckenstein, board-certified Hepatologist and Gastroenterologist at Washington University School of Medicine, have documented the severe health risks and life-threatening impact of Missouri's failure to cover DAAs in accordance with the standard of care in the medical community. According to these physicians, Plaintiffs' untreated HCV could lead to "liver failure, liver cancer and kidney problems" and "irreversible organ damage." Bacon Decl. ¶¶ 15, 16; see also Fleckenstein Decl. ¶ 13 (DAA treatment can reduce or eliminate "an array of other medical problems associated with HCV such as heart disease, lymphatic cancers, diabetes, kidney damage, and immune-related diseases."). Dr. Bacon states that Plaintiffs J.E.M. and J.L.M. "are at risk of **irreparable** damage to their livers," which is certainly irreparable harm. Bacon Decl. ¶ 25 (emphasis added). Delaying treatment "not only impacts the liver but also, because HCV is a systemic disease, the delay can cause heart attacks, fatigue, joint pain, depression, sore muscles, arthritis, and at times, premature death," not to mention the risk of transmission to others. Bacon Decl. ¶¶ 19, 23; Nemnich v. Stangler, No. 91-4517-CV-C-5, 1992 WL 178963, at *2 (W.D. Mo. Jan. 7, 1992) ("This Court finds death to be irreparable harm"). While Defendants delay curative treatment, Plaintiffs J.E.M. and J.L.M. live with pain, fatigue, and anxiety as a result of their HCV. J.E.M. Decl. ¶ 6; J.L.M. Decl. ¶ 5. In addition to the risk of severe physical damage and death from HCV, the lack of treatment

[16]In August 2016 alone, Defendants denied 34 prior authorization requests for drug treatment of Hepatitis C. Ex. 10. In May 2015, 73 requests were denied. Ex. 11.

has immediate negative life consequences, including an inability to live a normal life due to both the effects of the disease and the fear of transmitting it to their loved ones and others. J.L.M. Decl. ¶¶ 5, 12, 13; J.E.M. Decl. ¶¶ 6, 11, 12. They live in a constant state of fear and anxiety, worried not only about their own health and lives, but also those of their loved ones. J.E.M. Decl. ¶¶ 11, 12; J.L.M. ¶¶ 5, 12, 13.

IV. THE THREAT OF SERIOUS, HEALTH-RELATED INJURY TO THE PLAINTIFFS CLEARLY OUTWEIGHS ANY POTENTIAL HARM TO DEFENDANTS

The balance of hardships weighs decidedly in favor of Plaintiffs. As noted above, the harm suffered by the Plaintiffs absent an injunction is significant. Moreover, Plaintiffs seek only that Defendants comply with controlling federal law. As a matter of law, Defendants cannot be harmed by complying with federal Medicaid law requirements. As stated by the Seventh Circuit:

> Because the defendants are required to comply with the Food Stamp Act . . . , we do not see how enforcing compliance imposes any burden on them. The Act itself imposes the burden; this injunction merely seeks to prevent the defendants from shirking their responsibilities under it.

Haskins v. Stanton, 794 F.2d 1273, 1277 (7th Cir. 1986) (granting preliminary injunction). See also Ill. Hosp. Ass'n v. Ill. Dep't of Pub. Aid, 576 F. Supp. 360, 371 (N.D. Ill. 1983) ("Once a state has voluntarily elected to participate in the Medicaid program . . . [it cannot] characterize its duty to comply with the requirements of [the program] as constituting a hardship to its citizens.").

As the Eighth Circuit has noted, Missouri is required to adhere to the federal Medicaid requirements in the operation of its Medicaid program. Lankford, 451 F.3d at 504, citing Schweiker, 453 U.S. at 37; see also Mo. Rev. Stat. § 208.151 ("For the purpose of paying MO HealthNet benefits and to comply with Title XIX, Public Law 89-

97, 1965 amendments to the federal Social Security Act (42 U.S.C. Section 301, et seq.) as amended, the following needy persons shall be eligible to receive MO HealthNet benefits."). Missouri cannot claim hardship from compliance with the requirements that come with the substantial federal funding that Missouri receives for choosing to operate a Medicaid program. See Lankford, 451 F.3d at 510 (noting that the majority of expenditures for Medicaid benefits in Missouri are federal funds).

Any alleged harm to Defendants is far outweighed by the harm to Plaintiffs' lives and health. See, e.g., Lankford v. Sherman, No. 05-4285-CV-C-DW, 2007 U.S. Dist. LEXIS 14950, at *13 (W.D. Mo. Mar. 2, 2007); White v. Martin, 2002 U.S. Dist. LEXIS 27281, at *22 (W.D. Mo. Oct. 3, 2002) (collecting cases); Nemnich, 1992 WL 178963 at *3; Hiltibran, 2010 WL 6825306 at *7.

V. AN INJUNCTION IS IN THE PUBLIC INTEREST

When issuing injunctive relief against a government body, the Eighth Circuit has found that enforcement of the federal law is necessarily in the public interest. Glenwood Bridge, Inc. v. Minneapolis, 940 F.2d 367, 372 (8th Cir. 1991). See also Lankford v. Sherman, U.S. Dist. LEXIS 14950 at *13; Heather K. v. Mallard, 887 F. Supp. 1249, 1261 (N.D. Iowa 1995) (collecting Eighth Circuit decisions). "Congress and the Missouri General Assembly expressed the public interest by enacting the Medicaid program in the first place." Nemnich, 1992 WL 178963 at *4. It is always in the public interest to prevent a violation of federal law.[17]

[17]Budgetary constraints do not excuse a violation of federal law. See Amisub (PSL) Inc. v. Colo. Dep't of Soc. Servs., 879 F.2d 789, 800 (10th Cir. 1989) (holding "budgetary constraints cannot excuse noncompliance with federal Medicaid law"); Tallahassee Mem'l Reg'l Med. Ctr. v. Cook, 109 F.3d 693, 704 (11th Cir. 1997) (same); Miss. Hosp. Ass'n, Inc. v. Heckler, 701 F.2d 511, 518 (5th Cir. 1983) (same); Kan. Hosp. Ass'n v. Whiteman, 835 F. Supp. 1548, 1553 (D. Kan. 1993) (same); McNeill-Terry, 142

It is also clearly in the public interest to treat Plaintiffs' serious illness, save lives, and prevent transmission of Hepatitis C which will help to eradicate a major public health crisis in Missouri. Bacon Decl. ¶ 23; Fleckenstein Decl. ¶ 14. An injunction will allow Plaintiffs to obtain the treatment that their health care providers have determined to be medically necessary to address their life-threatening medical conditions. Coverage of these lifesaving medications will also save the State money in hospitalizations, transplants, and other areas as the disease is cured—and potentially eradicated—with DAA treatment. Bacon Decl. ¶ 24. Even Defendants acknowledge a "positive long-term financial impact on the MO HealthNet Program" from "[e]radication of HCV infection." Ex. 1.

VI. NO BOND SHOULD BE REQUIRED

The Court should not require Plaintiffs to post a bond as security for the preliminary injunction because they are low-income Medicaid beneficiaries. This case represents a challenge by indigent Medicaid recipients to illegal standards that are preventing them from obtaining treatment that might cure their disease. The Eighth Circuit has explained that "specific equitable or legal considerations in [a] case might require that the bond be waived or set at a nominal amount." Young v. Harris, 599 F.2d 870, 873 n.5 (8th Cir. 1979). It is appropriate to waive the bond requirement for "low-income individuals in need of medical services." Kerr v. Holsinger, No. 03-68-JMH, 2004 U.S. Dist. LEXIS 7804, at *36 (E. D. Ky. Mar. 25, 2004).

S.W.3d at 834 (Missouri's budgetary constraints were not sufficient to justify limitations on coverage of necessary Medicaid service). Compare Indep. Living Ctr. of S. Cal., Inc. v. Maxwell-Jolly, 572 F.3d 644, 659 (9th Cir. 2009) ("A budget crisis does not excuse ongoing violations of federal law, particularly where there are no adequate remedies available other than an injunction.").

CONCLUSION

This Court should preliminarily enjoin Defendants from enforcing their illegal regulation and policy and from denying medically necessary Hepatitis C drug therapies.

Dated: October 18, 2016

Respectfully submitted,

/s/ Joel Ferber
Joel Ferber # 35165
Jamie L. Rodriguez # 64323
Legal Services of Eastern Missouri
4232 Forest Park Avenue
St. Louis, Missouri 63108
(314) 534-4200 telephone
(314) 534-1028 facsimile
jdferber@lsem.org
jlrodriguez@lsem.org

/s/ John J. Ammann
John J. Ammann # 34308
Saint Louis University Legal Clinic
321 N. Spring Street
St. Louis, Missouri 63108
(314) 977-2778 telephone
(314) 977-1180 facsimile
ammannjj@slu.edu

/s/ Abigail K. Coursolle
Abigail K. Coursolle
M. Jane Perkins
National Health Law Program, Inc.
3701 Wilshire Blvd, Suite #750
Los Angeles, CA 90010
(310) 204-6010, Ext. 107 telephone
(213) 368-0774 facsimile
coursolle@healthlaw.org
perkins@healthlaw.org

ATTORNEYS FOR PLAINTIFFS