UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

J.E.M., J.L.M., H.L.O Plaintiffs, v. STEVEN CORSI, in his official capacity as Director of the Missouri Department of Social Services; and JAY LUDLAM, in his official capacity as Director of the MO HealthNet Division, Defendants.	)	Case No. 16-04273-CV-C-SRB

FIRST AMENDED COMPLAINT

I. PRELIMINARY STATEMENT

1. This case challenges the policies of the Missouri Department of Social Services which result in the denial of medically necessary treatment for Plaintiffs J.E.M., J.L.M., H.L.O., and numerous other Medicaid beneficiaries infected with the Hepatitis C virus (HCV), a serious and communicable disease that can cause severe liver scarring, liver damage, cancer, and death.

2. This case is filed on behalf of enrollees in the Missouri Medicaid program, also known as MO HealthNet, who are infected with HCV, who meet the FDA's standards for coverage of curative Hepatitis C medication, but who are denied coverage for medically necessary treatment because of the Defendants' arbitrary and improper policies that restrict treatment only to the sickest beneficiaries. Without this treatment, damage to enrollees' livers grows more severe and the risk of complications from the disease increases.

II. JURISDICTION AND VENUE

3. This action arises under Title XIX of the Social Security Act. The Court has jurisdiction pursuant to 28 U.S.C. § 1331, which gives district courts original jurisdiction over all civil actions arising under the Constitution, laws, or treaties of the United States, and 28 U.S.C. §§ 1343(a)(3) and (4), which give district courts original jurisdiction over suits to redress the deprivation under color of state law of any rights, privileges, or immunities guaranteed by the Constitution or acts of Congress.

4. This Court has jurisdiction over this action for declaratory relief pursuant to 28 U.S.C. § 2201 and Rule 57 of the Federal Rules of Civil Procedure. Injunctive relief is authorized by 28 U.S.C. § 2202, 42 U.S.C. § 1983, and Rule 65 of the Federal Rules of Civil Procedure.

5. Venue is proper under 28 U.S.C. § 1391(b).

III. PARTIES

Plaintiffs

6. Plaintiff J.E.M. is a 45-year-old Medicaid recipient living alone in Imperial, Missouri. He suffers from a variety of medical conditions, including Hepatitis C, pancreatitis, spinal osteoarthritis, and high blood pressure. Because of his Hepatitis C, J.E.M. has experienced a significant decrease in energy and motivation. He also experiences anxiety regarding his disease's progress and the potential fatal effect of the infection, which recently took the life of his father. His doctor has prescribed Harvoni®, ledipasvir-sofosbuvir ("Harvoni"), a drug that will likely cure his Hepatitis C. MO HealthNet denied his prior authorization request for Harvoni.

7. Plaintiff J.L.M. is a 36-year-old Medicaid recipient living with her two teenage daughters in Foley, Missouri. She has Hepatitis C and also fibromyalgia. Because of her Hepatitis C, J.L.M.'s underlying fibromyalgia pain and fatigue has worsened. She also experiences continual anxiety and fear that she may inadvertently infect her children. Her doctor has prescribed Epclusa®, sofosbuvir-velpatasvir ("Epclusa"), a drug which will likely cure her Hepatitis C. MO HealthNet denied her prior authorization request for Epclusa.

8. Plaintiff H.L.O. is a 27 year old Medicaid recipient living with her three children in Belton, Missouri. H.L.O. was diagnosed with Hepatitis C early in 2017. Her fibrosis score is F0. She has no other chronic diseases. H.L.O.'s doctor has prescribed Viekira Pak™, ombitasvir/paritaprevir/ritonavir plus dasabuvir ("Viekira Pak") for her, a drug combination that will likely cure her Hepatitis C. MO HealthNet denied her doctor's request for a prior authorization for the drug.

Defendants

9. Defendant Steven Corsi is the Director of the Missouri Department of Social Services ("DSS") and, as such, is responsible for the administration and implementation of laws concerning the social welfare of the people of the State of Missouri, including the Medicaid program. Defendant Corsi is the chief administrative officer of DSS and is responsible for administration of the single state agency for the Missouri Medicaid program. Defendant Corsi is charged with the ultimate control and administration of DSS, including the duty to administer the Missouri Medicaid program in compliance with the Medicaid Act. He is sued in his official capacity. His principal office is located in Jefferson City, Missouri.

10. Defendant Jay Ludlam is the Director of MO HealthNet, a division of DSS, and, as such, is responsible for the administration of the Missouri Medicaid program with the

exception of determining eligibility. Defendant Ludlam holds ultimate administrative power within the MO HealthNet Division, subject to the supervision of Defendant Corsi. He is sued in his official capacity. His principal office is located in Jefferson City, Missouri.

IV. TREATMENT STANDARDS OF CARE FOR HEPATITIS C

11. HCV is a chronic, life-threatening, communicable, blood-borne viral disease. The Missouri Department of Social Services estimates that 13,000 Missouri Medicaid beneficiaries are infected with HCV.

12. In addition to the baseline manifestation of chronic inflammation throughout the body, HCV can lead to severe liver damage, infections, liver cancer, and death. Nearly 20,000 people in the United States die each year due to liver disease caused by HCV. See https://www.cdc.gov/hepatitis/statistics/2015surveillance/commentary.htm (last visited 5/24/17). Even before the advanced stages of the disease, individuals with HCV can suffer from heart attacks, fatigue, joint pain, depression, sore muscles, and arthritis. Up to 70% of those with HCV will develop chronic liver disease, 20% will develop cirrhosis, and 5% will develop liver cancer. HCV is the leading indication for liver transplants in the United States. See http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm (last visited 5/24/17).

13. The severity of HCV is measured by a fibrosis score, which assesses the health of the liver according to the level of liver scarring. The scoring ranges from a score of F0 (mild scarring or scarring absent) to F4 (significant liver damage; cirrhosis).

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

death.

15. On November 22, 2013, the U.S. Food and Drug Administration ("FDA") approved a new direct acting antiviral (DAA) treatment for HCV: a single-pill treatment containing simeprevir sold by Janssen Pharmaceutical under the trade name Olysio®. The FDA designated Olysio® a "breakthrough treatment" because it showed potential to provide a substantial improvement over existing therapies. Since approving Olysio®, the FDA has approved seven other DAA treatments for HCV: Solvaldi®, Harvoni®, Viekira Pak™, Daklinza™, Technivie™, Zepatier®, and Epclusa®. All of the approved DAA treatments for HCV have been granted breakthrough status by the FDA. Clinical studies of each DAA treatment find that the treatment cures HCV in upwards of 90% of cases.

16. DAAs are the standard of medical care for the treatment of nearly all those with HCV, regardless of fibrosis score. Treatment guidelines approved by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America ("AASLD/IDSA") provide that DAAs should ***not*** be reserved for only individuals with fibrosis scores of F3 and F4. See http://hcvguidelines.org/ (last visited 5/24/17). Rather, the standard of care is treating "all patients with chronic HCV infection, except those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy." See http://hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy (last visited 5/24/17). Treating nearly all HCV patients is the standard of care in the community.

17. There are no equally effective alternative medications or medical interventions to the use of DAAs. DAAs are the only medication or medical intervention for HCV that produce a sustained virologic response ("SVR") in more than 90% of patients. Without treatment with DAAs, individuals infected with chronic HCV will never rid themselves of the inflammatory

disease, thus placing them at significantly higher risk for extrahepatic symptoms, liver disease, liver cancer, and even death.

18. HCV is a communicable disease. The CDC lists groups of people known to be at increased risk for HCV infection, including health care workers after needle-sticks involving HCV-positive blood and infants born to HCV-positive mothers. See http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm (last visited 5/24/17). HCV can be transmitted through sexual contact, and can also be passed from mother to child during pregnancy. Because of the risk of transmission, individuals infected with HCV are advised to avoid reproduction or unprotected sexual contact.

V. STATUTORY AND REGULATORY FRAMEWORK

Medicaid

19. Title XIX of the Social Security Act, codified at 42 U.S.C. §§ 1396–1396w-2 ("Medicaid Act"), establishes the Medicaid program. The objective of the Medicaid Act is to enable each State to furnish medical assistance to families with children and to aged, blind, or disabled individuals whose incomes and resources are insufficient to meet the costs of necessary medical services and to furnish "rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care." 42 U.S.C. § 1396-1.

20. Medicaid is a cooperative federal-state program. Participation in the Medicaid program is not mandatory for the states, but once they choose to participate, they must operate their programs in conformity with federal statutory and regulatory requirements. 42 U.S.C. § 1396a.

21. Each state choosing to participate in the Medicaid program must designate a single state agency which is responsible for administering the program. 42 U.S.C. § 1396a(a)(5).

22. The Medicaid Act requires participating states to "provide for making medical assistance available . . . to [all eligible individuals]." 42 U.S.C. § 1396a(a)(10)(A). "Medical assistance" is defined as "payment of part or all of the cost of . . . care and services" included in an enumerated list of twenty-nine general categories of assistance. 42 U.S.C. § 1396d(a). Some of the categories of assistance are mandatory and must be included within a state's Medicaid plan, whiles others are optional. See 42 U.S.C. § 1396a(a)(10)(A).

23. States have the option to cover prescription drugs. 42 U.S.C. § 1396d(a)(12). Missouri has chosen to provide prescription drug coverage as part of its State Medicaid Plan.

24. Among other things, the Medicaid Act requires states' coverage of prescription drugs to comply with the requirements of 42 U.S.C. § 1396r-8. With limited exceptions not relevant here, Missouri must cover the drugs that are manufactured by companies that have entered into rebate agreements with the Secretary of the U.S. Department of Health and Human Services for their "medically accepted indications." A medically accepted indication means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act or a use that is supported by one of three congressionally-approved drug compendia. 42 U.S.C. §§ 1396a(a)(54), 1396d(a)(12), 1396r-8(d), 1396r-8(k)(6).

25. All of the manufacturers of the drugs at issue here have entered into rebate agreements, and the U.S. Food and Drug Administration (FDA) has approved use of the drugs for treatment of Hepatitis C.

26. Under the federal Medicaid Act, the state can impose utilization review techniques on drugs, as long as the state ensures access to drugs for their medically accepted

indications. 42 U.S.C. § 1396r-8(d)(5).

27. In November 2015, the Centers for Medicare & Medicaid Services ("CMS"), the federal Medicaid agency, issued policy guidance for states on the outpatient drug coverage requirements for direct-acting antiviral ("DAA") treatment for HCV treatments, such as Harvoni and Epclusa. CMS, Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Medications (2015), https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-172.pdf. After specifying the limited circumstances in which states may exclude or restrict coverage of an FDA-covered drug, CMS advised states that they "*are required to provide coverage*" for FDA-approved drugs once the manufacturer enters into the rebate agreements described in the Act "*when such drugs are prescribed for medically accepted indications, including the new DAA drugs*." Id. at 2-3 (emphasis added). While noting that states have the discretion to establish utilization controls on the coverage of these drugs, such as preferred drug lists and use of prior authorization processes, CMS underscored that the practices must be consistent with the Act, and that states' "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." Id. at 3.

28. Defendants cover DAAs, including Harvoni and Epclusa, under the Missouri State Medicaid Plan, but only for the most severely ill individuals. Defendants refuse to cover the medication for Medicaid enrollees with less severe liver damage or other symptoms of HCV, even though the coverage is for a medically accepted indication as recognized by the FDA and the medications will likely cure them. Since DAAs meet the standard for coverage under the Medicaid program, the Medicaid Act requires coverage of the medicine when it is for a

medically accepted indication. 42 U.S.C. §§ 1396a(a)(10)(A), 1396r-8.

29. Covered prescription drugs, including DAAs, must be made available to Medicaid beneficiaries when medically necessary, with "reasonable promptness," for all comparable Medicaid enrollees. 42 U.S.C. § 1396a(a)(8).

30. The prescription drug coverage, including access to Harvoni, Epclusa, and other DAAs, that is made available to an individual eligible under the State Medicaid Plan cannot be less in amount, duration or scope than the coverage made available to any other such individual. 42 U.S.C. § 1396a(a)(10)(B), 42 C.F.R. § 440.240, 42 C.F.R. § 440.230(b) (requiring states to ensure that the amount, duration, and scope of coverage are reasonably sufficient to achieve the purpose of the service). This is known as Medicaid's "comparability" requirement.

31. Controlling Eighth Circuit precedent requires the State to cover all non-experimental, medically necessary services, within a covered Medicaid category. Lankford v. Sherman, 451 F.3d 496 (8th Cir. 2006); Weaver v. Reagen, 886 F.2d 194, 198 (8th Cir. 1989). "[A] state's failure to cover non-experimental, medically necessary services within a covered Medicaid category is both per se unreasonable and inconsistent with the stated goals of Medicaid." 451 F.3d at 511.

32. The Eighth Circuit has rejected 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 (emphasis added).

Due Process

33. The Due Process Clause of the U.S. Constitution requires the state Medicaid agency and its agents to provide each Medicaid recipient with adequate written notice and an

opportunity for an impartial hearing before services are denied, reduced or terminated. U.S. Const. XIV Amend.

34. The state Medicaid agency must provide a Medicaid beneficiary with written notice when it takes the time of any action affecting his or her eligibility or coverage of services. 42 U.S.C. § 1396a(a)(3); 42. C.F.R. §§ 431.206(c)(2), 431.210, 431.220(a)(2)

35. The notice must contain: (a) a statement of what action the State intends to take; (b) the reasons for that action; (c) the specific regulations that support, or the change in Federal or State law that requires the action; (d) an explanation of – (1) the individual's right to request an evidentiary hearing, if one is available, or a State agency hearing; or (2) in cases of an action based on a change in law, the circumstances under which a hearing will be granted; and (e) an explanation of the circumstances under which Medicaid is continued if a hearing is required. 42 C.F.R. § 431.210.

36. Due Process also requires the Medicaid program to be administered so to insure fairness and to avoid the risk of arbitrary decision making.

37. The state Medicaid program must adopt and implement ascertainable standards and procedures for determining eligibility for and the extent of medical assistance provided.

The Americans with Disabilities Act

38. The Americans with Disabilities Act, codified at 42 U.S.C. §§ 12101-12181 (hereinafter "ADA") was enacted for the purpose of the "elimination of discrimination against individuals with disabilities." 42 U.S.C. § 12101(b)(1).

39. Title II of the ADA prohibits discrimination against individuals with disabilities by public entities, including state and local governments, their departments, and agencies. 42 U.S.C. §§ 12131, 12132. "[N]o qualified individual with a disability shall, by reason of such

disability, be excluded from participation in or be denied the benefits of the services, programs, or activities of a public entity, or be subjected to discrimination by any such entity." 42 U.S.C. § 12132; 28 C.F.R. §§ 35.130(b)(1)(iv), 35.130(b)(7), 35.130(b)(8), and 35.130(d).

40. Regulations implementing the ADA provide: "A public entity may not, directly or through contractual or other arrangements, utilize criteria or other methods of administration: (i) that have the effect of subjecting qualified individuals with disabilities to discrimination on the basis of disability; [or] (ii) that have the purpose or effect of defeating or substantially impairing accomplishment of the objectives of the entity's program with respect to individuals with disabilities. . . ." 28 C.F.R. § 35.130(b)(3).

41. The ADA requires state governments and agencies to make reasonable modifications to policies, practices and procedures to avoid discrimination on the basis of disability. 28 C.F.R. § 35.130(b)(7).

VI. MISSOURI'S COVERAGE CRITERIA FOR HEPATITIS C

42. The State of Missouri has elected to participate in the Medicaid program and has designated DSS as the single state Medicaid agency. DSS is a department of state government.

43. The federal government shares the cost of the Missouri Medicaid program by providing funding to the State of Missouri. The federal government pays approximately 63 cents of each dollar spent on Medicaid services in Missouri. 79 Fed. Reg. 71428 (Dec. 2, 2014).

44. The MO HealthNet Division indicated on June 23, 2016 that it "agrees with the AASLD/IDSA recommendation that ALL patients should be treated" and that it welcomes the opportunity for every HCV infected patient to have the chance to be "cured."

45. However, Defendants have adopted coverage criteria with respect to when and under what conditions it will approve Harvoni and other similar DAAs for coverage under

Missouri's Medicaid program that are more restrictive than the national standards of care. Missouri Pharmacy Program Preferred Drug List Hepatitis C Therapy (Effective 8/01/2005, Revised 1/5/2017, http://dss.mo.gov/mhd/cs/pharmacy/pdf/hepatitis-c-therapy.pdf.)

46. Defendants have presented these coverage criteria to the MO HealthNet Oversight Committee, a statutorily-created body that advises Missouri's Medicaid program. See http://dss.mo.gov/mhd/oversight/pdf/150217-hepatitis-c-therapy.pdf.

47. Defendants do not provide coverage for all Medicaid beneficiaries with HCV. Defendants' coverage criteria exclude coverage of DAAs for Medicaid enrollees with HCV genotypes 1, 2, and 4 with fibrosis scores of F0, F1 and F2; and exclude coverage of DAAs for Medicaid enrollees with HCV genotype 3 at fibrosis scores of F0 and F1.

48. In January 2017, Defendants reported to the Missouri General Assembly that they have "policies in place that limit treatment to people who have more severe cases of cirrhosis and do not have . . . clinical contraindications to usage."

49. Defendants report that they have approved "some participants" for coverage of DAAs with fibrosis scores of less than F3 based on other specifics of their condition. Defendants revised these standards on January 5, 2017, to note that: "In addition to Metavir fibrosis score, Clinical Consultant will review all therapy requests for documentation of comorbidities that may result in approval." http://dss.mo.gov/mhd/oversight/pdf/150217-hepatitis-c-therapy.pdf. The standards do not say which comorbidities will result in approval, however, nor do they allow any other basis for an exception to the fibrosis score requirement.

50. Fibrosis score is not an acceptable medical reason for denying access to medically necessary DAAs. Plaintiffs were denied DAAs because they did not have fibrosis scores of F3 or F4.

51. Defendants prioritize treatment for Hepatitis C patients who they believe "most urgently need it" rather than provide it to patients for whom such treatment is medically necessary. Defendants' policy is to "defer" treatment until a patient reaches a more advanced stage of liver disease, as measured by fibrosis requirements. The deferral policy has resulted in Plaintiff J.L.M. waiting over nine months, so far, Plaintiff J.E.M waiting over fourteen months, so far, and Plaintiff H.L.O has waited approximately two months, so far, for coverage.

52. Defendants' coverage criteria are inconsistent with accepted medical practice. Defendants have no clinical or medical basis to deny treatment to Medicaid enrollees who have a fibrosis score of F0, F1 or F2. On the contrary, the HCV Guidelines provide that "[b]ecause of the myriad benefits associated with successful HCV treatment, clinicians should treat HCV-infected patients with antiviral therapy with the goal of achieving an SVR, preferably early in the course of their chronic HCV infection before the development of severe liver disease and other complications." See http://hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy (last visited 5/24/17). Treatment of HCV even in patients with mild or no liver disease decreases complications and death rate due to liver disease and prevents transmission of HCV to others.

53. Medicaid enrollees who meet the standards set forth by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America, but who are excluded under Defendants' coverage criteria, are at risk. They are needlessly exposed to health conditions caused by HCV, including cirrhosis, cancer, fatigue, joint pain, depression, sore muscles, arthritis, avoidable liver transplants, jaundice and even death. In addition, the lack of treatment of infected individuals increases the chance that members of the insured's household and the public will be exposed to and contract HCV.

54. Previously, Defendants' authorization criteria also denied DAAs to anyone who

has tested positive for alcohol or illicit drug use. Patients were required to undergo three months of "abstinence" testing (which means they must test negatively for drug and alcohol use three times over three months) before MO HealthNet would consider an authorization request for DAAs. On February 2, 2017, this Court preliminary enjoined the Defendants from continuing to implement this "abstinence test" requirement. Defendants revised their authorization criteria to remove this abstinence requirement.

55. This abstinence requirement was inconsistent with AASLD/IDSA guidelines, which do not require abstinence as precondition for treatment. This requirement further delayed medically necessary treatment to infected patients, allowing their liver disease to progress unnecessarily, and placing them at additional risk. Denying access to DAAs for individuals who test positive for drug use means that such individuals are more likely to spread the disease through sharing of needles.

56. Defendants' coverage criteria are not based on requirements of the Medicaid Act. Rather, Defendants' denial of coverage is an effort to ration care because of its concern over the cost of DAAs. The Defendants' coverage policies result in long delays for medically necessary services, and they exclude some Medicaid enrollees with HCV from medically necessary DAA treatment while providing the same treatment to other Medicaid enrollees with HCV.

Plaintiffs Require DAAs to Treat Their HCV

57. Plaintiffs are enrolled in the Missouri Medicaid program. Both individuals qualify for Medicaid because they meet requirements of 42 U.S.C. § 1396a(a)(10)(A).

58. Plaintiffs have been diagnosed with HCV. Plaintiffs seek treatment with DAAs, which are recommended for nearly *all* patients diagnosed with chronic HCV infection by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of

America, and have been prescribed by their treating physicians. There is no alternative medication or medical intervention that will provide Plaintiffs with equally beneficial results.

Plaintiff J.E.M.

59. J.E.M. is 45 years old and lives alone in Imperial, Missouri.

60. J.E.M. has been diagnosed with Hepatitis C for approximately five years. He also suffers from pancreatitis, spinal osteoarthritis, and high blood pressure.

61. Because of his disabilities, J.E.M. is unable to work. He receives Supplemental Security Income of $733 per month and approximately $190 in food stamps. He has Medicaid coverage based on his disabilities.

62. Because of his Hepatitis C, J.E.M. has experienced a significant decrease in energy and motivation. He is concerned about the possibility of infecting others and takes daily precautions to ensure he does not pass the disease on to others.

63. If he were to attempt to conceive a child, J.E.M. would impose a significant risk of infection on the woman with whom he attempted such conception. J.E.M. takes precautions to avoid conception.

64. J.E.M.'s father recently passed away due to his Hepatitis C and resulting liver cancer. J.E.M. is especially concerned about the effects additional liver damage will have on his life due to this first-hand experience witnessing the impact it had on his father. Because Defendants' policies require his liver to incur more damage before he can be cured, J.EM. feels he is in a hopeless situation.

65. J.E.M.'s treating physician has prescribed Harvoni to cure his Hepatitis C. J.E.M.'s doctor wrote a prescription to Premier Pharmacy Services on March 3, 2016.

66. Prescriptions for Harvoni require prior authorization approval from MO HealthNet. However, at the time J.E.M's doctor wrote the prescription, before MO HealthNet would consider approval, it required three clean "drug screens."

67. Abstinence from drugs or alcohol is not a condition for the receipt of antiviral drugs according to the standard of care for DAA treatment.

68. J.E.M. underwent urine testing on March 25, 2016; May 19, 2016; and June 16, 2016. All of his tests were "clean," showing no non-prescription drug or alcohol use.

69. On or about July 6, 2016, Premier submitted a prior authorization request to MO HealthNet for J.E.M.'s Harvoni.

70. On July 6, 2016, MO HealthNet denied this request.

71. MO HealthNet letter sent a letter to J.E.M. stating that the request was denied because "the information submitted did not meet the criteria established to obtain authorization for this drug."

72. A denial notice sent to J.E.M.'s doctor stated that "the patient does not meet Mo HealthNet's criteria for a fibrosis score of F3 or greater. The patient's fibrosis score is F2 [F1-F2]."

73. MO HealthNet did not offer J.E.M. any other medication as an alternative to treat his Hepatitis C.

74. Waiting for his fibrosis to progress from F2 to F3 means J.E.M. will have to incur further irreversible organ damage before his disease can be cured.

Plaintiff J.L.M.

75. Plaintiff J.L.M. is 36 years old and lives with her two teenage daughters in Foley, Missouri.

76. J.L.M. was diagnosed with Hepatitis C in April 2016. She also has a diagnosis of fibromyalgia.

77. Because of her disabilities, J.L.M. is unable to work. She is a widow and receives $768 in Social Security survivor's benefits each month. J.L.M. is covered by Medicaid based on her disabilities.

78. Because of her Hepatitis C, J.L.M.'s fibromyalgia has worsened, and she experiences frequent pain and fatigue. Her preexisting anxiety has also increased significantly.

79. J.L.M. underwent a tubal ligation to prevent pregnancy. If she reversed her tubal ligation to conceive a child, she would impose a significant risk of infection on her partner, and on any child she conceived.

80. J.LM. lives in constant fear of inadvertently infecting her children. She takes many safety precautions in her home, including bleaching her bathtub each time she shaves her legs. She is also afraid of infecting strangers and worries about what might happen if she were hurt in public and a stranger stopped to help her and then also became infected. J.L.M. is reluctant to leave her home because she is afraid of putting others in danger.

81. J.L.M.'s treating nurse practitioner has prescribed Epclusa to cure her Hepatitis C. J.L.M.'s nurse practitioner wrote a prescription to Walgreens Specialty Pharmacy on July 19, 2016.

82. Prescriptions for Epclusa require prior authorization approval from MO HealthNet. Walgreens submitted a prior authorization request to MO HealthNet for J.L.M.'s Epclusa.

83. J.L.M. underwent urine testing on June 8, 2016; July 7, 2016; and July 22, 2016. All of her tests were "clean," showing no non-prescription drug or alcohol use.

84. On August 26, 2016 MO HealthNet denied the prior authorization request for Epclusa.

85. J.L.M. did not receive a letter explaining the reason for this denial.

86. Walgreens sent a fax to J.L.M.'s doctor that stated the request was "denied Epclusa due to low F-score. At this point there are no other options in which to proceed as she has MO Medicaid. She will need to advance to F3/F4 in order for MO Medicaid to approve her."

87. A denial notice sent to J.L.M.'s nurse practitioner stated that "the patient does not meet Mo HealthNet's criteria for a fibrosis score of F3 or greater. The patient's fibrosis score is F0."

88. MO HealthNet did not offer any other medication as an alternative to treat her Hepatitis C.

89. Waiting for her fibrosis to progress from F0 to F3 means that J.L.M. will have to incur further irreversible organ damage before her disease can be cured.

Plaintiff H.L.O.

90. Plaintiff H.L.O. is a 27 year old Medicaid recipient living with her three children in Belton, Missouri.

91. H.L.O. is a single mother of three children, ages five, six and nine. She survives on $200 a month in child support and financial assistance from her mother.

92. H.L.O. was diagnosed with Hepatitis C early in 2017. Her fibrosis score is F0. She has no other diseases.

93. H.L.O. suffers pain in her abdomen frequently.

94. H.L.O. is constantly anxious about the risk that her children will be infected with Hepatitis C. She has to ensure that her children don't touch her tooth brush, razor, or other personal hygiene items. She and the children use hand sanitizer often throughout the day.

95. If H.L.O. attempted to conceive another child, she would impose a significant risk of infection on her partner, and on any child she conceived. H.L.O takes precautions to avoid conception.

96. H.L.O.'s doctor has prescribed Viekira Pak for her, a drug combination that will likely cure her Hepatitis C. On April 11, 2017, MO HealthNet sent H.L.O.'s doctor a notice indicating that his request for prior authorization "could not be processed at this time" without any explanation. Later that same day, MO HealthNet denied her doctor's request for a prior authorization MO HealthNet for Viekira Pak. The denial notice simply stated, "The patient does not meet MO HealthNet's criteria." On April 25, 2017, MO HealthNet denied her doctor's request for prior authorization a second time, stating the same reason. On May 10, 2017, the MO HealthNet Division sent another notice to her doctor indicating that H.L.O.'s request for prior authorization "could not be processed at this time" because the "patient does not meet MO HealthNet's criteria." On May 12, 2017, MO HealthNet again denied her doctor's request for prior authorization, providing the same rationale for the denial. MO HealthNet did not offer H.LO. any other medication as an alternative to treat her Hepatitis C.

Other Plaintiff Facts

97. Treatment with DAAs is "medically necessary" for Plaintiffs and others, as determined by their treating physicians, and is consistent with the standard of care in the medical community.

98. Defendants take the position that Plaintiffs' treatment may be delayed until a

fibrosis score of F3 or F4 is reached. This position is inconsistent with clinical studies of HCV treatments, the AASLD/IDSA Treatment Recommendations and the standard of care for treatment of HCV in Missouri.

99. Defendants' authorization criteria permit exceptions to its fibrosis score requirement, but do not state the criteria that will be used to evaluate exceptions, or explain when an exception request will be approved. The authorization criteria allow some individuals with a fibrosis score lower than F3 to obtain treatment based on unnamed comorbidities, but do not allow other individuals without these comorbidities to obtain treatment.

100. Defendants' notices also do not explain the reason that Plaintiffs' requests for DAA treatment were denied, nor do they provide the factual or legal basis for the denial. They merely state that Plaintiffs did "not meet the criteria established to obtain authorization for this drug."

101. At all times relevant, Defendants have acted under color of state law in failing and refusing to provide coverage of medically necessary DAAs for Plaintiffs.

102. There is no plain, adequate, or complete remedy at law to prevent or redress the harm suffered by Plaintiffs as a result of Defendants' failure and refusal to provide coverage of medically necessary Hepatitis C drugs.

103. Plaintiffs are suffering and will suffer irreparable harm as a result of Defendants' ongoing unlawful failure to cover medically necessary drugs for treating Hepatitis C.

VII. CLAIMS FOR RELIEF

First Claim for Relief: Violations of Medicaid Entitlement to Appropriate Amount, Duration, and Scope of Treatment

104. Plaintiffs restate and incorporate by reference paragraphs 1 through 103 above.

105. Plaintiffs are entitled to declaratory and injunctive relief pursuant to 42 U.S.C. § 1983 and 28 U.S.C. §§ 2201 and 2202 because Defendants are violating Title XIX of the Social Security Act by excluding Medicaid beneficiaries from medically necessary treatment as required by 42 U.S.C. §§ 1396a(a)(10)(A) and 1396d(a)(12).

Second Claim for Relief: Violations of Medicaid Comparability

106. Plaintiffs restate and incorporate by reference paragraphs 1 through 105 above.

107. Plaintiffs are entitled to declaratory and injunctive relief pursuant to 42 U.S.C. § 1983 and 28 U.S.C. §§ 2201 and 2202 because Defendants, by discriminating among similarly situated Medicaid beneficiaries on the basis of categorical restrictions that are not based upon prevailing clinical standards, are violating Medicaid Act comparability requirements, 42 U.S.C. § 1396a(a)(10)(B)(i).

Third Claim for Relief: Violations of Reasonable Promptness

108. Plaintiffs restate and incorporate by reference paragraphs 1 through 107 above.

109. Plaintiffs are entitled to declaratory and injunctive relief pursuant to 42 U.S.C. § 1983 and 28 U.S.C. §§ 2201 and 2202 because Defendants are violating the "reasonable promptness" requirement of Title XIX of the Social Security Act, 42 U.S.C. § 1396a(a)(8), by implementing a policy that *de facto* rations coverage for Medicaid enrollees seeking HCV treatment, thereby requiring Plaintiffs and those like them to wait until they have developed severe liver damage before receiving medically necessary treatment.

Fourth Claim for Relief: Ascertainable Standards

110. Plaintiffs restate and incorporate by reference paragraphs 1 through 109 above.

111. In order to comply with due process, a State Medicaid program must use reasonable, ascertainable, non-arbitrary standards and procedures for determining eligibility for and the extent of medical assistance provided.

112. Defendants' authorization criteria for DAAs use vague, subjective, arbitrary and secret criteria and procedures for determining which Medicaid beneficiaries with HCV will receive DAA treatment. Defendants' authorization criteria for DAAs are therefore inconsistent with the Due Process Clause of the Fourteenth Amendment to the U.S. Constitution.

Fifth Claim for Relief: Procedural Due Process

113. Plaintiffs restate and incorporate by reference paragraphs 1 through 112 above.

114. In order to comply with due process, when it denies a beneficiary a requested service, a State Medicaid program must provide notice provides the reason for the denial and the specific laws or regulations that support the agency's decision.

115. Defendants' notices that deny Plaintiffs' access to DAA treatment because they "do not meet criteria" violates Plaintiffs' due process rights under the Federal Medicaid Act pursuant to 42 U.S.C. § 1396a(a)(3) and under the Due Process Clause of Fourteenth Amendment to the U.S. Constitution, enforceable pursuant to 42 U.S.C. § 1983.

Sixth Claim for Relief: Americans with Disabilities Act

116. Plaintiffs restate and incorporate by reference paragraphs 1 through 115 above.

117. Each of the Plaintiffs is a "qualified individual with a disability" within the meaning of 42 U.S.C. § 12131(2). Each of the Plaintiffs has a disability that significantly limits his or her life activities including the ability to reproduce, and other major life activities.

118. Defendants' policy of not providing DAA treatment to Plaintiffs treats them differently than other qualified people with disabilities, based solely on the severity of their

disability. It therefore violates the Americans with Disabilities Act, 42 U.S.C. § 12131-12134, and its implementing regulations, which prohibit discrimination on the basis of disability, and requires that reasonable modifications be made to state programs to avoid discrimination on the basis of disability.

REQUEST FOR RELIEF

A. Assume jurisdiction over this action;

B. Issue a declaratory judgment holding that Defendants may not apply policies or practices that exclude or impermissibly limit treatment of HCV with Harvoni, Epclusa, Viekira Pak, or other similar DAAs pursuant to coverage criteria that are inconsistent with the current AASLD/IDSA Treatment Guidelines;

C. Grant preliminary and permanent injunctions that prohibit Defendants from implementing and enforcing the current HCV Treatment Policy (dated October 1, 2015) or otherwise impermissibly limiting access to medically necessary DAAs, and from refusing to provide Medicaid coverage of medically necessary Hepatitis C drugs for Plaintiffs as determined by their physicians;

D. Require Defendants to provide corrective notice to all Medicaid beneficiaries including Plaintiffs, denied coverage under DSS's current HCV Treatment Policy, informing them of a state-based procedure that will be developed, implemented, and available to them for determining whether they qualify for DAAs pursuant to revised criteria that are consistent with the current AASLD/IDSA Treatment Guidelines;

E. Award Plaintiffs their reasonable attorneys' fees and costs; and

F. Grant such other and further relief as may be just and proper.

Respectfully submitted,

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ATTORNEYS FOR PLAINTIFFS

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing was filed electronically with the Clerk of Court on June 6, 2017, to be served by operation of the Court's electronic filing system upon all parties.

/s/ Joel Ferber