IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

JAMIE HARPER and JESSICA OWENS, on their own behalf and on behalf of all similarly situated individuals, **Plaintiffs,** v. **JEFF ANDERSEN**, in his official capacity as the Secretary of the Kansas Department of Health and Environment, and **JON HAMDORF**, in his official capacity as the Director of the Kansas Division of Health Care Finance, **Defendants.**	**CASE NO.:**

CLASS ACTION COMPLAINT

This case challenges the policies of the Kansas Department of Health and Environment that result in the denial of medically necessary treatment for Plaintiffs Jamie Harper, Jessica Owens 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.

This case is filed on behalf of enrollees in the Kansas Medicaid program, also known as KanCare, 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, enrollees' liver damage grows more severe and the risk of complications from the disease increases, thereby depriving them of a cure.

I. JURISDICTION AND VENUE

1. 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.

2. 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.

3. Venue is proper under 28 U.S.C. § 1391(b). A substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in the District of Kansas, and Defendants may be found here.

II. PLAINTIFFS

4. ***Jamie Harper.*** Plaintiff Jamie Harper is a resident of Leavenworth, Leavenworth County, Kansas. Mr. Harper is currently eligible for and enrolled in Medicaid, which is administered by the Kansas Department of Health and Environment ("KDHE"). Mr. Harper is diagnosed with HCV. His treating provider prescribed direct-acting antiviral ("DAA") drugs, prescription medication that effectively cures the disease in more than ***90%*** of the individuals who are treated with it. When he attempted to fill his prescription through his Medicaid coverage, KanCare denied Mr. Harper's request because he was not "sick enough." Mr. Harper has exhausted all review and appeal processes through KanCare.

5. ***Jessica Owens.*** Plaintiff Jessica Owens is a resident of Kansas City, Wyandotte County, Kansas. Ms. Owens is currently eligible for and enrolled in Medicaid, which is administered by the KDHE. Ms. Owens is diagnosed with HCV. Her treating provider prescribed DAA drugs, prescription medication that effectively cures the disease in more than ***90%*** of the individuals who are treated with it. When she attempted to fill her prescription through her

Medicaid coverage, KanCare denied Ms. Owens' request because she was not "sick enough." Ms. Owens has exhausted all review and appeal processes through KanCare.

III. DEFENDANTS

6. ***Jeff Andersen.*** Mr. Andersen is the Acting Secretary of the Kansas Department of Health and Environment ("KDHE"), which is located in Topeka, Shawnee County, Kansas. The KDHE was created in 1974 to replace the Kansas State Board of Health, established in 1885. The Department consists of the Office of the Secretary with all supporting services, and oversees the Kansas Division of Health Care and Finance. The Division works with local health departments and other organizations to help assure the health of Kansans through public health services and regulatory programs. Mr. Andersen is responsible for ensuring that the Medicaid program is administered in a manner consistent with all state and federal laws, including the Medicaid Act. Mr. Andersen is sued in his official capacity only. All alleged acts by Mr. Andersen and KDHE were made under color of state law.

7. ***Jon Hamdorf.*** Jon Hamdorfis the Director of the Kansas Division of Health Care Finance, which is located in Topeka, Shawnee County, Kansas. The Division of Health Care Finance ("DHCF") is responsible for purchasing health services for children, pregnant women, people with disabilities, the aged, and the elderly through the Medicaid program, the Children's Health Insurance Program (CHIP), and the state-funded MediKan program. On average, about 360,000 Kansas are enrolled in these programs each month. Health services are purchased through either a managed care model or a fee-for-service model. The KanCare program is the State of Kansas' managed care program. KanCare is provided to all Medicaid and CHIP consumers. Kansas has contracted with three health plans, or managed care organizations (MCOs), to coordinate health care for nearly all beneficiaries. The KanCare program began in January 2013. The KanCare health plans are Amerigroup of Kansas, Inc. (Amerigroup), Sunflower State Health

Plan (Sunflower), and UnitedHealthcare Community Plan of Kansas (United). Additional information about KanCare, is available at the KanCare website at www.KanCare.ks.gov. Mr. Hamdorf is responsible for ensuring that the Medicaid program is administered in a manner consistent with all state and federal laws, including the Medicaid Act. Mr. Hamdorf is sued in his official capacity only. All alleged acts by Mr. Hamdorf and DHCF were made under color of state law.

IV. FACTUAL ALLEGATIONS

8. HCV is a life-threatening, communicable, blood-borne viral disease of the liver.

9. An estimated 2.7 to 3.9 million people in the United States have chronic Hepatitis C.[1] The United States Census Bureau in 2014 estimated that nearly 35,000 Kansans suffer from Hepatitis C.[2]

10. HCV can lead to chronic infection, chronic liver disease, cirrhosis, liver cancer, and death. Of every 100 persons infected with HCV, approximately:

- 75–85 will go on to develop chronic infection;
- 60–70 will go on to develop chronic liver disease;
- 5–20 will go on to develop cirrhosis over a period of 20–30 years;
- 1–5 will die from the consequences of chronic infection (liver cancer or cirrhosis).[3]

11. HCV is the leading indication for liver transplants in the United States.[4] Nearly 20,000 people in the United States die each year due to liver disease caused by HCV.[5]

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1 *See* http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm (last visit 2/9/18).

2 See http://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf

3 *See* http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm (last visit 2/9/18).

4 *See Id.*

5 *See* http://www.cdc.gov/hepatitis/Statistics/index.htm (last visited 2/9/18).

12. Even before the advanced stages of the disease, individuals with HCV can suffer from heart attacks, fatigue, joint pain, depression, sore muscles, arthritis and jaundice. In addition to the baseline manifestation of chronic inflammation throughout the body, HCV can lead to severe liver damage, infections, liver cancer, and death. Statistics from the Centers for Disease Control and Prevention indicate that up to 70% of those with HCV will develop chronic liver disease, 20% will develop cirrhosis, and 5% will develop liver cancer.

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).

A. Treatment Standards for Hepatitis C

14. Prior to 2013, the standard of care for the treatment of HCV was a three-drug regimen (boceprevir, interferon and ribavirin) that 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 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. Immediately after the FDA approved the first DAA drug, the CDC / Infectious Diseases Society of America ("IDSA") / American Association for the Study of Liver Diseases

("AASLD") updated the standard of care and provided "prioritization tables" and guidance on selecting patients with the greatest need because the "infrastructure . . . did not yet exist to treat all patients immediately."

17. On July 6, 2016, these organizations updated the standard of care in recognition of the fact that continuing medical research has demonstrated the safety, tolerability, and dramatic benefits of DAAs in treating all persons with chronic HCV.

18. Since July 6, 2016, 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 AASLD and IDSA provide that DAAs should ***not*** be reserved for only individuals with fibrosis scores of F3 and F4 or complications from HCV infection. 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."[6]

19. 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.

20. 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.[7]

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[6] *See* https://www.hcvguidelines.org/evaluate/when-whom (last visited 1/9/18).

[7] *See* http://www.cdc.gov/ hepatitis/hcv/hcvfaq.htm (last visited 1/9/18).

B. Federal Medicaid Statutory and Regulatory Framework

21. 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.

22. 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.

23. 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).

24. 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).

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

26. 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, Kansas 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).

27. 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.

28. 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).

29. 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 DAA treatment for HCV, such as Harvoni and Epclusa.[8] 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*."[9] 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

[8] 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.

[9] *Id.* at 2-3 (emphasis added).

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."[10]

30. Defendants cover DAAs, including Harvoni and Epclusa, under the Kansas State Medicaid Plan, but only for the most severely ill individuals. Defendants refuse to cover the medication for Medicaid enrollees unless they meet each of the following conditions:

- Patient must have a diagnosis of chronic Hepatitis C (CHC);
- Patient must have genotype 1, 2, 3, or 4 Hepatitis C;
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist;
- Patient must be 18 years of age or older;
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Solvaldi;
- Patient must not have been on previous or concurrent direct-acting Hepatitis C agents;
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months;
- Dose must not exceed 1 capsule per day;
- Patient must have one of the following:
    - Advanced fibrosis (as defined by a Metavir score of F3)
    - Compensated cirrhosis
    - Organ transplant
    - Type 2 or 3 essential mixed cytoglobulinemia with end-organ manifestations (e.g., vasculitis)
    - Proteinuria
    - Nephrotic syndrome
    - Membranoproliferative glomerulonephritis

[10] *Id*. at 3.

- For Genotypes 1 and/or 4: the PDL preferred drug, which covers Genotypes 1 and 4, is required unless the patient has a documented clinical rationale for using the non-preferred agent supported by the label or AASLD/IDSA HCV guidelines.

31. 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.

32. 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).

33. 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.

34. Controlling Tenth Circuit precedent requires the State to cover all non-experimental, medically necessary services, within a covered Medicaid category.

C. Kansas Medicaid ("KanCare") Coverage Criteria for Hepatitis C Violates Federal Law

35. The State of Kansas has elected to participate in the Medicaid program and has designated the Kansas Department of Health and Environment as the state Medicaid agency.

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

37. 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 Kansas' Medicaid program that are more restrictive than the national standards of care. Kansas Criteria for Prior Authorization (Effective 01/08/2014, Revised 04/12/2017, 01/11/2017, 10/14/2015; 04/08/2015; 07/09/2014; 04/09/2014).

38. Defendants do not provide coverage for all Medicaid beneficiaries with HCV. Defendants' coverage criteria exclude coverage of DAAs for Medicaid enrollees with fibrosis scores of F0 or F1 or F2, unless they also meet the Kansas Criteria for Prior Authorization.

39. Defendants' criteria do not include specific factors under which individuals with these lower scores can seek to qualify for coverage of DAAs.

40. 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 and could not meet the Kansas Criteria for Prior Authorization.

41. Defendants' policy is to deny DAA coverage to all individuals regardless of medical efficacy unless they have a fibrosis score of F3 or meet their restrictive prior authorization requirements.

42. 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 and cannot meet the Kansas Criteria for Prior Authorization. On the contrary, the HCV Guidelines provide that "[b]ecause of the many 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 chronic HCV infection before

the development of severe liver disease and other complications."[11] 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.

43. 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 of increasing severity of their illness. 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.

44. Defendants' authorization criteria also deny DAAs to anyone who has tested positive for alcohol or illicit drug use. Patients must undergo six months of "abstinence" testing before KanCare will consider an authorization request for DAAs.

45. This abstinence requirement is inconsistent with AASLD/IDSA guidelines, which do not require abstinence as precondition for treatment. This requirement further delays 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.

46. 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

[11] *See* https://www.hcvguidelines.org/evaluate/when-whom (last visited 1/9/18).

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.

D. Plaintiffs Require DAAs to Treat Their HCV

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

48. 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.

49. Treatment with DAAs is recommended and prescribed for Plaintiffs by their treating physicians. Both Plaintiffs are diagnosed with HCV and had DAAs prescribed by their treating medical providers.

50. Plaintiffs' requests for coverage of DAAs were denied under Defendants' Uniform Coverage Criteria as set forth in their coverage criteria.

51. 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 and Kansas and federal law.

52. Defendants take the position that Plaintiffs' treatment may be delayed until a fibrosis score of F3 or F4 is reached or one of the Kansas Criteria for Prior Authorization is met. 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 Kansas, and subjects Plaintiffs and other similarly situated to the loss of a chance for a cure.

53. 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.

54. 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.

55. 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.

V. CLASS ACTION ALLEGATIONS

56. Plaintiffs bring this class action on behalf of themselves and all others similarly situated pursuant to Rule 23(a) and 23(b)(2).

57. Plaintiffs seek to represent the following Class:

a. all individuals who:

i were, are, or will be enrolled in the Kansas Medicaid Program ("KanCare") on or after October 31, 2016;

ii require, or are expected to require treatment for Hepatitis C with Harvoni/ledipasvir-sofosbuvir or other similar direct acting antivirals under the current guidelines adopted by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America[12]; and

iii do not meet the Defendants' coverage criteria for HCV medication.

58. As a result of Defendants' deliberate indifference to the serious medical needs of the class, members of the class are or will be denied medically necessary treatment as required by 42 U.S.C §§ 1396a(a)(10)(A) or 1396d(a)(12), suffer discrimination among similarly situated Medicaid beneficiaries on the basis of categorical restrictions that are not based on prevailing clinical standards in violation of 42 U.S.C § 1396a(a)(10)(B) and be denied reasonably prompt

[12] *See* https://www.hcvguidelines.org/evaluate/when-whom (last visited 2/9/18)

medical care in violation of 42 U.S.C § 1396a(a)(8). Plaintiffs seek declaratory and injunctive relief to remedy Defendants' illegal and unconstitutional actions, policies and customs, and practices.

59. The information as to the precise size of the class and the identity of enrollees who are in the class is in the exclusive control of Defendants. The class encompasses thousands of individuals who are geographically dispersed throughout the State of Kansas. The number of persons who are members of the class described above are so numerous that joinder of all members in one action is impracticable.

60. Because the Class seeks prospective relief only, questions of law and fact that are common to the entire Class predominate over individual questions because the actions of Defendants complained of herein were generally applicable to the entire class. These legal and factual questions include, but are not limited to:

(a) Whether Defendants maintain a policy or custom of withholding treatment with DAA drugs from individuals enrolled in the Kansas Medicaid Program who have been or will be diagnosed with HCV;

(b) Whether the policy and custom of Defendants of withholding treatment with DAA drugs from individuals enrolled in the Kansas Medicaid Program who have been diagnosed with HCV constitutes deliberate indifference to a serious medical need;

(c) Whether the policy and custom of Defendants of withholding treatment with DAA drugs from individuals enrolled in the Kansas Medicaid Program who have been diagnosed with HCV discriminates among similarly situated Medicaid beneficiaries on the basis of categorical restrictions that are not based upon prevailing clinical standards in violation of 42 U.S.C. § 1396a(a)(10)(B)(i); and

(d) Whether the policy and custom of Defendants of withholding treatment with DAA drugs from individuals enrolled in the Kansas Medicare Program denies reasonably prompt medical care in violation of 42 U.S.C. § 1396a(a)(8).

61. Plaintiffs' claims for prospective relief are typical of the members of the class because Plaintiffs and all class members are subject to ongoing harm by the same wrongful policy and custom of Defendants of withholding treatment from them. Plaintiffs' claims arise from the same practices and course of conduct that give rise to the claims of the class members, and they are based on the same legal theories.

62. Plaintiffs will fairly and adequately protect the interests of the Class. Plaintiffs have no interests that are contrary to or in conflict with those of the Class they seek to represent. Plaintiffs are represented by competent and skilled counsel whose interests are fully aligned with the interests of the Class.

63. Relief concerning Plaintiffs' rights under the laws herein alleged and with respect to the Class would be proper. Defendants have acted or refused to act on grounds generally applicable to the Class, thereby making appropriate final injunctive relief or corresponding declaratory relief with regard to Class Members as a whole and certification of the Class under Rule 23(b)(2) proper.

COUNT I

Violations of Medicaid Entitlement to Appropriate Amount, Duration, and Scope of Treatment (Asserted on Behalf of the Class)

64. Plaintiffs restate and incorporate by reference paragraphs 1 through 63 above.

65. The Class is 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).

66. The individual Plaintiffs are entitled to damages for personal injuries incurred as a result of Defendants' violation of 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).

COUNT II

Violations of Medicaid Comparability (Asserted on Behalf of the Class)

67. Plaintiffs restate and incorporate by reference paragraphs 1 through 66 above.

68. The Class is 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).

69. The individual Plaintiffs are entitled to damages for personal injuries incurred as a result of Defendants' 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).

COUNT III

Violations of Reasonable Promptness (Asserted on Behalf of the Class)

70. Plaintiffs restate and incorporate by reference paragraphs 1 through 69 above.

71. The Class is 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.

72. The individual Plaintiffs are entitled to damages for personal injuries incurred as a result of Defendants' 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 to wait until they have developed severe liver damage before receiving medically necessary treatment.

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, 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 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 Defendants' 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 damages individually for harm caused by the Defendants' HCV Treatment Policy.

(f) Award Plaintiffs their reasonable attorneys' fees and costs; and

(g) Grant such other and further relief as may be just and proper.

DEMAND FOR JURY TRIAL

In accordance with Fed. R. Civ. P. 38. Plaintiffs demand a jury trial on any issue triable of right to a jury.

REQUEST FOR PLACE OF TRIAL

In accordance with D. Rule Kan. 40.2, Plaintiffs request trial be held in Topeka, Kansas.

Dated: February 15, 2018

Respectfully submitted,

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