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UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

B. E. and A. R., on their own behalf and on
behalf of all similarly situated individuals,

NO. 2:16-cv-227

Plaintiffs,

v.

COMPLAINT
(CLASS ACTION)

DOROTHY F. TEETER, in her official
capacity as Director of the Washington State
Health Care Authority,

Defendant.

I. INTRODUCTION

Plaintiffs are Medicaid enrollees who have contracted Hepatitis C, a communicable disease that afflicts millions of Americans. There is a cure for Plaintiffs and thousands of others, but the Washington State Health Care Authority does not cover curative, breakthrough drugs for all Medicaid beneficiaries for one impermissible reason: they are expensive. It is unlawful to withhold prescription drugs that cure a disease from Medicaid beneficiaries based on the cost of those drugs. Plaintiffs ask this Court to order the Health Care Authority to cover these drugs so they and others similarly situated may be cured.

II. PARTIES

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1. **B.E.** Plaintiff B.E. is a resident of Seattle, Washington. Ms. E. is eligible for and enrolled in Medicaid, which is administered by the Washington state Health Care Authority (“WHCA”). Ms. E. is diagnosed with Hepatitis C virus (“HCV”). Her treating provider prescribed Harvoni®, ledipasvir-sofosbuvir (“Harvoni”), a prescription drug 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, WHCA denied Ms. E.’s request because Harvoni is expensive. WHCA did not offer Ms. E. any other medication as an alternative to treat her HCV.

2. **A.R.** Plaintiff A.R. is a resident of Lakewood, Washington. Mr. R. is also eligible for and enrolled in Medicaid. He is also diagnosed with HCV for which his treating medical provider has prescribed Harvoni. WHCA also denied Mr. R.’s request for Harvoni for the same reason it denied B.E.’s request. WHCA did not offer Mr. R. any other medication as an alternative to treat his HCV.

3. **Dorothy F. Teeter.** Defendant Dorothy F. Teeter is the Director of the Washington State Health Care Authority. WHCA is the designated single state agency for Washington’s Medicaid programs. Ms. Teeter is responsible for ensuring that the Medicaid program is administered in a manner consistent with all state and federal laws, including the Medicaid Act. Ms. Teeter is sued in her official capacity only. All alleged acts by Ms. Teeter and WHCA were made under color of state law.

III. JURISDICTION AND VENUE

4. **Jurisdiction.** Jurisdiction of this Court arises under 28 U.S.C. § 1331 because this action arises under the laws of the United States, and 28 U.S.C. § 1343(3) and (4), which confer on the federal district courts original jurisdiction over all claims asserted pursuant to 42 U.S.C. § 1983 to redress deprivations of rights, privileges or immunities guaranteed by Acts of Congress and the United States Constitution.

1 5. **Venue.** Venue is proper pursuant to 28 U.S.C. § 1391(b). A substantial part
2 of the events or omissions giving rise to plaintiffs' claims occurred in the Western District
3 of Washington, and defendants may be found here.

4 **IV. NATURE OF THE CASE**

5 6. ***Plaintiffs' Need for Treatment with Harvoni.*** Both Ms. E. and Mr. R. have
6 been diagnosed with Hepatitis C ("HCV"). Both seek treatment with Harvoni, one of
7 several direct-acting antiviral medications ("DAAs") recommended for nearly *all*
8 patients diagnosed with chronic HCV infection by the American Association for the
9 Study of Liver Diseases and the Infectious Diseases Society of America. Treatment
10 results in a more than *90% cure rate*. There is no alternative medication or medical
11 intervention that would provide Ms. E. or Mr. R. with equally beneficial results.

12 7. ***WHCA Limits Coverage for Harvoni and other DAAs for Fiscal Reasons***
13 ***Only.*** WHCA, pursuant to a uniform coverage policy, will not approve plaintiffs'
14 treatment with Harvoni. WHCA has put in place internal coverage restrictions that
15 impermissibly restrict DAA coverage. Specifically, WHCA rations HCV treatment,
16 excluding all coverage except to its insureds who are most severely ill. The restrictions
17 on coverage do not have a clinical purpose, but are imposed solely due to WHCA's fiscal
18 concerns.

19 8. ***WHCA's Uniform Policy Risks the Lives and Health of Medicaid***
20 ***Enrollees.*** WHCA's restrictive internal coverage criteria require that infected
21 individuals wait for treatment - potentially for years - until they demonstrate serious
22 scarring or cirrhosis of the liver from HCV infection. In the meantime, Ms. E., Mr. R. and
23 others are forced to live with a chronic inflammatory disease, including the pain, fatigue,
24 depression, deteriorating health and increased risk of cancer and death that accompany
25 it.

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1 9. ***WHCA's Restrictive Coverage Criteria Violate the Medicaid Act.*** This
2 lawsuit seeks to end WHCA's improper exclusion of Harvoni and other DAAs for the
3 treatment of HCV for certain enrollees. It seeks legal and equitable remedies against
4 WHCA on behalf of plaintiffs and the class they seek to represent. It also seeks a court
5 order declaring WHCA's internal categorical exclusionary criteria illegal, void, and
6 inconsistent with its obligations to provide reasonably prompt coverage of medically
7 necessary prescription drugs to all Medicaid enrollees to whom they are prescribed. The
8 lawsuit further seeks an injunction to prevent any future or ongoing efforts by WHCA
9 to use and enforce any policies or practices that impermissibly deny, exclude or limit its
10 insureds' access to medically necessary prescription drugs to treat HCV, in addition to
11 ensuring that both coverage and corrective notice be provided to its insureds.

12 **V. FACTUAL AND LEGAL FRAMEWORK**

13 ***HCV TREATMENT***

14 10. ***HCV Is Widespread.*** HCV is a chronic, life-threatening, communicable,
15 blood-borne viral disease. It is estimated that approximately five million individuals in
16 the United States are living with HCV, accounting for over 1% of the population. The
17 Washington Department of Health estimates over 100,000 Washington residents are
18 infected with HCV.

19 11. ***HCV Is a Serious Disease.*** In addition to the baseline manifestation of
20 chronic inflammation throughout the body, HCV can lead to severe liver damage,
21 infections, liver cancer, and death. Nearly 20,000 people in the United States die each
22 year due to liver disease caused by HCV. See [http://www.cdc.gov/hepatitis/
23 Statistics/index.htm](http://www.cdc.gov/hepatitis/Statistics/index.htm) (last visited 1/25/16). Even before the advanced stages of the
24 disease, individuals with HCV can suffer from heart attacks, fatigue, joint pain,
25 depression, sore muscles, arthritis and jaundice. Statistics from the Centers for Disease
26 Control and Prevention indicate that up to 70% of those with HCV will develop chronic

1 liver disease, 20% will develop cirrhosis, and 5% will develop liver cancer. HCV is the
2 leading indication for liver transplants in the United States. See
3 <http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm> (last visited 2/3/16).

4 12. *Severity of HCV Is Measured by a Fibrosis Score.* Liver health for those
5 who are infected with HCV is graded according to the level of liver scarring under a
6 fibrosis score. The scoring ranges from a score of F0 (mild scarring or scarring absent)
7 to F4 (significant liver damage; cirrhosis).

8 13. *Prior Treatments Were Expensive, Often Ineffective and Accompanied by*
9 *Significant Side Effects.* Until DAAs were approved, the standard of care for the
10 treatment of HCV was a three-drug treatment containing boceprevir, interferon and
11 ribavirin. The treatment only provided at most a 70% cure rate, and was accompanied
12 by significant adverse side effects such as anemia, insomnia, anxiety, depression, nausea,
13 bone pain, muscle, liver failure, joint pain, memory loss and death. On information and
14 belief, WHCA covered the three-drug treatment for any Medicaid beneficiary who was
15 HCV irrespective of the person's Metavir Fibrosis score.

16 14. *FDA Approves Harvoni and other DAAs as a "Breakthrough Therapy."*
17 Fortunately for Ms. E., Mr. R. and others like them, the federal Food and Drug
18 Administration ("FDA") has approved DAAs, a class of curative pharmaceutical drug
19 treatments for HCV. One such DAA, Harvoni, was approved on October 10, 2014. It
20 has a success rate over 90% and is accompanied by few, if any, side effects. Harvoni was
21 designated a "breakthrough therapy" by the FDA, a classification reserved for drugs that
22 have proven to provide substantial improvement over available therapies for patients
23 with serious or life-threatening diseases.

24 15. *Harvoni and Other DAAs Are Recommended for Nearly All Patients with*
25 *HCV, Without Regard for Fibrosis Score.* Harvoni and other DAAs are the standard of
26 medical care for the treatment of all HCV. This includes treatment of all individuals

1 irrespective of fibrosis score. Treatment guidelines approved by the American
2 Association for the Study of Liver Diseases and the Infectious Diseases Society of
3 America (“AASLD/IDSA”) confirm that Harvoni and other DAAs should *not* be
4 reserved for only individuals with fibrosis scores of F3 and F4. See
5 <http://hcvguidelines.org/> (last visited 1/25/16). Rather, the standard of care is treating
6 “all patients with chronic HCV infection, except those with short life expectancies that
7 cannot be remediated by treated HCV, by transplantation, or by other directed therapy.”
8 See <http://hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy> (last
9 visited 1/25/16). Treating nearly all HCV patients is the standard of care in the
10 community.

11 16. *There Is No Equally Effective Alternative Medication or Medical*
12 *Intervention.* DAAs are the only medication or medical intervention for HCV that
13 produce a sustained virologic response (“SVR”) in more than 90% of patients. SVR
14 status means that the virus is virtually undetectable in a patient; this is considered to be
15 a cure of the infection. The prior intervention offered to HCV patients, treatment with
16 boceprevir, interferon and ribavirin, only produced SVR in approximately 70% of
17 patients, resulted in a host of adverse side effects. Without treatment, Medicaid enrollees
18 infected with chronic HCV will never rid themselves of the inflammatory disease,
19 placing these Medicaid enrollees at significantly higher risk for extrahepatic symptoms,
20 liver disease, liver cancer, and even death.

21 17. *People with HCV Can Transmit It.* HCV is a communicable disease. The
22 CDC lists people known to be at increased risk for HCV infection. See
23 <http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm> (last visited 2/3/16). Among those at
24 risk are health care workers after needle-sticks involving HCV-positive blood, and
25 infants born to HCV-positive mothers. WHCA’s policy of restricting DAAs ignores the
26 public health risks associated with not curing HCV.

THE MEDICAID ACT REQUIRES COVERAGE OF DAAs TO TREAT HCV.

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18. *The Medicaid Act Includes Prescription Drug Coverage.* The Medicaid Act requires participating state programs (known as “State Medicaid Plans”) to make medical assistance available to qualified individuals for certain services. 42 U.S.C. § 1396a(a)(10)(A). The State Medicaid Plan has the option to make medical assistance available for other specified services, including prescription drugs. 42 U.S.C. § 1396d(a)(12). Once the state chooses to provide medical assistance prescription drugs, it must comply with the requirements of § 1396r-8(k) for payments of covered outpatient drugs. 42 U.S.C. § 1396a(a)(54). Washington state has chosen to provide prescription drug coverage as part of its State Medicaid Plan.

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19. *All of the Requirements for Coverage Of DAAs Under Washington’s State Medicaid Plan Are Met.* State Medicaid plans, including Washington’s, are generally required to provide coverage for any covered outpatient drug that is medically necessary once the drug manufacturer enters into a rebate agreement and the medicine is approved by the FDA and prescribed by a provider. *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 652, 123 S. Ct. 1855 (2003) (“PHARMA”); 42 U.S.C. §§ 1396r-8(a)(1), 1396r-8(d)(B), 1396r-8(k)(2)(A); (6). WHCA covers DAAs, including Harvoni, under the Washington State Medicaid Plan, but only for the most severely ill individuals with HCV. WHCA refuses to cover the medication for Medicaid enrollees with less severe liver damage or other symptoms of HCV, even though the medications will likely cure them.

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20. *Covered Prescription Drugs, Including DAAs, Must Be Provided When Medically Necessary, with “Reasonable Promptness,” for All Comparable Medicaid Enrollees.* Since Harvoni and other DAAs meet the standard for coverage under Washington’s Medicaid program, the Medicaid Act requires coverage of the medicine when it is medically indicated. 42 U.S.C. §§ 1396a(a)(10)(A); 1396r-8. *See also* WAC 182-500-0070 (defining “medical necessity” in Washington’s Medicaid program). Under

1 Washington’s Medicaid program, if the treatment is covered and medically necessary, it
 2 must also be provided with “reasonable promptness,” typically within 90 days.
 3 42 U.S.C. § 1396a(a)(8); *Doe v. Chiles*, 136 F.3d 709, 714 (11th Cir. 1988). In addition,
 4 medically necessary prescription drug coverage, including access to Harvoni and other
 5 DAAs, cannot be made available in a lesser amount, duration or scope than the coverage
 6 made available to any other individual eligible under the State Medicaid Plan. 42 U.S.C.
 7 § 1396a(a)(10)(B); 42 C.F.R. § 440.240. This is known as Medicaid’s “comparability”
 8 requirement. See *Jenkins v. Washington Department of Social and Health Services*, 162 Wn.
 9 2d 287, 296-97 (2007). WHCA’s coverage criteria for HCV treatment must comply with
 10 all three of these Medicaid Act requirements.

11 **WHCA’S UNIFORM EXCLUSIONARY COVERAGE CRITERIA**

12 21. ***WHCA Has Adopted Coverage Criteria for Harvoni and Other DAAs.***

13 WHCA has adopted a uniform coverage approach with respect to when and under what
 14 conditions it will approve Harvoni and other similar DAAs for coverage under
 15 Washington’s Medicaid program. A copy of WHCA’s Coverage Criteria is attached as
 16 *Appendix 1*.

17 22. ***WHCA Does Not Provide Coverage for All Its HCV-infected Insureds.***

18 WHCA’s coverage criteria generally exclude coverage for Harvoni and other DAAs for
 19 Medicaid enrollees with fibrosis scores of F0, F1 and F2 where no other conditions are
 20 present.

21 23. ***WHCA’s Coverage Criteria Are Inconsistent With Accepted Medical***
 22 ***Practice.*** WHCA has no clinical or medical basis to deny treatment to Medicaid

23 enrollees who have a fibrosis score of F0, F1 or F2. On the contrary, the HCV Guidelines
 24 provide that “[b]ecause of the myriad benefits associated with successful HCV
 25 treatment, clinicians should treat HCV-infected patients with antiviral therapy with the
 26 goal of achieving an SVR, *preferably early in the course of their chronic HCV infection*

1 *before the development of severe liver disease and other complications.” See*
2 <http://hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy> (last
3 visited 1/25/16) (emphasis added). Treatment of HCV even in patients with mild or no
4 liver disease decreases complications and death rate due to liver disease and prevents
5 transmission of HCV to others.

6 24. *WHCA’s Coverage Criteria Put Medicaid Enrollees at Risk of Multiple*
7 *HCV Complications, Including Death.* WHCA’s Medicaid enrollees who meet the
8 standards set forth by the American Association for the Study of Liver Diseases and the
9 Infectious Diseases Society of America, but who are excluded under WHCA’s coverage
10 criteria, are put at risk. They are needlessly exposed to health conditions caused by
11 HCV, including cirrhosis, cancer, fatigue, joint pain, depression, sore muscles, arthritis,
12 avoidable liver transplants, jaundice and even death. In addition, the lack of treatment
13 of infected individuals increases the chance that members of the insured’s household
14 and the public will be exposed to and contract HCV.

15 25. *WHCA Has Publicly Stated Its Coverage Position.* WHCA’s coverage
16 position is publicly posted on WHCA’s website. See [http://www.hca.wa.gov/](http://www.hca.wa.gov/medicaid/pharmacy/Documents/hepatitis_c_treatment_policy.pdf)
17 [medicaid/pharmacy/Documents/hepatitis_c_treatment_policy.pdf](http://www.hca.wa.gov/medicaid/pharmacy/Documents/hepatitis_c_treatment_policy.pdf) (last visited
18 02/02/16). It is known by many doctors treating Medicaid enrollees.

19 26. *WHCA’s Coverage Criteria Impermissibly Ration Care.* WHCA’s
20 coverage criteria are not tied to the requirements of the Medicaid Act, or to WHCA’s
21 regulations governing coverage of medically necessary prescription medications.
22 Rather, WHCA’s denial of coverage is an effort to ration care because of its concern over
23 the perceived expense of Harvoni and other DAAs. As stated by Donna L. Sullivan,
24 M.S., Pharm. D., HCA’s Chief Pharmacy Officer, the real reason that HCA continues to
25 employ the excessively restrictive coverage criteria is a *political* one:
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1 I've had discussions with Dr. Lessler, with Charissa and with
 2 the specialists in the community with the Department of
 3 Corrections as well as Labor and Industries, and *I can*
 4 *guarantee you that all of us agree that everyone should be*
 5 *treated* whether they are at stage 2, stage 3, stage 4.
 6 However, we have received funding only based on the
 7 criteria that we gave for F3. So we are having discussions
 8 with the Office of Financial Management with legislative
 9 staff. We have requested a supplemental budget to expand
 10 our coverage criteria to F3, but we can't just open up our
 11 doors right now and do that. ... *It's out of our hands. None*
 12 *of us would argue that we should not expand it*, that it's not
 13 the right thing to do, but we live in a *political* environment
 14 as a state that I have to operate within the resources and rules
 15 around those resources that have been given to us.

16 See http://www.hca.wa.gov/pdp/ptmeetingdocuments/Transcript_102115.pdf, p. 64
 17 (emphasis added). These concerns cannot usurp WHCA's obligations under the
 18 Medicaid Act.

19 ***PLAINTIFFS E. AND R. REQUIRE HARVONI TO TREAT HCV.***

20 27. *Plaintiffs Are Enrolled in Medicaid.* During certain time periods on and
 21 after October 10, 2014, Plaintiffs E. and R. have been, are or will be enrolled in
 22 Washington state's Medicaid program, which is administered by WHCA. Both are
 23 "qualified individuals" as defined in 42 U.S.C. § 1396a(a)(10)(A).

24 28. *Treatment With Harvoni Is Recommended and Prescribed for Both*
 25 *Plaintiffs.* Plaintiffs E. and R. both are diagnosed with HCV. Plaintiffs both have a
 26 Metavir Fibrosis Score of F0. Both plaintiffs had Harvoni prescribed by their treating
 medical providers.

27 29. *Treatment With Harvoni Is "Medically Necessary" for Plaintiffs B.E.,*
 28 *R.A. and Similarly Situated Others Under the WHCA Definition of Medical*
 29 *Necessity.* Treatment with Harvoni is "medically necessary" for plaintiffs and similarly
 30 situated others under the established definition of "medically necessary" located in
 31 WAC 182-500-0070, and established by the consent order in *Mead v. Burdman*, No. 818663

1 (King Cty. Sup. Ct., J. Hunter, March 20, 1978). Harvoni and other similar DAAs are
2 likely to cure plaintiffs E., R. and other similarly situated individuals. There is no equally
3 effective, less costly alternative prescription drug or medical intervention, and WHCA
4 has offered none. WHCA apparently takes the position that treatment may be delayed
5 because the adverse health effects of chronic HCV can be reversed until a Metavir
6 Fibrosis Score of F3 or F4 is reached. This position is inconsistent with clinical studies of
7 HCV treatments, the AASLD/ISDA Treatment Recommendations and the standard of
8 care for treatment of HCV in Washington state.

9 30. *Plaintiffs' Request for Coverage of Harvoni Was Denied Under WHCA's*
10 *Uniform Coverage Criteria.* WHCA denied Ms. E.'s preauthorization request for
11 treatment with Harvoni on January 12, 2016 because her Metavir Fibrosis Score was
12 under F3 and she had no qualifying co-morbid condition. WHCA did not offer Ms. E.
13 any other medication as an alternative to treat her HCV. WHCA denied Mr. R.'s
14 pre-authorization request for treatment with Harvoni on June 15, 2015 because his
15 Metavir Fibrosis Score was under F3 without a qualifying co-morbid condition. WHCA
16 did not offer Mr. R. any other medication as an alternative to treat his HCV. Neither
17 plaintiff was provided with notice of the denial that met constitutional due process
18 requirements. Nonetheless, Mr. R. appealed. An administrative hearing was held on
19 September 30, 2015. Mr. R. appeared *pro se*, and the Administrative Law Judge issued
20 an initial decision, upholding WHCA's denial. Mr. R. appealed the decision to the
21 WHCA Board of Appeals, which, *sua sponte*, remanded the case to the Administrative
22 Law Judge for an additional hearing.

VI. CLASS ALLEGATIONS

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2 31. *Size and Definition of Class.* The class consists of:

3 (a) all individuals who:

4 (i) were, are, or will be enrolled in Washington state
5 Health Care Authority's Medicaid Program on or
6 after October 10, 2014;

7 (ii) require, or are expected to require treatment for
8 Hepatitis C with Harvoni/ledipasvir-sofosbuvir
9 or other similar direct acting antivirals under
10 the current guidelines adopted by the American
11 Association for the Study of Liver Diseases and the
12 Infectious Diseases Society of America (*see*
13 [http://www.hcvguidelines.org/full-report/when-
and-whom-initiate-hcv-therapy](http://www.hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy)) (last visited
1/25/16); and

14 (iii) do not meet the coverage criteria for HCV
15 medication adopted by WHCA, as set forth in
16 *Appendix 1*.

17 32. *Class Representatives B.E. and A.R.* As noted above, named plaintiffs B. E.
18 and A. R. are enrolled in WHCA's Medicaid Program. Both have HCV and require
19 treatment with Harvoni. Both have been denied coverage of Harvoni because their
20 Metavir Fibrosis Score is under F3 and they have no qualifying co-morbid condition.
21 Both plaintiffs meet the criteria for treatment under the guidelines approved by the
22 American Association for the Study of Liver Diseases and the Infectious Diseases Society
23 of America. Their claims are typical of the claims of the other members of the class, and
24 they will fairly and adequately represent the interests of the class. Neither have any
25 conflicts of interest with the class.

26 33. *Size of Class.* The class is sufficiently numerous. WHCA has denied
coverage of Harvoni and other DAAs to at least 900 Medicaid consumers since January 1,

1 2015, likely because the enrollees had a Fibrosis Score of F0, F1 or F2.¹ WHCA estimates
 2 that if it expanded its coverage to include all enrollees with Fibrosis Score of F2, an
 3 additional 4700 Medicaid enrollees would be affected.² As a result, the class numbers in
 4 the thousands and is so large that joinder of all members is impracticable.

5 34. *Common Questions of Law and Fact.* This action requires a determination
 6 of whether WHCA's coverage criteria that denies, excludes and/or limits coverage of
 7 Harvoni and other similar DAAs violates the Medicaid Act. A determination of this
 8 issue will in turn determine whether plaintiffs and the class are entitled to declaratory
 9 and injunctive relief.

10 35. *WHCA Has Acted on Grounds Generally Applicable to the Class.* WHCA,
 11 by applying a uniform policy that results in the exclusion of Harvoni and other similar
 12 DAAs to plaintiffs and others similarly situated, has acted on grounds generally
 13 applicable to the class. Certification is therefore proper under Fed. R. Civ. P. 23(b)(2).

14 36. *Class Counsel.* Plaintiff has retained experienced and competent class
 15 counsel capable of representing the class expertly and without conflict of interest.

16 VII. CLAIMS FOR RELIEF

17 **FIRST CLAIM: EXCLUSION OF QUALIFIED INDIVIDUALS FROM 18 COVERED MEDICAL ASSISTANCE UNDER THE MEDICAID ACT**

19 37. Plaintiff re-alleges all of the above paragraphs.

20 38. Plaintiffs and the class are entitled to declaratory and injunctive relief
 21 pursuant to 42 U.S.C. § 1983 and 28 U.S.C. §§ 2201 and 2202 that defendant has violated
 22 Title XIX of the Social Security Act (also known as the Medicaid Act) by excluding
 23 qualified Medicaid recipients from medically necessary treatment as required by

24 _____
 25 ¹ See http://www.hca.wa.gov/pdp/ptmeetingdocuments/Hep_C_DUR_1015.pdf, p. 3 (WHCA
 26 received 1695 requests for HCV treatment from January-June 2015, and only approved 45% of the requests, denying more than 900 Medicaid enrollees curative treatment).

² http://www.hca.wa.gov/Documents/budget/2016_PL-2_Hepatitis_C_Treatment_Expansion.pdf.

1 42 U.S.C. §1396a(a)(10)(A).

2 **SECOND CLAIM: VIOLATIONS OF MEDICAID COMPARABILITY**

3 39. Plaintiff re-alleges all of the above paragraphs.

4 40. Plaintiffs and the class are entitled to declaratory and injunctive relief
5 pursuant to 42 U.S.C. § 1983 and 28 U.S.C. §§ 2201 and 2202 because defendant, by
6 discriminating among similarly situated Medicaid recipients on the basis of categorical
7 restrictions that are not based upon prevailing clinical standards, has violated Medicaid
8 Act comparability requirements, 42 U.S.C. § 1396a(a)(10)(B)(i) and (ii); 42 C.F.R.
9 § 440.240.

10 **THIRD CLAIM: VIOLATIONS OF REASONABLE PROMPTNESS**

11 41. Plaintiff re-alleges all of the above paragraphs.

12 42. Plaintiffs and the class are entitled to declaratory and injunctive relief
13 pursuant to 42 U.S.C. § 1983 and 28 U.S.C. §§ 2201 and 2202 that defendant has violated
14 the “reasonable promptness” requirement of Title XIX of the Social Security Act, 42
15 U.S.C. § 1396a(a)(8), by implementing a policy that *de facto* rations coverage for Medicaid
16 enrollees seeking HCV treatment, thereby requiring plaintiffs and the class to wait until
17 they have developed severe liver damage before receiving medically necessary
18 treatment.

19 **VIII. DEMAND FOR RELIEF**

20 WHEREFORE, plaintiffs request that this Court:

21 (a) Certify this case as a class action, designate the named plaintiffs as class
22 representatives, and designate SIRIANNI YOUTZ SPOONEMORE HAMBURGER, Richard E.
23 Spoonemore and Eleanor Hamburger, COLUMBIA LEGAL SERVICES, Amy L. Crewdson,
24 and CENTER FOR HEALTH LAW AND POLICY INNOVATION, Kevin Costello, as class counsel;

25 (b) Declare that WHCA may not apply policies or practices that exclude or
26 impermissibly limit treatment of HCV with Harvoni or other similar DAAs pursuant to

1 coverage criteria that are inconsistent with the current AASLD/IDSA Treatment
2 Guidelines;

3 (c) Enjoin WHCA from continuing to implement and apply its current HCV
4 Treatment Policy, attached as *Appendix 1*;

5 (d) Require WHCA to provide corrective and constitutionally adequate notice
6 to class members, and to reprocess and approve coverage for all class members who
7 were previously denied coverage under WHCA's current HCV Treatment Policy;

8 (e) Award plaintiffs and the class their attorney fees and costs pursuant to 42
9 U.S.C. § 1988; and

10 (f) Award such other relief as is just and proper.

11 DATED: February 16, 2016.

12 SIRIANNI YOUTZ
13 SPOONEMORE HAMBURGER

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15 By: s/ Eleanor Hamburger

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