

THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No.

ROBERT CUNNINGHAM, on behalf
of himself and all others similarly situated,

Plaintiff,

v.

SUSAN E. BIRCH, in her official capacity only as
Executive Director of the COLORADO STATE DEPARTMENT OF HEALTH
CARE POLICY & FINANCING,

Defendant.

CLASS ACTION COMPLAINT

For his Class Action Complaint against Defendant, Plaintiff alleges as follows on behalf of himself and the class of similarly situated people he seeks to represent.

I. NATURE OF CASE

1. This is a case about the unlawful denial by the State of Colorado of treatment to potentially thousands of Medicaid eligible individuals who are infected by the insidious and life threatening Hepatitis C Virus. Plaintiff is a Medicaid enrollee who suffers from this communicable disease that afflicts millions of Americans. It is, in fact, the most deadly infectious disease in this country, killing more Americans than the next 60 infectious diseases combined. Untreated, the chronic Hepatitis C Viral disease not only causes serious existing symptoms such as pain, fatigue, depression, deteriorating overall health, and an increased risk of liver failure, but can lead to fibrosis, cirrhosis, and cancer of the liver, the need for a liver transplant, and death. Yet along with thousands of other Coloradoans, Plaintiff has been denied a

cure the FDA has labeled as a “breakthrough therapy,” because he has not yet suffered measurable and potentially irreversible liver damage. The treatment denied is approved by the U.S. Food and Drug Administration; is strongly urged by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America; and is recommended by the federal agency responsible for administering Medicaid. It is provided by Medicare, the VA and the overwhelming majority of commercial health insurers. And it is the consensus medical standard of care in the United States, for the simple reason that it is the only feasible cure for the disease. The denial of this cure is effected in Colorado through the illegal imposition of a criterion of eligibility that forbids the disease ridden individual access to the cure until the disease has caused serious liver damage. This is the story of how the State of Colorado brought about this discordant and disconsonant result. And this case is about overturning it.

II. JURISDICTION AND VENUE

2. Jurisdiction is proper under 28 U.S.C. § 1331, because this action arises under the laws of the United States. Specifically, Plaintiff’s causes of action arise under 42 U.S.C. § 1983 to redress deprivations of rights guaranteed him by 42 U.S.C. §§1396a(a)(10)(A), 1396a(a)(10)(B)(i) & (ii), and 1396a(a)(8).

3. Venue is proper under 28 U.S.C. § 1391(b)(1) and (2), because all of the actions, events or omissions giving rise to Plaintiff’s claims occurred in the District of Colorado and the defendant resides here.

III. PARTIES

4. **Plaintiff Robert Lee Cunningham** lives in Denver, Colorado. He is enrolled in Medicaid as an income-eligible recipient, and in 2004 was diagnosed as chronically infected by

the Hepatitis C Virus. Based on a liver, biopsy he has a Metavir Fibrosis Score (“MFS”) of F1¹. Under current Colorado Medicaid restrictions, he is categorically ineligible to receive Direct Acting Antiviral medications (“DAAs”), which are now available as “breakthrough medications” to treat HCV, because his MFS is less than F2. Mr. Cunningham’s doctor submitted a Prior Authorization form to Colorado Medicaid requesting that Mr. Cunningham be provided with DAAs. Relying on a previous version of its Policy, Colorado Medicaid denied that application because Mr. Cunningham’s MFS was F1. Based on his MFS, Mr. Cunningham remains ineligible for DAA treatment under the categorical restrictions embodied in the current Policy. Mr. Cunningham is “frustrated, irritated, disheartened, and disappointed,” because other insurances offer the treatment that he needs. He is very stressed that the disease could kill him, that he could pass it on to others, and that it will continue to limit him physically. He has agreed to participate in this litigation not only to secure treatment for himself, but to help others in his position secure treatment as well.

5. **Defendant Susan E. Birch** is the Executive Director of the Colorado State Department of Health Care Policy & Financing (“HCPF”). HCPF is a Department of the State of Colorado and is the sole state agency responsible for administering the Colorado Medicaid Program. It is HCPF that has established and is implementing the restriction on access to DAAs challenged here. At all times relevant to this Complaint, the actions and inactions of Ms. Birch

¹ The severity of liver damage due to the Hepatitis C Virus (“HCV”) is measured by a scoring system. Liver disease is graded according to the level of liver scarring and assigned a Metavir Fibrosis Score (“MFS”). An MFS of F0 or F1 indicates no or minimal liver scarring; F2 is an intermediate stage of fibrosis or liver scarring; a score of F3 indicates severe fibrosis; F4 indicates cirrhosis. HCV is a chronic inflammatory condition. Lack of liver damage does not suggest that the individual does not have the disease (which can be confirmed by blood tests) or that the individual is not suffering other, extrahepatic symptoms of the disease. All the F score measures is liver damage, which is only one of multiple effects of the disease. See generally, Gill, Ghazianian, Manch, Gish, *Hepatitis C Virus as a Systemic: Reaching Beyond the Liver*, HEPATOLOGY INTERNATIONAL, Vol. 9, No. 4 (2015).

were and are being carried out under color of state law. Ms. Birch is sued in her official capacity, for prospective relief only.

IV. THE ESSENTIAL STORY

The Disease

6. Hepatitis is an inflammation of the liver. The condition can be self-limiting or can progress to fibrosis (scarring), cirrhosis (liver impairment due to scarring) or liver cancer. Chronic Hepatitis viruses are the most common cause of Hepatitis in the world, but other infections, toxic substances, and autoimmune diseases can also cause Hepatitis.

7. Chronic HCV is one of the viruses that can cause Hepatitis. It is a life-threatening, communicable, blood-borne viral disease which, when left untreated, can cause liver damage, liver failure, liver cancer, and death. There is no vaccine for it.

8. HCV is mostly transmitted through exposure to infected blood. This may happen through transfusions of HCV-contaminated blood and blood products, transplants of infected organs and tissues, contaminated injections during medical procedures, and through injection drug use. Sexual transmission is also possible, but is much less common, because the disease must be passed by blood. However, there are patients who get HCV without any known exposure to blood or to drug use.

9. Those individuals most at risk for HCV infection are people who had blood transfusions, blood products, or organ transplants before June 1992, when sensitive tests for HCV were introduced for blood screening. Also at risk are health care workers from needlesticks involving HCV-positive blood, and infants born to HCV-positive mothers.

10. Infection with HCV is an inflammatory disease in and of itself, regardless of liver involvement.

11. Actual damage to the liver is an acute and severe result of infection with HCV. The severity of liver damage due to HCV is measured by the Metavir Fibrosis Score scoring system described in footnote 1. As noted there, lack of liver damage does not suggest that an individual infected with HCV does not have the disease, or that the individual is not suffering other, non-hepatic symptoms of the disease.

12. The Center for Disease Control and Prevention (“CDC”) estimates that nearly 20,000 deaths were associated with HCV in 2014, making it the most deadly infectious disease in the United States.

13. Approximately 70,000 Coloradoans suffer HCV infections. *See* David Olinger, *Ninety Percent of Colorado Residents with Hepatitis C Going Untreated*, DENVER POST (May 18, 2016 8:22 AM).²

14. It is estimated that approximately five million individuals in the United States are infected with HCV, accounting for over 1% of the population.

15. HCPF recently reported that 14,400 Colorado Medicaid beneficiaries are infected with the virus. It also recently boasted to the Colorado Legislature that it had saved \$49,814,827 through denying requests for authorization for treatment with DAAs by HCV-infected individuals. DEPARTMENT OF HEALTH CARE POLICY AND FINANCING’S LEGISLATIVE REPORT ON

² Available at <http://www.denverpost.com/2016/05/18/ninety-percent-of-colorado-residents-with-hepatitis-c-going-untreated/>

THE PHARMACY UTILIZATION PLAN TO THE HOUSE HEALTH, INSURANCE, AND ENVIRONMENT COMMITTEE, December 1, 2015.³

16. Even in the initial stages of the disease, individuals infected with HCV can experience serious symptoms, including kidney disease, hypertension, lymphoma, intractable fatigue, joint pain, arthritis, vasculitis, thyroid disease, depression, memory loss, sore muscles, mental changes, heart attacks, diabetes, nerve damage, jaundice, and various cancers.

17. William J. Burman, M.D., the interim CEO of Denver Health and Hospital Authority, recently advised Director Birch that:

HCV causes a chronic infection in 70-80% of infected persons, leading to severe, irreversible liver damage (advanced fibrosis and cirrhosis) in 20-30% of individuals with persistent infection. Furthermore, HCV infection at all stages of liver fibrosis is associated with adverse health effects. The burden of HCV-related disease is alarming; CDC estimates that HCV kills more people than the 60 other reportable infections combined.

WILLIAM J. BURMAN LETTER TO SUE BIRCH, JUNE 29, 2016 (Attached as Exhibit A). This statement is supported by statistics from the CDC, which indicate that an estimated 2.7-3.9 million people in the United States have chronic Hepatitis C. HEPATITIS C FAQs FOR HEALTH PROFESSIONALS.⁴ It further estimates that HCV infection becomes chronic in approximately 75%–85% of cases; that 60%–70% will develop chronic liver disease; that 5%-20% will develop cirrhosis over a period of 20–30 years; and that up to 5% will die as a result of the disease from liver cancer or cirrhosis. *Id.* Not surprisingly, HCV is the leading indicator for liver transplants in the United States. *Id.*

³ Available at <http://www2.cde.state.co.us/artemis/hcpserials/hcp118internet/hcp118201516internet.pdf>.

⁴ Available at <http://www.cdc.gov/Hepatitis/hcv/hcvfaq.htm>.

The Cure

18. Until recently, the standard therapy for HCV consisted of a three-drug treatment regimen consisting of boceprevir, interferon, and ribavirin. At best, this course of treatment cured HCV in only 70% of patients, and it was often accompanied by significant adverse side effects such as bone pain, muscle pain, joint pain, anemia, insomnia, memory loss, anxiety, depression, nausea, liver failure, and death. In addition, this treatment regimen was lengthy, often requiring almost one year to complete.

19. Starting in 2013, FDA has approved a series of DAAs for the treatment of HCV, which, unlike the earlier HCV drugs, are capable of curing the disease within a relatively short course of once-daily pills over the course of 8-12 weeks, with minimal side effects. They include Viekira Pak (ombitasvir, paritaprevir, ritonavir, dasabuvir); Daklinza (daclatasvir); Epclusa (sofosbuvir/velpatasvir); Harvoni (sofosbuvir/ledipasvir); Olysio (simeprevir); Solvadi (sofosbuvir); Technivie (ombitasvir, paritaprevir, ritonavir); Zepatier (elbasvir/grazoprevir). These medications have been shown to result in a cure for more than 90% of patients, when treated according to the recommended protocol. For example, Harvoni, approved by the FDA on October 10, 2014, has a success rate approaching 100%, and is accompanied by few, if any, side effects. All of these drugs were designated as “breakthrough therapies” by the FDA, an official classification that is reserved for drugs that have proven to provide substantial improvement over available therapies for patients with serious or life-threatening diseases.

20. There are no limits in the FDA approved label on whom should be treated with DAAs. The FDA has thusly approved their use on HCV infected patients regardless of fibrosis score.

21. All of the FDA approved DAAs are supported by multiple, well-designed controlled studies or well-designed experimental studies.

22. There is no alternative treatment, or sequence of treatments, for HCV that are at least as likely to produce equivalent therapeutic results.

23. According to evidence-based, expert-developed guidelines published by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America (“AASLD/IDSA Guidelines”), DAAs are now “recommended for *all* patients with chronic HCV infection,” with the narrow exception of patients “with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy.”

AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES & INFECTIOUS DISEASES SOCIETY OF AMERICA, HCV GUIDANCE: RECOMMENDATIONS FOR TESTING, MANAGING, AND TREATING HEPATITIS C.⁵ (emphasis added).

24. DAAs are the only medication or medical intervention for HCV that produce a Sustained Virological Response (“SVR”) in more than 90% of patients. SVR status means that the virus is virtually undetectable in a patient, and is considered to be a *de facto* cure of the infection. The prior treatment with boceprevir, interferon, and ribavirin produced SVR in only approximately 70% of patients, and resulted in a host of adverse side effects.

25. The AASLD/IDSA GUIDELINES specifically urge early treatment of HCV (as in patients with fibrosis scores of F0 and F1), explicitly repudiating the idea that DAA drugs should be prescribed only for patients with significant liver damage, and instead urging that virtually all individuals infected by HCV receive DAA treatments regardless of their fibrosis score.

⁵ Available at <http://www.hcvguidelines.org/>

26. The AASLD/IDSA GUIDELINES represent the professionally-accepted clinical standard of care for treatment of HCV in the United States and in Colorado.

27. Treatment of HCV with DAAs is cost-effective. Although “expensive,” DAAs cost the same as the combination treatment for HCV given prior to the advent of the DAAs, and are cost effective to the health care system in the long term, when the costs of treating advanced liver disease, cancer and associated manifestations of HCV are considered. Not surprisingly, the treatment is the most cost-effective when provided to patients with lower fibrosis scores, because it provides a cure before the virus evolves into more serious diseases.

28. As a result of the consensus over treatment of HCV infected individuals with DAAs, the Centers for Medicare and Medicaid Services (“CMS”) (the federal agency responsible for administering Medicaid) issued Guidance on November 5, 2015, advising state Medicaid agencies that the new DAAs should be included in coverage of outpatient prescription drugs. CENTERS FOR MEDICARE AND MEDICAID SERVICES, ASSURING MEDICAID BENEFICIARIES ACCESS TO HEPATITIS C (HCV) DRUGS (Release No. 172), Nov. 5, 2015.

29. In issuing this Guidance, CMS was clear that its animating purpose was its concern “that some states are restricting access to DAA HCV drugs contrary to the statutory requirements in section 1927 of the Act by imposing conditions for coverage that may unreasonably restrict access to these drugs.” *Id.*

30. Further, CMS warned the States that any restrictions on access to DAAs “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.* Specifically,

CMS identified limiting treatment to beneficiaries with fibrosis scores of F3 and F4 as an unjustifiable restriction. *Id.*

31. More than ten months after receiving this Notice from CMS, Colorado Medicaid continued to ignore CMS's guidance and enforced the Policy, as alleged below. Also as alleged below, it continued to ignore CMS's guidance even when it changed its policy on September 1, 2016, and rather than eliminate an MFS criteria completely, took the quarter step of only reducing the fibrosis score minimum from F3 to F2 and eliminating fibrosis score as a criteria for women planning to become pregnant in the following year.

32. Without treatment, Medicaid enrollees infected with chronic HCV will never rid themselves of the inflammatory disease, placing these Medicaid enrollees at significantly higher risk for symptoms not involving the liver. This is because, while the DAAs cure HCV, they do not reverse the effects of the virus that have already been caused, in the liver or elsewhere. Thus, delay in the provision of DAAs to infected persons until their liver deteriorates causes some irreversible non-hepatic damage and damage to their livers that may likely prove irreversible even with the delayed administration of a DAA. Moreover, the disease does not progress linearly, and someone could move from F0 to F3 in a short period of time and long before they are tested again, which belies the oft-heard excuse "oh, there's no harm in letting an F0 patient wait for a period of time because they're not going to have an F3 score for a while." Moreover, researchers have determined that common methods of determining fibrosis score do not always produce accurate results, leading to delays in treatment even among individuals with already significantly damaged livers.

33. Not surprisingly, the huge populations of patients covered by the Veteran's Administration, Medicare, and many commercial insurers are universally approved for HCV treatment with the new treatment regimens. Medicaid enrollees in Colorado are therefore being unduly subjected to a second-class standard of health insurance coverage for the sole reason they are poor.

The Obligation to Cover the Cure

34. Medicaid is a financial, needs-based medical assistance program cooperatively funded by the federal and state governments, and administered by the states. The Medicaid Program was established under Title XIX of the Social Security Act of 1965 (42 U.S.C. Ch. 7, Subch. XIX) for the express purpose of enabling each State to furnish medical assistance to people "whose income and resources are insufficient to meet the costs of **necessary medical services.**" 42 U.S.C. § 1396-1 (emphasis added); *see also*, 42 C.F.R. § 430.0.

35. On the federal level, the Medicaid program is administered by CMS. On the state level, Medicaid in Colorado is administered by HCPF.

36. Although state participation is voluntary, once a state opts into the Medicaid program, it must administer the program in accordance with Federal law. All states have opted in, including Colorado. Colorado has also opted into the expansion of Medicaid under the Affordable Care Act, known colloquially as "Obamacare," which is embodied in the PATIENT PROTECTION AND AFFORDABLE CARE ACT, Pub. L. No. 111-148, 124 Stat. 119 (2010) and the HEALTH CARE AND EDUCATION RECONCILIATION ACT OF 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010).

37. In order to participate in Medicaid, a state must submit a plan to the Federal government for approval. Colorado’s plan can be found at <https://www.colorado.gov/pacific/hcpf/colorado-medicaid-state-plan>. (“COLORADO STATE PLAN”).

38. A state Medicaid plan must provide treatment that is deemed “medically necessary” in order to comport with the objectives of the Social Security Act. 42 U.S.C. § 1396a(a)(17); *Beal v. Doe*, 432 U.S. 438, 444–45 (1977); *Weaver v. Reagen*, 886 F.2d 194, 198 (8th Cir. 1989).

39. Thus, under federal law, participating states such as Colorado have a general obligation to fund covered services and treatments that are “medically necessary.” *Hern v. Beye*, 57 F.3d 906, 911 (10th Cir. 1995).

40. A state plan must provide “for making medical assistance available” to a wide variety of people know as “Categorically Needy” under 42 U.S.C. §1396d. 42 U.S.C.A. § 1396a(a)(10).

41. “Medical Assistance” means “payment of part or all of the cost of” identified goods and services to various defined groups of people “whose income and resources are insufficient to meet all of such cost.” 42 U.S.C. 1396d(a). Those services include prescription drugs if the state has opted to provide them. 42 U.S.C. 1396d(a)(12).

42. Colorado has opted to provide prescriptions drugs. *See*, C.R.S. § 25.5-5-102(1)(g); C.R.S § 25.5-5-506; COLORADO DEPARTMENT OF HEALTH CARE POLICY AND FINANCING, PREFERRED DRUG LIST(“PDL”).⁶ It is thus required by 42 U.S.C. 1396d(a)(12) to

⁶ Available at <https://www.colorado.gov/pacific/sites/default/files/PDL%20effective%20January%201%202015.pdf>

make them available in accordance with federal law to eligible individuals. Depending on certain income requirements, eligible individuals include, among many other categories, the following major categories:

- (a) Children under the age of 21, or, if the state chooses a younger age, 20, 19 or 18;
- (b) Relative caretakers of dependent children;
- (c) Persons 65 years of age or older;
- (d) Certain blind or disabled people;
- (e) Pregnant women; and
- (f) Individuals under 65 years of age not otherwise covered whose income does not exceed 133 percent of the federal poverty line.

42 U.S.C.A. § 1396d(a); *see*, C.R.S § 25.5-5-101(1); COLORADO STATE PLAN.

43. State Medicaid plans, including Colorado’s, are generally required to provide coverage for any outpatient drug for its indicated use once the drug manufacturer enters into a rebate agreement and the medicine is approved by the FDA and prescribed by a provider.

42 U.S.C. §§ (a)(1), 1396r-8(d)(B), 1396r-8(k)(2)(A), 1396r-8 (k)(6); *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 652 (2003). Covered prescription drugs, including DAAs, must be provided when medically necessary to treat an extant illness or condition. 42 U.S.C. §§ 1396a(a)(10)(A); 1396r-(d)1(B)(i); 42 U.S.C.A. § 1396r-8(k)(6); 42 CFR 440.230(d); *see also* C.R.S. § 25.5-4-102; C.R.S. § 25.5-4-104 (1); C.R.S. § 25.5-5-102 (2); *Beal*, 432 U.S. at 444–45.

44. Under Colorado law, a drug is a “medical necessity” (and thus “medically necessary”) when it “will, or is reasonably expected to prevent, diagnose, cure, correct, reduce, or ameliorate the pain and suffering, or the physical, mental, cognitive, or developmental effects of an illness, injury, or disability,” or is included in “a course of treatment that includes mere

observation or no treatment at all.” 10 COLO. CODE REGS. § 2505-10:8.076(8); *see also*, 10 COLO. CODE REGS. § 2505-10:8.280; 10 COLO. CODE REGS. § 2505-10:8.590. A drug is a “medical necessity” under Colorado law if it is:

- (a) Prescribed by a doctor of medicine;
- (b) Provided in accordance with generally accepted standards of medical practice in the United States;
- (c) Clinically appropriate in terms of type, frequency, extent, site, and duration;
- (d) Not primarily for the economic benefit of the provider or for the convenience of the client, caretaker, or provider; and
- (e) Administered in a cost effective and most appropriate setting required by the client's condition.

10 COLO. CODE REGS. § 2505-10:8.076(8); *see also*, *T.L. v. Colorado Dep't of Health Care Policy & Fin.*, 42 P.3d 63, 65 (Colo. App. 2001). For all of the reasons set forth in this Complaint, DAA treatment for Plaintiff and the class is “medically necessary” under these criteria.

45. Further, under Colorado’s Medicaid program, if the treatment is covered and medically necessary, it must be provided with “reasonable promptness.” 42 U.S.C.

§ 1396a(a)(8).

46. In addition, medically necessary prescription drug coverage, including access to DAAs, cannot be made available in a “lesser amount, duration or scope” than the coverage made available to any other individuals eligible under the State Medicaid Plan. 42 U.S.C. § 1396a(a)(10)(B); 42 C.F.R. § 440.240. This is known as Medicaid’s “comparability” requirement.

47. HCPF's coverage criteria for HCV treatment must comply with all three of these requirements. It complies with none.

The Wrongful Denial of the Cure

48. Starting on June 1, 2014, HCPF adopted and implemented a policy of categorically denying coverage to individuals diagnosed as infected by HCV unless they had an MFS of F3 or F4. This policy was illegal when first enacted, and throughout its implementation.

49. HCPF implemented the policy adopted on June 1, 2014 continuously until September 1, 2016. Its application was illegal throughout this entire time period, because it denied infected individuals access to medically necessary treatment with no medical justification.

50. On September 1, 2016, HCPF amended its DAA Policy to be effective October 1, 2016. In that amendment, HCPF lowered the minimum MFS needed to obtain treatment to F2, and eliminated it altogether for women who intend to get pregnant in the next 12 months. This was a step in the right direction, but is still illegal for the same reasons that the old policy was illegal.

51. Specifically, contrary to the AASLD/IDSA GUIDELINES and the CMS Notice, HCPF's restriction of DAAs, first to those infected individuals with MFSs of F3 or F4, and now to those with MFSs of F2, F3, or F4, illegally restricts the access of otherwise covered Medicaid beneficiaries to the medically necessary treatment that can be provided only by DAAs. This restriction forces (and has in the past forced) stricken individuals to wait for treatment until they have suffered measurable, and potentially irreparable and irreversible liver damage; flatly contradicts the AASLD/IDSA Guidelines, which advise that virtually all chronic HCV patients, regardless of their fibrosis score, receive DAA treatment upon diagnosis; violates the standard of medical care

universally accepted throughout the United States and Colorado; and flaunts the clear instructions and warnings of CMS. Aside from the Kafkaesque effect of requiring eligible beneficiaries, who could be treated immediately and most likely cured, to wait until their disease causes actual adverse physical effects on the liver before they can access curative treatment, the policy puts the healthy population at risk from the communicability of the disease.

52. Similar restrictions have been successfully challenged in the State of Washington, where a federal district court recently issued a preliminary injunction enjoining the state Medicaid agency from enforcing its policy of denying treatment based on MFS scores, the very type of categorical denial Colorado Medicaid currently enforces, and ordered that DAAs be provided to beneficiaries without regards to those scores. *B.E. v. Teeter*, 2016 WL 3033500, at *1 (D.C. Wash. May 27, 2016). Similar litigation is pending in Indiana. *Jackson v. Secretary of the Indiana Family and Social Services Administration*, Case No. 1:15-cv-01874 SEB-DKL, UNITED STATES DISTRICT COURT, SOUTHERN DISTRICT OF INDIANA (INDIANAPOLIS DIVISION), Filed 11/25/15. Medicaid agencies in a number of states, including Delaware, Florida, Massachusetts, and New York, have recently responded to legal and policy advocacy by rescinding such restrictions. This Court must order Colorado to do the same.

V. WRONGS TO INDIVIDUAL PLAINTIFF

53. At all pertinent times, Plaintiff was enrolled in Colorado's Medicaid Program, which is administered by HCPF.

54. Plaintiff is a "qualified individual" as defined in 42 U.S.C. § 1396a(a)(10)(A).

55. Plaintiff is currently diagnosed with chronic HCV, and has been prescribed treatment with DAAs by his treating medical provider, who is a specialist in HCV and liver diseases.

56. Plaintiff has an MFS score of F1, which disqualifies him for DAA treatment even under HCPF's current Policy.

57. Plaintiff's treating physician applied for treatment for Plaintiff with DAAs.

58. This application was denied because Plaintiff's MFS score was F1, below the then required minimum of F3.

59. Treatment with the DAAs was at the time Plaintiff applied, and is now, "medically necessary" for him. Those DAAs are likely to cure him completely; there is no equally effective, less costly alternative prescription drug or medical intervention available to him; and HCPF has offered none.

60. Plaintiff remains ineligible for treatment with DAAs under HCPF's current policy, because his MFS is below the new F2 threshold.

VI. CLASS ALLEGATIONS

61. **Class Definition.** The class for which Plaintiff seeks certification consists of all individuals:

(i) who are or will in the future be enrolled in the Colorado Medicaid Program; and

(ii) who have been or will be diagnosed as having a chronic infection of the Hepatitis C Virus;

(iii) who require, or who will in the future require treatment for the Hepatitis C Virus with a Direct Acting Antiviral medication under the Recommendations for Testing, Managing, and Treating Hepatitis C published by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America; and

(iv) who do not meet that portion of the Defendant's coverage criteria for Direct Acting Antiviral medication that restrict coverage to persons based on fibrosis score either: (a) because they have had a fibrosis test and obtained a fibrosis score of less than F2 , and are therefore ineligible or (b) because their fibrosis score is unknown because they have not taken a test to determine that score.

The class consists exclusively of individuals diagnosed as chronically infected with the Hepatitis C Virus, who require treatment with Direct Acting Antiviral medication **AND** who either (i) are ineligible under the existing HCPF criterial because they had a fibrosis test which showed a fibrosis score of less than F2 **OR** (ii) whose fibrosis score is unknown because they have not had a fibrosis test, which may not be practically available because of location and may require a liver biopsy, which is an unpleasant, painful and potentially risky medical procedure. All class members are injured by the existence of fibrosis criteria, either because it renders them ineligible for medically necessary treatment or requires them taking a test to determine eligibility which may prove unfruitful. All class members will benefit by the relief Plaintiff seeks of eliminating the fibrosis score restriction entirely.

62. Plaintiff seeks certification of a class under F.R.C.P. 23(b)(2). The requirements for class certification under Rule 23(b)(2) are the following:

- (a) **Numerosity.** The class is so numerous that joinder of all members is impracticable;
- (b) **Commonality.** There are questions of law or fact common to the class;
- (c) **Typicality.** The claims or defenses of the representative parties are typical of the claims or defenses of the class;
- (d) **Adequacy of Representation.** The representative parties will fairly and adequately protect the interests of the class; and
- (e) **Action Common to Class.** The party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole.

All of these requirements are satisfied here.

63. **Typicality.** Plaintiff claims that: (i) he is Medicaid eligible under 42 U.S.C. §1396d; (ii) he has been diagnosed as infected by the HCV Virus; (iii) his doctor has recommended treatment with one of the DAAs now on the market; and (iv) he is, has been, and will in the future be illegally categorically precluded from receiving these drugs by HCPF's requirement of a Metavir Fibrosis Score, now of at least F2. These are precisely the claims he wishes to litigate on behalf of the class.

64. **Commonality.** All legal and factual questions inherent in the ultimate question of whether the restrictions on access to DAAs based on MFSs are illegal under the Medicaid Act are common to all or members of the class.

65. **Numerosity.** It has been estimated that approximately 70,000 Coloradoans suffer HCV infections. HCPF itself recently reported that 14,400 Colorado Medicaid beneficiaries are infected with the virus. Thus, the class consists of at least multiple thousands of people, joinder of which is not only impracticable but impossible.

66. **Adequacy of Representation.** Plaintiff will fairly and adequately protect the interests of the class. Plaintiff has no interest that is now or may be potentially antagonistic to the interests of the class. He is committed to and passionate about the case, and fully understands responsibilities as class representative. Plaintiff is represented by highly competent attorneys with extensive experience in litigating class action cases in federal court.

67. **Action Common to the Class:** The Policy challenged by Plaintiff applies class-wide and categorically to each member of the class by restricting access to coverage for DAA treatment as alleged above; and therefore, Defendant has acted or refused to act on grounds that

apply generally to the class, such that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole.

FIRST CLAIM FOR RELIEF.

(42 U.S.C. § 1983; 42 U.S.C. §1396a(a)(10)(A))

(EXCLUSION OF QUALIFIED INDIVIDUALS FROM COVERED AND NECESSARY MEDICAL ASSISTANCE UNDER THE MEDICAID ACT, IN VIOLATION OF 42 U.S.C. §1396a(a)(10)(A))

68. Plaintiff incorporates paragraphs 1-60.

69. Since at least June 1, 2104, when HCPF amended the PDL to limit access to DAAs based on MFSs, HCPF has systematically, categorically, and uniformly denied access to all FDA approved and AASLD/IDSA recommended DAAs to qualified Medicaid beneficiaries infected with HCV by refusing to approve prescription requests for prior authorization of treatment with DAAs unless the applicant had an MFS score at or above a specified level, and by publishing and implementing a proscription of access to such drugs in the Preferred Drug List. Until September 1, 2016, the specified minimum level was F3. On September 1, 2016, HCPF lowered the MFS to F2 and excluded women who intended to become pregnant within a year from any MFS requirement.

70. Even the revised Policy directly and categorically contradicts the prevailing clinical standard of care, and therefore denies Plaintiff and those like him medically necessary care, as defined under federal and state law.

71. Pursuant to 42 U.S.C. § 1983 and 28 U.S.C. § 2201, Plaintiff and the class are entitled to a judgment declaring that HCPF has violated Title XIX of the Social Security Act by denying treatment with DAAs to qualified Medicaid beneficiaries chronically infected with the Hepatitis C Virus based solely on their having a Metavir Score of less than a specified minimum in violation 42 U.S.C. §1396a(a)(10)(A).

72. Based on the law governing the issuance of injunctions, and also upon 28 U.S.C. § 2202, Plaintiff and the class are also entitled to a permanent injunction enjoining HCPF from denying treatment with DAAs to qualified Medicaid beneficiaries chronically infected with the Hepatitis C Virus based solely on their having a Metavir Score of less than a specified minimum.

SECOND CLAIM FOR RELIEF

**(42 U.S.C. § 1983; 42 U.S.C. § 1396a(a)(10)(B)(i) AND (ii))
(DENIAL OF COMPARABLE TREATMENT ACCESS IN VIOLATION OF 42 U.S.C.
§1396a(a)(10)(B)(i) AND (ii) AND 42 C.F.R. § 440.240.)**

73. Plaintiff incorporates paragraphs 1-60 and 69.

74. While denying access to DAAs to Medicaid eligible individuals infected with HCV, as alleged above, HCPF has at the same time provided access to similarly situated Medicaid enrollees, with no medically justifiable basis for such differential treatment.

75. Pursuant to 42 U.S.C. § 1983 and 28 U.S.C. § 2201, Plaintiff and the class are entitled to a judgment declaring that HCPF has violated Title XIX of the Social Security Act by discriminating amongst similarly situated Medicaid individuals infected with the Hepatitis C Virus by denying treatment with DAAs to those with Metavir Scores of less than a specified minimum in violation of the Medicaid Act comparability requirements under 42 U.S.C. §1396a(a)(10)(B)(i) and (ii) and 42 C.F.R. § 440.240.

76. Based on the law governing the issuance of injunctions, and upon 28 U.S.C. § 2202, Plaintiff and the class are also entitled to a permanent injunction enjoining HCPF from discriminating amongst similarly situated Medicaid individuals infected with the Hepatitis C Virus by denying treatment with DAAs to those with Metavir Scores of less than a specified minimum in violation of the Medicaid Act comparability requirements under 42 U.S.C. §1396a(a)(10)(B)(i) and (ii) and 42 C.F.R. § 440.240.

THIRD CLAIM FOR RELIEF

(42 U.S.C. 1983; 42U.S.C. §1396a(a)(8))

(FAILURE TO PROVIDE NECESSARY MEDICAL ASSISTANCE WITH REASONABLE PROMPTNESS IN VIOLATION OF 42U.S.C. §1396a(a)(8))

77. Plaintiff incorporates paragraphs 1-60.

78. By denying access to DAAs to Medicaid eligible individuals diagnosed as currently infected with HCV, as alleged above, HCPF delays the treatment of demonstrably sick individuals until their disease has progressed to the point of causing measurable and potentially irreparable and irreversible liver damage. This constitutes a *de facto* rationing of treatment for Medicaid enrollees seeking the only available treatment for an extant infection with HCV, and violates the requirement that medical assistance be provided with “reasonable promptness” under 42 U.S.C. § 1396a(a)(8).

79. Pursuant to 42 U.S.C. § 1983 and 28 U.S.C. § 2201, Plaintiff and the class are entitled to a judgment declaring that HCPF has violated the “reasonable promptness” requirement of Title XIX of the Social Security Act by implementing a policy that delays the treatment of qualified Medicaid beneficiaries chronically infected with the Hepatitis C Virus, based solely on their having a Metavir Score of less than a specified minimum in violation, 42 U.S.C. §1396a(a)(10)(A), and thus delaying treatment to demonstrably sick individuals until their disease has progressed to the point of causing measurable and potentially irreparable and irreversible liver damage.

80. Based on the law governing the issuance of injunctions, and upon 28 U.S.C. § 2202, Plaintiff and the class are also entitled to a permanent injunction enjoining HCPF from denying treatment with DAAs to qualified Medicaid beneficiaries chronically infected with the Hepatitis C Virus based solely on their having a Metavir Score of less than a specified minimum.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests that the following judgments and orders be entered against Defendant:

A. Certification of this case as a class action consisting of a class defined as all individuals:

- (i) who are or will in the future be enrolled in the Colorado Medicaid Program; and
- (ii) who have been or will be diagnosed as having a chronic infection of the Hepatitis C Virus; and
- (iii) who require, or who will in the future require treatment for the Hepatitis C Virus with a Direct Acting Antiviral medication under the Recommendations for Testing, Managing, and Treating Hepatitis C published by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America; and
- (iv) who do not meet that portion of the Defendant's coverage criteria for Direct Acting Antiviral medication that restrict coverage to persons based on fibrosis score either: (a) because they have had a fibrosis test and obtained a fibrosis score of less than F2 , and are therefore ineligible or (b) because their fibrosis score is unknown because they have not taken a test to determine that score.

B An order designating Robert Cunningham as class representative;

C An Order appointing Lawrence W. Treece, Lauren E. Schmidt, Emily R. Garnett, Joshua A. Weiss, Mark Silverstein, Sara R. Neel, and Kevin Costello as class counsel;

D. A Judgment declaring that HCPF's policy of denying access to Viekira Pak, Daklinza, Epclusa, Harvoni, Olysio, Solvadi, Technivie, or any other Direct Acting Antiviral medication now or hereafter approved by the U.S. Food and Drug Administration for treatment of the Hepatitis C Virus and recommended for such use by the treatment Guidelines of AASLD/IDSA of any qualified Medicaid beneficiary diagnosed as infected by the Hepatitis C Virus because of a Metavir Fibrosis Score of any level violates Title XIX of the Social Security

Act (also known as the Medicaid Act): (i) by excluding qualified Medicaid recipients from medically necessary treatment as required by 42 U.S.C. §1396a(a)(10)(A); (ii) by discriminating among similarly situated Medicaid recipients on the basis of categorical restrictions that are not based upon prevailing clinical standards as forbidden by 42 U.S.C. §1396a(a)(10)(B)(i); and (ii) by denying qualified Medicaid recipients the provision of necessary medical assistance with “reasonable promptness” as required by 42 U.S.C. § 1396a(a)(8) and 42 C.F.R. § 440.240;

E. A permanent injunction, enjoining HCPF from promulgating, instituting, or implementing any policy or protocol that denies access to Viekira Pak, Daklinza, Epclusa, Harvoni, Olysio, Solvadi, Technivie, or any other Direct Acting Antiviral medication now or hereafter approved by the U.S. Food and Drug Administration for treatment of the Hepatitis C Virus and recommended for such use by the treatment Guidelines of AASLD/IDSA to any qualified Medicaid beneficiary diagnosed as chronically infected by the Hepatitis C Virus because of a Metavir Fibrosis Score of any level;

F. An Order requiring HCPF to provide notice to all class members of the Court’s judgment, in a form and by means to be determined by the Court;

G. An Order requiring HCPF to re-process, in light of paragraphs E and F, the denials of all requests for medical assistance issued since June 1, 2014 requesting treatment with Viekira Pak, Daklinza, Epclusa, Harvoni, Olysio, Solvadi, Technivie, or any other Direct Acting Antiviral medication approved by the U.S. Food and Drug Administration for treatment of the Hepatitis C Virus and recommended for such use by the treatment Guidelines of AASLD/IDSA; and ordering HCPF to provide notice of the Court’s judgment, and that their previously denied

claims are being reprocessed for evaluation without regard to Metavir scores, to all affected class members, in a form and by means to be determined by the Court;

H. An Order awarding Plaintiff a service award for his service as class representatives in an amount to be determined by the Court;

I. An Order awarding Plaintiff and the class their attorney fees and costs pursuant to 42 U.S.C. § 1988; and

J. Such other relief as the Court may deem appropriate.

Dated: September 19, 2016

/s/ Lawrence W. Treece

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In cooperation with the ACLU
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Kevin Costello (application to admission to
practice before this Court in Process)

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