THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 17-CV-00904-KLM

MICHAEL RYAN,
SHARON MOLINA,
EARBY MOXON, and
HEATHER MYERS, on behalf of themselves,
and all others similarly situated,

Plaintiffs,

v.

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

Defendant.

AMENDED CLASS ACTION COMPLAINT

For their Class Action Complaint against Defendant, Plaintiffs allege as follows on behalf of themselves and a class of similarly situated people they seek to represent.

I. INTRODUCTION

1. This is a case about the unlawful denial by the State of Colorado of treatment coverage to Medicaid eligible individuals who are infected by the insidious and life threatening Hepatitis C Virus ("HCV"). Plaintiffs are Medicaid enrollees who suffer from this communicable disease that afflicts millions of Americans. According to the Centers for Disease Control, HCV is the most deadly infectious disease in the United States, killing more Americans than the next 60 infectious diseases combined. Left untreated, the Hepatitis C Viral disease is a chronic, systemic inflammatory illness that can cause health problems both within and outside of

the liver at all stages of its progression. Manifestations of the disease outside of the liver, known as "extrahepatic" effects, include 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. HCV can also progressively destroy the liver by scarring its tissue and impairing function. When allowed to proceed unabated, HCV can thus lead to fibrosis, cirrhosis, and cancer of the liver, as well as the need for a liver transplant, and, in some instances, even death.

2. Fortunately for the thousands of Coloradoans who are living with HCV, the U.S. Food and Drug Administration began approving in 2011 a series of pharmaceutical treatments belonging to a drug class called "Direct Acting Antivirals" ("DAAs") that constitute a *de facto* cure for HCV. Over the course of the next several years, the FDA labeled these drugs as "breakthrough therapy," and approved a succession of treatments within the DAA class.

3. DAA treatment is now the standard of care for the treatment of Hepatitis C at all stages of disease progression. DAA treatment is strongly urged by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. The importance of covering DAA treatment is expressly urged by the federal agency responsible for administering Medicaid. DAA treatment is covered without regard to disease severity by Medicare, the Veteran's Administration and the overwhelming majority of commercial health insurers. DAA treatment is the consensus medical standard of care in Colorado and across the United States, for the simple reason that it is the only feasible solution to the disease.

4. The promise of DAA treatment has proven illusory, however, for thousands of Coloradoans because the Defendant has imposed an illegal access criterion that withholds

Medicaid coverage until the disease has caused significant liver damage, as measured by tests for fibrosis, which is scarring of the liver tissue. This case 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

5. Jurisdiction is proper under 28 U.S.C. § 1331, because this action arises under the laws of the United States. Specifically, Plaintiffs' 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).

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

III. PARTIES

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

7. **Plaintiff Michael Ryan** is a 59-year-old carpenter who lives in northern Colorado and is infected with chronic HCV. He is enrolled in Colorado Medicaid.

8. **Plaintiff Sharon Molina** is a 48-year-old resident of Colorado who is infected with chronic HCV. She is enrolled in Colorado Medicaid.

9. **Plaintiff Earby Moxon** is a resident of Colorado and is infected with chronic HCV. He is enrolled in Colorado Medicaid.

10. **Plaintiff Heather Myers** is a resident of Colorado and is infected with chronic HCV. She is enrolled in Colorado Medicaid.

11. Each of the plaintiffs challenges a policy of the Defendant that denies treatment coverage for chronic Hepatitis C to patients on the ground that their disease has not yet progressed to the point of demonstrating a specified level of damage to the liver, as measured by tests for liver fibrosis.

IV. THE ESSENTIAL STORY

The Disease

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

21. Hepatitis 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.

22. 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.

23. 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 needle-sticks involving HCV-positive blood, and infants born to HCV-positive mothers.

24. Infection with HCV is a systemic, inflammatory disease in and of itself, regardless of liver involvement.

25. 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 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.

26. 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, Ghazinian, Manch, Gish, *Hepatitis C Virus as a Systemic Disease: Reaching Beyond the Liver*, Hepatology International, Vol. 9, No. 4 (2015).

27. The Centers 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.

28. 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).[1]

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

30. 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 THE PHARMACY UTILIZATION PLAN TO THE HOUSE HEALTH, INSURANCE, AND ENVIRONMENT COMMITTEE, December 1, 2015.[2]

31. 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.

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

[1] Available at http://www.denverpost.com/2016/05/18/ninety-percent-of-colorado-residents-with-hepatitis-c-going-untreated/

[2] Available at http://www2.cde.state.co.us/artemis/hcpserials/hcp118internet/hcp118201516internet.pdf.

> 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. *See* **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.[3] The CDC 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.*

33. Delaying treatment by observation has a variety of adverse effects including increasing the risk of death, causing irreversible liver damage, heightening the risk of cancer and other adverse health outcomes, and needlessly prolonging suffering associated with the disease. It also significantly increases the chance that the individual will require a liver transplant. Conversely, the benefit of treatment at low fibrosis stages is well documented in the medical literature.

The Cure

34. Prior to the introduction of DAA treatment, 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,

[3] Available at http://www.cdc.gov/Hepatitis/hcv/hcvfaq.htm.

memory loss, anxiety, depression, nausea, liver failure, and death. In addition, this treatment regimen was lengthy, often requiring almost one year to complete.

35. Starting in 2011, 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, paritaprevlr, ritonavir, dasabuvir); Daklinza (daclatisvlr); Epclusa (sorosbuvir/velpatasivir); Harvoni (sofosbuvir/ledipasvir); Olysio (simeprevir); Solvadi (sofosbuvir); Technivie (ombitasvir, paritaprevir, ritonavir); Zepatier (elbasvir/grazoprevir). These medications have been shown to result in a *de facto* 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.

36. There are no disease severity 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.

37. The efficacy, safety and FDA approval of DAAs are supported by multiple, well-designed controlled studies or well-designed experimental studies.

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

39. 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 "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.[4] (emphasis added).

40. 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.

41. 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.

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

[4] Available at http://www.hcvguidelines.org/

43. In addition to the benefits of SVR to the patient herself, individuals who achieve SVR are no longer able to transmit the virus to others, thereby compounding the benefits of treatment across the population.

44. Treatment of HCV with DAAs is cost-effective. Although "expensive," DAAs cost the same or less 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 accounted for. The treatment is specifically cost-effective when provided to patients with lower fibrosis scores, because it provides a cure before the virus causes more serious adverse health outcomes.

45. 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. *See* **Exhibit B.**

46. 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*.

47. 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*.

48. More than ten months after receiving this Notice from CMS, Colorado Medicaid continued to ignore CMS's guidance, 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 for coverage from F3 to F2 and eliminating fibrosis score as a criterion for women planning to become pregnant in the following year.

49. Without treatment coverage, 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 rid the body of HCV, they do not always 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 can cause 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.

50. Thus, it is simply not true that delays in treatment coverage for patients with low fibrosis score is a harmless policy decision. In addition to losing the connection to care during treatment for some patients, there is also the possibility that some patients who are turned away for treatment coverage may miss their opportunity to treat the disease altogether. For example, in an opinion finding that Washington's nearly identical Medicaid policy was illegal, the United States District Court for the Western District of Washington found as follows:

> An experience endured by a Medicaid enrollee provides a clear example of the substantial risk of deteriorating health and death presented by the Policy. L.B., a

> Washington Medicaid enrollee, was prescribed Solvaldi, a DAA, in July 2014. His request was denied. The [Agency]'s letter on August 21, 2014 states that because L.B. did not have a fibrosis score of "F3 or greater," the treatment was not 'medically necessary.' Soon after, in October 2014, Harvoni was approved by the FDA and L.B.'s provider submitted his prescription to WHCA. His provider noted that his 'cirrhosis and renal function [were] worsening. [He n]eeds HCV treatment ASAP' and that '[w]ithout it, [he will] likely die.' (*Id.*) Again, his request was denied. While he awaited a hearing on his Medicaid administrative appeal, 'his kidneys deteriorated so significantly that his provider could no longer recommend Harvoni.' **In other words, the window of L.B.'s ability to seek a cure for his HCV has likely closed**. This is not speculative harm. It is concrete evidence that under the Policy, an enrollee suffered such severe liver damage that DAA treatment may no longer be an available option.

B.E. v. Teeter, No. C16-227-JCC, 2016 WL 3033500, at *5 (W.D. Wash. May 27, 2016) (citations omitted) (emphasis added). The Court's example underscores the fact that HCV has systemic effects that should be treated at the earliest possible opportunity – in L.B.'s case, a worsening kidney condition ultimately doomed his candidacy for DAA treatment that would have been appropriate earlier.

51. 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.

52. 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 that they are poor.

The Obligation to Cover the Cure

53. 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; Colo. Rev. Stat. Ann. § 25.5-4-104 ("The state department, by rules, shall establish a program of medical assistance **to provide necessary medical care** for the categorically needy.")

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

55. 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, 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).

56. In order to participate in Medicaid, a state must submit a plan to the Federal government for approval. Colorado participates in Medicaid and has an approved state plan. The State Plan for Colorado is publicly available at https://www.colorado.gov/pacific/hcpf/colorado-medicaid-state-plan. ("COLORADO STATE PLAN").

57. A state Medicaid plan must provide coverage for treatment that is deemed "medically necessary" in order to comport with the objectives of the Social Security Act. *Beal v. Doe*, 432 U.S. 438, 444–45 (1977); *Weaver v. Reagen*, 886 F.2d 194, 198 (8th Cir. 1989). Thus, under federal law, participating states such as Colorado have a general obligation to fund

covered services and treatments that are medically necessary. *B.E. v. Teeter*, No. C16-227-JCC, 2016 WL 3033500, at *2 (W.D. Wash. May 27, 2016) ("Under § 1396a(a)(10)(A), the Medicaid Act 'prohibits states from denying coverage of 'medically necessary' services that fall under a category covered in their Medicaid plans.'") (indirectly quoting *Beal,* 432 U.S. at 444). *See also* 42 C.F.R. § 440.230(b) ("Each [Medicaid] service must be sufficient in amount, duration, and scope to reasonably achieve its purpose.")

58. 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).

59. "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).

60. Colorado has opted to provide prescriptions drugs. Colo. Rev. Stat. § 25.5-5-202(1)(a); C.R.S § 25.5-5-500, *et seq.*; COLORADO DEPARTMENT OF HEALTH CARE POLICY AND FINANCING, PREFERRED DRUG LIST ("Preferred Drug List").[5] It is thus required to make them available in accordance with federal law to eligible individuals.

61. State Medicaid plans that opt into the prescription drug benefit, 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-

[5] Available at https://www.colorado.gov/pacific/sites/default/files/PDL%20effective%20January%201%202015.pdf

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); 1396d(a)(12); 1396r-8; 42 C.F.R. 440.230(b); *Teeter*, 2016 WL 3033500, at *2. *See also* Colo. Rev. Stat. §§ 25.5-4-102 (legislative declaration); 25.5-5-202(1)(a) (prescription drugs); 25.5-5-202(3) (amount, duration and scope); 10 Colo. Code Regs. § 2505-10:8.800.

62. Colorado regulations define the term "medical necessity" as encompassing a program, good or service that "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). *Cf.* 10 COLO. CODE REGS. §§ 2505-10:8.280; 2505-10:8.590. The definition goes on to describe "medical necessity" further to mean:

> (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 coverage for Plaintiffs and the class is "medically necessary."

63. Further, under Colorado's Medicaid program, if the treatment is covered and medically necessary, coverage must be provided with "reasonable promptness." 42 U.S.C. § 1396a(a)(8).

64. 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.

65. 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

66. 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, or fell into an extraordinarily narrow set of exceptions. This policy was illegal when first enacted, and throughout its implementation.

67. 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 coverage of medically necessary treatment with no medical justification.

68. On September 1, 2016, HCPF amended its Preferred Drug List to be effective October 1, 2016, which included modifications to the Prior Authorization Criteria used to determine eligibility for DAA treatment coverage ("Prior Authorization Criteria" or "the Policy"). *See* **Exhibit C** at 22. The Policy lowered the minimum MFS needed to obtain treatment coverage to F2, and eliminated it altogether for women who intend to get pregnant in the next 12 months. This half-measure is a step in the right direction, but is still illegal for the same reasons that the former policy was illegal.

69. There is an extraordinarily limited set of exceptions to these categorical coverage restrictions described above, related to "serious extrahepatic manifestations." "Extrahepatic" refers to effects of the disease beyond the liver, and the exceptions contain a short list of such conditions. *See id*. In practice, these exceptions are rarely utilized.

70. 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 coverage of medically necessary treatment. This restriction forces (and has in the past forced) stricken individuals to wait for treatment coverage 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, to wait until they get sicker for treatment coverage, the policy puts the healthy population at risk from the communicability of the disease.

71. Similar restrictions have been successfully challenged in the State of Washington, where a federal district court last year issued a preliminary injunction enjoining the state Medicaid agency from enforcing its policy of denying treatment coverage based on MFS scores, the very type of categorical denial Colorado Medicaid currently enforces, and ordered that DAA coverage be provided to beneficiaries without regard to those scores. *B.E. v. Teeter*, 2016 WL 3033500, at *1 (D.C. Wash. May 27, 2016). Similar litigation is pending in Indiana and Missouri. Medicaid agencies in a number of additional states, including Delaware, Florida, Pennsylvania, 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 PLAINTIFFS

72. At all pertinent times, Plaintiffs were enrolled in Colorado's Medicaid Program, which is administered by HCPF.

73. Plaintiffs are "qualified individual[s]" as defined in 42 U.S.C. § 1396a(a)(10)(A).

74. Plaintiffs are currently diagnosed with chronic HCV, and have been prescribed treatment with DAAs by their treating medical providers, who are specialists in HCV and liver diseases.

75. HCPF has denied coverage for all Plaintiffs due to insufficient MFS score. Plaintiffs do not qualify for any of the extremely-limited exceptions to HCPF's fibrosis-score-based restriction.

76. Plaintiffs' treating physicians applied for treatment coverage for Plaintiffs with DAAs.

77. Treatment coverage for DAAs is "medically necessary" for Plaintiffs. Those DAAs are likely to cure each Plaintiff completely; there is no equally effective, less costly alternative prescription drug or medical intervention available to them; and HCPF has offered none.

78. Plaintiffs remain ineligible for treatment coverage with DAAs under HCPF's current policy.

Michael Ryan

79. Michael Ryan does not meet the eligibility requirements of the Policy due to his fibrosis score.

80. Mr. Ryan is a patient of Dr. Daniel Freese, a gastroenterologist at UC Health. Dr. Freese determined DAA treatment to be medically necessary to treat chronic HCV and wrote a prescription, in accordance with the standard of care. In order to seek Medicaid coverage for this treatment, Dr. Freese submitted a prior approval request to Medicaid.

81. On December 8, 2016, the Defendant issued a denial for Mr. Ryan's treatment coverage. *See* **Exhibit D.**

82. Dr. Freese sought a formal appeal of this denial by resubmitting the request. On January 24, 2017, this second request was denied with a note stating:

> EPCLUSA PAR FOR MEMBER Y406764 DENIAL UPHELD. NO NEW INFORMATION PRESENTED TO OVERTURN DENIAL. NO EVIDENCE OF MINIMUM METAVIR F2. YOU MAY ASSIST MEMBER WITH FORMAL APPEAL PER INSTRUCTIONS IN DENIAL LETTER. M SUTTON 012417 1742.

See **Exhibit E.**

83. Mr. Ryan is a member of the putative class who is ineligible for coverage of DAA treatment under the Prior Authorization Criteria and hereby seeks to strike down HCPF's policy and practice with respect to its utilization of fibrosis score to determine Medicaid coverage of DAA treatment.

Sharon Molina

84. Sharon Molina does not meet the eligibility requirements of the Policy due to her fibrosis score.

85. Ms. Molina's physician determined DAA treatment to be medically necessary to treat chronic HCV and wrote a prescription, in accordance with the standard of care.

86. Ms. Molina and her physician applied for coverage of DAA treatment in February 2017, after HCPF amended its Prior Authorization Criteria. On February 13, 2017, HCPF denied Ms. Molina's application on the basis of her fibrosis score. *See* **Exhibit F**.

87. Ms. Molina is a member of the putative class who is ineligible for coverage of DAA treatment under the Prior Authorization Criteria and hereby seeks to strike down HCPF's policy and practice with respect to its utilization of fibrosis score to determine Medicaid coverage of DAA treatment.

Earby Moxon

88. Earby Moxon does not meet the eligibility requirements of the Policy due to his fibrosis score.

89. Mr. Moxon's physician determined DAA treatment to be medically necessary to treat chronic HCV and wrote a prescription, in accordance with the standard of care.

90. Mr. Moxon applied for treatment coverage with DAAs under HCPF's previous Prior Authorization Criteria and was denied on June 11, 2016 because his fibrosis score did not evidence sufficient liver damage under HCPF's fibrosis score restrictions.

91. Mr. Moxon and his physician re-applied for coverage of DAA treatment in October 2016, after HCPF amended its Prior Authorization Criteria. On October 11, 2016, HCPF again denied Mr. Moxon's application because of an insufficient fibrosis score. *See* **Exhibits G & H**. Mr. Moxon's request for Medicaid coverage of DAA treatment was specifically denied on the basis of his fibrosis score.

92. Mr. Moxon is a member of the putative class who is ineligible for coverage of DAA treatment under the Prior Authorization Criteria and hereby seeks to strike down HCPF's policy and practice with respect to its utilization of fibrosis score to determine Medicaid coverage of DAA treatment.

Heather Myers

93. Heather Myers does not meet the eligibility requirements of the Policy due to her fibrosis score.

94. Ms. Myers' physician determined DAA treatment to be medically necessary to treat chronic HCV and wrote a prescription, in accordance with the standard of care.

95. Ms. Myers and her physician applied for coverage of DAA treatment in November 2016, after HCPF amended its Prior Authorization Criteria. On or around November 11, 2016, HCPF denied Ms. Myers' application because of insufficient fibrosis score. *See* **Exhibit I**.

96. Ms. Myers is a member of the putative class who is ineligible for coverage of DAA treatment under the Prior Authorization Criteria and hereby seeks to strike down HCPF's policy and practice with respect to its utilization of fibrosis score to determine Medicaid coverage of DAA treatment.

VI. CLASS ALLEGATIONS

97. **Class Definition**. The class for which Plaintiffs seek 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; and
>
> (iii) who have been prescribed treatment by an infectious disease specialist, gastroenterologist, or hepatologist or by a primary care provider in consultation with an infectious disease specialist, gastroenterologist, or hepatologist; and
>
> (iv) who would be eligible for coverage of Direct Acting Antiviral medication but for the Policy's fibrosis score threshold.

All class members will benefit by the relief Plaintiffs seek -- elimination of the fibrosis score restriction in the Policy entirely.

98. Plaintiffs seek 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.

99. **Typicality**. Plaintiffs allege that: (i) they are Medicaid eligible under 42 U.S.C. §1396d; (ii) they have been diagnosed as infected with HCV; (iii) their doctors have recommended treatment with DAAs; and (iv) they are, have been, and will in the future be illegally precluded from receiving Medicaid coverage for these drugs by HCPF's Metavir Fibrosis Score requirement. These are precisely the claims they wish to litigate on behalf of the class.

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

101. **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. Normal distribution ranges thus suggest that the class consists of thousands of people, joinder of which is not only impracticable but impossible.

102. **Adequacy of Representation**. Plaintiffs will fairly and adequately protect the interests of the class. Plaintiffs have no interest that is now or may be potentially antagonistic to the interests of the class. They are committed to and passionate about the case, and fully understand responsibilities as class representatives. Plaintiffs are represented by highly competent attorneys with extensive experience in litigating class action cases in federal court.

103. **Action Common to the Class**: The Policy challenged by Plaintiffs 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))

104. Plaintiffs incorporate all of the preceding paragraphs herein.

105. HCPF systematically denies coverage of all FDA approved and AASLD/IDSA recommended DAAs to qualified Medicaid beneficiaries infected with HCV by refusing, with *de minimis* exceptions, to approve prescription requests for prior authorization of treatment coverage with DAAs unless the applicant had an MFS score at or above a specified level, and by publishing and implementing a proscription of coverage of such drugs in the Preferred Drug List.

106. The Policy directly and categorically contradicts the prevailing clinical standard of care, and therefore denies Plaintiffs and those like them medically necessary care, as defined under federal and state law.

107. Pursuant to 42 U.S.C. § 1983 and 28 U.S.C. § 2201, Plaintiffs and the class are entitled to a judgment declaring that HCPF has violated Title XIX of the Social Security Act by denying treatment coverage for 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).

108. Based on the law governing the issuance of injunctions, and also upon 28 U.S.C. § 2202, Plaintiffs and the class are also entitled to a permanent injunction enjoining HCPF from denying treatment coverage for 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.)

109. Plaintiffs incorporate all of the preceding paragraphs herein.

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

111. Pursuant to 42 U.S.C. § 1983 and 28 U.S.C. § 2201, Plaintiffs 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 coverage for 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.

112. Based on the law governing the issuance of injunctions, and upon 28 U.S.C. § 2202, Plaintiffs 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 coverage for 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))

113. Plaintiffs incorporate all of the preceding paragraphs herein.

114. By denying coverage of DAAs to Medicaid eligible individuals diagnosed as chronically infected with HCV, as alleged above, HCPF delays the coverage of demonstrably sick individuals until their disease has progressed to the point of causing measurable and potentially irreparable and irreversible liver damage.

115. Pursuant to 42 U.S.C. § 1983 and 28 U.S.C. § 2201, Plaintiffs 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 coverage 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 of 42 U.S.C. §1396a(a)(10)(A), and thus delaying coverage to demonstrably sick individuals until their disease has progressed to the point of causing measurable and potentially irreparable and irreversible liver damage.

116. Based on the law governing the issuance of injunctions, and upon 28 U.S.C. § 2202, Plaintiffs and the class are also entitled to a permanent injunction enjoining HCPF from denying treatment coverage for 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, Plaintiffs request 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 have been prescribed treatment by an infectious disease specialist, gastroenterologist, or hepatologist or by a primary care provider in consultation with an infectious disease specialist, gastroenterologist, or hepatologist; and

(iv) who would be eligible for coverage of Direct Acting Antiviral medication but for the Policy's fibrosis score threshold.

B. An order designating Sharon Molina, Earby Moxon, Michael Ryan and Heather Myers as class representatives;

C. An Order appointing Mark Silverstein, Sara R. Neel, Paul Karlsgodt, and Kevin Costello as class counsel;

D. A Judgment declaring that the Policy's use of the Metavir Fibrosis Score as a criterion for DAA coverage violates Title XIX of the Social Security Act (also known as the Medicaid Act): (i) by excluding qualified Medicaid recipients from medically necessary treatment coverage 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 coverage 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 coverage of Direct Acting Antiviral medication now or hereafter approved by the U.S. Food and Drug Administration for treatment of the Hepatitis C Virus, recommended for such use by the treatment Guidelines of AASLD/IDSA, and prescribed by an infectious disease specialist, gastroenterologist, or hepatologist (or by a primary care provider in consultation with an infectious disease specialist, gastroenterologist, or hepatologis) 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 of the Court's judgment to known class members, in a form and by means to be determined by the Court;

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

I. An Order awarding Plaintiffs 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: May 9, 2017

/s/ Paul G. Karlsgodt
Paul G. Karlsgodt, #29004

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CERTIFICATE OF SERVICE

I hereby certify that on the 9th day of May 2017, a true and correct copy of the foregoing **AMENDED CLASS ACTION COMPLAINT** was served by CM/ECF on the following:

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