UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

DORENA COLEMAN, CURTIS JACKSON, and FEDERICO PEREZ on behalf of themselves and all others similarly situated, Plaintiffs, v. PHIL WILSON, Acting Executive Commissioner, VICTORIA FORD, Chief Policy and Regulatory Officer, MAURICE MCCREARY, Chief Operating Officer and MICHELLE ALLETTO, Chief Program and Services Officer, in their official capacities with the Texas Health and Human Services Commission, Defendants.	No. 1:20-cv-00847 **CLASS ACTION COMPLAINT**

PLAINTIFFS' ORIGINAL CLASS ACTION COMPLAINT

I. INTRODUCTION

1. This case challenges the state of Texas's systematic and unlawful denial of coverage for curative Hepatitis C treatment to Medicaid-enrolled Texans suffering from Hepatitis C's insidious and life-threatening effects.

2. Plaintiffs are categorically needy Medicaid enrollees with chronic Hepatitis C, the deadliest infectious disease in the United States before the current pandemic arose. According to the Centers for Disease Control and Prevention ("CDC"), between two and four million

individuals in the United States live with the Hepatitis C virus ("HCV").[1] Globally, an estimated 71 million people have chronic HCV infection.[2] The Texas Health and Human Services Commission ("HHSC") and Texas Department of State Health Services estimate that over 500,000 Texans suffer from the disease.[3]

3. "Hepatitis" means inflammation of the liver.[4] Chronic Hepatitis C is an infection of the liver that results from the Hepatitis C virus, however, it affects far more than just the liver.[5] Even before the advanced stages of the disease, individuals with chronic Hepatitis C can suffer severe medical conditions and effects, including kidney disease, hypertension, lymphoma, intractable fatigue, joint pain, arthritis, vasculitis, thyroid disease, depression, memory loss, muscle soreness, mental changes, heart attacks, diabetes, nerve damage, jaundice, and various cancers.

4. Chronic Hepatitis C also progressively damages the liver, leading to liver scarring and eventually preventing effective liver function altogether.

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[1] CDC, *Surveillance for Viral Hepatitis – United States, 2016* ("CDC, *Surveillance for Viral Hepatitis*"), https://www.cdc.gov/hepatitis/statistics/2016surveillance/pdfs/2016HepSurveillanceRpt.pdf (last visited Aug. 6, 2020); CDC, *Hepatitis C Questions and Answers for the Public* ("CDC, *HCV Q's & A's*") (CDC last reviewed July 28, 2020), https://www.cdc.gov/hepatitis/hcv/cfaq.htm#D5.

[2] *See* WORLD HEALTH ORG. (WHO), *Factsheet: Hepatitis C* ("WHO, *Factsheet: HCV*") (July 27, 2020), https://www.who.int/news-room/fact-sheets/detail/hepatitis-c.

[3] *See* TEX. HEALTH & HUMAN SERVS., *2020 State Plan for Hepatitis C: As Required by Texas Health & Safety Code Section 94.001* ("TEX. HHS, *2020 State Plan for HCV*"), 4 (Aug. 2019), https://www.dshs.state.tx.us/legislative/2019-Reports/2020-State-Plan-for-Hepatitis-C.pdf (*also available via* https://dshs.texas.gov/legislative/Reports-2019.aspx); TEX. HEALTH & HUMAN SERVS., *HIV/STD Program: Hepatitis C* ("TEX. HHS, *HIV/STD Program: HCV*") (updated June 11, 2020), https://dshs.texas.gov/hivstd/info/hcv/.

[4] *See* CDC, *HCV Q's & A's*, https://www.cdc.gov/hepatitis/hcv/cfaq.htm#D5.

[5] *Id.*; WHO, *Factsheet: HCV*, https://www.who.int/news-room/fact-sheets/detail/hepatitis-c.

5. As a result, chronic Hepatitis C can lead to fibrosis, cirrhosis, liver cancer, need for a liver transplant, and in certain instances, death.[6]

6. Chronic HCV is typically defined as HCV detectable in the body at least six months after the origination of the Hepatitis C infection. Once the infection is chronic, spontaneous clearance of HCV is exceedingly rare.

7. Beginning in 2011, the U.S. Food and Drug Administration ("FDA"), started approving a series of new prescription drugs in a class called "direct acting antivirals" ("DAAs"). These DAAs cause the Hepatitis C virus to become virtually undetectable in more than 90 percent of patients. **DAA treatment is considered a *de facto* cure for HCV**.

8. Many DAAs are formally identified as "breakthrough therapies" by the FDA because they provide substantial improvement over previously-available therapies for patients with life-threatening diseases.[7] At this time, there is no other treatment for HCV that achieves comparable results with respect to the near-eradication of the virus in the human body (referred to as Sustained Virologic Response ("SVR") status), and prevention of its transmission to uninfected individuals.

9. In addition to the benefits patients receive in reaching SVR status, where the virus is virtually undetectable, these patients are no longer able to transmit the virus to others.[8] This compounds the benefits of DAA treatment across the population and is essential to halting the

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[6] *See* CDC, *Hepatitis C Questions and Answers for the Public* (CDC last reviewed July 28, 2020), https://www.cdc.gov/hepatitis/hcv/cfaq.htm#D5; WHO, *Factsheet: HCV*, https://www.who.int/news-room/fact-sheets/detail/hepatitis-c.

[7] *See* Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 356(a).

[8] *See* AM. LIVER FOUND., *Hepatitis C Information Center* ("AM. LIVER FOUND., *HCV Info. Ctr.*"), https://liverfoundation.org/for-patients/about-the-liver/diseases-of-the-liver/hepatitis-c/#faqs (last visited Aug. 7, 2020).

current HCV epidemic in Texas and across the United States.

10. DAA treatment typically consists of taking a single pill orally each day over the course of 8–12 weeks.

11. In Texas and across the United States, provision of DAAs is the standard of care for treatment of *all* individuals living with HCV, with the *de minimis* exception of individuals with a limited life expectancy due to comorbid conditions.

12. The American Association for the Study of Liver Diseases ("AASLD") and the Infectious Diseases Society of America ("IDSA"), publishes the leading up-to-date source of evidence-based guidelines for treatment of HCV (the "Guidelines").[9] The Guidelines direct that DAAs be provided to anyone who has been diagnosed with HCV—regardless of the condition of their liver—unless their life expectancy is too short to be remedied by treatment, liver transplant, or another directed therapy.[10]

13. The standard of care reflected in the Guidelines has been recognized and incorporated into coverage policies by Medicare, the U.S. Department of Veterans Affairs, and the majority of commercial health insurers across the country. The vast majority of state

[9] *See* AM. ASS'N FOR THE STUDY OF LIVER DISEASES & THE INFECTIOUS DISEASES SOC'Y OF AM., *HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C* ("AASLD & IDSA, *HCV Guidance*") (updated Nov. 6, 2019), https://www.hcvguidelines.org/sites/default/files/full-guidance-pdf/200206_HCVGuidance_November_06_2019_a.pdf (*also available at* https://www.hcvguidelines.org).

[10] *Id.* at *HCV Guidance 203: When and in Whom to Initiate HCV Therapy*, 1/11. This is the case in Texas as it is across the United States. In 2018, a cross-section of Texas doctors and other medical professionals wrote to HHSC urging abandonment of the Policy based on its extant conflict with the national standard of care.

Medicaid programs across the nation adhere to this same standard.[11] The Centers for Medicare & Medicaid Services ("CMS"), the federal agency responsible for administering the Medicaid program, has specifically notified states that restrict access to DAA treatment in the same manner as does Texas, that such restrictions violate federal law.[12]

14. Despite the promise of DAA treatment for hundreds of thousands of Texas residents living with HCV, Texas illegally discriminates against Medicaid beneficiaries like the Plaintiffs by restricting access to these curative drugs.

15. Specifically, the policies and practices of Texas HHSC prohibit Medicaid coverage for medically necessary treatment of some Medicaid beneficiaries with HCV—including Plaintiffs—while providing it to other similarly situated Medicaid beneficiaries, without clinical or medical justification.

16. Texas HHSC's policies and practices in this regard are vestiges of outmoded beliefs regarding the cost of DAA treatment coverage. These policies and practices are not only wrongheaded and costly, they are also illegal under the Social Security Act of 1965 ("Medicaid Act"), 42 U.S.C. §§ 1396–1396w-5.

17. Texas HHSC's policies and practices regarding DAA treatment coverage necessarily require Plaintiffs to wait to access care until their disease has progressed to the point of severe liver scarring. The health risks associated with this delay is a significant reason why the standard of care prohibits the withholding of treatment in this manner.

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[11] *See* HEPATITIS C: STATE OF MEDICAID ACCESS, *See How Your State Matches Up*, https://stateofhepc.org (last visited Aug. 6, 2020).

[12] *See* CMS, *Medicaid Drug Rebate Program Notice, Release No. 172* ("CMS, *Medicaid Drug Rebate Program Notice*") (Nov. 5, 2015), https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-172.pdf.

18. Treatment coverage policies similar to those at issue here have been condemned, overturned, and struck down in a variety of forums across the nation over the last several years. This includes relief awarded by federal district courts identical to that sought here,[13] guidance issued by the federal agency that administers Medicaid,[14] and settlements between state officials and advocates across the country.[15]

19. To remedy the violations of the Medicaid Act described herein, Plaintiffs seek prospective, injunctive, and declaratory relief, by which the Court orders Texas HHSC to reform its coverage policies and practices for DAAs, as well as other related relief described below.

II. JURISDICTION AND VENUE

20. Jurisdiction is proper under 28 U.S.C. § 1331 because these causes of action arise under the laws of the United States. Specifically, Plaintiffs' causes of action arise under the Civil Rights Act of 1871, 42 U.S.C. § 1983 ("Civil Rights Act"), to redress deprivations of rights guaranteed under the Medicaid Act, 42 U.S.C. §§ 1396a(a)(8), 1396a(a)(10)(A), and 1396a(a)(10)(B)(i) and (ii).

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

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[13] *See, e.g.*, *B.E. v. Teeter*, No. C16-227-JCC, 2016 WL 3033500 (W.D. Wash. May 27, 2016).

[14] *See* CMS, *Medicaid Drug Rebate Program Notice*, https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-172.pdf.

[15] *See, e.g.*, Dani Hunter, *Illinois Medicaid Finally to Provide Life-Saving Medication to Cure Hepatitis C*, LEGAL COUNCIL FOR HEALTH JUSTICE (Nov. 8, 2018), https://legalcouncil.org/illinois-medicaid-hepatitis-c-cure.

22. Venue is proper under 28 U.S.C. §§ 1391(b)(1) and (2) because the Defendants reside in the Western District of Texas and a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred here.

III. PARTIES

23. **Plaintiff Dorena Coleman** is a resident of Texas who has been diagnosed with chronic HCV and prescribed DAA treatment. Ms. Coleman is enrolled in Texas Medicaid as a categorically needy individual. Officials acting pursuant to a policy for which HHSC has responsibility have denied her treating physician's request to approve Medicaid coverage for Ms. Coleman's DAA treatment.

24. **Plaintiff Curtis Jackson** is a resident of Texas who has been diagnosed with chronic HCV and prescribed DAA treatment. Mr. Jackson is enrolled in Texas Medicaid as a categorically needy individual. Officials acting pursuant to a policy for which HHSC has responsibility have denied his treating physician's request to approve Medicaid coverage for Mr. Jackson's DAA treatment.

25. **Plaintiff Federico Perez** is a resident of Texas who has been diagnosed with chronic HCV and prescribed DAA treatment. Mr. Perez is enrolled in Texas Medicaid as a categorically needy individual. Officials acting pursuant to a policy for which HHSC has responsibility have denied his treating physician's request to approve Medicaid coverage for Mr. Perez's DAA treatment.

26. **Defendant Phil Wilson** is the Acting Executive Commissioner of the Texas Health and Human Services Commission. HHSC is the single state agency responsible for administering Medicaid in Texas, and it has established and implemented the DAA restrictions challenged in this action. At all times relevant to this Complaint, the actions and inactions of Mr.

Wilson were and are being carried out under color of state law. Mr. Wilson is sued in his official capacity, for prospective relief only.

27. **Defendant Victoria Ford** is the Chief Policy and Regulatory Officer, overseeing rules and policy. HHSC is the single state agency responsible for administering Medicaid in Texas, and it has established and implemented the DAA restrictions challenged in this action. At all times relevant to this Complaint, the actions and inactions of Ms. Ford were and are being carried out under color of state law. Ms. Ford is sued in her official capacity, for prospective relief only.

28. **Defendant Maurice McCreary** is the Chief Operating Officer of the Texas Health and Human Services Commission. HHSC is the single state agency responsible for administering Medicaid in Texas, and it has established and implemented the DAA restrictions challenged in this action. At all times relevant to this Complaint, the actions and inactions of Mr. McCreary were and are being carried out under color of state law. Mr. McCreary is sued in his official capacity, for prospective relief only.

29. **Defendant Michelle Alletto** is the Chief Program and Services Officer of the Texas Health and Human Services Commission, overseeing the management of medical and social services. HHSC is the single state agency responsible for administering Medicaid in Texas, and it has established and implemented the DAA restrictions challenged in this action. At all times relevant to this Complaint, the actions and inactions of Ms. Alletto were and are being carried out under color of state law. Ms. Alletto is sued in her official capacity, for prospective relief only.

IV. FACTUAL ALLEGATIONS CONCERNING HCV

A. HCV is a Widespread, Communicable, and Life-Threatening Disease

30. HCV is an increasingly common, life-threatening bloodborne infection. Left untreated, HCV causes a number of serious health effects, including death.

31. HCV is most commonly transmitted through infected blood. Individuals most at risk of HCV include recipients of blood transfusions or organ transplants before 1992, current or former drug users, health care workers exposed to needle sticks containing HCV-infected blood, and children born to mothers with HCV.

32. Since 2010, new cases of Hepatitis C have increased rapidly. Injection drug use, fueled by the recent opioid crisis, has caused a "dramatic rise" in Hepatitis C infections.[16] An estimated 2.7–3.9 million people in the U.S. are infected with HCV.[17] In 2017 alone, nearly 20,000 HCV-related deaths were reported to the CDC, but this is believed to be a low estimate.[18]

33. According to the Texas Department of State Health Services, as of 2018, over 500,000 Texans were estimated to be living with HCV.[19] In Texas, HCV disproportionately affects racial minorities and populations living along the Texas-Mexico border. South Texas has one of the highest liver cancer death rates in the nation, in part due to high HCV prevalence in

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[16] CDC, *Addressing the Infectious Disease Consequences of the U.S. Opioid Crisis: CDC's Work Improves Health and Saves Money* (CDC last reviewed Mar. 18, 2019), https://www.cdc.gov/nchhstp/budget/infographics/docs/NCHHSTP-opioids-P.pdf.

[17] *See* AM. LIVER FOUND., *HCV Info. Ctr.*, https://liverfoundation.org/for-patients/about-the-liver/diseases-of-the-liver/hepatitis-c/#faqs.

[18] *See* CDC, *Hepatitis C Questions and Answers for the Public* (CDC last reviewed July 28, 2020), https://www.cdc.gov/hepatitis/hcv/cfaq.htm#D5.

[19] *See* TEX. HHS, *2020 State Plan for HCV* at 4, https://www.dshs.state.tx.us/legislative/2019-Reports/2020-State-Plan-for-Hepatitis-C.pdf (*also available via* https://dshs.texas.gov/legislative/Reports-2019.aspx).

the region.[20] The Texas Department of State Health Services is required to develop a state plan for prevention and treatment of Hepatitis C biennially to address such a serious concern.[21]

34. The dangers of HCV are widespread. At all stages of its progression, HCV can cause "hepatic" and "extrahepatic" effects. Hepatic effects directly impact the liver, while extrahepatic effects affect other organ systems and may impact the body more broadly.

35. Damage to the liver is a common and severe result of HCV. HCV progressively scars liver tissue and impairs liver function. Without treatment, HCV can cause fibrosis (liver scarring), cirrhosis (liver impairment due to scarring), liver disease, liver cancer, and even death. HCV is the most common reason for liver transplantation in the U.S.

36. HCV also causes a number of serious extrahepatic effects. Such 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. By way of additional example, cryoglobulinemia is a disorder related to abnormal blood proteins, and can be associated with HCV regardless of the impact of the infection directly on the liver.

37. 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 ("fibrosis score"). A fibrosis score of F0 or F1 indicates no or minimal liver scarring; F2 is an intermediate stage of fibrosis or liver scarring; F3 indicates severe fibrosis; and F4 indicates

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[20] *See generally* Laura Tenner, et al., *The Cost of Cure: Barriers to Access for Hepatitis C Virus Treatment in South Texas*, 15 J. ONCOLOGY PRAC. 61 (2019), https://ascopubs.org/doi/full/10.1200/JOP.18.00525.

[21] *See* State Plan for Hepatitis C; Educ. & Prevention Program, TEX. HEALTH & SAFETY CODE § 94.001.

cirrhosis.

38. A 2015 study using unpublished data from the CDC estimated that, at initial diagnosis, 70 percent of individuals with HCV have a fibrosis score of F0, F1, or F2, while only 30 percent have a fibrosis score of F3 or F4.[22]

39. Liver damage from HCV does not always progress in a predictable or linear fashion. For example, the fibrosis score of a person living with HCV could suddenly advance from F0 to F3 in a short period of time. It is currently impossible to reliably anticipate how quickly a patient's liver will deteriorate, as suggested by progression from one fibrosis score to another.

40. Because HCV is a systemic inflammatory condition, an HCV-infected individual can have no or minimal liver damage, as indicated by an F0 or F1 fibrosis score, but still experience the extrahepatic effects associated with HCV. While the fibrosis score measures the extent of an individual's liver damage, hepatic effects constitute only part of the disease's manifestation.[23]

41. Therefore, regardless of fibrosis score, failure to treat HCV increases the risk of a number of adverse health effects, including irreversible liver damage, liver and other various cancers, likelihood of need for liver transplant, mental and physical suffering, and preventable death.

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[22] David B. Rein, et al., *The Cost-effectiveness, Health Benefits, and Financial Costs of New Antiviral Treatments for Hepatitis C Virus*, 61 CLINICAL INFECTIOUS DISEASES 157, Table 2 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5759765/pdf/nihms929766.pdf; MD. DEP'T OF HEALTH, *2017 Joint Chairmen's Report on Hepatitis C Treatment* 1, 5–6 (2018), https://mmcp.health.maryland.gov/Documents/JCRs/2017/hepcJCRfinal10-17.pdf.

[23] *See generally* Kirat Gill, et al., *Hepatitis C virus as a systemic disease: reaching beyond the liver*, 9 HEPATOLOGY INT'L 415 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4819925/pdf/12072_2015_Article_9684.pdf.

B. DAA Treatment Can Cure HCV Before It Causes Significant, Potentially Irreversible Liver Damage and Severe Health Effects

42. Prior to 2011 and FDA approval of DAA treatment, the standard treatment for HCV cured the disease in only 70 percent of patients and caused significant adverse side effects, including bone, muscle, and joint pain, anemia, insomnia, memory loss, anxiety, depression, liver failure, and death. Additionally, the course of treatment could take up to one year. The previous standard of care has now been rendered obsolete and replaced by DAAs.[24]

43. In 2011, the FDA began to approve a series of DAAs for the treatment of HCV, and specialists heralded "the beginning of the end of HCV."[25] Unlike earlier HCV treatments, DAAs consist of a course of once-daily pills taken for 8–12 weeks, with minimal side effects.

44. DAAs include drugs with brand names such as Viekira Pak (ombitasvir, paritaprevir, ritonavir, dasabuvir), Daklinza (daclatasvir), Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Mavyret (glecaprevir/pibrentasvir), Olysio (simeprevir), Sovaldi (sofosbuvir), Technivie (ombitasvir, paritaprevir, ritonavir), and Zepatier (elbasvir/grazoprevir).

45. The FDA has designated many of these drugs as "breakthrough therap[ies],"[26] a classification reserved for drugs that provide substantial improvement over available therapies for patients with serious or life-threatening diseases.

46. Prescription of FDA-approved DAAs are supported by multiple, well-designed,

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[24] *See* CDC, *Surveillance for Viral Hepatitis* at 8, https://www.cdc.gov/hepatitis/statistics/2016surveillance/pdfs/2016HepSurveillanceRpt.pdf ("Newer, all-oral agents are being added continually and have become the standard of care in the United States.").

[25] Marie-Louise Vachon & Douglas T. Dieterich, *The Era of Direct-acting Antivirals Has Begun: The Beginning of the End for HCV?*, 31 SEMINARS IN LIVER DISEASE 399 (2011), https://pubmed.ncbi.nlm.nih.gov/22189979/ (abstract).

[26] *See* 21 U.S.C. § 356(a) (defining "breakthrough therapy" and the process for expedited approval of such drugs under this Act).

controlled studies or well-designed experimental studies.

47. Due to the benefits associated with successful HCV treatment, clinicians following the standard of care treat HCV patients with DAAs, regardless of fibrosis score. The goal of DAA treatment is to achieve SVR status, when the virus is virtually undetectable in a patient. Thus, DAA treatment is considered a *de facto* cure of the infection. Achieving SVR status ameliorates extrahepatic effects, stems hepatic effects, and prevents the worsening of the disease and condition.

48. DAAs are the only medication or medical intervention for HCV that produce an SVR in more than 90 percent of patients. In addition to the curative effects of SVR each individual patient, individuals who achieve SVR become unable to transmit the virus to others, thereby reducing future transmissions and curbing the incidence rate of a highly infectious disease.

49. There is no equally effective alternative treatment for HCV. *See Teeter*, 2016 WL 3033500, at *3–4. Where a patient is infected with HCV, a clinical decision to monitor the infection until such a time as liver fibrosis has progressed to a more severe form, is not medical treatment. Indeed, such a course of inaction constitutes *the lack of* medical treatment.

50. The FDA has approved DAA treatment for anyone with HCV, regardless of fibrosis score.

C. DAA Treatment is the Standard of Care for Virtually All Patients with HCV, Regardless of Fibrosis Score

51. DAA treatment is currently the standard of care for the treatment for all patients with HCV, regardless of fibrosis score, in Texas and across the United States.

52. As identified above, the AASLD and IDSA jointly publish the Guidelines for

treatment of HCV.[27] The Guidelines reflect the universally-accepted standard of care for HCV treatment. The Guidelines direct treatment for *all* patients with HCV—regardless of fibrosis score—with a narrow exception for those with a shortened life expectancy that cannot be remedied by HCV treatment, liver transplantation, or another directed therapy.[28]

53. The AASLD/IDSA Guidelines specifically direct early treatment of HCV for patients with lower fibrosis scores,[29] directly repudiating Texas's current approach limiting access to DAAs to only patients who have already suffered significant liver damage.

54. As noted above, CMS, the federal agency in charge of administering Medicaid, has further emphasized the importance of access to DAAs for Medicaid recipients and condemned unreasonable restrictions on access to this curative treatment. On November 5, 2015, CMS issued guidance to state Medicaid agencies to direct that DAAs should be included in Medicaid coverage of outpatient prescription drugs.[30]

55. As part of such guidance, CMS expressed concern "that some states are restricting access to DAA HCV drugs contrary to the statutory requirements in section 1927 of the [Medicaid] Act by imposing conditions for coverage that may unreasonably restrict access to these drugs."[31]

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[27] AASLD & IDSA, *HCV Guidance at HCV Guidance 203: When and in Whom to Initiate HCV Therapy* 1/11, https://www.hcvguidelines.org/sites/default/files/full-guidance-pdf/200206_HCVGuidance_November_06_2019_a.pdf (*also available at* https://www.hcvguidelines.org).

[28] *See id.*

[29] *Id.* at 2/11.

[30] *See* CMS, *Medicaid Drug Rebate Program Notice*, https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-172.pdf.

[31] *Id.* at 2.

D. Texas HHSC's Policies and Practices Restrict Access to DAA Treatment Based on Fibrosis Score

56. According to Texas HHSC's current Prior Authorization Criteria and Policy,

> Immediate [DAA] treatment is assigned the highest priority for patients with advanced fibrosis (Metavir stage F3) or cirrhosis (Metavir stage F4), liver transplant recipients, and patients with hepatocellular carcinoma. Patients with Metavir scores less than stage 3 may not be approved.[32]

Texas HHSC policies are followed by the managed care entities that administer Medicaid benefits for putative class members seeking coverage for DAA treatment.[33] In practice, Texas HHSC's policies and practices deny Plaintiffs and all those similarly situated life-saving treatment, for which there is no equally efficacious alternative, until their disease has become "severe enough."

57. Texas HHSC has implemented these restrictions because of cost concerns.[34]

58. Even putting aside the propriety of restricting access to coverage of medically

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[32] TEX. HEALTH & HUMAN SERVS., *Texas Vendor Drug Program: Antiviral Agents for Hepatitis C Virus Initial Authorization Request (Medicaid), Form 1335* (Mar. 2018-E), https://paxpress.txpa.hidinc.com/hepc_initial_request.pdf (*also available via* https://www.txvendordrug.com/formulary/prior-authorization/ffs-clinical-pa).

[33] *Id.*

[34] *See* Sean Price, *Reaching for the Cure: Texas Medicaid Doesn't Cover Hepatitis C Drugs Until Patients Are Seriously Ill* ("S. Price, *Reaching for the Cure*"), TEX. MED. ASS'N (updated Feb. 18, 2020), https://www.texmed.org/TexasMedicineDetail.aspx?Pageid= 46106&id=52386 (*published at* 116 Tex. Med. 38); Allie Morris, *Patients get sicker as Texas refuses to cure them of deadly hepatitis C*, SAN ANTONIO EXPRESS NEWS (July 20, 2018, 1:34 PM), https://www.expressnews.com/news/politics/texas_legislature/article/Patients-get-sicker-as-Texas-refuses-to-cure-them-13089981.php; Chris Tomlinson, *Health care prices should be based on costs, not need*, HOUS. CHRON. (Jan. 28, 2019), https://www.houstonchronicle.com/business/columnists/tomlinson/article/Health-care-prices-should-be-based-on-costs-not-13561938.php.

necessary care on strictly fiscal grounds, such concerns are misplaced.[35] Treatment of HCV with DAAs is cost-effective. As for up-front price, DAAs cost the same as or less than the combination treatment for HCV prior to the advent of DAAs, and are cost-effective to the health care system in the long term compared to the costs of treating extrahepatic effects, advanced liver disease, cancer, and other associated manifestations of HCV.[36] Treating patients with lower fibrosis scores is particularly cost effective because it provides them with a cure before the virus causes more serious and costly health outcomes.

59. While the current price of DAA treatment to Texas HHSC is not publicly available, it is clear that the cost has fallen dramatically in the years since the policies and practices at issue were first put in place.[37]

E. The Policies and Practices of Texas HHSC for DAA Treatment Coverage Cause Significant Harm

60. The effect of Texas HHSC's policies and practices with respect to DAA treatment coverage is that individuals with fibrosis scores between F0 and F2 are categorically prohibited

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[35] Plaintiffs note that the Texas Legislature has passed a budget measure designed to explore a new method of making Hepatitis C medications affordable for Medicaid patients, although that process remains unresolved. *See* S. Res. 834, 86th Leg., Reg. Sess. (Tex. 2019) (asking the state to "explore the feasibility of implementing a model allowing the state to pay a flat monthly rate for unlimited access to medications or other bulk purchasing or negotiating opportunities to treat individuals with Hepatitis C who are eligible to have prescription drugs provided with state funds").

[36] *See* Gigi A. Moreno, et al., *Value of Comprehensive HCV Treatment among Vulnerable, High-Risk Populations*, 20 VALUE HEALTH 736, 736, 741 (2017), https://www.valueinhealthjournal.com/action/showPdf?pii=S1098-3015%2817%2930085-2; *see also* Jacquelyn W. Chou, et al., *Short-term budget affordability of hepatitis C treatments for state Medicaid programs*, 19 BMC HEALTH SERVS. RES. 140, 1, 11 (2019), https://bmchealthservres.biomedcentral.com/track/pdf/10.1186/s12913-019-3956-x.

[37] *See* S. Price, *Reaching for the Cure*, https://www.texmed.org/TexasMedicineDetail.aspx?Pageid= 46106&id=52386 (noting that the wholesale price for DAA treatment has dropped from $84,000 to $94,000 in 2013–2014 to the $20,000 to $35,000 range currently).

from essential medical assistance. Providers who prescribe treatment consistent with the standard of care are thus forced to inform such patients that they are "not sick enough" to be cured, regardless of how the disease is currently affecting them.

61. While it is possible that such individuals will qualify for treatment coverage at some hypothetical time in the future, delayed treatment may come too late to avoid significant health consequences.

62. Without access to coverage for DAA treatment, Medicaid beneficiaries at all stages of fibrosis are at a significantly higher risk for severe hepatic and extrahepatic symptoms. Although DAAs rid the body of HCV, they cannot always reverse the damage that has already been caused to the liver and other organ systems. As such, delay in or denial of DAA treatment to individuals with HCV can cause irreversible hepatic and extrahepatic damage.

63. In some past cases, patients subject to similar policies or practices have missed the opportunity to treat their HCV due to the significant deterioration of their medical condition. As the United States District Court for the Western District Washington stated in an opinion holding that Washington's nearly identical DAA policy was illegal:

> 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." 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.

Teeter, 2016 WL 3033500, at *5 (alterations in original) (emphasis added) (citations omitted). This example highlights the necessity of treating HCV's harmful systemic effects at the earliest possible opportunity.[38]

64. Not surprisingly, delaying treatment to individuals with HCV can also increase psychological stressors including anxiety, illness uncertainty (the inability to determine the meaning of illness-related events), and depressive symptoms. Patients who are cured of HCV with treatment report an improvement in their mental well-being.

65. Because of its "severe[] restrict[ion]" of DAA treatment coverage to individuals living with HCV, Texas ranks among the worst state Medicaid programs nationally. Moreover, the policies and practices at issue contradict the goal of the latest Texas State Plan for Hepatitis C to "expand prevention, testing, and treatment" of the disease.

66. Treating all HCV patients with DAAs also leads to considerable cost savings and better health outcomes. Expanded access to DAA therapies will decrease the pool of individuals who can transmit the infection and lower expenditures by lessening the substantial costs of treating advanced liver diseases.

V. STATUTORY AND REGULATORY FRAMEWORK

A. The Medicaid Act Regulates Texas's Provision of Prescription Drug Coverage, Including Prior Authorization Criteria

67. The Medicaid program is operated cooperatively between the federal and state

[38] *Cf. Abu-Jamal v. Kerestes*, No. 3:15-CV-967, 2018 WL 2166052, at *4 (M.D. Pa. May 10, 2018) (noting that the delay caused by a fibrosis score threshold in the HCV policy of state corrections department resulted in the patient developing liver cirrhosis), *aff'd in part, appeal dismissed in part*, 779 F. App'x 893 (3d Cir. 2019).

governments. While participation in the Medicaid program is optional, once a state elects to participate, it "must comply with certain requirements imposed by the Medicaid Act and regulations promulgated by the Secretary of Health and Human Services." *Romano v. Greenstein*, 721 F.3d 373, 374–75 (5th Cir. 2013) (internal quotation marks and citation omitted).

68. All states, including Texas, have elected to administer a Medicaid program.[39] At the federal level, the Medicaid program is administered by CMS. At the state level, Medicaid in Texas is administered by Texas HHSC.[40]

69. Under Title XIX of the Social Security Act, the purpose of the Medicaid program is to "furnish [] medical assistance on behalf of" certain groups of individuals, including "families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of *necessary* medical services[.]" 42 U.S.C. § 1396-1 (emphasis added); *see also Beal v. Doe*, 432 U.S. 438, 438 (1977) ("[S]erious statutory questions might be presented if state Medicaid plans did not cover necessary medical treatment[.]"). These groups are deemed "categorically needy" individuals under 42 U.S.C. § 1396a(a)(10)(A)(i). The Act allows states to further expand their coverage to "optional categorically needy" groups defined under 42 U.S.C. § 1396a(a)(10)(A)(ii). The Texas State Plan, for example, opts to include women with breast and cervical cancer and independent foster care adolescents. *See* TEX. HUM. RES. CODE § 32.024(y); *id.* at § 32.0247. States, including Texas, have also applied "spend down" standards in calculating income to provide medical assistance for "medically needy" individuals, who have significant health needs but whose income is too high to otherwise

[39] *See* TEX. GOV'T CODE § 531.021(a).

[40] *See id.* at § 531.021(b)(2).

qualify under Subsection A. 42 U.S.C. § 1396a(a)(10)(C)(i); *see also Blum v. Caldwell*, 446 U.S. 1311, 1312 (1980); TEX. HUM. RES. CODE § 32.0247.

70. According to the Medicaid Act, medical assistance means "payment of part or all of the cost of [certain] care and services or the care and services themselves[.] . . ." 42 U.S.C. § 1396d(a). As a condition of participation in the Medicaid program, states must make certain categories of care and services available to Medicaid-eligible individuals. *See id.* §§ 1396a(a), 1396a(a)(10), 1396a(a)(10)(A) ("A State plan for medical assistance must . . . provide . . . for making medical assistance available . . . to—all [eligible] individuals."); *see also S.D. ex rel. Dickson v. Hood*, 391 F.3d 581, 588 (5th Cir. 2004).

71. The statute categorizes certain services as mandatory for the Medicaid program to provide and others as optional. The provision of prescription drugs is an optional service under the Act, *see* 42 U.S.C. § 1396d(a)(12). If a state opts to provide coverage of prescription drugs, it is subject to the restrictions found in the Act and related regulations. *See Montoya v. Johnston*, 654 F. Supp. 511, 514 (W.D. Tex. 1987) (citing *Meyers ex rel. Walden v. Reagan*, 776 F.2d 241 (8th Cir. 1985)). All states, including Texas, have opted to provide prescription drugs as part of their Medicaid programs.

72. State Medicaid plans that opt into the prescription drug benefit, including Texas Medicaid, 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. §§ 1396r-8(a)(1), 1396r-8(d)(1)(B), 1396r-8(k)(2)(A), 1396r-8(k)(6); *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 652 (2003).

73. Services provided as part of the Medicaid program must be "sufficient in amount, duration, and scope to reasonably achieve its purpose," 42 C.F.R. § 440.230(b), and the state

"may place appropriate limits on a service based on such criteria as medical necessity," *id.* § 440.230(d); *see also Hope Med. Grp. for Women v. Edwards,* 63 F.3d 418, 427–428 (5th Cir. 1995) ("Although Title XIX and 42 C.F.R. § 440.230 allow state Medicaid programs to adopt appropriate limits based on medical necessity, such restrictions must be consistent with the Act's objective of providing a broad range of health-sustaining services."). Moreover, states are restricted from "arbitrarily deny[ing] or reduc[ing] the amount, duration, or scope of a required service . . . to an otherwise eligible beneficiary solely because of the diagnosis, type of illness, or condition." 42 C.F.R. § 440.230(c); *see also Curtis v. Taylor*, 625 F.2d 645, 652 (5th Cir. 1980) ("Considering medical treatment generally provided through a Medicaid program, [relevant case law] prohibit[s] its denial to individuals solely on the basis of the 'diagnosis, type of illness, or condition' those individuals suffered from if the denial is unrelated to medical necessity.").

74. Texas defines "medically necessary" as the "need for medical services in an amount and frequency sufficient, according to accepted standards of medical practice, to preserve health and life and to prevent future impairment."[41]

75. DAA treatment is "medically necessary" for Plaintiffs, those like them, and for nearly all individuals with HCV.

B. Texas Must Provide Comparable Treatment to All Medicaid Enrollees

76. Under the Medicaid Act's "comparability" requirement, Medicaid services made available to categorically needy individuals "shall not be less in amount, duration, or scope" to any other Medicaid enrollee, including any other categorically needy individual or medically

[41] TEX. HEALTH & HUMAN SERVS., *Medicaid for the Elderly and People with Disabilities Handbook* H-2120 (revision 16-2; effective June 1, 2016), https://hhs.texas.gov/laws-regulations/handbooks/mepd/chapter-h-co-payment/h-2000-incurred-medical-expenses#H2120 (*full report available at* https://hhs.texas.gov/book/export/html/4454); *see also* 1 TEX. ADMIN. CODE § 353.2(69) (offering a similar definition of "medically necessary" in a different context).

needy individual. 42 U.S.C. § 1396a(a)(10)(B); Med. Assistance Programs Servs.: Comparability of services for groups, 42 C.F.R. § 440.240; *see also Equal Access for El Paso, Inc. v. Hawkins*, 428 F. Supp. 2d 585, 616 (W.D. Tex. 2006), *rev'd on other grounds*, 509 F.3d 697 (5th Cir. 2007). The comparability requirement "is 'violated when some recipients are treated differently than others where each has the same level of need.'" *See, e.g.*, *Pashby v. Cansler*, 279 F.R.D. 347, 354 (E.D.N.C. 2011) (citing *V.L. v. Wagner*, 669 F. Supp. 2d 1106, 1114–15 (N.D. Cal. 2009)), *aff'd and remanded sub nom*., *Pashby v. Delia*, 709 F.3d 307 (4th Cir. 2013).

C. Texas Must Provide Reasonably Prompt Medical Assistance to All Medicaid Enrollees

77. The Medicaid Act further dictates that a state Medicaid plan "provide that all individuals wishing to make application for medical assistance . . . shall have opportunity to do so, and that such assistance shall be furnished with reasonable promptness to all eligible individuals." 42 U.S.C. § 1396a(a)(8); *see also Romano*, 721 F.3d at 377.

78. In administering the Medicaid program, Texas HHSC is obligated to comply with each of these provisions – providing nondiscriminatory coverage for medically necessary, comparable treatments with reasonable promptness to its Medicaid enrollees. The current policies and practices prohibiting access to curative DAAs for most Medicaid-eligible individuals with HCV in the state flatly fails in this regard.

VI. TEXAS'S PRIOR AUTHORIZATION CRITERIA FOR DAA TREATMENT COVERAGE OF HEPATITIS C VIOLATES THE MEDICAID ACT

A. Defendant's Prior Authorization Criteria for HCV Violate the Comparability Provision by Treating Similarly Situated Enrollees with Hepatitis C Differently

79. The DAA treatment coverage policies and practices of Texas HHSC treat comparable Medicaid enrollees with HCV differently based on degree of liver scarring without

medical justification. Enrollees with fibrosis scores of F3 and F4 have coverage for curative treatment, while enrollees with fibrosis scores of F0, F1, and F2 do not. Based on general distribution ranges, this categorical exclusion leaves approximately 70 percent of all Texas Medicaid beneficiaries with HCV without access to care.

80. This distinction is based on fiscal concern, rather than medical or clinical grounds.

81. Indeed, the categorical exclusion at issue makes it certain that some Texas Medicaid enrollees exhibiting severe extrahepatic effects, or who are otherwise seriously ill, at risk of serious illness, or who may have a limited window of opportunity to be cured of HCV, will be denied care.

82. These policies and practices thus provide some categorically needy individuals with less medical assistance than others with similar medical needs, in direct contravention of 42 U.S.C. §§ 1396a(a)(10)(B)(i) and (ii), and 42 C.F.R. § 440.240.

B. Defendant's Prior Authorization Criteria for HCV Violate the Comparability Provision by Treating Similarly Situated Enrollees with Chronic Illnesses Differently

83. There is a second manner in which the DAA treatment coverage policies and practices of Texas HHSC violate the Medicaid Act's comparability provision. Unlike the prior authorization criteria for treatment of comparable chronic illnesses, the Texas HHSC policies and practices for coverage of DAA treatment target HCV as a condition for which a sufficient level of disease severity is required to access medically necessary prescription drugs.

84. Categorically needy Texas Medicaid enrollees diagnosed with diabetes or rheumatoid arthritis or Parkinson's disease, for example, are not subjected to a Texas Medicaid policy that categorically excludes coverage based on disease severity in conflict with the standard of care.

85. As such, the policies and practices of Texas HHSC deny some categorically

eligible Medicaid beneficiaries the same level of medical assistance provided to other categorically eligible and medically needy beneficiaries, without medical justification. The distinction employed by Texas HHSC is based on fiscal concern, rather than medical or clinical grounds.

86. Such policies or practices violate the plain language of 42 U.S.C. §§ 1396a(a)(10)(B)(i) and (ii) and the interpreting regulations at 42 C.F.R. § 440.240.

C. Defendant's Prior Authorization Criteria for HCV Violate the State's Obligation to Provide Treatment with Reasonable Promptness

87. Defendant's Prior Authorization Criteria and Policy has resulted in a failure to furnish medically necessary DAA treatment coverage to categorically needy Medicaid beneficiaries with reasonable promptness.

88. By categorically excluding Plaintiffs from DAA treatment coverage, the Defendants make unavailable the only available and effective treatment to Plaintiffs' disease, and forces them to wait until their disease has caused substantial, possibly irreversible damage to their health.

89. Mere observation, monitoring, or repeated testing for HCV and fibrosis does not constitute treatment - the provision of DAAs is the only treatment for chronic HCV under the universally accepted standard of care. *See Teeter*, 2016 WL 3033500, at *3–4.

90. In addition, the reasonable promptness requirement prohibits state Medicaid agencies, such as Defendants, from responding to state budgetary concerns by keeping Medicaid beneficiaries waiting for medically necessary treatment. *See Sobky v. Smoley*, 855 F. Supp. 1123, 1148 (E.D. Cal. 1994); *see also Boulet*, 107 F. Supp. 2d at 79–80 (holding that "inadequate funding does not excuse failure to comply with the reasonable promptness requirement") (citing *Doe ex rel. Doe v. Chiles*, 136 F.3d 709, 722 (11th Cir. 1998)).

91. "Reasonable promptness" is "readily susceptible to judicial assessment." *See Chisholm ex rel. Minors v. Gee*, No. CV 97-3274, 2017 WL 3730514, at *5 (E.D. La. Aug. 30, 2017) (internal quotation marks and citation omitted). A delay in services for conditions that require "early and intensive intervention[]" lasting over six months, and in some cases, over a year, has been found to violate the reasonable promptness provision. *Id.* at *6.

92. Thus, Defendant's ongoing, lengthy delay in providing DAA treatment coverage to Plaintiffs for HCV—a severe condition for which the universal standard of are requires early treatment—violates the reasonable promptness provision outlined in 42 U.S.C. § 1396a(a)(8).

D. Defendant's Prior Authorization Criteria for HCV Violate the State's Obligation to Cover Prescription Drug Treatment

93. Defendant's prior authorization policy for DAA treatment coverage illegally withholds treatment from Medicaid beneficiaries for whom such treatment is medically necessary.

94. Such policy contravenes the standard of care for treatment of HCV, as described herein.

95. Defendant's policy thus illegally denies DAA treatment coverage to categorically needy Medicaid beneficiaries for whom such treatment is medically necessary, violating 42 U.S.C. § 1396a(a)(10)(A), and 42 C.F.R. §§ 440.230(b) and (c).

96. In sum, the policies and practices of Texas HHSC categorically require Medicaid enrollees with HCV to wait to access DAA treatment until they have experienced significant, potentially irreversible liver damage, contravene the universally-accepted standard of care for treatment of HCV, disregard directives made by CMS, and violate the Medicaid Act.

97. Furthermore, the policies and practices of the Texas HHSC are at odds with the policies of CMS, the Centers for Disease Control, AASLD, IDSA, Medicare, the U.S.

Department of Veterans Affairs, most commercial health insurers, and as discussed below, many state Medicaid programs.

98. Such an irresponsible and overly restrictive policy puts otherwise healthy Texans at risk of becoming infected with HCV due to unwillingness to prevent the communicability of the disease upon its diagnosis.

99. Texas's unreasonable cost concerns cannot excuse its failure to comply with federal standards. *See Miss. Hosp. Ass'n, Inc. v. Heckler*, 701 F.2d 511, 518 (5th Cir. 1983); *see also Planned Parenthood of Cent. Tex. v. Sanchez*, 280 F. Supp. 2d 590, 606 (W.D. Tex. 2003) ("[A] state's budget problems cannot serve as an excuse for altering federal eligibility requirements for federal funding; if they could, the federal requirements would become superfluous.").

100. In recognition of the mandates of federal law, restrictions similar to the Medicaid policies have been successfully challenged through litigation in Washington, Colorado, Michigan, Missouri, Indiana and Kansas. In addition, Medicaid agencies in other states including Delaware, Florida, Pennsylvania, Massachusetts, Rhode Island, Vermont, New York, Illinois, and Louisiana have responded to advocacy efforts by removing such restrictions and implementing policy changes to increase access to curative DAA treatment for their Medicaid enrollees suffering from HCV.

101. Texas HHSC officials have met or communicated with advocates seeking to reform Texas Medicaid coverage policy for HCV on multiple occasions over the last several years. For example, in 2018, a coalition of nearly three dozen Texas health care providers and professionals joined with national advocacy organizations to send a letter to HHSC demanding that the policies and practices of Texas Medicaid be conformed to the standard of care.

Defendants ignored this plea for help, Texas Medicaid remains one of only a few programs in the United States that requires a fibrosis score of F3 to receive coverage for DAA treatment.

102. The Medicaid program provides health care coverage to Texas's neediest individuals, who do not have the financial means to pay out of pocket for DAA treatment. The devastating result of the policies and practices at issue is that Medicaid beneficiaries in Texas receive a second-class standard of health care coverage that renders them unable to access the curative treatment they desperately need and fails to address an infectious disease epidemic ***with an existing cure for infected populations***.

VII. WRONGS TO INDIVIDUAL PLAINTIFFS

A. Dorena Coleman

103. At all relevant times, Dorena Coleman was enrolled in Texas's Medicaid Program as a categorically needy individual as described by 42 U.S.C. § 1396a(a)(10)(A).

104. Ms. Coleman is eligible for Medicaid through the Medicaid for Breast and Cervical Cancer Program and is entitled to Medicaid benefits. 42 U.S.C. § 1396a(a)(10)(A)(ii)(XVIII); 42 U.S.C. § 1396a(aa); 1 TEX. ADMIN. CODE § 366.405.

105. Ms. Coleman is currently diagnosed with HCV and has been prescribed treatment with DAAs by Dr. Jonathan Ramirez, a gastroenterologist at Baylor Scott & White Medical Center.

106. Ms. Coleman suffers from chronic fatigue, diabetes, joint disorder, and arthritis, which Dr. Ramirez believes may be linked to her HCV. As a result of such extrahepatic effects, Ms. Coleman experiences chronic pain and exhaustion on a daily basis which affects her ability to work, eat, and partake in physical activity.

107. Dr. Ramirez determined DAA treatment to be medically necessary to treat Ms.

Coleman's HCV and wrote a prescription, in accordance with the standard of care.

108. Ms. Coleman and Dr. Ramirez applied for coverage of DAA treatment in June 2019.

109. On July 16, 2019, the Medicaid managed care organization that administers Ms. Coleman's Medicaid benefits on behalf of Texas HHSC denied Ms. Coleman's application due to her fibrosis score. Ms. Coleman has tested with a fibrosis score of F1.

110. In this way, Ms. Coleman was denied coverage for DAA treatment under the policies and practices of Texas HHSC due to insufficient degree of liver damage and fibrosis score.

111. Ms. Coleman sought a formal appeal of this denial in September 2019.

112. As of the date of the filing of this complaint, Ms. Coleman remains ineligible for DAA treatment coverage under Defendant's current Prior Authorization Criteria and Policy.

113. Treatment coverage for DAAs is medically necessary for Ms. Coleman. DAAs are likely to cure Ms. Coleman's HCV completely. There is no equally effective, less costly alternative prescription drug or medical intervention available to them, and HHSC has offered none.

114. Ms. Coleman is a member of the putative class who is ineligible for coverage of DAA treatment under HHSC's Prior Authorization Criteria and Policy and hereby seeks to strike down HHSC's policy and practice of using fibrosis score to determine Medicaid coverage of DAA treatment.

B. Curtis Jackson

115. At all relevant times, Curtis Jackson was enrolled in Texas's Medicaid Program as a categorically needy individual as described by 42 U.S.C. § 1396a(a)(10)(A).

116. Mr. Jackson is currently diagnosed with HCV and has been prescribed treatment with DAAs by Dr. Jose Luna, MD, a primary care physician at Centro San Vicente in El Paso.

117. Mr. Jackson suffers from a prediabetic condition, which Dr. Luna believes may be linked to his HCV.

118. Dr. Luna determined DAA treatment to be medically necessary to treat Mr. Jackson's HCV and wrote a prescription, in accordance with the standard of care.

119. Mr. Jackson and Dr. Luna applied for coverage of DAA treatment in October 2018.

120. The Medicaid managed care organization that administers Mr. Jackson's Medicaid benefits on behalf of Texas HHSC denied Mr. Jackson's application due to his fibrosis score. Mr. Jackson has tested with a fibrosis score of F1-F2.

121. In this way, Mr. Jackson was denied coverage for DAA treatment under the policies and practices of Texas HHSC due to insufficient degree of liver damage and fibrosis score.

122. As of the date of the filing of this complaint, Mr. Jackson remains ineligible for DAA treatment coverage under Texas HHSC Prior Authorization Criteria and Policy.

123. Treatment coverage for DAAs is medically necessary for Mr. Jackson. DAAs are likely to cure Mr. Jackson's HCV completely. There is no equally effective, less costly alternative prescription drug or medical intervention available to them, and Texas Medicaid has offered none.

124. Mr. Jackson is a member of the putative class who is ineligible for coverage of DAA treatment under HHSC's Prior Authorization Criteria and Policy and hereby seeks to strike down HHSC's policy and practice of using fibrosis score to determine Medicaid coverage of

DAA treatment.

C. Federico Perez

125. At all relevant times, Federico Perez was enrolled in Texas's Medicaid Program as a categorically needy individual as described by 42 U.S.C. § 1396a(a)(10)(A).

126. Mr. Perez is currently diagnosed with HCV and has been prescribed treatment with DAAs by Dr. Jose Luna, MD, a primary care physician at Centro San Vicente in El Paso.

127. Mr. Perez suffers from a diabetes, fatty liver, hypertension and other conditions which Dr. Luna believes may be linked to his HCV.

128. Dr. Luna determined DAA treatment to be medically necessary to treat Mr. Perez's HCV and wrote a prescription, in accordance with the standard of care.

129. Mr. Perez and Dr. Luna applied for coverage of DAA treatment in September 2019.

130. The Medicaid managed care organization that administers Mr. Perez's Medicaid benefits on behalf of Texas HHSC denied Mr. Perez's application due to his fibrosis score. Mr. Perez has tested with a fibrosis score of F0.

131. In this way, Mr. Perez was denied coverage for DAA treatment under the policies and practices of Texas HHSC due to insufficient degree of liver damage and fibrosis score.

132. As of the date of the filing of this complaint, Mr. Perez remains ineligible for DAA treatment coverage under Texas HHSC Prior Authorization Criteria and Policy.

133. Treatment coverage for DAAs is medically necessary for Mr. Perez. DAAs are likely to cure Mr. Perez's HCV completely. There is no equally effective, less costly alternative prescription drug or medical intervention available to them, and Texas Medicaid has offered none.

134. Mr. Perez is a member of the putative class who is ineligible for coverage of DAA treatment under HHSC's Prior Authorization Criteria and Policy and hereby seeks to strike down HHSC's policy and practice of using fibrosis score to determine Medicaid coverage of DAA treatment.

VIII. CLASS ALLEGATIONS

135. **Class Definition**. The class for which Plaintiffs seek certification consists of all individuals:

a. are or will in the future be enrolled in the Texas Medicaid Program as categorically needy individuals, as defined by 42 U.S.C. 1396a(a)(10)(A);

b. have been or will be diagnosed as having an infection of the Hepatitis C Virus;

c. have been or will be prescribed DAA treatment by a qualified prescriber; and

d. would be eligible for DAA treatment coverage but for the Prior Authorization Criteria and Policy's fibrosis score threshold.

136. All class members will benefit by the relief Plaintiffs seek: the complete elimination of the fibrosis score restriction in the DAA treatment coverage policies and practices of Texas Medicaid.

137. Plaintiffs seek certification of a class under Rules 23(a) and 23(b)(2) of the Federal Rules of Civil Procedure. The requirements for class certification under Rules 23(a) and (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 interest of the class.

e. **Action common to the class**: The party opposing the class has acted or refused to act on the grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole.

Each of these requirements is satisfied here.

138. **Numerosity**. Texas HHSC reports that approximately 1.8 percent of Texans, or just over 500,000 individuals, are living with HCV.[42] As of April 2020, over 4 million individuals were enrolled in Medicaid and CHIP programs in Texas.[43] According to an HHSC report in 2017, less than 1 percent of the Texas full beneficiary caseload in 2015 comes from medically needy spend down programs.[44] Normal distribution ranges thus suggest that the class likely consists of hundreds or thousands of individuals, joinder of which is not only impracticable, but impossible.

139. **Commonality**. All legal and factual questions inherent in the ultimate question of whether the restrictions on coverage of DAAs based on the Prior Authorization Criteria and Policy are illegal under the Medicaid Act are common to all members of the class.

140. **Typicality**. Plaintiffs allege that: (i) they are categorically needy and Medicaid eligible under 42 U.S.C. § 1396a(a)(10)(A); (ii) they have been diagnosed as infected with HCV; (iii) their doctors have prescribed or recommended, or will prescribe or recommend treatment

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[42] TEX. HHS, *HIV/STD Program: HCV*") (updated June 11, 2020), https://dshs.texas.gov/hivstd/info/hcv/.

[43] CMS, *Medicaid & CHIP in Texas*, https://www.medicaid.gov/state-overviews/stateprofile.html?state=Texas (last visited Aug. 7, 2020).

[44] TEX. HHSC, *Texas Medicaid and CHIP in Perspective* 35 (11th ed. 2017), *available at* https://hhs.texas.gov/sites/default/files/documents/laws-regulations/reports-presentations/2017/medicaid-chip-perspective-11th-edition/11th-edition-complete.pdf.

with DAAs; and (iv) they are, have been, and will in the future be precluded from receiving Medicaid coverage for these drugs by Defendant's Prior Authorization Criteria and Policy. These are precisely the claims they wish to litigate on behalf of the class.

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

142. **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. Therefore, Defendants have 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.

IX. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Denial of Comparable Treatment Coverage to Beneficiaries with Hepatitis C Compared with Other Beneficiaries with Hepatitis C in Violation of the Medicaid Act, 42 U.S.C. § 1983; 42 U.S.C. § 1396a(a)(10)(B) and 42 C.F.R. § 440.240.

143. Plaintiffs incorporate all of the preceding paragraphs herein.

144. While denying coverage of DAAs to some categorically needy individuals with HCV, as alleged above, HHSC has at the same time provided coverage to other similarly situated Medicaid beneficiaries with HCV, with no medically justifiable basis for such differential treatment. Instead, the distinction is based on a concern that coverage would be too costly.

145. Pursuant to 42 U.S.C. § 1983 and 28 U.S.C. § 2201, Plaintiffs and the class are entitled to a judgment declaring that Defendants have violated Title XIX of the Social Security

Act by discriminating among similarly situated Medicaid beneficiaries infected with the Hepatitis C Virus via the denial of treatment coverage for DAAs to those with a fibrosis score of less than a specified minimum, in violation of the comparability requirements under 42 U.S.C. §§ 1396a(a)(10)(B)(i) and (ii), and 42 C.F.R. § 440.240.

146. Based on 28 U.S.C. § 2202 and associated law governing the issuance of injunctions, Plaintiffs and the class are also entitled to a permanent injunction enjoining Defendants from discriminating amongst similarly situated Medicaid participants with HCV by denying treatment coverage for DAAs to those with a fibrosis score less than a specified minimum, in violation of the comparability requirements under 42 U.S.C. §§ 1396a(a)(10)(B)(i) and (ii), and 42 C.F.R. § 440.240.

SECOND CLAIM FOR RELIEF

Denial of Comparable Treatment Coverage to Beneficiaries with Hepatitis C Compared with Other Beneficiaries with Chronic Illnesses in Violation of the Medicaid Act, 42 U.S.C. § 1983; 42 U.S.C. § 1396a(a)(10)(B) and 42 C.F.R. § 440.240.

147. Plaintiffs incorporate all of the preceding paragraphs herein.

148. While denying coverage of medically necessary prescription drugs to some categorically needy individuals with HCV, as alleged above, HHSC has at the same time provided such coverage to other similarly situated Medicaid beneficiaries with comparable chronic illnesses, with no medically justifiable basis for such differential treatment. In effect, the policies and practices of Texas HHSC have singled out HCV as a medical condition to apply a disease severity threshold.

149. Pursuant to 42 U.S.C. § 1983 and 28 U.S.C. § 2201, Plaintiffs and the class are entitled to a judgment declaring that Defendants have violated Title XIX of the Social Security Act by discriminating among similarly situated Medicaid beneficiaries via the application of a disease severity threshold for Hepatitis C, in violation of the comparability requirements under

42 U.S.C. §§ 1396a(a)(10)(B)(i) and (ii), and 42 C.F.R. § 440.240.

150. Based on 28 U.S.C. § 2202 and associated law governing the issuance of injunctions, Plaintiffs and the class are also entitled to a permanent injunction enjoining Defendants from discriminating amongst similarly situated Medicaid participants with HCV by denying treatment coverage for DAAs to those with a fibrosis score less than a specified minimum, in violation of the 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

Failure to Provide Necessary Medical Assistance with Reasonable Promptness in Violation of the Medicaid Act, 42 U.S.C. § 1983; 42 U.S.C. § 1396a(a)(8).

151. Plaintiffs incorporate all of the preceding paragraphs herein.

152. By denying coverage of DAAs to Medicaid eligible individuals diagnosed with HCV, as alleged above, HHSC delays coverage of curative DAA treatment to HCV-infected individuals until their disease has progressed to the point of causing severe and potentially irreparable and irreversible liver damage.

153. Pursuant to 42 U.S.C. § 1983 and 28 U.S.C. § 2201, Plaintiffs and the class are entitled to a judgment declaring that Defendants have violated the "reasonable promptness" requirement of Title XIX of the Social Security Act by implementing a policy that delays the coverage of DAAs to qualified Medicaid beneficiaries chronically infected with the Hepatitis C Virus until their disease has progressed to the point of causing severe and potentially irreversible liver damage, in violation of 42 U.S.C. § 1396a(a)(8).

154. Based on 28 U.S.C. § 2202 and associated law governing the issuance of injunctions, Plaintiffs and the class are also entitled to a permanent injunction enjoining HHSC from failing to provide reasonably prompt treatment coverage for DAAs to qualified Medicaid

beneficiaries due to their having a fibrosis score of less than a specified minimum, in violation of the obligation to provide reasonably prompt medical assistance under 42 U.S.C. § 1396a(a)(8).

FOURTH CLAIM FOR RELIEF

Exclusion of Qualified Individuals from Covered and Necessary Medical Assistance in Violation of the Medicaid Act, 42 U.S.C. § 1983; 42 U.S.C. § 1396a(a)(10)(A).

155. Plaintiffs incorporate all of the preceding paragraphs herein.

156. Texas HHSC categorically denies coverage of DAAs to qualified Medicaid beneficiaries with HCV by refusing to approve prescription requests for prior authorization of treatment coverage with DAAs unless the beneficiary has a fibrosis score at or above a specified level.

157. The policies and practices of Texas HHSC here at issue directly and categorically contradict the prevailing clinical standard of care, and therefore deny Plaintiffs and those like them medically necessary care, as defined under federal and state law.

158. Pursuant to 42 U.S.C. § 1983 and 28 U.S.C. § 2201, Plaintiffs and the class are entitled to a judgment declaring that Defendants have violated Title XIX of the Social Security Act by denying treatment coverage for DAAs to qualified Medicaid beneficiaries chronically infected with HCV due to their having an insufficient fibrosis score less than a specified minimum, in violation of 42 U.S.C. §1396a(a)(10)(A).

159. Based on 28 U.S.C. § 2202 and associated law governing the issuance of injunctions, Plaintiffs and the class are also entitled to a permanent injunction enjoining Defendants from denying treatment coverage for DAAs to qualified Medicaid beneficiaries chronically infected with HCV due to their having an insufficient fibrosis score less than a specified minimum.

X. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that the following judgments and orders be entered against Defendant:

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

A. are or will in the future be enrolled in the Texas Medicaid Program as categorically needy individuals, as defined by 42 U.S.C. 1396a(a)(10)(A);

B. have been or will be diagnosed as having an infection of the Hepatitis C Virus;

C. have been or will be prescribed DAA treatment by a qualified prescriber; and

D. would be eligible for DAA treatment coverage but for the Prior Authorization Criteria and Policy's fibrosis score threshold;

161. An order designating Plaintiffs Coleman, Jackson, and Perez as class representatives;

162. An order appointing **The Edwards Law Group, Latham and Watkins,** and Kevin Costello as class counsel;

163. A judgment declaring that HHSC's Prior Authorization Criteria and Policy's use of fibrosis score as a criterion for DAA coverage violates Title XIX of the Social Security Act: (i) by discriminating among similarly situated Medicaid recipients on the basis of categorical restrictions that are not based upon prevailing clinical standards, as prohibited by 42 U.S.C. §§ 1396a(a)(10)(B)(i) and (ii), and 42 C.F.R. § 440.240; (ii) by denying qualified Medicaid participants the provision of necessary medical assistance and treatment coverage with "reasonable promptness," as required by 42 U.S.C. § 1396a(a)(8); and (iii) by excluding

qualified Medicaid recipients from medically necessary treatment coverage as required by 42 U.S.C. § 1396a(a)(10)(A);

164. A permanent injunction enjoining HHSC from promulgating, instituting, or implementing any policy or protocol that denies coverage of DAA medication now or hereafter approved by the FDA for treatment of the Hepatitis C Virus, directed by the treatment Guidelines of AASLD/IDSA, and prescribed by a qualified prescriber to any Medicaid enrollee diagnosed as infected by the Hepatitis C Virus due to an insufficient fibrosis score;

165. Grant preliminary and permanent injunctions that prohibit Defendants from implementing and enforcing the current Prior Authorization Criteria or otherwise impermissibly limiting access to medically necessary Direct Acting Antivirals and from refusing to provide Medicaid coverage of medically necessary Hepatitis C drugs to Plaintiffs and the class as determined by their physicians;

166. Require Defendants to provide corrective notice to all Medicaid participants denied coverage under existing criteria, informing them of a state-based procedure that will be developed, implemented, and available to them to request coverage of Direct Acting Antivirals that is consistent with the Medicaid Act;

167. Require Defendants to issue a provider notice to inform physicians of a state-based procedure that will be developed, implemented, and available to them to request coverage of Direct Acting Antivirals that is consistent with the Medicaid Act;

168. Require Defendants to re-process all recent denials of prior authorization requests for DAAs and to inform relevant class members that their previously denied claims are being reprocessed for evaluation without regard to the Prior Authorization Criteria, subject to the prescribing physician's approval;

169. An Order requiring Defendants to provide notice of the Court's judgment to known class members, in a form and by means to be determined by the Court;

170. An Order awarding Plaintiffs and the class their attorneys' fees and costs pursuant to 42 U.S.C. § 1988; and

171. Such other and further relief as the Court may deem just and proper.

Date: August 13, 2020

Respectfully submitted,

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