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. CECILE ERWIN YOUNG, Executive Commissioner, VICTORIA FORD, Chief Policy and Regulatory Officer, and MICHELLE ALLETTO, Chief Program and Services Officer, in their official capacities with the Texas Health and Human Services Commission (HHSC), Defendant.	)	No. 1:20-CV-00847-RP

PLAINTIFFS' OPPOSITION TO DEFENDANTS' PARTIAL MOTION TO DISMISS

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SUMMARY OF THE RESPONSE

Plaintiffs, three Texas Medicaid beneficiaries, bring this suit on behalf of themselves and thousands of other individuals who are diagnosed with the Hepatitis C virus ("HCV"), an increasingly common, life-threatening, blood-borne infection. Complaint, ECF No. 1 ("Compl.") ¶ 30. Texas Medicaid – operated by Defendants – denies Plaintiffs coverage of the cure for HCV. Defendants arbitrarily limit coverage by making it contingent on a threshold fibrosis score, intended to measure liver scarring, such that about 70% of all HCV patients are excluded from treatment. A restriction of this type flatly violates the medical standard of care and has been expressly rejected by the federal agency that administers Medicaid.

Defendants move to dismiss only the first two of Plaintiffs' claims, leaving the balance of the Complaint unchallenged. The Court should deny Defendants' partial motion to dismiss for three reasons.

First, Plaintiffs have adequately pleaded facts necessary to state their first claim for relief, which alleges that Texas Medicaid violates the comparability provision of the Medicaid Act, 42 U.S.C. § 1396a(a)(10)(B), by way of "HCV discrimination." According to the standard of care, all individuals with HCV (except those with life expectancies too short to benefit) should have access to the cure. *Id.* ¶ 52. By employing a policy that discriminates between individuals with comparable medical needs – that is, as between HCV infected individuals with qualifying fibrosis scores versus HCV infected individuals with fibrosis scores that exclude them from coverage – Defendants violate Section 1396a(a)(10)(B). *Id.* ¶¶ 79-82. Instead of offering comparable coverage to all individuals encompassed by the standard of care, Texas Medicaid restricts access using a single, arbitrary metric that forecloses treatment to the majority of eligible beneficiaries on terms that are divorced from consideration of overall individual medical need. *See id.* ¶ 40.

Second, Plaintiffs have adequately pleaded facts necessary to state their second claim for relief, which alleges that Texas Medicaid violates Section 1396a(a)(10)(B) through "chronic condition discrimination." Across all of Texas Medicaid, Defendants have singled out HCV for a unique coverage restriction. *Id.* ¶¶ 83-86. HCV is the only chronic condition for which Texas Medicaid fails to provide coverage consistent with the corresponding medical standard of care. *Id.* In this way, Plaintiffs are denied access to comparable care relative to other Texas Medicaid beneficiaries who likewise suffer from chronic conditions. *Id.*

Third, the Court should decline the Defendants' invitation to recognize within the Medicaid program a scope of state discretion so broad as to permit violations of federal law. Accepted as true, Plaintiffs' allegations plainly state two claims that the Medicaid comparability requirement is being violated, notwithstanding appropriate deference to the Defendants' decision-making authority.

Accordingly, the Court should deny the Defendants' partial motion to dismiss.

FACTUAL BACKGROUND

A. Plaintiffs suffer from HCV – a widespread, communicable, life-threatening disease that can have significant effects at all stages.

Plaintiffs Dorena Coleman, Curtis Jackson, and Federico Perez are ill. Like thousands of other Texas Medicaid beneficiaries, they suffer from an infection of HCV, a widespread, communicable and life-threatening disease. Compl. ¶ 30. Left untreated, HCV causes serious health effects, and can even be fatal. *Id.* Once infected, individuals with HCV experience varying symptoms, including progressively worsening liver damage that can lead to cirrhosis, liver disease, liver cancer, and eventually death. *Id.* ¶ 35. In addition to liver damage, individuals with HCV may face debilitating extrahepatic (*i.e.*, non-liver) effects such as 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. *Id.* ¶ 36. Individuals can exhibit minimal liver damage and still experience serious extrahepatic effects, making HCV a significant health problem at all stages of an individual's infection. *Id.* ¶ 40.

The degree of damage to a patient's liver is sometimes measured using a "Metavir" fibrosis score that indicates the level of a patient's liver scarring.[1] *Id.* ¶ 37. Accurately measured, 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 cirrhosis. *Id.* Patients can experience extrahepatic effects regardless of their fibrosis score. *Id.* ¶ 40. Though liver damage generally increases over time, it does not always progress in a predictable or linear fashion. *Id.* ¶ 39. It is currently impossible to anticipate reliably how quickly a patient's liver will deteriorate, as measured by progression from one fibrosis score to another. *Id.* Because of the unpredictability of disease progression and the consistent risk of extrahepatic effects, fibrosis scores are not definitive measures of disease severity or medical need in HCV infected individuals. *Id.* ¶¶ 39-41.

HCV is also a significant public health problem. Recent estimates indicate that 500,000 Texans are living with HCV. *Id.* ¶ 33. HCV can be transmitted via various pathways including drug use, needle sticks in healthcare settings, and childbirth. *Id.* ¶ 31. The nation is seeing a dramatic rise in HCV cases due to the opioid epidemic. *Id.* ¶ 33. South Texas has one of the highest liver cancer death rates nationally, in part due to HCV prevalence in the region. *Id.*

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[1] "Metavir" is an abbreviation for "Meta-analysis of Histological Data in Viral Hepatitis." *See* Kelly S. Wells, et al., DRUGS FOR CHRONIC HEPATITIS C INFECTION: CLINICAL REVIEW (2016), https://www.ncbi.nlm.nih.gov/books/NBK350717/.

B. **DAA treatment is the standard of care for Plaintiffs and all individuals with HCV in Texas and across the United States**.

Ostensibly, there is good news for individuals infected with HCV; this serious medical condition can be cured by taking one pill a day for 8-12 weeks, with no significant side effects. Compl. ¶¶ 7-12, 43. These pills, known as direct-acting antiviral ("DAA") treatment are FDA-approved for all individuals with HCV, regardless of fibrosis score. *Id.* ¶ 50. The medical standard of care for HCV – at all stages of fibrosis – is treatment with DAAs. *Id.* ¶ 51. With a course of DAA treatment, the virus is reduced to an undetectable level in over 90 percent of HCV patients. *Id.* ¶ 48. Previous HCV treatments required up to a year of adherence to a drug, with a far lower efficacy rate and severe side effects. *Id.* Widespread use of DAAs could herald "the beginning of the end of HCV," *id.* ¶ 43, and prevent unnecessary death and infection in Texas and across the country.

DAA treatment is the standard of care for HCV in Texas and across the United States. Compl. ¶¶ 11, 51-52.[2] Plaintiffs' allegations in this regard are supported by the declaration of a preeminent infectious disease clinician specializing in HCV. ECF No. 10-2 at 4-5. And Dr. Trooskin is not alone. The American Association for the Study of Liver Diseases ("AASLD") and the Infectious Diseases Society of America ("IDSA"), publish the leading up-to-date source of evidence-based guidelines for treatment of HCV ("Guidelines"). Compl. ¶ 12. 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. *Id.*

[2] The medical standard of care is a question of fact under Texas law. *Trimble v. Millwood Hosp.*, 420 F. Supp. 3d 550, 556 (N.D. Tex. 2016) (citing *St. Paul Med. Ctr. v. Cecil*, 842 S.W.2d 808, 812 (Tex. App.--Dallas 1992)).

This standard of care is widely recognized. The Centers for Medicare & Medicaid Services ("CMS"), the federal agency responsible for administering the Medicaid program, has issued sub-regulatory guidance indicating that restrictions on coverage for DAA treatment – identical to those still employed by Texas – violate federal law. Compl. ¶¶ 13, 54-55. The standard of care has also been incorporated into coverage policies by Medicare, the U.S. Department of Veterans Affairs, and most commercial health insurers across the country. *Id.* ¶ 13. The vast majority of state Medicaid programs adhere to this same standard. *Id.*

Despite this landscape, Texas Medicaid maintains an outlier coverage policy for DAA treatment that ignores individualized medical need and flatly contradicts the standard of care.[3]

C. Texas Medicaid policy draws an arbitrary line that improperly denies coverage and causes significant harm to Plaintiffs.

Texas Medicaid beneficiaries do not enjoy coverage congruent with the standard of care. Texas Medicaid includes DAA treatment on the list of pharmaceuticals for which it generally provides coverage. Compl. ¶¶ 56 & n.32. Nonetheless, Plaintiffs have been denied Medicaid coverage for DAA treatment based solely on the Texas Medicaid Prior Authorization Criteria and Policy ("Policy") for DAAs. *Id.* The Policy makes coverage contingent on the severity of a single diagnostic metric correlated with liver scarring. *Id.* In effect, Texas Medicaid has told Ms. Coleman, Mr. Jackson, Mr. Perez, and the thousands of putative class members they seek to represent, that their livers are not scarred enough to merit DAA treatment coverage, despite the

[3] Texas Medicaid is administered by Texas Health and Human Services. Cecile Erwin Young, Victoria Ford, and Michelle Alletto, are officials employed by the Texas Health and Human Services Commission (collectively, "Defendants"), and are sued in their official capacities for prospective injunctive relief. Compl. ¶¶ 26-29 (naming predecessor officials in some cases).

fact that DAA treatment is the standard of care for them, as with almost all patients with chronic HCV. *Id.* ¶ 60.

Instead, the Policy states: "Patients with Metavir scores less than stage 3 may not be approved." *Id.* ¶ 56. Nothing in the Policy justifies or explains the decision to exclude coverage below this fibrosis score. The effect of the Policy and Texas HHSC's resulting practice is that individuals whose testing registers fibrosis scores between F0 and F2 are categorically prohibited from essential medical assistance. *Id.* ¶ 60. Providers who prescribe treatment consistent with the standard of care are thus forced to inform such patients that their liver scarring is not registering as severe enough for them to receive the cure, regardless of how the disease is currently affecting the patient overall. *Id.* Delayed treatment creates a far higher risk for severe hepatic and extrahepatic symptoms. *Id.* ¶ 62. Although DAAs rid the body of HCV, they cannot always reverse damage to the liver and other organ systems. *Id.* As such, the harm caused by the Defendants' refusal to treat HCV until a F3 fibrosis score is registered can cause irreversible hepatic and extrahepatic damage. *Id.*

Rather than being medically justified (which it is not), the Policy stems from fiscal concerns. *Id.* ¶¶ 57, 80. Yet even this motivation is hollow. DAAs cost the same as or less than the combination treatment for HCV that preceded them, and are cost-effective to the health care system in the long term. *Id.* ¶ 58. Cost-effectiveness measures have only improved as the falling up-front price of DAAs is compared to the costs of treating extrahepatic effects, advanced liver disease, cancer, and other associated manifestations of HCV. *Id.* ¶¶ 58-59. Facilitating treatment at an early stage of disease severity is particularly cost-effective, because it avoids ever costlier downstream medical interventions, such as organ transplants and cancer treatments, and slows the

spread of the virus among the population. *Id.* ¶ 58. There is no equivalent treatment for HCV that can be given at lower cost. *Id.* ¶ 49.

There is no reasoned basis for the Policy – fiscal, medical or otherwise.

LEGAL STANDARD

"[W]hen ruling on a defendant's motion to dismiss, a judge must accept as true all of the factual allegations contained in the complaint." *Erickson v. Pardus*, 551 U.S. 89, 94 (2007). Thus, "[m]otions to dismiss are viewed with disfavor and are rarely granted." *Test Masters Educ. Servs., Inc. v. Singh*, 428 F.3d 559, 570 (5th Cir. 2005).

A claim is adequately pleaded when the facts go beyond "threadbare recital of the elements of a cause of action, supported by mere conclusory statements." *Patrick v. Wal-Mart, Inc.*, 681 F.3d 614, 622 (5th Cir. 2012) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). "Specific facts are not necessary; the statement need only give the defendant fair notice of what the claim is and the grounds upon which is rests." *Erickson*, 551 U.S. at 93. Thus, "the pleading standard Rule 8 announces does not require detailed factual allegations," it only "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Iqbal*, 556 U.S. at 678.

Defendants only challenge Plaintiffs' two "comparability" claims. The comparability provision of the Medicaid Act, 42 U.S.C. § 1396a(a)(10)(B),[4] is designed to ensure that coverage

[4] "A State plan for medical assistance must— . . . provide . . .
(B) that the medical assistance made available to any [categorically needy] individual—
(i) shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual, and
(ii) shall not be less in amount, duration, or scope than the medical assistance made available to individuals not described in subparagraph (A)"
42 U.S.C. § 1396a(a)(10)(B). The Plaintiffs appropriately allege that they are enrolled in Texas Medicaid as "categorically needy" individuals, such that the provisions of the Medicaid Act's comparability requirement apply to them. Compl. ¶¶ 23-25.

is not arbitrarily limited for one categorically needy individual or group of individuals relative to fellow beneficiaries with *comparable* medical needs. "Under federal Medicaid law, a state plan must provide that 'the medical assistance made available to any individual . . . shall not be less in amount, duration, or scope than the medical assistance made available to any other [such] individual . . . .'" *Blanchard v. Forrest*, 71 F.3d 1163, 1166 (5th Cir. 1996) (quoting 42 U.S.C. § 1396a(a)(10)(B)). Discrimination in the "amount, duration, or scope" of medical assistance is forbidden as between individuals or groups with comparable medical needs.

Comparability jurisprudence shows that the provision has long served as a safeguard against arbitrary Medicaid policies that single out disfavored individuals or groups for lesser coverage relative to others with similar levels of medical need. The comparability requirement is thus intended to "assure comparable treatment for all of the needy . . . and eliminate some of the unevenness which has been apparent in the treatment of the medical needs of various groups of the needy." *Schweiker v. Hogan*, 457 U.S. 569, 573 n.6 (1982) (quoting 1965 House Report). Stated simply, the Medicaid Act's comparability provision requires that Texas Medicaid provide "comparable services for individuals with comparable needs." *Cota v. Maxwell-Jolly*, 688 F. Supp. 2d 980, 993 (N.D. Cal. 2010).

ARGUMENT

Plaintiffs allege that they are eligible Medicaid enrollees infected with HCV, that DAA treatment is the standard of care for nearly every Medicaid enrollee infected with HCV, and that the Defendants have denied Plaintiffs coverage of DAA treatment, while at the same time allowing coverage of such treatment for Medicaid enrollees who register fibrosis scores of F3 or above, as well as permitting coverage of appropriate treatment consistent with the corresponding standard of care for other chronically ill Medicaid enrollees. These facts in the Complaint describe

incomparable treatment that is more than sufficient to state a claim that the Defendants are violating the Medicaid Act's comparability provision.

The Defendants here challenge just two of Plaintiffs' claims, those arising under the comparability requirement of the Medicaid Act: (1) "HCV discrimination" within the group of Medicaid beneficiaries who are living with HCV (Compl. ¶¶ 143-46); and (2) "chronic condition discrimination" as between Medicaid beneficiaries with HCV and Medicaid beneficiaries with other chronic conditions (Compl. ¶¶ 147-50).[5] Plaintiffs sufficiently allege facts in support of both claims. In both cases, Texas Medicaid provides coverage consistent with the standard of care to one group, but categorically fails to do so for a cohort of beneficiaries with comparable needs – the Plaintiffs and the putative class.

Defendants also invoke Texas's "broad discretion" over its Medicaid program as justification for the Policy. No amount of discretion permits the Texas Health and Human Services Commission ("HHSC") to violate federal law.

A. "HCV discrimination" violates the comparability provision of the Medicaid Act.

Plaintiffs adequately plead that the Policy violates the comparability provision of the Medicaid Act because it constitutes "HCV discrimination," as among all Texas Medicaid beneficiaries living with HCV. The line drawn by the Policy segregates beneficiaries living with HCV into two subgroups – those whose testing registers a fibrosis score at F3 or above, thus qualifying for coverage, and those who do not, thus being categorically blocked from coverage. This line constitutes an arbitrary exclusion in violation of Section 1396a(a)(10)(B) for at least two principal reasons.

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[5] This Opposition addresses the Defendants' arguments from the Motion for Partial Dismissal, ECF No. 19, in reverse order.

1. All Texas Medicaid beneficiaries living with HCV have a comparable need for coverage, as evidenced by the standard of care.

First, the standard of care for all individuals living with HCV – without regard to fibrosis score – is DAA treatment. Compl. at ¶¶ 11, 51. This is true in Texas and across the country, with the only exception relating to individuals with life expectancies too short to benefit from treatment. Compl. ¶¶ 11, 47, 52. The AASLD's Guidance specifically states that DAAs should *not* be limited only to individuals with fibrosis scores of F3 and F4. *Id.* ¶ 12. Likewise, the same standard of care is incorporated into coverage policies by Medicare, the U.S. Department of Veterans Affairs, and most commercial health insurers across the country. *Id.* ¶ 13. The vast majority of state Medicaid programs adhere to this same standard. *Id.* CMS has admonished that state Medicaid restrictions on coverage for DAA treatment – identical to those employed by Defendants – violate federal law. *Id.* ¶¶ 13, 54-55.

The import of the standard of care is clear – all Texas Medicaid beneficiaries living with HCV have a comparable need for DAA treatment coverage. By arbitrarily segregating individuals into two subgroups – one with coverage, and one without – the Defendants violate Section 1396a(a)(10)(B).[6] If accurately measured, it is true that individuals with different fibrosis scores generally have different amounts of liver scarring – such is the point of the Metavir fibrosis scoring

[6] Other courts have found comparability violations in similar circumstances. *See, e.g.*, *Pashby v. Delia*, 709 F.3d 307, 325 (4th Cir. 2013) (restrictions to personal care services based on residency violated comparability provision); *V.L. v. Wagner*, 669 F. Supp. 2d 1106, 1115-17 (N.D. Cal. 2009); *Parry By & Through Parry v. Crawford*, 990 F. Supp. 1250, 1257 (D. Nev. 1998) (restrictions to disability services based on diagnosis violated comparability provision); *Jenkins v. Dep't of Soc. & Health Servs.*, 157 P.3d 388, 393 (Wash. 2007); *Jasset v. Rhode Island Dep't of Human Servs.*, 2006 R.I. Super. LEXIS 93, at *18 (R.I. July 31, 2006) (restrictions to binaural hearing aids based on arbitrary factors such as age violated comparability provision).

system. *Id.* ¶ 37. Yet the standard of care identifies all HCV patients as comparably situated with respect to medical need for DAA treatment because denial or delay increases the risk of adverse health effects, including irreversible liver damage, various cancers, mental and physical suffering, and preventable death. *Id.* ¶¶ 62-65. 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. *Id.*[7]

Defendants' Motion does not acknowledge the standard of care, nor explain why approximately 70% of affected beneficiaries must wait to access care until their HCV has progressed to the point of severe liver scarring. *Id.* ¶ 38. Defendants' motion mistakes the purported *urgency* of an individual's medical need for DAA treatment with the *existence* of that need at all. The Policy's mandate that putative class members wait, indefinitely, until their fibrosis score is far advanced "brings to mind Lord Keynes' rejoinder that 'in the long run we are all dead.'" *Sobky v. Smoley*, 855 F. Supp. 1123, 1142 (E.D. Cal. 1994) (quoting Pigou, John Maynard Keynes, 32 PROCEEDINGS OF THE BRITISH ACADEMY 407) ("In the long run all categorically needy persons may receive services . . . [b]ut in the meantime they do not, and life does not stop for them during this interim period."). Just as the *Sobky* court found that the Medicaid comparability provision was violated when Medicaid beneficiaries were arbitrarily forced to endure waiting lists before being approved for substance use disorder treatment, so too is it violated here.

[7] The health risks associated with delayed treatment are a significant reason why the standard of care prohibits withholding treatment based on fibrosis score. Compl. ¶ 63 (recounting the Court's description in *B.E. v. Teeter* of a Washington Medicaid recipient for whom such delay made it impossible to receive treatment altogether). *See also Ryan v. Birch,* 2017 U.S. Dist. LEXIS 143568, at *11 (D. Colo. Sept. 5, 2017) (denying a motion to dismiss and holding that plaintiffs sufficiently alleged Colorado Medicaid violated the comparability provision by denying DAA treatment based on fibrosis scores).

2. HCV discrimination violates Section 1396a(a)(10)(B) because it erects a categorical barrier to coverage based on an arbitrary metric without regard to individualized medical need.

The Complaint identifies a second fatal flaw in the Policy with respect to "HCV discrimination." By erecting a categorical exclusion that fails to account for individualized medical need, the Policy runs afoul of the Medicaid Act's comparability provision. The Policy purports to rest on a proxy for medical necessity – a single diagnostic measurement of the function of one organ. Yet, as amply demonstrated by the facts pleaded in the Complaint, this method results in exactly the type of arbitrary outcomes that are the hallmark of a Medicaid comparability violation.

HCV is a systemic inflammatory condition. Compl. ¶ 40. While an accurately determined fibrosis score can measure the extent of an individual's liver damage, hepatic effects constitute only part of the disease's manifestation. As Defendants concede, HCV is "generally a disease that affects individuals differently at different stages of the illness." ECF No. 19 at 6. Even before the advanced stages of the disease, individuals with HCV can suffer from extrahepatic effects such as kidney injury, diabetes, autoimmune diseases, depression, sore muscles, and fatigue. Compl. ¶¶ 36, 42. The many extrahepatic effects of HCV infection are not necessarily correlated with fibrosis scores. Compl. ¶ 40. Thus, a categorically needy Texas Medicaid beneficiary with extrahepatic manifestations of the disease and a fibrosis score of F1 might be suffering from more severe symptoms than a counterpart beneficiary with a fibrosis score of F3, but with relatively few additional effects. The latter is eligible for DAA treatment, while the former is not. Preventing such arbitrary line drawing is at the core of the Medicaid Act's comparability requirement. *See Jenkins v. Dep't of Soc. & Health Servs.*, 157 P.3d 388, 393 (Wash. 2007) (finding the Medicaid comparability provision violated where the Defendant's policy is "based on a consideration other than the recipient's actual need" and in fact "ignores, the realities of the recipients' individual

situations."); *V.L. v. Wagner*, 669 F. Supp. 2d 1106, 1115-17 (N.D. Cal. 2009). As in *Jenkins* and *V.L.*, the Defendants use a blunt force categorical exclusion for coverage of services that fails to account for individualized need in a manner that leads to arbitrary outcomes.

Moreover, liver damage from HCV does not always progress in a predictable or linear fashion. Compl. ¶ 39. A significant number of individuals with HCV who have fibrosis scores of F0–F2 will progress to cirrhosis if they do not receive treatment, yet there is no way to predict who in this cohort will develop advanced liver disease. *Id.* For example, an HCV-infected individual's fibrosis score could suddenly advance from F0 to F3 in a short period of time. *Id.* It is not possible using existing diagnostic tools to anticipate reliably the pace or course of liver damage based on fibrosis score. *Id.* As a result, the Policy does not even accomplish the apparent goal of minimizing liver damage. *See V.L. v. Wagner*, 669 F. Supp. 2d at 1115 (finding plaintiffs would likely prevail under a comparability claim because the state's use of "numerical rank" and "FI scores" did not "reasonably measure" medically need).

Defendants do not treat Plaintiffs and putative class members comparably to other individuals with HCV, and this discrimination wholly disregards individualized considerations of medical need. Because the Policy establishes a categorical distinction in services without a valid distinction in medical need amongst those Medicaid beneficiaries with HCV, Defendants violate the comparability provision and their partial motion to dismiss must be denied.

B. "Chronic condition discrimination" violates the comparability provision of the Medicaid Act.

The Defendants also move to dismiss Plaintiffs' second claim for relief, alleging a violation of Section 1396a(a)(10)(B) resulting from "chronic condition discrimination." The Medicaid Act's comparability provision is not limited to comparisons between individuals suffering from the same medical condition. A violation may also exist where Medicaid coverage

is denied to disfavored individuals with one medical condition, yet granted to others with a different diagnosis, but comparable need. *See, e.g., Cruz v. Zucker*, 116 F. Supp. 3d 334, 348 (S.D.N.Y. 2015) (holding that a violation of the comparability provision is pleaded where plaintiffs suffering from gender dysphoria "clearly allege that defendant provides medical coverage to similarly situated Medicaid recipients suffering from conditions other than [gender dysphoria] for the surgical procedures and other treatments that are denied to them …."); *Rolland v. Cellucci*, 52 F. Supp. 2d 231, 238 (D. Mass. 1999) ("Some courts have also held that the comparability provision is violated if there is a disparity of treatment among the categorically needy even when those individuals have differing disabilities.").[8] Here, the Complaint states a claim that the comparability provision is violated because Defendants target a single group of chronically ill Medicaid beneficiaries to apply a coverage restriction that contradicts the standard of care, while all other enrollees with similar chronic conditions receive coverage in line with the corresponding standard of care. Compl. ¶¶ 83-86.[9]

1. "Chronic condition discrimination" can be understood by way of an analogy to syphilis.

It is clear that putative class members are not receiving comparable coverage as relative to individuals with other chronic conditions if one considers an analogy to how a similar restriction might unfold in a different context. Syphilis, like HCV, is a curable, chronic, infectious disease that can be slow progressing and, if left untreated, potentially deadly. Both can

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[8] *Cf. Blanchard*, 71 F.3d at 1166 (finding difference in provision of assistance across Medicaid applicants with different medical conditions based on medically irrelevant criteria violates comparability provision).

[9] The Defendants identify no other chronic condition with a coverage policy that contradicts the corresponding standard of care.

have lasting and sometimes irreversible effects on a patient's health, both progress at unpredictable rates with variable manifestations that may not prove fatal to every patient, both have been "cured" by modern medical advances, and the universal standard of care is to administer simple pharmaceutical drugs as early in the course of the disease as possible.[10] The similarities between syphilis and HCV are striking in this context. Yet Texas Medicaid covers universal treatment upon diagnosis for only one of these two conditions.[11] Indeed, it would be unconscionable to modern sensibilities to watch and wait as a syphilis patient's disease progressed before administering a known curative treatment.

Government health care policy once allowed individuals with syphilis to be left untreated while their disease progression was observed, an episode that is roundly condemned as a nadir in

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[10] Both HCV and syphilis also pose a risk not just to the infected individuals themselves but to the community at large. Diligent and widely accessible treatment has made syphilis far less common than it once was. *See* CENTERS FOR DISEASE CONTROL, Sexually Transmitted Disease Surveillance: Syphilis (July 24, 2018), https://www.cdc.gov/std/stats17/syphilis.htm#:~:text=In%202017%2C%20a%20total%20of,Figure%2035%2C%20Table%201.

[11] In Texas, any Medicaid beneficiary who tests positive for syphilis is immediately eligible for coverage for treatment in line with the medical standard of care: long-acting penicillin. *See* TEXAS HEALTH AND HUMAN SERVICES, Syphilis (July 28, 2020), https://www.dshs.texas.gov/hivstd/info/syphilis/ (noting the importance of early treatment and linking to CDC guidelines supporting same); CENTERS FOR DISEASE CONTROL AND PREVENTION, Syphilis (June 4, 2015), https://www.cdc.gov/std/tg2015/syphilis.htm ("Penicillin G, administered parenterally, is the preferred drug for treating persons in all stages of syphilis.").

the history of American medicine.[12] This comparison is stark but apposite. Leaving early-stage HCV untreated is no more medically justifiable than would be applying a similar policy to syphilis. Medicaid enrollees infected with HCV but who fall below the threshold fibrosis score required for treatment are not receiving Medicaid benefits in the same "amount, duration and scope" as those with syphilis, all of whom receive coverage for curative treatment upon diagnosis. The Complaint asks this Court to ensure that the medical needs of Plaintiffs and putative class members are covered comparably to those of other Medicaid enrollees who are afforded access to medically necessary treatments consistent with the standard of care.

2. "Chronic condition discrimination" violates Section 1396a(a)(10)(B) because coverage for treatment according to the standard of care is denied to one group of chronically ill Medicaid beneficiaries, while afforded to another.

All chronically ill individuals have a comparable need for treatment in conformity with the standard of care, driven by their individual medical circumstances. Whether it is individuals

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[12] *See* CENTERS FOR DISEASE CONTROL, *U.S. Public Health Service Syphilis Study at Tuskegee* (Mar. 2, 2020), https://www.cdc.gov/tuskegee/index.html (describing the infamous 1932-1972 Tuskegee Experiment, in which the U.S. Public Health Service intentionally "withheld adequate treatment from a group of poor black men who had [syphilis], causing needless pain and suffering for the men and their loved ones.").

The Policy is a far cry from the Tuskegee Experiment. Rather than being motivated by invidious racism, the Complaint alleges that the discrimination resulting from the Policy stems from the state's fiscal concern. *See* Compl. ¶¶ 57, 80. Yet budgetary concern alone cannot justify Medicaid policy that prevents beneficiaries from accessing medically necessary care. *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."). Whatever the motivation, the decision of Texas government to block access for otherwise eligible Medicaid beneficiaries to the cure for a potentially deadly, communicable viral disease cannot be justified on legal, fiscal, or medical grounds.

living with HIV, tuberculosis, or some other chronic illness, Texas Medicaid provides coverage consistent with the standard of care for comparable chronically ill beneficiaries. For HCV, however, the Defendants limit coverage in a way that is unique. The Complaint plausibly alleges that the Defendants single out HCV for cost-based rationing contrary to the standard of care in a manner not applied to any other chronically ill beneficiaries. Compl. ¶¶ 57, 80, 83–85. The Defendants run afoul of Section 1396a(a)(10)(B) by providing coverage in line with the standard of care to one group of Medicaid beneficiaries, but not the other. Defendants leave class members' "needs unmet while others with comparable disabilities receive adequate care." *Jenkins*, 157 P.3d at 393.

In *Davis v. Shah*, the Court made clear that the scope of the Medicaid Act's comparability provision focused on the needs of the beneficiaries, rather than turning on the nature of the medical condition giving rise to that need. 821 F.3d 231, 257-58 (2d Cir. 2016). Noting that "[m]edical services are always, by nature, diagnosis-specific, and rarely are two diagnoses or medical histories exactly alike," the *Davis* Court held that the comparability "provision prohibits discrimination among individuals with the same medical needs stemming from different medical conditions." *Id.* at 258 (citations omitted).

Defendants suggest that Plaintiffs must detail all the ways in which treatment protocols for other chronic conditions would be "equal" to DAA treatment for HCV patients. ECF No. 19 at 6 (citing *King by King v. Sullivan*, 776 F. Supp. 645, 654 (D.R.I. 1991)). In *Sullivan*, the court's summary judgment decision was based on the plaintiffs' failure to support their claims of comparability with specific evidence. *See id.* ("Plaintiffs have not sufficiently addressed the factual issue of comparability within eligibility groups[.]") Here, Plaintiffs bear no such evidentiary burden. The Complaint alleges that the Policy imposes unequal treatment coverage because it does

not afford comparable coverage consistent with the standard of care, unlike the coverage enjoyed by other chronically ill Texas Medicaid beneficiaries. Compl. ¶¶ 83-86. At least at the pleading stage, this is all that is required. As this litigation advances, Plaintiffs will show, using discovery and expert testimony, precisely what the court found to be missing in *Sullivan* – namely, facts relating to the eligibility groups to which Plaintiffs belong and the distribution of services within each group. At this stage, the Court must accept Plaintiffs' allegations as true that Medicaid enrollees with HCV are treated differently, despite having comparable levels of medical need to other chronically ill beneficiaries.

C. Texas HHSC's discretion to implement its Medicaid program is bounded by the Medicaid Act.

The Defendants also raise the specter of "state discretion" to implement Medicaid as an excuse for discriminating among comparable Medicaid enrollees. The Motion characterizes Plaintiffs' Complaint as an invitation to the Court to interfere in a matter reserved to the state's judgment, arguing that Congress provided states with "broad discretion to implement" their Medicaid programs. ECF No. 19 at 5. This is not an argument that can justify dismissal of a pleading. While it may be true as a general matter that a state has discretion to implement its Medicaid program, the Defendants must still abide by federal law. Congress explicitly cabined state discretion with limitations, including Section 1396a(a)(10)(B)'s prohibition on discrimination against categorically needy individuals. *See Parry By and Through Parry v. Crawford*, 990 F. Supp. 1250, 1257 (D. Nev. 1998) (explaining that despite a state's "great flexibility" in determining the scope and duration of services, the state cannot "exclude an entire class of categorically needy individuals.").

Enforcement of comparability requirements will necessarily require the Court to assess whether the Defendants have arbitrarily discriminated in provisioning coverage to categorically

needy enrollees. *See Davis*, 821 F.3d at 258 ("[A]ny genuine enforcement of the Medicaid Act's comparability requirements must entail some independent judicial assessment of whether a state has made its services available to all categorically needy individuals with equivalent medical needs."); *Women's Hosp. Found. v. Townsend*, 2008 U.S. Dist. LEXIS 52549, at *21 (M.D. La. July 10, 2008) ("The language of the Comparability Provision . . . invites a comparison of the medical assistance to persons covered under Medicaid and the community at large."). Defendants cannot absolve their violations of the Medicaid Act simply by pointing to their "broad discretion."

Moreover, CMS itself has already announced its view that Texas HHSC's discretion is being misapplied here. In November 2015, CMS issued subregulatory guidance condemning just the sort of exclusion that underlies the Policy. Compl. ¶¶ 13, 54-55. Despite this admonition, the Defendants continue to restrict treatment access, contrary to the requirements of the Medicaid Act.

Nevertheless, Defendants cite *Watson v. Weeks*, 436 F.3d 1152 (9th Cir. 2006), incorrectly characterizing the decision as a blanket indictment of courts' capacities to engage in these sorts of comparisons absent "concrete standards in the statute." *Watson* is inapposite, arising in the context of an entirely different provision – the "reasonable standard" requirement under 42 U.S.C. § 1396a(a)(17). *Watson* held that Section 1396a(a)(17) does not create a private right of action for beneficiary enforcement. 436 F.3d at 1162. Defendants have sensibly foregone such an argument here, as courts, including in this Circuit, widely recognize a private right of action under Section 1396a(a)(10)(B). *See, e.g.*, *Equal Access for El Paso, Inc. v. Hawkins*, 428 F. Supp. 2d 585, 617 (W.D. Tex. 2006), *rev'd and remanded on other grounds*, 509 F.3d 697 (5th Cir. 2007).[13]

[13] The Supreme Court has instructed courts to analyze the justiciability of the Medicaid Act provision by provision, breaking it down "into manageable analytic bites." *Blessing v. Gonzaga*, 520 U.S. 329, 342 (1980).

From *Watson*, Defendants extract a general presumption of judicial abdication when determining comparability of services under the Medicaid Act. But whereas in *Watson* the court was understandably hesitant to oversee the construction of a reasonable standard from scratch, its reasoning is unpersuasive here where the standards for HCV treatment are already established by Texas Medicaid's own definition of medical necessity, *see* Compl. ¶ 74, the widely recognized medical standard of care, Compl. ¶¶ 11, 51-52, professional treatment guidelines, *see* Compl. ¶ 12, and expert testimony, *see generally* ECF Nos. 10-2 & 10-3. This Court is asked only to apply these standards in comparing Plaintiffs' access to treatment with that of other groups and to determine whether HHSC's Policy results in unlawful discrimination. Such an inquiry is apt for judicial determination. *See Hawkins*, 428 F. Supp. 2d at 617 ("[T]he Comparability Provision is not so 'vague and amorphous' that it would strain judicial competence to enforce it. The provision requires a court 'to compare the level of services provided to one recipient with those given another and to determine whether those services are comparable.'"). This Court need not hesitate to engage in this routine analysis, which Congress has specifically reserved to it.

CONCLUSION

For the reasons stated above, the Defendants' Partial Motion to Dismiss should be denied.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 28, 2020, a true and correct copy of the foregoing document was served via the Court's CM/ECF system to all counsel of record.

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