THE HONORABLE JOHN C. COUGHENOUR

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

B.E. and A.R., on their own behalf and on behalf of all similarly situated individuals, Plaintiffs, v. DOROTHY F. TEETER, in her official capacity as Director of the Washington State Health Care Authority, Defendant.	CASE NO. C16-227-JCC ORDER GRANTING PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

This matter comes before the Court on Plaintiffs' motion for a preliminary injunction (Dkt. No. 18), Defendant's opposition to both motions (Dkt. No. 29), and Plaintiffs' reply (Dkt. Nos. 35). Having thoroughly considered the parties' briefing and the relevant record, the Court finds oral argument unnecessary and hereby GRANTS the motion for the reasons explained herein.

I. BACKGROUND

Plaintiffs in this action are Washington Medicaid enrollees who have contracted Hepatitis C ("HCV"), a chronic, contagious liver disease, but have not received the life-altering medication they have been prescribed, known as Direct-Acting Antivirals ("DAAs"). (Dkt. No. 1 at 3.) Plaintiffs bring this case on behalf of others similarly situated.

As it progresses, HCV causes severe liver damage, among the many other effects

including heart attacks, diabetes, fatigue, joint and muscle pain, depression, nerve damage, and jaundice. (Dkt. No. 19 at 2.) The virus's progressive damage, known as "fibrosis," is scored on an ascending fibrosis score of F0 (no liver damage) through F4 (cirrhosis of the liver). (*Id.* at 3.) HCV is both widespread and deadly: over 20,000 people in the United States die every year due to liver disease caused by HCV. (*Id.* at 2.)

Before DAAs were available, the main treatment for HCV was a three-drug course of treatment that resulted in, at most, a 70% cure rate, and was accompanied by significant adverse side effects. (Dkt. No. 19 at 3–4.) The FDA began approving DAAs in 2011 and designated them as "breakthrough therapies," a classification given to "drugs that have proved to provide substantial improvement over available therapies for patients with serious or life-threatening diseases." (*Id.* at 4.) Harvoni, a DAA treatment, was FDA-approved on October 10, 2014 and has a success rate of achieving "sustained virological response [] of nearly 100%, with little to no side effects. (*Id.*)

Plaintiffs bring a claim under 42 U.S.C. § 1983, alleging violation of Title XIX of the Social Security Act (also known as the "Medicaid Act") against the Washington State Health Care Authority ("WHCA") and seek declaratory and injunctive relief pursuant to 28 U.S.C. §§ 2201 and 2202. (Dkt. No. 1 at 13–15.) On March 18, 2016, Plaintiffs moved to certify their class and also moved for a preliminary injunction. (Dkt. Nos. 17 and 18.) Plaintiffs, on behalf of the proposed class, request that the Court "enjoin [the] WHCA from continuing to apply its February 25, 2015 HCV treatment policy, including its exclusion of all treatment based on fibrosis score, and to require WHCA to return to providing coverage for prescription medications to treat Hepatitis C virus ("HCV") without regard to fibrosis score, consistent with existing state and federal Medicaid requirements." (Dkt. No. 18 at 10.) In this Order, the Court addresses Plaintiffs' request for injunctive relief but does not yet reach the class certification question.

At the center of this dispute is the WHCA's HCV treatment policy, which excludes Plaintiffs from receiving these breakthrough therapies, DAAs. On February 25, 2015, the WHCA

implemented a Hepatitis C Treatment Policy ("Policy") restricting DAA coverage based on enrollees fibrosis score and other health conditions. (Dkt. No. 1-1.) Plaintiffs contend that the Policy categorically excludes "all monoinfected patients—patients without another diagnosis, such as HIV—who have a fibrosis score of F0 through F2." (Dkt. No. 18 at 13.) Many insurers in Washington State have voluntarily removed similar restrictions on the availability of HCV treatment, including Premera BlueCross, Aetna, United Healthcare, Medicare, and the VA. (*See* Dkt. No. 18 at 8) (linking to policies). Other insurers, Bridgespan, Regency BlueShield, and Group Health Cooperative, changed their policies within weeks after lawsuits were filed against them on similar grounds to those brought in the above-captioned matter. (Dkt. No. 24 at 4.)

II. PRELIMINARY INJUNCTION

A. Legal Standard

Under Fed. R. Civ. P. 65(a), the Court may issue a preliminary injunction if a plaintiff establishes that she "[1] is likely to succeed on the merits, [2] that [s]he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in [her] favor, and [4] that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). Mandatory preliminary injunctions, the kind requested here, are generally disfavored in the law as they seek relief beyond maintaining the status quo, and will only be ordered when the law and facts clearly favor the moving party. *Stanley v. Univ. of S. Cal.*, 13 F.3d 1313, 1319–20 (9th Cir. 1994).

B. Success on the Merits

Plaintiffs assert claims under 42 U.S.C. § 1983, alleging that the WHCA failed to provide medically necessary treatment as required by the Medicaid Act. Plaintiffs claim that the WHCA's HCV policy violates three distinct provisions of federal Medicaid law: (1) excluding qualified Medicaid recipients from "medically necessary" treatment as required by 42 U.S.C. § 1396a(a)(10(A); (2) discriminating among similarly situated Medicaid recipients in violation of 42 U.S.C. § 1396a(a)(10)(B)(i); and (3) failing to provide medically necessary treatment with

"reasonable promptness" as required by 42 U.S.C. § 1396a(a)(8). The Court first considers the likelihood of Plaintiffs' success on the merits of these claims.

a. Medically Necessary Treatment

The Court first considers the likelihood that Plaintiffs will prevail on their claim that the WHCA failed to provide "medically necessary" DAAs for enrollees in violation of 42 U.S.C. § 1396a(a)(10(A). WHCA participates in Medicaid, receiving federal matching funds, and therefore is required to provide payment for FDA-approved, covered prescription drugs to all Medicaid enrollees when the treatment is "medically necessary." *Alvarez v. Betlach*, 572 F. App'x 519, 520–21 (9th Cir. 2014); *see also Armstrong v. Exceptional Child Ctr., Inc.*, 135 S. Ct. 1378, 1382 (2015) ("Medicaid offers the States a bargain: Congress provides federal funds in exchange for the State's agreement to spend them in accordance with congressionally imposed conditions.").

i. State and Federal Legal Structure

The federal Medicaid Act and Washington Administrative Code set forth the legal structure that guides the Court's analysis. The crux of this claim is whether the WHCA's Policy excludes DAAs that are "medically necessary." Plaintiffs have provided strong evidence that DAAs are, in fact, "medically necessary," as defined by law, for all enrollees with HCV, regardless of fibrosis score. They submitted a plethora of exhibits showing that providing DAAs to all HCV-infected enrollees is the standard espoused by national liver disease organizations and experts, leading medical officers of major Washington providers and the federal agency responsible for administering Medicaid. These facts "clearly favor" Plaintiffs' claim that the WHCA's Policy excluding monoinfected enrollees with a Fibrosis score of F0-F2 violates Federal law. *Stanley* at 1319–20.

The WHCA is the sole state agency responsible for implementing the Medicaid program. (Dkt. No. 18 at 13.) As the agency has opted to provide prescription drug coverage, the Medicaid program must adhere to the Medicaid Act's specific limits regarding prescription drugs. (*Id.*)

(Citing RCW §§ 74.04.055; 74.08.090); *see also* 42 U.S.C. § 1396a(a)(54). Under § 1396a(a)(10)(A), the Medicaid Act "prohibits states from denying coverage of 'medically necessary' services that fall under a category covered in their Medicaid plans." *Alvarez v. Betlach*, 572 F. App'x 519, 521 (9th Cir. 2014) (quoting *Beal v. Doe*, 432 U.S. 438, 444 (1977)). The Washington Administrative Code provides the definition of "[m]edically necessary":

> [A] term for describing requested service which is reasonably calculated to prevent, diagnose, correct, cure, alleviate or prevent worsening of conditions in the client that endanger life, or cause suffering or pain, or result in an illness or infirmity, or threaten to cause or aggravate a handicap, or cause physical deformity or malfunction. There is no other equally effective, more conservative or substantially less costly course of treatment available or suitable for the client requesting the service. For the purposes of this section, "course of treatment" may include mere observation or, where appropriate, no medical treatment at all.

Wash. Admin. Code 182-500-0070.

The WHCA's procedure for determining whether a requested service is "medically necessary" is established in Wash. Admin. Code 182-501-0165(6). First, the agency rates the evidence of the service's effectiveness and safety on a scale from A to D, with A being the highest level. Wash. Admin. Code 182-501-0165(6). If the requested service has an evidence level of A or B, then it must be approved so long as it does not expose the enrollee "to a greater risk of mortality or morbidity" and "is not more costly" when compared to an equally effective treatment. Wash. Admin. Code 182-501-0165(6)(c)(i).

ii. Plaintiffs' Evidence

It is undisputed that DAAs such as Harvoni have been rated at an "A" evidence level. (Dkt. No. 19 at 10.) Defendants concede that there is no equally effective alternative medication. (Dkt. No. 16 at 4.) Despite this rating, the current WHCA Policy mandates rejecting DAA requests from enrollees who have an F0-F2 fibrosis score, absent other concerning health factors, and instead offering "monitoring" as the "equally effective treatment" in lieu of DAAs. (*See* Dkt. No. 1-1.) Plaintiffs argue that mere "monitoring" is not an equally effective treatment

because "waiting until a Medicaid enrollee's liver is damaged before providing treatment is harmful to his/her health and significantly increases the risk of both morbidity and mortality." (Dkt. No. 18 at 19–20.) Plaintiffs provide a plethora of evidence to support this assertion.

Plaintiffs provide a letter from liver specialists, physicians, and the medical officers of nearly every major health care provider in the State of Washington, urging the Washington Insurance Commissioner to remove restrictions on the availability of life-saving HCV treatment. (Dkt. No. 19-1 at 32–35.) The letter states in part, "The cost of these drugs cannot compare to the human toll on our patients and their families and the eventual cost and expense we would pay as a society by postponing treatment." (Dkt. No. 19-1 at 33.)

Plaintiffs attach an internal meeting transcript in which Donna L. Sullivan, M.S., Pharm.D., the WHCA's Chief Pharmacy Officer, stated with respect to patients with HCV: "I can guarantee you that all of us agree that everyone should be treated whether they are at stage 2, stage 3, stage 4." (Dkt. No. 24-1 at 10.) Ms. Sullivan identified fiscal concerns as the sole basis for the WHCA's exclusionary policy, adding, "we have received funding only based on the criteria that we gave for F3 . . . It's out of our hands. None of us would argue that we should not expand it, that it's not the right thing to do, but we live in a political environment as a state that I have to operate within the resources and the rules around those resources that have been given to us." (*Id.*)

Furthermore, the Centers for Medicare and Medicaid Services ("CMS"), the federal agency responsible for the administration of Medicaid, has specifically rejected the WHCA's current policy. On November 5, 2015, CMS issued a Notice entitled, "Assuring Medicaid Beneficiaries Access to Hepatitis C Drugs." (Dkt. No. 24-1 at 27–30.) In the Notice, CMS explicitly states: "CMS is concerned that some states are restricting access to DAA HCV drugs contrary to the statutory requirements . . . by imposing conditions for coverage that may unreasonably restrict access to these drugs. For example, several state Medicaid programs are limiting treatment to those beneficiaries whose extend of liver damages has progressed to [a]

fibrosis score [of] F3 . . .” (*Id.* at 28.) This interpretation of the Medicaid Act is entitled to deference. *Katie A. v. L.A. Cnty.*, 481 F.3d 1150, 1155, n. 11 (9th Cir. 2007).

Finally, the use of DAAs such as Harvoni is considered the “standard of care” by the American Association for the Study of Liver Disease (“AASLD”) and the Infectious Diseases Society of America (“IDSA”). (Dkt. No. 19 at 4.)

Despite these facts, the WHCA argues that the Policy is in line with the “medically necessary” definition because monitoring is suitable for people who have HCV but show either mild or no symptoms. (Dkt. No. 29 at 16.) The WHCA does not address the liver damage that enrollees could suffer during this “monitoring” period and, instead, argues that by refusing to provide the DAA drugs, the Policy “ensures these people are not unnecessarily exposed to the currently ill-defined risks of these new medications.” (*Id.*) This assertion of “ill-defined risks” is not supported by any clinical evidence and is contradicted by the WHCA’s own documents.

In fact, when the WHCA was making a budget request to cover DAAs like Harvoni, it presented a completely opposite argument. The WHCA’s 2016 Supplemental Budget Request Adjustment states that DAAs like Harvoni are “highly effective,” “safe,” and even “cost-effective.” (Dkt. No. 24-1 at 2–3.) The Budget Request refutes the argument now presented by the WHCA that there are “ill-defined risks” associated with DAAs, stating instead that “because the new therapies are so effective, there is the potential to completely eradicate [HCV].” (Dkt. No. 24-1 at 15.) The extensive evidence provided by the Plaintiffs and the lack of substantial counter-evidence from the WHCA establishes that there is a consensus among medical experts and providers that the life-saving DAAs are “medically necessary” for all HCV-infected persons, regardless of Fibrosis score. Plaintiffs have adequately demonstrated that they are likely to prevail on their claim.

The WHCA argues that its interpretation of what is “medically necessary” is entitled to deference. (Dkt. No. 19 at 10–11.) This Court has previously considered a similar argument in *A.H.R. v. Washington State Health Care Authority*, 2016 WL 98513, at *14 (W.D. Wash. Jan. 7,

2016) (Robart, J.). In *A.H.R.*, the Court declined to defer to the WHCA because there was no indication that CMS was aware of the WHCA's practices. *Id.* In this case, unlike in *A.H.R.*, CMS has explicitly stated that policies like the WHCA's contravene the Medicaid Act. (*See* Dkt. No. 24-1 at 27–30.) In other words, the agency to defer to under *Chevron*, CMS, has clearly stated that the WHCA's HCV policy defies the relevant statutory requirements.

The WHCA does not address whether its Policy is in line with the procedure enumerated in Wash. Admin. Code 182-501-0165(6). Instead, the WHCA asserts that the "Policy is the agency's best attempt at making reasonable medical necessity determinations." (Dkt. No. 29 at 15.) However, whether the WHCA made its "best" attempt is not the pertinent standard. The appropriate legal test is whether Plaintiffs will likely establish that the current WHCA Hepatitis C Treatment Policy deprives Medicaid enrollees from access to a life-saving drug in situations where it is "medically necessary." And this turns on whether there is an equally effective alternative treatment that does not expose the enrollee to "a greater risk of mortality or morbidity." WAC 182-501-0165(6)(c)(i)(A). The Court is satisfied that Plaintiffs' evidence will likely establish that the WHCA is failing to follow its own definition of medical necessity by refusing to provide DAAs to monoinfected enrollees with a F0-F2 score and offering only "monitoring" in lieu of this breakthrough treatment.

b. Medicaid Comparability & Reasonable Promptness

The Court finds that Plaintiffs are likely to succeed on the merits of their first claim. Plaintiffs' latter two claims similarly turn on whether DAAs are "medically necessary" because if they are given that designation, then the Medicaid Act requires the WHCA to provide that treatment with "reasonable promptness" in a non-discriminatory manner. For the same reasons discussed above, the Court concludes that Plaintiffs are likely to succeed on the merits with respect to their second and third claims.

C. Likelihood of Irreparable Harm

Next, the Court considers whether Plaintiffs are likely to suffer irreparable harm in the

absence of this preliminary injunction. *Winter*, 555 U.S. at 20.

It is well-established that denying necessary Medicaid services causes irreparable harm. *Rodde v. Bonta*, 357 F.3d 988, 999 (9th Cir. 2004) (finding that while the injunction would cause the county financial hardship, the plaintiffs met their burden by showing delayed or lack of necessary treatment, increased pain, and medical complications); *Beltran v. Myers*, 677 F.2d 1317, 1322 (holding that plaintiffs' showing of risk of irreparable injury as a result of denying needed medical care was sufficient to meet this factor for a preliminary injunction).

Plaintiffs argue, persuasively, that without an injunction "they are at imminent risk of deteriorating health, liver damage and even death." (Dkt. No. 18 at 25.) Plaintiffs maintain that denying "necessary medical benefits directly impacts an individual's health, creating '(1) substantial risk to plaintiffs' health; (2) severe financial hardship; (3) the inability to purchase life's necessities; and (4) anxiety associated with uncertainty.'" (*Id.*) (quoting *LaForest v. Former Clean Air Holding Co., Inc.*, 376 F.3d 48, 55 (2nd Cir. 2004)).) The WHCA argues that this claim of imminent risk is "completely speculative." (Dkt. No. 29 at 20.)

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. (Dkt. No. 23 at 1–2.) His request was denied. (*Id.* at 2.) The WHCA'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." (Dkt. No. 23-1 at 5.) Soon after, in October 2014, Harvoni was approved by the FDA and L.B.'s provider submitted his prescription to WHCA. (Dkt. No. 23 at 2.) His provider noted that his "cirrhosis and renal function [were] worsening. [He n]eeds HCV treatment ASAP" and that [w]ithout it, [he will] likely die." (*Id.*) Again, his request was denied.[1] (*Id*). While he awaited a

[1] The WHCA notes that L.B.'s request for Harvoni was denied because "his provider did not provide requested documentation" and asserts that if documentation of Hepatitis C induced renal disease would have been sent the Harvoni request would have been approved. (Dkt. No. 29 at 21, n. 9.) However, under the proposed injunction, L.B.'s provider would not need to submit additional documentation because the

hearing on his Medicaid administrative appeal, "his kidneys deteriorated so significantly that his provider could no longer recommend Harvoni." (*Id.* at 2–3.) 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.

In arguing that Plaintiffs will not suffer irreparable harm, the WHCA again contradicts its own pronouncements. The WHCA argues in its response brief that a HCV diagnosis alone, "without further complicating factors, does not warrant authorization" of DAAs like Harvoni. (Dkt. No. 29 at 20.) And in a budget request, the WHCA noted that only treating "people with more severe disease[,] those patients who by definition have cirrhosis, liver cancer or are in need of a liver transplant[,] . . . would be objectionable from a medical ethical standpoint." (Dkt. No. 24-1 at 16.)

Plaintiffs have introduced compelling evidence that they will suffer irreparable harm if the preliminary injunction is denied. This factor weighs strongly in favor of a preliminary injunction.

D. Balance of Equities and Public Interest

Next, the Court assesses whether the balance of equities tips in Plaintiffs' favor and the injunction is in the public interest. *Winter*, 555 U.S. at 20. These factors may be considered together. *A.H.R. v. Wash. State Health Care Auth.*, 2016 WL 98513, at *17 (W.D. Wash. Jan. 7, 2016). As discussed above, Plaintiffs' evidence establishes they will suffer severe hardship if the WHCA continues to follow the Policy. The Ninth Circuit holds that "the balance of hardship favors beneficiaries of public assistance who may be forced to do without needed medical

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request would have been approved on the basis of his HCV diagnosis alone. He suffered irreparable damage to his liver because the WHCA's policy required proof of other concerning health factors with an F2 fibrosis score. Moreover, his initial request for DAA treatment in July 2014 was denied because WHCA determined it was not "medically necessary." (Dkt. No. 23 at 2.) The WHCA does not address this determination.

services over a state concerned with conserving scarce resources." *M.R. v. Dreyfus*, 697 F.3d 706, 737–38 (9th Cir. 2012). The Ninth Circuit also noted the strong public interest in protecting access to health care for Medicaid enrollees, those deemed by Congress as "the most needy in the country." *Id.* (quoting *Schweiker v. Hogan*, 457 U.S. 569, 590 (1982)).

Plaintiffs argue that the injunction is in the public interest because it seeks to bar a public agency from violating "existing law." (Dkt. No. 18 at 27.) The Court agrees. "[H]aving government officials act in accordance with law . . . invokes a public interest of the highest order." *Seattle Audubon Soc. v. Evans*, 771 F. Supp. 1081, 1096 (W.D. Wash. 1991). Furthermore, as Plaintiffs emphasize, an injunction is an important matter for the public because it deals with the treatment and management of a communicable disease. (Dkt. No. 18 at 27.)

The WHCA argues that the injunction would double the State's Medicaid outpatient Pharmacy budget and cause them to reduce Medicaid enrollments, benefits, or provider rates to compensate for the increased expenditure in HCV treatment. (Dkt. No. 29 at 22.) The Ninth Circuit has also addressed the question of balancing the risk of irreparable harm with the risk of financial hardship for the enjoined institution. Posed with this question, the Ninth Circuit held that when "[f]aced with such a conflict between financial concerns and human suffering, we have little difficulty concluding that the balance of hardships tips decidedly in plaintiffs' favor." *Lopez v. Heckler*, 713 F.2d 1432, 1437 (9th Cir. 1983).

In conclusion, the Court finds that the Plaintiffs have satisfied all factors necessary to warrant granting a preliminary injunction.

E. Scope of Injunction

The WHCA is hereby ENJOINED from continuing to apply its February 25, 2015 HCV treatment policy, including its exclusion of all treatment based on fibrosis score, and is required to return to providing coverage for prescription medications to treat Hepatitis C virus ("HCV") without regard to fibrosis score, consistent with existing state and federal Medicaid requirements. The parties are hereby ORDERED to submit a joint status report to the Court sixty (60) days

after the date of this order with an update as to the implementation of these changes.

F. Pending Class Certification Motion

The Court's review of Plaintiffs' motion for class certification (Dkt. No. 17) remains pending.

III. CONCLUSION

For the foregoing reasons, Plaintiffs' motion for a preliminary injunction (Dkt. No. 18) is GRANTED.

DATED this 27th day of May 2016.

John C. Coughenour
UNITED STATES DISTRICT JUDGE