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IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

COMMUNITY HEALTH CENTER ALLIANCE FOR PATIENT ACCESS; AVENAL COMMUNITY HEALTH CENTERS; COMMUNITY HEALTH CENTERS OF THE CENTRAL COAST; FAMILY HEALTH CENTERS OF SAN DIEGO; IMPERIAL BEACH COMMUNITY CLINIC; LA MAESTRA FAMILY CLINIC; OMNI FAMILY HEALTH; OPEN DOOR COMMUNITY HEALTH CENTERS; SHASTA COMMUNITY HEALTH CENTER; SOUTH COUNTY COMMUNITY HEALTH CENTER, INC., Plaintiffs, **v.** **MICHELLE BAASS, Director of the California Department of Health Care Services, CHIQUITA BROOKS-LaSURE; Administrator of the Centers for Medicare and Medicaid Services,** Defendants.	2:20-cv-02171-JAM-KJN **DEFENDANT MICHELLE BAASS' OPPOSITION TO PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER [AMENDED]** Date: TBD Time: TBD Dept: Courtroom 6, 14th Floor Judge: The Honorable John A. Mendez

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

FEDERAL STATUTES

FEDERAL REGULATIONS

TABLE OF AUTHORITIES
(continued)

Page

CALIFORNIA STATUTES

OTHER AUTHORITIES

INTRODUCTION

Plaintiffs have failed to demonstrate any likelihood of success on their claims that the California Department of Health Care Services' (DHCS or Department) new initiative to decrease Medi-Cal program costs and improve Medi-Cal pharmacy services contravenes federal law or deprives Plaintiffs of any potential revenue to which they are entitled under law. And Plaintiffs' contentions that they will not be able to continue to enjoy the same level of profits from their pharmacy services fails to establish any threat of immediate irreparable injury before a regularly noticed motion for preliminary injunction may be heard, as necessary to support their request for a temporary restraining order (TRO).

If granted, a restraining order against the State's Medi-Cal Rx initiative would upset the status quo and lead to substantial disruption for millions of low-income Californians receiving health coverage through Medi-Cal. The equities and public interest, therefore, tip sharply against issuance of a TRO. Plaintiffs have simply not demonstrated that the extraordinary and drastic remedy of a TRO against an important State government initiative is warranted.

BACKGROUND

I. THE REGULATORY BACKGROUND AND MEDI-CAL RX INITIATIVE

A. Medicaid and Medi-Cal

Medicaid is a cooperative federal-state program that provides federal financial assistance to participating states to reimburse certain costs of medical treatment for the poor, elderly, and disabled. 42 U.S.C. § 1396 *et seq.* California participates in Medicaid through the Medi-Cal program, and has designated the Department as the single State agency responsible for its administration. Cal. Welf. & Inst. Code §§ 10740, 14000 *et seq.* In order to receive federal financial participation, the Department must submit its State Plan and any amendments to the State Plan for approval to the Centers for Medicare and Medicaid Services (CMS), part of the U.S. Department of Health and Human Services (HHS), which has been delegated authority for implementing the Medicaid Act. 42 U.S.C. § 1396a; 42 C.F.R. § 430.14–430.15 [delegation]. The State Plan is an agreement between a state and the federal government describing how that state administers its Medicaid program, and defines the groups of individuals to be covered,

services to be provided, methodologies for providers to be reimbursed, and the administrative requirements that states must meet to participate. 42 U.S.C. §§ 1396d(a), 1396a(a)(10), 1396d(a)(1)-(5), (17), (21).

The Medi-Cal program currently utilizes two primary delivery systems for provision of covered benefits by Medi-Cal beneficiaries: managed care and fee-for-service (FFS). In Medi-Cal managed care, the Department contracts with managed care plans or public health authorities that arrange for covered services within a county or region, in exchange for a monthly per-beneficiary "capitation" payment. *See* First Amended Complaint (FAC) ¶ 39. In Medi-Cal FFS, the State reimburses enrolled healthcare providers directly for covered services and items provided to eligible beneficiaries. Approximately eighty percent (80%) of Medi-Cal beneficiaries are currently enrolled in managed care. *Id.*

B. Medi-Cal Rx Transition from Managed Care to FFS

On January 7, 2019, Governor Gavin Newsom issued Executive Order N-01-19, requiring the establishment of a single purchaser for Medi-Cal covered prescription drugs. FAC ¶ 37. The expressed intent of EO N-01-19 was to establish a single purchaser for the covered prescription drugs to allow the State to negotiate and purchase prescription drugs at discounted prices for the millions of low-income, disabled, and vulnerable Californians enrolled in Medi-Cal. *Id.* Governor Newsom ordered that the Department take all necessary steps to transition all pharmacy services for Medi-Cal managed care to a FFS benefit by January 2021.

DHCS engaged in extensive stakeholder outreach beginning in 2019 regarding the Medi-Cal Rx initiative. Declaration of Harry Hendrix ("Hendrix Decl.") ¶¶ 13-15. Additionally, the Department formed the Medi-Cal Rx Advisory Workgroup consisting of thirty member representatives from managed care plans, pharmacies, health care providers, tribal health entities, and advocacy groups to help facilitate and provide advice regarding DHCS' ongoing Medi-Cal Rx implementation efforts. Hendrix Decl. ¶ 14.

DHCS initially sought to implement Medi-Cal Rx one year ago, on January 1, 2021, as part of a much broader package of Medi-Cal reforms and initiatives for which DHCS sought approval pursuant to CMS' authority under section 1115 and 1915 of the Social Security Act.

The Department delayed its intended implementation of these reforms and initiatives, titled "California Advancing and Innovating Medi-Cal" ("CalAIM"), to January 1, 2022. *See* Def.'s Ntc. of Scheduling Medi-Cal Rx Implementation Date (Dkt. No. 42).

Medi-Cal Rx is authorized under Section 1915(b) of the Social Security Act, 42 U.S.C. § 1396n(b), under which CMS may waive certain requirements of the Medicaid Act for "innovative programs or activities on a time-limited basis" that are "subject to specific safeguards for the protection of beneficiaries" where CMS deems the measures to be "cost effective, efficient, and consistent with the objectives of the Medicaid program." 42 C.F.R. § 430.25(b).

C. FQHC Reimbursement and the Pharmacy "Carve-Out"

FQHCs are federally subsidized healthcare providers receiving or eligible for grants under Section 330 of the Public Health Service Act for providing services to underserved communities. 42 U.S.C. § 1396*l*(b)(2). FQHCs receive these "Section 330" grants independent of funding or reimbursement these clinics receive from the federal Medicaid and Medicare programs. 42 U.S.C. §§ 254b(a)(1); 1395x(aa)(4).

From 1998 to 2000, Medicaid required State Plans to reimburse FQHCs for one hundred percent (100%) of their reasonable costs for services provided to Medicaid patients. *See Three Lower Counties Comm. Health Services, Inc. v. State of Maryland, Dept. of Health & Mental Hygiene,* 498 F.3d. 294, 297–298 (4th Cir. 2007). This methodology was repealed in 2000, when Congress amended the Medicaid Act to implement a fixed prospective "per-visit" reimbursement rate methodology. *Id.* pp. 298–99. This rate methodology remains in use at present. *See* Harrington Decl. ¶ 11.

Under this per-visit rate methodology, called the Prospective Payment System (PPS), a baseline PPS rate is generally set for each FQHC based on its reasonable costs for providing FQHC services in years 1999 and 2000 (or other baseline years for new FQHCs) divided by the total number of visits by FQHC patients during those years. *Three Lower Counties*, 498 F.3d. at 298–99; 42 U.S.C. § 1396a(bb)(2). Going forward, this initial "per-visit" PPS rate is adjusted by a cost of living index ("Medicare Economic Index" or "MEI"), and any change in scope of

services. *Three Lower Counties*, 498 F.3d. at 298–99; 42 U.S.C. § 1396a(bb)(2)-(3)(A), (4); Cal. Welf. & Inst. Code § 14132.100(d), (e)(1), (e)(2).

Medi-Cal's PPS rate methodology is included in the State Plan, and was approved by CMS on February 28, 2012. Harrington Decl. ¶ 11. Under the State Plan, FQHCs have the option to have the costs of providing pharmacy services to their patients included in their PPS rate, or to "carve out" pharmacy services from their PPS rate. *Id.* ¶¶ 14–16. If, prior to Medi-Cal Rx, an FQHC carved out pharmacy services from its PPS rate, any payments it received from managed care plans or other third parties for providing covered prescriptions to Medi-Cal patients were not counted in determining whether the FQHC had received full payment of its PPS rate from Medi-Cal for visits by Medi-Cal patients over the course of its fiscal year. Harrington Decl. ¶ 12. Thus, most FQHCs elected to carve out pharmacy services from their PPS rate, since that allowed FQHCs to take advantage of the revenues they generated based on the difference between the cost of drugs they purchase under the federal "340B" drug discount program, discussed below, and the higher payments received from Medi-Cal managed care plans for providing prescriptions to the plan's members. Hendrix Decl. ¶ 37. Although Plaintiff FQHCs do not expressly indicate whether that they have elected to carve out the pharmacy benefit, each of the Plaintiff FQHCs filing declarations in support of the TRO Motion have represented that they utilize these revenues or profits (which they refer to as "savings")—suggesting that they have elected to carve out the pharmacy benefit from their respective PPS rates. *See* FAC ¶ 97; Buada Decl. ¶ 3; Curtis Decl. ¶ 5; Castle Decl., ¶ 7; Germano Decl. ¶ 3.

Any FQHC that has not carved out pharmacy services from its scope of services receives reimbursement under its PPS rate for pharmacy services. *See* 42 U.S.C. § 1396a(bb); Harrington Decl. ¶¶ 14-16. The FQHC's initial per-visit PPS rate will include all costs associated with the pharmacy services. Harrington Decl. ¶ 11. This is true even if those pharmacy services did not occur in the context of a "visit" that would trigger a PPS payment. *Id.* These costs incurred outside a "visit" increase the per-visit average cost, and thus the amount of the FQHC's initial or baseline PPS rate. *Id.* An FQHC that previously elected to carve out pharmacy services, but wishes to include them in its PPS rate after Medi-Cal Rx may do so by seeking a change in the

scope of services, under which its PPS rate will be re-evaluated, including the costs of providing pharmacy services. Harrington Decl. ¶ 14; State Plan, Att. 4.19-B, p. 6-M, ¶ K.

Contrary to Plaintiffs' allegations, the transition of the managed care pharmacy benefit to Medi-Cal Rx did not alter Medi-Cal's federally-approved PPS reimbursement methodology for FQHCs. Nor did Medi-Cal Rx implementation modify the pharmacy benefit election the State's FQHCs have in accordance with the State Plan.

D. FQHC Revenue Under the 340B Program

The 340B Drug Pricing program ("340B Program") requires the HHS Secretary and manufacturers of designated drugs to enter into contracts, where such drug manufacturers must agree to sell the designated, outpatient drugs at sharply discounted rates to covered entities, including FQHCs. 42 U.S.C. §§ 256b(a)(1), (4), 1396r-8. Drug manufacturers participating in Medicaid are required to participate in the 340B Program. *See* FAC ¶ 95. As Plaintiffs acknowledge, the 340B programs allows FQHCs to buy certain outpatient drugs at a discount, but seek payment through the patient or a third-party payer, such as a managed care plan, at a higher price, thereby providing an additional revenue stream (i.e., profit) to 340B covered entities, such as Plaintiffs. *See* FAC ¶ 97. These revenues are not shared with the State, nor are the precise amounts of such revenues known or available to the State. Hendrix Decl. ¶ 37.

As a result of the transition of the pharmacy benefit from managed care to FFS under Medi-Cal Rx, those FQHCs electing to carve out their pharmacy benefits from their PPS reimbursement rate structure will no longer be able to bill their acquired 340B drugs to managed care plans at a price above their acquisition cost.

E. CMS Approval of SPA 17-002

In 2016, following an extensive public comment process, CMS updated the methodology states must follow under Medicaid for reimbursing pharmacies for covered prescription drugs reimbursed under FFS delivery systems. Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5170 (Feb. 1, 2016) (codified 42 C.F.R. pt. 447, subpart I). The methodology requires use of a drug's Actual Acquisition Cost in determining the applicable Medicaid reimbursement ceiling in place of the previous standard, the drug's Estimated Acquisition Cost. *Id*. DHCS

implemented this change under State Plan Amendment (SPA) 17-002, which established reimbursement for covered outpatient drugs using the Actual Acquisition Cost methodology and implemented professional dispensing fees as a component of reimbursement in accordance with the new rule. Hendrix Decl., ¶ 36. CMS approved SPA 17-002 on August 25, 2017, to be effective retroactively on April 1, 2017. *See* FAC ¶ 25 & n.1. An FQHC that chooses to carve out the pharmacy benefit from their PPS will receive reimbursement under SPA 17-002.

II. PROCEDURAL BACKGROUND

Plaintiffs, ten California FQHCs and an association representing FQHCs, filed their initial complaint against the DHCS Director (Director) and DHCS on October 29, 2020, seeking to enjoin Medi-Cal Rx and the broader waiver initiative under which it was proposed. The Court denied Plaintiffs' motion for a temporary restraining order (TRO) on November 24, 2020. Dkt. No. 19. In a bench ruling on March 9, 2021, the Court granted a motion to dismiss by Defendants without prejudice on various grounds, including that Plaintiffs' action was premature before CMS had granted approval of the DHCS' waiver request. *See* Dkt. No. 37. The Court, accordingly, denied a motion for preliminary injunction by Plaintiffs as moot. Dkt. No. 38. CMS approved the Medi-Cal Rx transition on December 29, 2021, as part of DHCS' CalAIM initiative, and Plaintiffs filed the present Motion and their First Amended Complaint the next day, December 30, 2021, asserting claims against the Director and Administrator of CMS.

LEGAL STANDARD

A temporary restraining order, like a preliminary injunction, is "an extraordinary remedy that may only be awarded upon a clear showing that the Plaintiff is entitled to such relief." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). The purpose of a temporary restraining order "is to preserve the status quo and prevent irreparable harm until a hearing may be held on the propriety of a preliminary injunction." *Gish v. Newsom*, No. EDCV 20-755-JGB (KKx), 2020 WL 1979970 (C.D. Cal., Apr. 23, 2020), at *3 (citing *Reno Air Racing Ass'n, Inc. v. McCord*, 452 F.3d 1126, 1131 (9th Cir. 2006)).

"A party can obtain a preliminary injunction by showing that (1) it is 'likely to succeed on the merits,' (2) it is 'likely to suffer irreparable harm in the absence of preliminary relief,' (3)

'the balance of equities tips in its favor,' and (4) 'an injunction is in the public interest.'" *Disney Enters., Inc. v. VidAngel, Inc*., 869 F.3d 848, 856 (9th Cir. 2017) (internal brackets omitted) (quoting *Winter*, 555 U.S. at 20). "When the government is a party, these last two factors merge." *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014). A plaintiff, as the party seeking an injunction, bears the burden of proving each of the elements necessary for an injunction. *Klein v. City of San Clemente*, 584 F.3d 1196, 1201 (9th Cir. 2009).

ARGUMENT

I. PLAINTIFFS HAVE NO LIKELIHOOD OF SUCCESS ON THEIR CLAIMS AGAINST THE DIRECTOR

Plaintiffs assert two causes of action against the Director: (1) for allegedly violating federal rights under 42 U.S.C. § 1983 (First Cause of Action); and (2) for declaratory relief (Fourth Cause of Action). Plaintiffs have no likelihood of success as to either claim.

A. Plaintiffs' First Cause of Action Is Based on Incorrect and Fundamentally Flawed Allegations

Plaintiffs' First Cause of Action alleges that Medi-Cal Rx requires Plaintiffs to receive reimbursement under FFS, and that the costs and dispensing fees reimbursed under the FFS methodology for pharmacy services approved under SPA 17-002 are insufficient to meet the PPS rate requirements of 42 U.S.C. § 1396a(bb). FAC ¶¶ 108-09. Neither are true. Plaintiffs' contentions rest on two fundamentally flawed premises.

First, Plaintiffs' contention that Medi-Cal Rx requires Plaintiffs to accept FFS reimbursement for pharmacy services in accordance with SPA 17-002 is misleading and incorrect. FAC ¶ 109. As discussed above—but nowhere in Plaintiff's First Amended Complaint or Motion—FQHCs may elect to include or "carve in" the pharmacy benefit into their PPS rate. Harrington ¶¶ 14-16. If an FQHC already included the pharmacy benefit in their PPS rate, or elects now to include it, then the FQHC is no longer reimbursed for the pharmacy benefit on the basis of the fee-for-service fee schedule. Rather, the FQHC will be reimbursed for these costs *through its PPS per-visit rate*. Harrington Decl. ¶ 16. Thus, when pharmacy is included in an FQHC's PPS rate, the FQHC's reimbursement is *not* based on any initial FFS payment it receives

for providing the prescription. Under the PPS methodology, that payment is merely included in the year-end reconciliation of all its payments for covered services and the amount to which it is entitled based on its PPS rate multiplied by the number of FQHC visits. If the total payments already received are less than the amount owed pursuant to its PPS reimbursement, DHCS makes up the difference. Harrington Decl. ¶ 14.

Second, Plaintiffs' contention that FFS reimbursement for the pharmacy benefit under SPA 17-002 fails to meet the federal PPS rate requirements set forth in 42 U.S.C. § 1396a(bb) (Section 1396a(bb)) is also fundamentally misguided. As discussed, FQHCs that have *"carved in"* the pharmacy benefit are reimbursed through the PPS rate established under Section 1396a(bb)—not through FFS reimbursement. Moreover, Section 1396a(bb) is inapplicable when an FQHC has elected to "carve out" their pharmacy benefits from PPS reimbursement. Accordingly, there is no basis for Plaintiffs' assertion that the FFS reimbursement rates authorized under SPA 17-002 fail to meet the requirements of Section 1396a(bb).

Plaintiffs' contention that the reimbursement fails to meet PPS rate requirements of Section 1396a(bb) is based, in any event, on Plaintiffs' flatly incorrect, but repeatedly emphasized, assertion that FQHCs are entitled to reimbursement under section 1396a(bb) at 100 percent of their reasonable costs. FAC ¶ 4, 31, 39, 46, 55, 66, 92; TRO Mem. at 1, 2, 9, 10, 13, 15, 17, 21. No such requirement exists. Rather, as numerous courts already have explained, Section 1396a(bb) requires, that the PPS be set at 100 percent of FQHC's average reasonable costs *during the FQHC's base period year or years* used to determine the center's initial PPS rate, after which the rate is adjusted *only* by a Medicaid economic indicator, or in the event of a recognized change in the scope of the FQHC's services.[1] 42 U.S.C. § 1396a(bb)(2)-(4); *see Cmty. Health Care*

[1] Specifically, for clinics existing in or before 1999, subsection (2) provides for the PPS rate to be initially set *in 2001* at an amount "equal to 100 percent of the average of the costs of the center or clinic of furnishing [covered] services *during fiscal years 1999 and 2000* which are reasonable and related to the cost of furnishing such services . . . ." 42 U.S.C. § 1396a(bb)(2). In subsequent years, that rate is adjusted only by the Medicaid Economic Index, or any change in scope of services. *Id.* § 1396a(bb)(3). As the court noted in *Rullan*, as the baseline PPS rate increases automatically pursuant to the MEI, "costs are no longer re-audited every year as the 1999 and 2000 per visit cost figures are the baseline for the calculation." *Rullan*, 397 F.3d at 62.

For "new" clinics, the initial PPS must be set at an amount equal to 100 percent of the costs of furnishing covered services during the first fiscal year in which the center qualifies as an

Ass'n of New York v. Shah, 770 F.3d 129, 137 (2d Cir. 2014); *Three Lower Counties,* 498 F.3d at 298; *Rio Grande Cmty. Health Ctr., Inc. v. Rullan*, 397 F.3d 56, 61 (1st Cir. 2005). As section 1396a(bb) generally provides only for the establishment of a *baseline* rate equal to 100 percent of an FQHC's reasonable costs of services, after which actual costs are not considered (apart from a change in scope of services), Plaintiffs' contention that FQHCs are entitled to 100 percent of their costs for providing pharmacy services is simply incorrect. Indeed, the initial PPS rate for clinics established after 1999 may be set based on the costs of *other* clinics in the same or adjacent area, and not the new clinic's own costs. 42 U.S.C. § 1396a(bb)(4).

Given these glaring inaccuracies, Plaintiffs have no likelihood of success on the merits of their Section 1983 claim against the Director.

B. Plaintiffs Are Unlikely to Succeed on Their Declaratory Relief Claim

Plaintiffs' catch-all cause of action for declaratory relief asserted against both the Director and the CMS Administrator alleges the same grounds, in part, for relief against the Director as those asserted in their Section 1983 claim. *See* FAC ¶ 130, 131 (alleging, in part, that Medi-Cal Rx is "forcing Plaintiffs into an FFS system" that fails to ensure pharmacy reimbursement consistent with section 1396a(bb)). Plaintiffs' contentions on those grounds fail to support a cause of action for declaratory relief on those grounds for the reasons addressed above. Plaintiffs' additional asserted grounds for declaratory relief are derivative of their allegations against the CMS Administrator in their Second and Third Causes of Action, and the Director joins in the Administrator's Opposition to Plaintiffs' Motion.

Plaintiffs are unlikely to succeed on the merits of their claim for declaratory relief for the additional reasons briefly addressed below.

FQHC "based on the rates established under this subsection for the fiscal year for *other such centers or clinics located in the same or adjacent area with a similar case load*," or otherwise consistently with two prior base years as under subsection (2). *Id*. § 1396a(bb)(4). New clinics, likewise, may only receive adjustments of the initial PPS rate based on the MEI, or upon a change in scope of services. *Id.*

1. Plaintiffs Lack Any Private Right of Action Under 340B, and Their Preemption Arguments Lack Merit

a. Plaintiffs Lack a Private Right of Action and Thus Cannot Seek Declaratory Relief Based on Section 340B

Plaintiffs allege in their Fourth Cause of Action that measures in California law and the State Plan to implement federal duplicate discount avoidance requirements under section 340B, and Medi-Cal Rx, are "preempted" by Section 340B. FAC ¶¶ 130, 131. However, Plaintiffs lack any private right of action to assert claims under section 340B and their preemption argument, in any event, lacks any merit.

The Supreme Court has explicitly held that there is no private right of action under section 340B for covered entities, which include FQHCs, nor may covered entities sue manufacturers as third-party beneficiaries of the drug pricing agreements entered into between the manufacturers and HHS. *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113, 118 (2011). Absent a private right of action, Plaintiffs also cannot state a successful claim under the Declaratory Judgment Act. *See, e.g., Am. Video Duplicating Inc. v. City Nat'l Bank*, 2020 WL 6882735, at *5 (C.D. Cal. Nov. 20, 2020) (citing *Lil' Man in the Boat, Inc. v. City & Cnty. of San Francisco*, 2018 WL 4207260, at *4 (N.D. Cal. Sept. 4, 2018) ("When a plaintiff lacks a private right of action under a particular statute, she cannot argue around that limitation by bootstrapping her cause of action onto a[ ] . . . declaratory relief claim.")). Because Plaintiffs lack a private right of action under both Section 340B and the Declaratory Judgment Act, they are unlikely to succeed on the merits of their 340B claim under a preemption theory.

b. Welfare and Institutions Code Section 14105.46 Is Not Preempted by Federal Law

Plaintiffs, nonetheless, contend that Welfare and Institutions Code section 14105.46 is preempted by federal law delegating to the HHS Secretary authority to create an exclusive mechanism to avoid duplicate discounts. FAC ¶ 87–93, 131; Mot. at 17-19. Plaintiffs' contention is misplaced. First, the Ninth Circuit has squarely held that Welfare and Institutions Code section 14105.46 is *not* preempted by the federal statutory law designed to preclude duplicate discounts set forth at 42 U.S.C. section 256b(a)(5)(a)(ii). *AIDS Healthcare Foundation*

v. Douglas, 457 Fed. App'x 676, 678 (9th Cir. 2011). There, the Ninth Circuit pertinently stated that "[s]imply put . . . [t]here is no actual conflict because the state and federal statutes can both easily be complied with; the state statute surely does not present an obstacle to the prevention of double discounts; and there is no indication that Congress intended to occupy the whole field in this part of the cooperative Medicaid program." *Id.* Without question, this authority disposes of Plaintiffs' preemption claim, and the Court need not analyze it further. As in *AIDS Healthcare Foundation*, a statute that supports and ensures compliance with federal law does not conflict with federal law, does not present an obstacle to the intent of the federal law, and does not step into a field wholly occupied by federal law. *Id.* at 678. Welfare and Institutions Code section 14105.46 is therefore not preempted by federal law.

Second, even if Plaintiffs were able to establish a "conflict" between Welfare and Institutions Code section 14105.46 and 42 U.S.C. section 256b(a)(5)(a)(ii), absent an underlying private right of action, Plaintiffs cannot prevail on their preemption claim. Unless a federal statute "*forbids State regulation* of the area that the State is purporting to regulate," a plaintiff may not pursue a stand-alone preemption claim. *Util. Reform Network v. Cal. Pub. Utils. Comm'n*, 26 F. Supp. 2d 1208, 1213–14 (N.D. Cal. 1997) (emphasis added). In other words, unless federal law occupies the field, thereby preventing State regulation in the same field, the preemption claim fails. *Id.* Here, DHCS has been given authority as the single state Medicaid agency to administer Medicaid in California through the Medi-Cal program. *See Guzman v. Shewry,* 552 F.3d 941, 946 (9th Cir. 2009). Federal law also authorizes and requires the State to administer its Medicaid program in accordance with a federally-approved State Plan (*see* 42 CFR Part 430, Subpart B), and such an approved State Plan amendment implemented the State statute. Plaintiffs, therefore, cannot base a preemption claim challenging the State's compliance with the Medicaid Act on the basis that the State's exercise of its federally granted authority "conflicts with" the Act. *See Util. Reform Network*, 26 F. Supp. 2d at 1213–14.

c. Medi-Cal Rx Does Not Frustrate the Purpose of Section 340B

In further support of a claim of preemption, Plaintiffs construe a statement of Congress' intent in establishing the 340B program, as being to enable covered entities "to stretch scarce

Federal resources as far as possible," as a basis for a purported entitlement to their managed care services profit margin. Mot. at 18–19. Plaintiffs' argument is misplaced.

The implementation of Medi-Cal Rx does not prevent FQHCs from receiving their federal entitlement to discounts on their purchase of qualifying 340B drugs. Hendrix Decl. ¶ 34. Furthermore, Plaintiffs' misconstrue the meaning of Congress's statement. Congress could not have intended for 340B covered entities to "stretch" federal funding by allowing providers to use Medicaid funds for non-Medicaid purposes. But surprisingly, according to Plaintiffs' own moving papers, that is exactly what they have sought to use the funds for. *See, e.g.,* Buada Decl. ¶ 3 (used to fund prescriptions for "Self-Pay clients); Curtis Decl. ¶ 8 (funds "reinvested" for costs not covered by Medi-Cal under PPS rate). While non-covered services and may be significant for FQHC patients who are not Medi-Cal beneficiaries, such services cannot be financed with Medicaid funds. Plaintiffs plainly misconstrue Congress's intent.

Medi-Cal Rx does not "frustrate" the purpose of section 340B, and Plaintiffs are not likely to succeed on the merits of any preemption claim.

2. SPA 17-002 and Medi-Cal Rx Do Not Violate the Medicaid Act or Regulations, and CMS Acted Reasonably in Approving Them

Plaintiffs acknowledge, as they must, that they have processed Medi-Cal FFS prescriptions, and therefore necessarily have received reimbursement under SPA 17-002 since its approval in 2017. *See, e.g.,* Buada Decl. ¶ 3; Curtis Decl. ¶ 3; Castle Decl. ¶ 7. Indeed, some drugs covered by the 340B program—particularly certain drugs with particularly high prescription costs—have been excluded from the managed care pharmacy benefit for many years, and instead have been subject to reimbursement provided under FFS. Hendrix Decl. ¶ 6. Yet, Plaintiffs now seek declaratory relief on the basis, in part, that SPA 17-002 and Medi-Cal Rx violate provisions of the Medicaid Act or Medicaid regulations and to enjoin the initiative under the Administrative Procedures Act (APA) on grounds that CMS acted arbitrarily and capriciously in approving the SPA and the Medi-Cal Rx initiative. Plaintiffs are unlikely to succeed on these contentions and causes of action.

First, Plaintiffs cannot pursue their arguments through the "back door" of a declaratory relief claim. The Medicaid Act precludes private enforcement of 42 U.S.C. § 1396a(a)(30)(A)—which Plaintiffs contend has been violated by SPA 17-002 and Medi-Cal Rx. *See* FAC ¶¶ 67-68. Plaintiffs cannot circumvent that exclusion by invoking the Court's equitable powers. *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 327–28 (2015). Plaintiffs' allegation that SPA 17-002 was adopted in violation of federal regulations requiring the Director to base proposed FFS pharmacy reimbursement on "reliable data" is not enforceable through a declaratory relief action. *See Save Our Valley v. Sound Transit*, 335 F.3d 932, 943–944 (9th Cir. 2003) (regulation not enforceable under section 1983.) Further, Plaintiffs' allegation that they lack any available administrative remedy to "challenge CMS' approval" of the SPA and Medi-Cal Rx is belied by their own Second and Third Causes of Action, alleging APA claims against the CMS Administrator for granting such approvals. FAC ¶ 132. Regardless, Plaintiffs are highly unlikely to succeed on the merits of their declaratory relief arguments asserting violations of federal law or on their APA claims.

Congress expressly delegated to HHS the responsibility and authority to administer the Medicaid program and to review and approve State Plan Amendments and waiver requests for compliance with federal law. 42 U.S.C. § 1396a(b); 42 U.S.C. § 1396n(b). As CMS determines whether a State Plan Amendment or proposed waiver comport with the complex web of Medicaid statutes, CMS's expertise is unquestionably required. Thus, *Chevron* deference "applies to SPA approvals." *Managed Pharmacy Care v. Sebelius*, 716 F.3d 1235, 1248 (9th Cir. 2013). The same necessarily holds true for CMS approval of Medi-Cal Rx as part of CalAIM. "Medicaid administration is nothing if not complex." *Id.* However, the "executive branch has been giving careful consideration to the ins and outs of the program since its inception, and the agency is the expert in all things Medicaid." *Id.* The Medicaid Act expressly delegates discretion to the Secretary for exercise of his discretion in the form and approval of SPAs. *See id.* Congress expressly conferred "on the Secretary authority to review and approve state Medicaid plans as a condition for disbursing federal Medicaid payments . . . . In carrying out this duty, the Secretary is charged with ensuring that each state plan complies with a vast network of specific statutory

requirements." *Id.* (citing *Pharmaceutical Research and Manufacturers of America v. Thompson*, 362 F.3d 817, 821-22 (D.C. Cir. 2004)). "An agency's interpretation 'prevails if it is a reasonable construction of the statute, whether or not it is the only possible interpretation of even the one a court might think best.'" *Id.* at 1249 (quoting *Holder v. Martinez Gutierrez*, 566 U.S. 583, 591 (2012)).

In light of the deference owed CMS, Plaintiffs' contention that SPA 17-002 did not comply with 42 U.S.C. § 1396a(a)(30)(A) or federal regulations governing consideration of cost surveys lack merit. Another United States District Court held last year that a pharmacy association was unlikely to succeed on a closely related claim that SPA 17-002 was flawed because it failed to include survey results for specialty pharmacies that, like FQHCs, failed to respond to the Department's contractor's survey utilized in determining relevant reimbursement rates. *California Pharmacists Ass'n v. Kent,* No. 19-CV-02999-JSW, 2020 WL 4460547, at *3 (N.D. Cal. Feb. 21, 2020). As the court determined, the Secretary's approval of SPA 17-002 was not likely to be deemed arbitrary and capricious because "the Secretary's approval of SPA 17-002 was based on his expertise and the data available, as well as a reasonable methodology in light of the requirements of Section 30(A)." *Id.* at *4.

II. PLAINTIFFS FAIL TO DEMONSTRATE THAT AWAITING A RULING ON A PRELIMINARY INJUNCTION WILL CAUSE IRREPARABLE HARM

Plaintiffs fail to identify, let alone demonstrate, any purported *imminent* or *immediate* harm stemming specifically from implantation of Medi-Cal Rx on January 1, 2022, that would justify the extraordinary emergency relief of a TRO. As Plaintiffs could have filed a properly noticed motion for preliminary injunction—giving the parties adequate time to fully brief the complex issues presented by Plaintiffs' filing and declarations, and giving the Court adequate time to consider those issues—the TRO should be denied. *See, e.g.*, *Baldwin v. Sebelius*, 2010 WL 2384588, at *2 (S.D. Cal. June 10, 2010) (TRO denied where there were "no allegations that Plaintiffs will suffer any specific harm between now and the regularly scheduled motion for preliminary injunction").

Plaintiffs' principal contention of harm is that they are losing under Medi-Cal Rx the revenues they previously were able to generate through the provision of pharmacy services to Medi-Cal managed care beneficiaries. Mot. at 19–20. However, while Plaintiffs may have had a unilateral expectation or hope that they could continue to take advantage of 340B drug discounts in this manner, the loss of profits to which there is no entitlement cannot constitute cognizable harm supporting a preliminary injunction. Plaintiffs, in any event, will likely continue receiving payment from managed care plans for services provided prior to January 1, 2022 for at least another month. Harrington Decl. ¶ 13. Particularly as any such lost revenues would accrue solely during the limited time needed to hear a motion for preliminary injunction, Plaintiffs cannot, and fail to identify or demonstrate, any likelihood of irreparable harm between now and the time needed to hear a motion for preliminary injunction.

Plaintiffs' own declarations predicting that they will have to limit operations fail to identify any such measures that they would be forced to take within the coming weeks. In any event, Plaintiffs fail to identify why such limitations are necessary or necessarily caused by Medi-Cal Rx. Plaintiffs have been aware of the State's intention to become the single purchaser of Medi-Cal prescription drugs since the Governor directed state authorities to seek to implement the initiative in January 2019, and have had the opportunity for three years to take measures to mitigate any anticipated financial consequences. Plaintiffs' conclusory assertions regarding the impact of Medi-Cal Rx on their operations cannot support a finding of the actual or imminent irreparable injury necessary to support a TRO. *Am. Passage Media Corp. v. Cass Communications, Inc.*, 750 F.2d 1470, 1473 (9th Cir. 1985).

Plaintiffs' contention that "administrative burdens" will increase for FQHCs under Medi-Cal Rx, pointing to the occasional need to seek prior authorization to prescribe certain medications, does not demonstrate any irreparable harm, and is unfounded as to any immediate harm, in any event. To help ensure services are not disrupted in the initial implementation period for Medi-Cal Rx if a drug is not listed on the State's new formulary, DHCS has provided a 180-day grace period during which prior authorization for ongoing therapies will be waived to ensure that the therapy to continue without interruption. Hendrix Decl. ¶ 23. This also will allow

providers the time necessary to submit an authorization request for treatment extending beyond the grace period, or to transition the beneficiary to a drug already on the formulary list that does not require prior authorization. *Id.* Additionally, DHCS contracted Magellan Medicaid Administration, Inc. ("Magellan") as administrator of the pharmacy benefit, specifically to ensure that claims processing, prior authorization transactions, rebates and other operational services continue to function smoothly. *Id.* at ¶¶ 9,19.

Plaintiffs' self-serving declarations aimed at maintaining previously enjoyed windfall profits fail to identify any irreparable harm that is likely to occur as a result of Medi-Cal Rx, much less any such harm that is likely imminent or immediate. Therefore, Plaintiff's Motion for a TRO must be denied.

III. THE EQUITIES AND PUBLIC INTEREST WEIGH STRONGLY IN DHCS'S FAVOR

Finally, Plaintiffs' Motion should be denied because the balance of equities and public interest tip sharply in the Director's favor. These last two factors of the preliminary injunction standard are merged when the government is a party. *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014). Plaintiffs' request for a TRO seeks to maintain a system that has allowed FQHCs to reap considerable windfall profits. An injunction, on the other hand, would halt a federally-approved initiative, resulting from a years-long public process, designed to ensure efficient delivery and continuity of pharmacy benefits to Medi-Cal beneficiaries, and would cause substantial disruption for beneficiaries and providers alike.

Medi-Cal Rx will improve the care and treatment of Medi-Cal beneficiaries. Because the intended beneficiaries of the Medicaid laws are not participating medical providers, but instead the patients who will benefit from the implementation of Medi-Cal Rx, the balance of the equities strongly weigh in favor of the Department.

A. Medi-Cal Rx Provides Essential Benefits and Access to Pharmaceuticals

Contrary to Plaintiffs' assertions, the intended beneficiaries of the Medicaid laws are not the participating health care providers, but rather the eligible beneficiaries of Medicaid services. *Armstrong*, 575 U.S. at 332; *see* 42 U.S.C. §§ 1396–1396q. Apart from providing savings to the State, Medi-Cal Rx will improve the quality of care for Medi-Cal beneficiaries by benefits by

eliminating obstacles to obtaining timely access to medications, helping avoid disruptions in continuity of care, reducing confusion for beneficiaries who may change counties or managed care plan assignments, removing impediments to provider's first choice of treatment for the beneficiary, and providing beneficiaries access to a more expansive pharmacy network and prescription options. Hendrix Decl. ¶¶ 16-33. As noted above, Plaintiffs' contention that Medi-Cal Rx will disrupt care coordination and management of patient care is speculative and unfounded.

B. Medi-Cal Rx Will Result in Substantial Program Benefits and Savings

Implementation of Medi-Cal Rx will facilitate policy uniformity and improved oversight of claims for qualifying, outpatient drugs dispensed and billed through the 340B program for the benefit of the Medi-Cal program. Hendrix Decl. ¶¶ 27-33. Moreover, the transition of the pharmacy benefit to Medi-Cal Rx is estimated to save the State General Fund over $400 million annually beginning fiscal year 2023. Hendrix Decl. ¶ 33. By establishing the State as a single purchaser for Medi-Cal covered outpatient drugs, Medi-Cal Rx is designed to strengthen the State's negotiating power with drug manufacturers for greater supplemental drug rebates and provide incentives for manufactures to offer higher rebates in order to be listed on the State's Contract Drug List. Hendrix Decl. ¶¶ 7, 18, 27, 32.

Courts have routinely held that the government's interest in preventing the waste of public resources constitutes a compelling government interest. *Erickson v. U.S. ex rel. Dep't of Health & Human Servs*., 67 F.3d 858, 862 (9th Cir. 1995); *Robinson v. Delgado*, No. C 02-1538 CW, 2008 WL 3286985, at *6 (N.D. Cal. Aug. 6, 2008). When pharmacy services were included under Medi-Cal managed care, reimbursements to FQHCs led to excessive prices for 340B drugs dispensed to Medi-Cal managed care beneficiaries, perpetuating higher overall drug costs in the Medi-Cal managed care delivery system. Hendrix Decl. ¶ 37. By lowering drug costs and reimbursements, Medi-Cal Rx serves a "compelling interest" in preventing the waste of resources intended for Medi-Cal program and saving taxpayer funds.

C. A TRO Would Substantially Disrupt Medi-Cal Services

An injunction against Medi-Cal Rx, therefore, would cause substantial disruption to the delivery of pharmacy services for managed care beneficiaries. Immediately, Medi-Cal managed care beneficiaries would be left without an authorized pharmacy benefit. Hendrix Decl. ¶ 40. Due to the complexity and long lead times needed to determine appropriate capitation rates with managed care plans and pharmacy contracts, changes to the scope of managed care benefits such as Medi-Cal Rx cannot be turned on and off like a spigot. *Id.* at ¶¶ 39-43; Harrington Decl. ¶¶ 18-20. Rather, changes require substantial background work and careful coordination to ensure that services are not disrupted. *See* Harrington Decl. ¶¶ 19-20.

As a result of the transition to Medi-Cal Rx, Medi-Cal managed care plans are no longer contracted with pharmacies, and capitation rates for plans have been negotiated on the understanding that the costs of pharmacy services are no longer included in plan costs for dates of service on and after January 1, 2022. Harrington Decl. ¶ 19. Pharmacy services are not covered under the Section 1915(b) waiver or the Department's contracts with the plans, and the Department would have to amend its Section 1915(b) waiver and obtain CMS approval before adding such benefits back into managed care plan contracts if Medi-Cal Rx is enjoined. *Id.* Moreover, managed care plans would be required to enter into contracts with pharmacy providers without sufficient usage information, and plans would be left without a viable pharmacy network for beneficiaries to access to obtain their vital medications until such contracts were established. Hendrix Decl. ¶ 42.

These complications would likely cause confusion and disruption in services for Medi-Cal beneficiaries, causing harm and in some circumstances severe consequences for beneficiaries unable to timely access essential medications. Harrington Decl. ¶ 18; Hendrix Decl. ¶¶ 39,40, 42.

The substantial disruption that beneficiaries, providers, and the Medi-Cal program would certainly face in the event a TRO is granted is distinctly not in the public interest.

D. Denial of the Motion for TRO Would Not Significantly Harm Plaintiffs

While enjoining the Medi-Cal Rx transition would cause confusion and disruption for millions of Medi-Cal beneficiaries and major disruption to the Medi-Cal program, Plaintiffs have

failed to establish that any temporary economic consequences from denying the request for TRO would cause any significant harm. Indeed, none of the harm alleged by Plaintiffs is certain to occur nor imminent.

Plaintiffs do not even address what, if any concrete, *immediate* harm they would face unless a TRO is granted, nor could they demonstrate any immediate harm. Before Medi-Cal Rx, and even if an injunction were issued, FQHCs do not generally receive real-time reimbursement from managed care plans, the source of the profit or "savings" they wish to retain. Although plans are required to pay claims from FQHCs on a timely basis, FQHCs will likely to continue to receive payments from their sales of 340B drugs to Medi-Cal managed care plans for services provided *before* Medi-Cal Rx became effective on January 1, 2022, as FQHCs continue to file claims related to the period prior to January 1, 2022, and Medi-Cal managed care plans complete their claims adjudication processes. Harrington Decl. ¶ 13. Thus, funds flowing to Plaintiffs from the plans under this arrangement have not abruptly been cut off on January 1. FQHCs will only experience the loss of any previously enjoyed 340B drug profits over the course of time, in any event.

Plaintiffs speculate in their own self-serving declarations that may have to eventually reduce services or close pharmacies or other facilities if Medi-Cal Rx is implemented. *See, e.g.,* Castle Decl. ¶ 5 (asserting patient services are "at risk"). However, they fail to identify particular harm that would accrue in the mere weeks it would take to hear Plaintiffs' claims on a regular noticed motion for preliminary injunction. Plaintiffs do not identify when they will begin to actually experience any decreased revenue or specifically when any particular services would be need to be reduced or eliminated.

Regardless, for reasons addressed above, Plaintiffs fail to and cannot demonstrate any entitlement to continue to receive profit from pharmacy services provided to Medi-Cal managed care beneficiaries, and the Medi-Cal program is not nor can it be a guarantor of such profits.

Additionally, FQHCs are anticipated to receive an entirely new stream of funding from a new supplemental payment pool to be distributed to non-hospital 340B clinics and health centers with retroactive effect back to January 1, 2022, which the Legislature has authorized, and for which the

Department has requested CMS approval. Harrington Decl. ¶ 17; Cal. Welf. & Inst. Code § 14105.467. This program is currently budgeted at $ 79.25 million, but is expected to grow to $105 million in Fiscal Year 2022-23 and continue annually thereafter. *Id*. The supplemental payment pool is not intended to replace loss of revenues, but rather to mitigate the impact on 340B covered entitles of the Medi-Cal Rx transition. *Id*. While Plaintiffs have no entitlement to continued profits from selling marked up 340B drugs, the supplemental payment pool is designed to mitigate the exact claimed impact on Plaintiffs caused by the Medi-Cal Rx transition.

CONCLUSION

For the reasons set forth above, Plaintiffs fail to satisfy any of the *Winter* prongs, including demonstrating a likelihood of immediate irreparable harm, required to warrant granting the extraordinary remedy of a TRO. Therefore, Plaintiffs' Motion should be denied.

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Respectfully submitted,

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