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 8

9 IN THE UNITED STATES DISTRICT COURT
 10 FOR THE EASTERN DISTRICT OF CALIFORNIA
 11

12 **COMMUNITY HEALTH CENTER**
 13 **ALLIANCE FOR PATIENT ACCESS;**
 14 **AVENAL COMMUNITY HEALTH**
 15 **CENTERS; COMMUNITY HEALTH**
 16 **CENTERS OF THE CENTRAL COAST;**
 17 **FAMILY HEALTH CENTERS OF SAN**
 18 **DIEGO; IMPERIAL BEACH**
 19 **COMMUNITY CLINIC; LA MAESTRA**
FAMILY CLINIC; OMNI FAMILY
HEALTH; OPEN DOOR COMMUNITY
HEALTH CENTERS; SHASTA
COMMUNITY HEALTH CENTER;
SOUTH COUNTY COMMUNITY
HEALTH CENTER, INC.,

20 Plaintiffs,

21 v.

22 **MICHELLE BAASS, Director of the**
 23 **California Department of Health Care**
 24 **Services, CHIQUITA BROOKS-LaSURE;**
Administrator of the Centers for Medicare
and Medicaid Services,

25 Defendants.
26

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

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1 **INTRODUCTION**

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

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

15 **BACKGROUND**

16 **I. THE REGULATORY BACKGROUND AND MEDI-CAL RX INITIATIVE**

17 **A. Medicaid and Medi-Cal**

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

1 services to be provided, methodologies for providers to be reimbursed, and the administrative
2 requirements that states must meet to participate. 42 U.S.C. §§ 1396d(a), 1396a(a)(10),
3 1396d(a)(1)-(5), (17), (21).

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

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

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

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

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

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

4 Medi-Cal Rx is authorized under Section 1915(b) of the Social Security Act, 42 U.S.C.
5 § 1396n(b), under which CMS may waive certain requirements of the Medicaid Act for
6 “innovative programs or activities on a time-limited basis” that are “subject to specific safeguards
7 for the protection of beneficiaries” where CMS deems the measures to be “cost effective,
8 efficient, and consistent with the objectives of the Medicaid program.” 42 C.F.R. § 430.25(b).

9 **C. FQHC Reimbursement and the Pharmacy “Carve-Out”**

10 FQHCs are federally subsidized healthcare providers receiving or eligible for grants under
11 Section 330 of the Public Health Service Act for providing services to underserved communities.
12 42 U.S.C. § 1396l(b)(2). FQHCs receive these “Section 330” grants independent of funding or
13 reimbursement these clinics receive from the federal Medicaid and Medicare programs. 42
14 U.S.C. §§ 254b(a)(1); 1395x(aa)(4).

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

22 Under this per-visit rate methodology, called the Prospective Payment System (PPS), a
23 baseline PPS rate is generally set for each FQHC based on its reasonable costs for providing
24 FQHC services in years 1999 and 2000 (or other baseline years for new FQHCs) divided by the
25 total number of visits by FQHC patients during those years. *Three Lower Counties*, 498 F.3d. at
26 298–99; 42 U.S.C. § 1396a(bb)(2). Going forward, this initial “per-visit” PPS rate is adjusted by
27 a cost of living index (“Medicare Economic Index” or “MEI”), and any change in scope of
28

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

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

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

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

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

7 **D. FQHC Revenue Under the 340B Program**

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

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

22 **E. CMS Approval of SPA 17-002**

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

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

7 **II. PROCEDURAL BACKGROUND**

8 Plaintiffs, ten California FQHCs and an association representing FQHCs, filed their initial
9 complaint against the DHCS Director (Director) and DHCS on October 29, 2020, seeking to
10 enjoin Medi-Cal Rx and the broader waiver initiative under which it was proposed. The Court
11 denied Plaintiffs' motion for a temporary restraining order (TRO) on November 24, 2020. Dkt.
12 No. 19. In a bench ruling on March 9, 2021, the Court granted a motion to dismiss by Defendants
13 without prejudice on various grounds, including that Plaintiffs' action was premature before CMS
14 had granted approval of the DHCS' waiver request. *See* Dkt. No. 37. The Court, accordingly,
15 denied a motion for preliminary injunction by Plaintiffs as moot. Dkt. No. 38. CMS approved
16 the Medi-Cal Rx transition on December 29, 2021, as part of DHCS' CalAIM initiative, and
17 Plaintiffs filed the present Motion and their First Amended Complaint the next day, December 30,
18 2021, asserting claims against the Director and Administrator of CMS.

19 **LEGAL STANDARD**

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

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

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

7 8 ARGUMENT

9 I. PLAINTIFFS HAVE NO LIKELIHOOD OF SUCCESS ON THEIR CLAIMS AGAINST THE 10 DIRECTOR

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

14 A. Plaintiffs’ First Cause of Action Is Based on Incorrect and Fundamentally 15 Flawed Allegations

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

21 First, Plaintiffs’ contention that Medi-Cal Rx requires Plaintiffs to accept FFS
22 reimbursement for pharmacy services in accordance with SPA 17-002 is misleading and
23 incorrect. FAC ¶ 109. As discussed above—but nowhere in Plaintiff’s First Amended Complaint
24 or Motion—FQHCs may elect to include or “carve in” the pharmacy benefit into their PPS rate.
25 Harrington ¶¶ 14-16. If an FQHC already included the pharmacy benefit in their PPS rate, or
26 elects now to include it, then the FQHC is no longer reimbursed for the pharmacy benefit on the
27 basis of the fee-for-service fee schedule. Rather, the FQHC will be reimbursed for these costs
28 *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

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

6 Second, Plaintiffs' contention that FFS reimbursement for the pharmacy benefit under SPA
 7 17-002 fails to meet the federal PPS rate requirements set forth in 42 U.S.C. § 1396a(bb) (Section
 8 1396a(bb)) is also fundamentally misguided. As discussed, FQHCs that have "carved in" the
 9 pharmacy benefit are reimbursed through the PPS rate established under Section 1396a(bb)—not
 10 through FFS reimbursement. Moreover, Section 1396a(bb) is inapplicable when an FQHC has
 11 elected to "carve out" their pharmacy benefits from PPS reimbursement. Accordingly, there is no
 12 basis for Plaintiffs' assertion that the FFS reimbursement rates authorized under SPA 17-002 fail
 13 to meet the requirements of Section 1396a(bb).

14 Plaintiffs' contention that the reimbursement fails to meet PPS rate requirements of Section
 15 1396a(bb) is based, in any event, on Plaintiffs' flatly incorrect, but repeatedly emphasized,
 16 assertion that FQHCs are entitled to reimbursement under section 1396a(bb) at 100 percent of
 17 their reasonable costs. FAC ¶ 4, 31, 39, 46, 55, 66, 92; TRO Mem. at 1, 2, 9, 10, 13, 15, 17, 21.
 18 No such requirement exists. Rather, as numerous courts already have explained, Section
 19 1396a(bb) requires, that the PPS be set at 100 percent of FQHC's average reasonable costs *during*
 20 *the FQHC's base period year or years* used to determine the center's initial PPS rate, after which
 21 the rate is adjusted *only* by a Medicaid economic indicator, or in the event of a recognized change
 22 in the scope of the FQHC's services.¹ 42 U.S.C. § 1396a(bb)(2)-(4); *see Cmty. Health Care*

23 ¹ Specifically, for clinics existing in or before 1999, subsection (2) provides for the PPS
 24 rate to be initially set *in 2001* at an amount "equal to 100 percent of the average of the costs of the
 25 center or clinic of furnishing [covered] services *during fiscal years 1999 and 2000* which are
 26 reasonable and related to the cost of furnishing such services . . ." 42 U.S.C. § 1396a(bb)(2). In
 27 subsequent years, that rate is adjusted only by the Medicaid Economic Index, or any change in
 28 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

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

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

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

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

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

23
24
25
26 _____
27 FQHC "based on the rates established under this subsection for the fiscal year for *other such*
28 *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 **1. Plaintiffs Lack Any Private Right of Action Under 340B, and Their**
 2 **Preemption Arguments Lack Merit**

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

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

10 The Supreme Court has explicitly held that there is no private right of action under section
 11 340B for covered entities, which include FQHCs, nor may covered entities sue manufacturers as
 12 third-party beneficiaries of the drug pricing agreements entered into between the manufacturers
 13 and HHS. *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113, 118 (2011). Absent a private
 14 right of action, Plaintiffs also cannot state a successful claim under the Declaratory Judgment Act.
 15 *See, e.g., Am. Video Duplicating Inc. v. City Nat’l Bank*, 2020 WL 6882735, at *5 (C.D. Cal.
 16 Nov. 20, 2020) (citing *Lil’ Man in the Boat, Inc. v. City & Cnty. of San Francisco*, 2018 WL
 17 4207260, at *4 (N.D. Cal. Sept. 4, 2018) (“When a plaintiff lacks a private right of action under a
 18 particular statute, she cannot argue around that limitation by bootstrapping her cause of action
 19 onto a[] . . . declaratory relief claim.”)). Because Plaintiffs lack a private right of action under
 20 both Section 340B and the Declaratory Judgment Act, they are unlikely to succeed on the merits
 21 of their 340B claim under a preemption theory.

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

24 Plaintiffs, nonetheless, contend that Welfare and Institutions Code section 14105.46 is
 25 preempted by federal law delegating to the HHS Secretary authority to create an exclusive
 26 mechanism to avoid duplicate discounts. FAC ¶ 87–93, 131; Mot. at 17-19. Plaintiffs’
 27 contention is misplaced. First, the Ninth Circuit has squarely held that Welfare and Institutions
 28 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*

1 v. *Douglas*, 457 Fed. App'x 676, 678 (9th Cir. 2011). There, the Ninth Circuit pertinently stated
2 that “[s]imply put . . . [t]here is no actual conflict because the state and federal statutes can both
3 easily be complied with; the state statute surely does not present an obstacle to the prevention of
4 double discounts; and there is no indication that Congress intended to occupy the whole field in
5 this part of the cooperative Medicaid program.” *Id.* Without question, this authority disposes of
6 Plaintiffs’ preemption claim, and the Court need not analyze it further. As in *AIDS Healthcare*
7 *Foundation*, a statute that supports and ensures compliance with federal law does not conflict
8 with federal law, does not present an obstacle to the intent of the federal law, and does not step
9 into a field wholly occupied by federal law. *Id.* at 678. Welfare and Institutions Code section
10 14105.46 is therefore not preempted by federal law.

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

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

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

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

3 The implementation of Medi-Cal Rx does not prevent FQHCs from receiving their federal
4 entitlement to discounts on their purchase of qualifying 340B drugs. Hendrix Decl. ¶ 34.
5 Furthermore, Plaintiffs’ misconstrue the meaning of Congress’s statement. Congress could not
6 have intended for 340B covered entities to “stretch” federal funding by allowing providers to use
7 Medicaid funds for non-Medicaid purposes. But surprisingly, according to Plaintiffs’ own
8 moving papers, that is exactly what they have sought to use the funds for. *See, e.g.*, Buada Decl.
9 ¶ 3 (used to fund prescriptions for “Self-Pay clients); Curtis Decl. ¶ 8 (funds “reinvested” for
10 costs not covered by Medi-Cal under PPS rate). While non-covered services and may be
11 significant for FQHC patients who are not Medi-Cal beneficiaries, such services cannot be
12 financed with Medicaid funds. Plaintiffs plainly misconstrue Congress’s intent.

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

15
16 **2. SPA 17-002 and Medi-Cal Rx Do Not Violate the Medicaid Act or
Regulations, and CMS Acted Reasonably in Approving Them**

17 Plaintiffs acknowledge, as they must, that they have processed Medi-Cal FFS prescriptions,
18 and therefore necessarily have received reimbursement under SPA 17-002 since its approval in
19 2017. *See, e.g.*, Buada Decl. ¶ 3; Curtis Decl. ¶ 3; Castle Decl. ¶ 7. Indeed, some drugs covered
20 by the 340B program—particularly certain drugs with particularly high prescription costs—have
21 been excluded from the managed care pharmacy benefit for many years, and instead have been
22 subject to reimbursement provided under FFS. Hendrix Decl. ¶ 6. Yet, Plaintiffs now seek
23 declaratory relief on the basis, in part, that SPA 17-002 and Medi-Cal Rx violate provisions of the
24 Medicaid Act or Medicaid regulations and to enjoin the initiative under the Administrative
25 Procedures Act (APA) on grounds that CMS acted arbitrarily and capriciously in approving the
26 SPA and the Medi-Cal Rx initiative. Plaintiffs are unlikely to succeed on these contentions and
27 causes of action.
28

1 First, Plaintiffs cannot pursue their arguments through the “back door” of a declaratory
2 relief claim. The Medicaid Act precludes private enforcement of 42 U.S.C. § 1396a(a)(30)(A)—
3 which Plaintiffs contend has been violated by SPA 17-002 and Medi-Cal Rx. *See* FAC ¶¶ 67-68.
4 Plaintiffs cannot circumvent that exclusion by invoking the Court’s equitable powers. *Armstrong*
5 *v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 327–28 (2015). Plaintiffs’ allegation that SPA
6 17-002 was adopted in violation of federal regulations requiring the Director to base proposed
7 FFS pharmacy reimbursement on “reliable data” is not enforceable through a declaratory relief
8 action. *See Save Our Valley v. Sound Transit*, 335 F.3d 932, 943–944 (9th Cir. 2003) (regulation
9 not enforceable under section 1983.) Further, Plaintiffs’ allegation that they lack any available
10 administrative remedy to “challenge CMS’ approval” of the SPA and Medi-Cal Rx is belied by
11 their own Second and Third Causes of Action, alleging APA claims against the CMS
12 Administrator for granting such approvals. FAC ¶ 132. Regardless, Plaintiffs are highly unlikely
13 to succeed on the merits of their declaratory relief arguments asserting violations of federal law or
14 on their APA claims.

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

1 requirements.” *Id.* (citing *Pharmaceutical Research and Manufacturers of America v. Thompson*,
2 362 F.3d 817, 821-22 (D.C. Cir. 2004)). “An agency’s interpretation ‘prevails if it is a reasonable
3 construction of the statute, whether or not it is the only possible interpretation of even the one a
4 court might think best.’” *Id.* at 1249 (quoting *Holder v. Martinez Gutierrez*, 566 U.S. 583, 591
5 (2012)).

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

17
18 **II. PLAINTIFFS FAIL TO DEMONSTRATE THAT AWAITING A RULING ON A
PRELIMINARY INJUNCTION WILL CAUSE IRREPARABLE HARM**

19 Plaintiffs fail to identify, let alone demonstrate, any purported *imminent* or *immediate* harm
20 stemming specifically from implantation of Medi-Cal Rx on January 1, 2022, that would justify
21 the extraordinary emergency relief of a TRO. As Plaintiffs could have filed a properly noticed
22 motion for preliminary injunction—giving the parties adequate time to fully brief the complex
23 issues presented by Plaintiffs’ filing and declarations, and giving the Court adequate time to
24 consider those issues—the TRO should be denied. *See, e.g., Baldwin v. Sebelius*, 2010 WL
25 2384588, at *2 (S.D. Cal. June 10, 2010) (TRO denied where there were “no allegations that
26 Plaintiffs will suffer any specific harm between now and the regularly scheduled motion for
27 preliminary injunction”).
28

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

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

22 Plaintiffs' contention that "administrative burdens" will increase for FQHCs under
23 Medi-Cal Rx, pointing to the occasional need to seek prior authorization to prescribe certain
24 medications, does not demonstrate any irreparable harm, and is unfounded as to any immediate
25 harm, in any event. To help ensure services are not disrupted in the initial implementation period
26 for Medi-Cal Rx if a drug is not listed on the State's new formulary, DHCS has provided a
27 180-day grace period during which prior authorization for ongoing therapies will be waived to
28 ensure that the therapy to continue without interruption. Hendrix Decl. ¶ 23. This also will allow

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

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

11 **III. THE EQUITIES AND PUBLIC INTEREST WEIGH STRONGLY IN DHCS’S FAVOR**

12 Finally, Plaintiffs’ Motion should be denied because the balance of equities and public
13 interest tip sharply in the Director’s favor. These last two factors of the preliminary injunction
14 standard are merged when the government is a party. *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d
15 1073, 1092 (9th Cir. 2014). Plaintiffs’ request for a TRO seeks to maintain a system that has
16 allowed FQHCs to reap considerable windfall profits. An injunction, on the other hand, would
17 halt a federally-approved initiative, resulting from a years-long public process, designed to ensure
18 efficient delivery and continuity of pharmacy benefits to Medi-Cal beneficiaries, and would cause
19 substantial disruption for beneficiaries and providers alike.

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

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

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

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

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

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

18 Courts have routinely held that the government’s interest in preventing the waste of public
19 resources constitutes a compelling government interest. *Erickson v. U.S. ex rel. Dep’t of Health*
20 *& Human Servs.*, 67 F.3d 858, 862 (9th Cir. 1995); *Robinson v. Delgado*, No. C 02-1538 CW,
21 2008 WL 3286985, at *6 (N.D. Cal. Aug. 6, 2008). When pharmacy services were included
22 under Medi-Cal managed care, reimbursements to FQHCs led to excessive prices for 340B drugs
23 dispensed to Medi-Cal managed care beneficiaries, perpetuating higher overall drug costs in the
24 Medi-Cal managed care delivery system. Hendrix Decl. ¶ 37. By lowering drug costs and
25 reimbursements, Medi-Cal Rx serves a “compelling interest” in preventing the waste of resources
26 intended for Medi-Cal program and saving taxpayer funds.

1 **C. A TRO Would Substantially Disrupt Medi-Cal Services**

2 An injunction against Medi-Cal Rx, therefore, would cause substantial disruption to the
3 delivery of pharmacy services for managed care beneficiaries. Immediately, Medi-Cal managed
4 care beneficiaries would be left without an authorized pharmacy benefit. Hendrix Decl. ¶ 40.
5 Due to the complexity and long lead times needed to determine appropriate capitation rates with
6 managed care plans and pharmacy contracts, changes to the scope of managed care benefits such
7 as Medi-Cal Rx cannot be turned on and off like a spigot. *Id.* at ¶¶ 39-43; Harrington Decl.
8 ¶¶ 18-20. Rather, changes require substantial background work and careful coordination to
9 ensure that services are not disrupted. *See* Harrington Decl. ¶¶ 19-20.

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

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

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

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

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

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

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

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

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

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

1 Department has requested CMS approval. Harrington Decl. ¶ 17; Cal. Welf. & Inst. Code
2 § 14105.467. This program is currently budgeted at \$ 79.25 million, but is expected to grow to
3 \$105 million in Fiscal Year 2022-23 and continue annually thereafter. *Id.* The supplemental
4 payment pool is not intended to replace loss of revenues, but rather to mitigate the impact on
5 340B covered entitles of the Medi-Cal Rx transition. *Id.* While Plaintiffs have no entitlement to
6 continued profits from selling marked up 340B drugs, the supplemental payment pool is designed
7 to mitigate the exact claimed impact on Plaintiffs caused by the Medi-Cal Rx transition.

8 **CONCLUSION**

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

12
13 Dated: January 5, 2022

Respectfully submitted,

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