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UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

COMMUNITY HEALTH CENTER ALLIANCE FOR PATIENT ACCESS, ET AL.,

Plaintiffs,

v.

WILLIAM LIGHTBOURNE, Director of the California Department of Health Care Services, CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES,

Defendants.

Case No.

PLAINTIFFS' MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR A TEMPORARY RESTRAINING ORDER

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I. INTRODUCTION

COVID-19 has dominated our lives for the past seven months. By the end of October 2020, over 930,000 Californians had been diagnosed with the virus and over 17,600 had died. The Governor declared a State of Emergency on March 4, 2020. The end of pandemic is nowhere in sight.

Understandably, defendants Department of Health Care Services and its Director (collectively, "DHCS") have pivoted their attention to addressing the pandemic and have delayed until January 2022 major changes to the Medi-Cal system, including the adoption of the "California Advancing and Innovating Medi-Cal" ("CalAIM") program, citing the pandemic as the reason for the need for the delay. Instead, DHCS has elected to request a one-year extension of its existing federally-approved Medi-Cal managed care project (the "1115 Waiver"), with one material change – DHCS is asking permission from the federal Centers for Medicare & Medicaid Services ("CMS") to carve-out the pharmacy benefit from Medi-Cal managed care and transfer it to fee-for-service ("FFS") reimbursement administered by DHCS (the "Medi-Cal Rx Transition" or "pharmacy benefit carve-out").

What is not understandable is why DHCS insists on pressing forward with the one element of the Medi-Cal managed care transition – the Medi-Cal Rx Transition – that will deprive safety net providers of critical funds needed to provide access to care to the populations hardest hit by the pandemic, and why the Medi-Cal Rx Transition should not be postponed like the rest of the Medi-Cal waiver transition to CalAIM. Federally qualified health centers ("FQHCs") are part of the "backbone" of the healthcare delivery system in many low income areas in California.[1] This is not the time to cripple FQHCs.

DHCS acknowledged the hit that FQHCs will suffer as a result of the Medi-Cal Rx Transition, and expressed a willingness to mitigate this harm. In late 2019, DHCS and the California Primary Care Association, a trade association of community health centers,

[1] *See, e.g.,* Decl. of the Hon. Adam C. Gray, Assembly member, 21st Assembly Dist., submitted herewith, ¶¶ 6-11.

agreed to support legislation to develop a supplemental payment pool ("SPP") to mitigate the financial harm that health centers that participate in the 340B drug program will suffer as a result of the Medi-Cal Rx Transition. (*See* decl. of C. Dean Germano, ¶ 4.) In the January 2020 budget, $105 million was appropriated for the SPP. (*Id*., ¶ 6.) However, after the pandemic struck, in the May revisions to the budget, the SPP appropriation was removed from the budget. (*Id*., ¶ 8.) Although the SPP appropriation was restored in the budget for the current fiscal year, these events illustrate the tenuous nature of the SPP as a remedy to mitigate the financial impact of the Medi-Cal Rx Transition on FQHCs. (*Id*., ¶ 9.) Moreover, while the Legislature appropriated $105 million (half State-half federal funds) for FY July 1, 2020 to June 30, 2021, at this point, due to implementation delays, the amount available is only $52.5 million (half State-half federal funds) for the period January 1, 2021 through June 30, 2021, and there is currently no agreed upon or federally-approved means for distribution of the SPP for that period. (*Id*., ¶¶ 11-14.)

In the meantime, DHCS is plunging ahead to implement the Medi-Cal Rx Transition on January 1, 2021, as part of its request to extend the federal approval of its existing Medi-Cal managed care program for another year. In other words, DHCS is requesting federal approval to maintain the existing Medi-Cal managed care program, and to amend it by carving out the pharmacy benefit. This would allow the State to get the benefit of discounted pricing under the 340B program that the health centers currently receive and use to provide access to care to the low income communities they serve, the same low income communities hit hardest by the coronavirus. As explained below, the State's request was untimely and otherwise fatally flawed. Moreover, although federal approval has not yet been granted, the State has an aggressive timeline to complete the transition, including notifying patients of the change and modifying Medi-Cal managed care contracts, between now and January 1, 2021, which is less than two months away, which is why a temporary restraining order ("TRO") is necessary. (*See* decl. of Regina M. Boyle ("Boyle decl."), ¶ 12 & Exh. K.)

Finally, DHCS has stated that the Medi-Cal Rx Transition would save the State

$5.5 to $6.0 billion. (See decl. of Kathryn E. Doi ("Doi decl."), ¶ 18 & Exh. D, p.37.) However, a DHCS analysis estimated the managed care pharmacy "**savings**" to Medi-Cal to be $5,822,082,000 per year and the additional **costs** to Medi-Cal for FFS pharmacy as $5,650,063,000 per year. (*Id*.) Moreover, net savings to the State related to non-hospital 340B clinics is projected to be only $147,000,000, which is about two-and-a-half percent (2.5%) of the cost of pharmacy to the Medi-Cal program under either the managed care or FFS model. (*Id*.) This 2.5% savings in pharmacy costs is pocket change to the Medi-Cal program (whose grand total appropriation for fiscal year 2020-21 was over $115 billion), whereas the impact of losing the 340B savings would be devastating for health centers and their patients.

Plaintiff FQHCs seek a TRO enjoining defendants from taking any further action to implement the Medi-Cal Rx Transition, or, in the alternative, the Waiver extension, because plaintiffs are likely to succeed on the merits of their claims that (1) the State does not have federal approval to implement the Medi-Cal Rx Transition and the State's 1115 Waiver extension request is void because the State failed to comply with the notice and comment and submission requirements in making its untimely request to CMS; (2) the Medi-Cal Rx Transition is preempted by federal law as to FQHCs because the State does not have in place a means for reimbursing FQHCs their actual and reasonable costs of providing pharmacy services outside of Medi-Cal managed care, as required by federal law; and (3) the State is prohibited from indirectly obtaining rebates for drugs covered by the 340B pharmacy reimbursement program with respect to FQHCs that have registered with the Medicaid Exclusion File. Plaintiffs are entitled to a TRO to preserve the status quo and to prevent irreparable harm to plaintiffs and their patients. Plaintiffs are likely to succeed on the merits and the equities tip in plaintiffs' favor.

II. REASONS A TRO IS NECESSARY

DHCS is moving quickly to implement the Medi-Cal Rx Transition. As explained in a power point presentation in late-October, prior to December 1, 2020, DHCS will be issuing 30-day notices to fee-for-service Medi-Cal beneficiaries, advising them of the

Medi-Cal Rx Transition, timed to arrive on December 1, 2020. (Boyle decl., ¶ 12 & Exh. K, pp.4 & 13.) In addition, Medi-Cal managed care plans will issue 30-day notices to their respective members and conduct a corresponding outreach campaign advising them of the Medi-Cal Rx Transition. (*Id*.) The provision of notices about a transition that has not received federal approval is a violation of federal law and will sow confusion among Medi-Cal beneficiaries. A TRO must issue prior to December 1, 2020 to prevent these notices from being sent.

III. BASIS FOR RELIEF

A party may obtain a TRO and/or a preliminary injunction to prevent interim harm that may occur during the pendency of an adversary proceeding. (*See* FRCP 65.) The standard for obtaining a TRO "is substantially identical" to the standard for a preliminary injunction. (*Stuhlbarg Int'l Sales Co. v. John D. Brush & Co*., 240 F.3d 832, 839 n.7 (9th Cir. 2001).) The primary differences between the two are timing and notice: the purpose of a TRO is to preserve the relative positions of the parties until such time as the court can rule on a noticed motion for a preliminary injunction, *Granny Goose Foods, Inc. v. Bhd. of Teamsters & Auto Truck Drivers*, 415 U.S. 423, 439 (1974), while "[t]he purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held." (*Univ. of Texas v. Camenisch*, 451 U.S. 390, 395 (1981).) A party seeking to obtain a TRO or preliminary injunction must satisfy the following *Winter* factors: (1) they are likely to succeed on the merits; (2) they are likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in their favor; and (4) a preliminary injunction is in the public interest. (*Doe #1 v. Trump*, 957 F.3d 1050, 1057 (9th Cir. 2020) (*citing Winter v. Nat. Res. Def. Council, Inc*., 555 U.S. 7, 20 (2008).) Plaintiffs satisfy all of the *Winter* factors.

A. Plaintiffs Are Likely To Succeed On The Merits

1. Defendants have failed to make a timely and proper request for an amendment of the Waiver to include the pharmacy benefit carve-out.

a. California's Medicaid Program

California participates in the Medicaid program through the California Medical Assistance Program, also known as "Medi-Cal." As a participant in the federal Medicaid program, California is required to comply with federal Medicaid Act and its regulations in administering its State program. (*Alaska Dept. of Health and Social Servs. v. Centers for Medicare and Medicaid Servs.* (9th Cir. 2005) 424 F.3d 931, 935. California has designated DHCS as the agency responsible for its administration. (*See* Cal. Welf. & Inst. Code (hereafter "WIC Code") §§ 10720, 14000 *et seq*.; 22 Cal. Code of Regs., §§ 50000 *et seq*.)) State Medicaid Agencies are permitted to implement a managed care delivery system using three basic types of federal authorities: (1) State plan authority under 42 U.S.C. § 1396u–2 ("State Plan Model"); (2) waiver authority under 1396n(a) and (b) (a "1915 Waiver"); or (3) waiver authority under 42 U.S.C. § 1315 ("1115 Waiver"). DHCS implements the Medicaid program at issue pursuant to a 1115 Waiver that permits states to enact pilot projects in their Medicaid programs. (42 U.S.C. § 1315.) (*See* Boyle decl., ¶ 10 & Exh. I.)

Medicaid managed care plans generally provide healthcare services to Medicaid enrollees through subcontracted providers. Unlike a traditional fee-for-service model, under a managed care program, the health maintenance organizations, generally referred to as Medicaid managed care organizations or "MCOs", enter into comprehensive risk contracts with the state. A comprehensive risk contract is a risk contract between the State and an MCO that covers comprehensive services, including, among other things, services provided by an FQHC. (42 C.F.R. § 438.2.)

Under a risk contract, the FQHC is paid a "capitation payment," and in return assumes risk for the costs of the services covered under the contract. (42 C.F.R. § 438.2 (defining risk contract).) Here, managed care plans provide insurance to Medicaid beneficiaries on a capitated per-member, per-month payment from DHCS. The plans experience a loss when they pay more for medical care than it receives in capitation payments, and earn a profit when they pay out less.

b. California's 1115 Waiver for Medi-Cal Managed Care

Under Section 1115 of the Social Security Act, the Secretary of Health and Human Services ("Secretary") may waive certain Medicaid requirements for an approved "experimental, pilot, or demonstration project" that the Secretary finds "is likely to assist in promoting the objectives of" the Medicaid Act. (42 U.S.C. § 1315(a).) In 2010, California obtained the approval of CMS to remove California's State Medicaid plan provisions requiring enrollment in Medicaid managed care into the California Medi-Cal 2020 1115 Demonstration (the "Waiver"). (Boyle decl., ¶ 10 & Exh. I.) The benefits that are covered by MCO plans are described in Attachment N to the Waiver. The Waiver currently identifies as MCO covered benefits both the mandatory FQHC services benefit (42 U.S.C. § 1396a(2)(C)) and the optional pharmacy benefit (42 U.S.C. § 1396a(a)(10), 1396d(a)(12) 1396d(a)(54), 1396r-8(d); 42 C.F.R. § 440.120).

As noted above, pre-COVID, DHCS intended to implement CalAIM as of January 1, 2021. (Doi decl., ¶ 4 & Exh. C, p.1.) On January 7, 2019, Governor Gavin Newsom issued an executive order directing DHCS to effectuate the Medi-Cal Rx Transition. (Doi decl., ¶ 2 & Exh. A.) However, in May 2020, DHCS announced the delay of CalAIM, due to the impact of COVID-19, instead determining to seek a 12-month extension request to CMS for the existing 1115 Waiver, to allow continuation of existing programs prior to their eventual transitions under CalAIM. (Doi decl., ¶ 4 & Exh. C, p.1.)

On July 22, 2020, the Department issued a Notice of Proposed Extension, giving public notice of the intended request for the 12-month extension. (Doi decl., ¶ 4 & Exh. C.) The Notice provides: "This proposal is intended to extend the current structure and objectives of the programs listed above **with no changes to** eligibility, **benefits** or cost sharing for beneficiaries." [Emphasis added.] (*Id.*, p.2.) In the extension request, explaining why it is seeking the extension, DHCS stated, "It is essential for the stability of the state's health care systems, particularly during the pandemic and its immediate aftermath, that the current Medi-Cal 2020 Section 1115 demonstration authorities be extended for one year to December 31, 2021." (*Id.*, Exh. F, p.1.)

Yet, while purporting to seek stability for the State's health care systems by maintaining the status quo, particularly during the pandemic, in its draft 1115 Waiver extension request, which was released for public comment, DHCS also assured CMS that the extension would be essentially revenue neutral because:

> Finally, the state projects that the overall budget impact of this twelve month waiver extension demonstration will not be extensive to the federal government. **The state is implementing a pharmacy benefit carve-out that is expected to result in a net decrease in managed care expenditures due to changes in the capitated benefits schedule for Medi-Cal managed care**. **The projected savings is estimated to be $5.5 to $6 billion due to the pharmacy benefit carve-out ….**

(Doi decl., ¶ 5 & Exh. D, p.37 [emphasis added].) When this assertion was challenged in public comments submitted by health centers (Doi decl., ¶ 7 & Exh. I), DHCS omitted it from its final 1115 Waiver extension request to CMS. (Doi decl., ¶ 8 & Exh. F, pp.37-38 (budget neutrality discussion).)

DHCS subsequently produced an analysis of the economic impact of the Medi-Cal Rx Transition that estimates while the managed care pharmacy **savings** to Medi-Cal would be $5,822,082,000 per year, the **additional costs** to Medi-Cal for FFS pharmacy as $5,650,063,000 per year. (Doi decl., ¶ 18 & Exh. N.) Net savings to the State related to non-hospital 340B clinics is projected to be only $147,000,000, which is approximately two-and-a-half percent (2.5%) of the cost of pharmacy to the Medi-Cal program under either the managed care or fee for service model.

Thus, the State initially stated that it would finance the 1115 Waiver extension by immediately implementing the Medi-Cal Rx Transition, while in actuality, the savings associated with the Medi-Cal Rx Transition are marginal at best based on the State's own analysis. On the other hand, the pharmacy benefit carve-out pulls the financial rug out from under FQHCs and their patients by failing to reimburse FQHCs for the actual cost of providing the pharmacy benefit to Medi-Cal beneficiaries as required by law.

c. The pharmacy benefit carve-out must be enjoined because the Waiver extension request was untimely

The State cannot proceed with the pharmacy benefit carve-out on January 1, 2021

because the State submitted its Waiver extension request untimely. Section 1115 requires that requests to extend a waiver project must be submitted **at least 120 days** prior to the expiration of the current period of the waiver project. (*See* 42 U.S.C. § 1315(f)(1).) The statutory 120-day advance application requirement cannot be waived.

The Special Terms and Conditions of the State's current 1115 Waiver confirm that a request to amend the demonstration must be submitted to CMS for approval no later than 120 days prior to the planned date of implementation of the change and may not be implemented until approved. (*See California Association of Rural Health Clinics v. Douglas*, 738 F.3d 1007 (9th Cir. 2013) [the State must submit and obtain approval of a State Plan amendment before implementation]; *Dev. Serv. Network v. Douglas*, 666 F.3d 540, 544-46 (9th Cir. 2011) [same]; *see also* 42 C.F.R. § 431.412(d).)

DHCS submitted its application for an extension of the 1115 Waiver on September 16, 2020, only **106 days** prior to the December 31, 2020 expiration date of the 1115 Waiver. (*See* Doi decl., ¶ 8, Exh. F, p.1.) As DHCS did not comply with either federal law or the terms and conditions of its own 1115 Waiver, no valid request for the pharmacy benefit carve-out has been made.

d. The pharmacy benefit carve-out must be enjoined because the Waiver extension request is materially deficient and inaccurate.

Not only was the extension request not timely filed but it was materially deficient in several additional respects. For example, Section 1115 requires that waiver applications and extension requests "be sent from the Governor of the State to the Secretary;" submission through a delegate is not permitted. (42 C.F.R. § 431.412(c); see also 42 U.S.C. § 1315(e)(2) & (f).) Yet, here, the 1115 Waiver extension request was sent under a cover letter signed by the Chief Deputy Director of Health Care Programs/State Medicaid Director, not by the Governor of the State of California. (*See* Doi decl., ¶ 8 & Exh. F, p.2.) Thus, on its face no valid Waiver extension request has been submitted because the request was not submitted by the Governor as required by law. (*See* 77 Fed. Reg. 11678, 11685 (rejecting a request to allow the submitting party of a

demonstration extension to include a Governor's designee, stating that "[w]e need to have an assurance that the demonstration is fully supported by State law and State executive authority").) .

In addition, public notice in connection with an 1115 Waiver extension request, is required to include a description of the proposed health care delivery system, including benefits coverage, and how such provisions vary from the State's current features. (42 C.F.R. §§ 431.408(a)(1)(i); 431.412(c)(2)(ii).) The extension request, as summarized by DHCS in its July 22, 2020, draft for public comment, as well as its Tribal Notice of Proposed Change to the Medi-Cal Program, fail to adequately describe significant changes in the benefits to be provided under the waiver, reflects a failure to consider the negative impact of these changes on the health care safety net, and, with respect to the Tribal Notice, misrepresents the impact of the changes proposed to the FQHC and pharmacy benefits currently covered through Medi-Cal managed care plans under the Waiver.

Namely, the Tribal Notice included the following statement on page 2:

> **IMPACT TO FEDERALLY QUALIFIED HEALTH CENTERS (FQHCs)**
>
> Medi-Cal 2020 Section 1115 Waiver. **There is no impact to Federally Qualified Health Centers** since DHCS would not be changing services, rates, or eligibility for programs authorized by the existing waiver authority." [Emphasis added.]

(Doi decl., ¶ 6 & Exh. E.)

Contrary to this representation, the Legislative Analyst's Office has stated that the impact of the Medi-Cal Rx Transition would result in significant losses in revenues for safety net providers, including FQHCs, finding that:

> In addition, health care providers, principally hospitals and community clinics [FQHCs] that are eligible to participate in the 340B drug discount program, would experience a significant loss of earnings currently generated by the margin between what they pay for pharmacy-dispensed drugs and what they charge Medi-Cal managed care plans for those drugs.

(Doi decl. ¶ 12 & Exh. I, pp.0120 to 0143, at p.0122.)

Thus, DHCS' representation of no impact to FQHCs as a result of the Waiver

extension is directly contrary to the findings of the State's own Legislative Analyst, who projected a "significant loss of earnings" for FQHCs if the Medi-Cal Rx Transition proceeds as the State proposes. This completely undermines the entire purpose of the public notice provisions. Inaccurate notice is not effective notice.

Furthermore, the Medi-Cal Rx Transition does not even serve an experimental or demonstration purpose within the meaning of Section 1315. As conceived, experimental projects were "expected to be selectively approved by the Department [of Health & Human Services] and to be those which are designed to improve the techniques of administering assistance." (S. Rep. No. 1589, 87th Cong., 2d Sess. 19, reprinted in 1962 U.S.C.C.A.N. 1943, 1962.) The State has not explained how the Medi-Cal Rx Transition will advance any such purpose, nor would it.

These deficiencies deprived providers and patients from notice and opportunity to comment on the scope and nature of the negative impact of the proposed changes on their ability to provide Medi-Cal covered services to their patients. Moreover, although the State apparently received 271 comments from the public, it has not made those comments publicly available and mischaracterized at least one comment letter that objected to the Medi-Cal Rx Transition in its submission to CMS for approval (a comment letter submitted by plaintiffs). (*See* Doi decl., ¶ 12 & Exh. I, pp.0254 to 0262.)

As DHCS has provided neither timely nor accurate notice of the Medi-Cal Rx Transition, the implementation of the transition must be enjoined.

2. Defendants will be unable to demonstrate that there is a reimbursement mechanism that reimburses health centers at 100% of their actual costs outside of Medi-Cal managed care

a. FQHC reimbursement

This action is brought on behalf of health centers that have been designed by the HRSA as FQHCs. FQHCs, are health centers that receive federal grants under Section 330 of the Public Health Services Act (42 U.S.C. § 254b). Section 330 requires that FQHCs be located in areas designated as medically-underserved, *i.e.*, areas with insufficient health care providers for their population, and FQHCs must treat all patients

regardless of their ability to pay for those services.

The FQHC payment designation entitles the health centers to enhanced payment under Medicaid. Specifically, for the purposes of this case, federal law requires States participating in the Medicaid program to reimburse FQHCs at 100 percent of their actual and reasonable costs of providing FQHC services to Medicaid beneficiaries. (42 U.S.C. § 1396a(bb).) This is accomplished by paying FQHCs a "prospective payment system" or "PPS" rate that is calculated by dividing an FQHC's actual costs for a rate-setting year by the number of patient visits for that year. Alternatively, a State and an FQHC can agree to the payment of an amount established as an "alternative payment methodology" ("APM"), which is based on a methodology other than a PPS rate, but must also reimburse the FQHC at 100 percent of its actual and reasonable costs for providing the FQHC service. This is to avoid a situation where the Medicaid program pays less than its fair share of the costs and the Section 330 grant ends up subsidizing the Medicaid program. It is this payment right that is the subject of this lawsuit.

Beginning in 2011, the State implemented Medi-Cal managed care through a waiver authorized by Section 1115 of the Social Security Act (42 U.S.C. § 1315). Under Medi-Cal managed care, the State enters into contracts with Medi-Cal managed care [health] plans ("MCPs") to pay the MCP a monthly rate for each Medi-Cal beneficiary enrolled in the plan. In return for this "per-member-per-month" or "capitated" payment, the MCP is "at risk" for the cost of Medicaid-covered health care services provided to Medi-Cal beneficiaries assigned to the plan. The MCP, in turn, enters into contracts with providers, including FQHCs, to provide Medi-Cal services to patients at a capitated rate. At the end of each fiscal year, the FQHC submits a reconciliation request, which reconciles the capitated payments received from the MCPs, as well as any interim payments received from the Medi-Cal program, with the amount that the FQHC would have received if it had been paid the PPS rate for the visits for the year.[2]

---

[2] In 2018, 82% of Medi-Cal beneficiaries were covered by and receiving services through a Medi-

One of the benefits that has been provided through Medi-Cal managed care plans in California since 2011 is the pharmacy benefit. The State is authorized to provide the pharmacy benefit via Medi-Cal managed care through 1115 Waiver at issue here. The negotiated reimbursement rate FQHCs receive for pharmacy services via the Waiver approximates the FQHCs actual costs of providing the pharmacy benefit consistent with the federal law governing FQHC reimbursement.

If the FQHC pharmacy benefit is carved out of Medi-Cal managed care as proposed by the State, FQHCs will be left with two options for reimbursement. (WIC § 14132.100(k).) The first is to include the pharmacy benefit in their PPS rates; the second is to be reimbursed without recognition of their FQHC status at a rate lower than for-profit Medi-Cal providers of the pharmacy benefit.[3] Neither of these options is consistent with the federal law.

b. Current FQHC PPS rates that include the pharmacy benefit are not compliant with federal law

Federal Medicaid law defines a rural health clinic "visit" as "a face-to-face encounter between a clinic patient and any health professional whose services are reimbursed under the State plan." (42 C.F.R. § 447.371(d).) California's Medi-Cal Provider Manual, required by 42 C.F.R. § 431.18, in effect at the time BIPA Section 702 was adopted, defined an FQHC and RHC "visit", in pertinent part, as follows:

> "Visit" means a face-to-face encounter between a clinic patient and any health professional whose services are reimbursed under the state plan. Encounters with more than one health professional, and multiple encounters with the same health professional, that take place on the same day and at a single location constitute a single visit (except for cases in which the patient, subsequent to the first encounter, suffers illness or injury requiring additional diagnosis or treatment). Furthermore, if a patient is receiving only laboratory services or X-ray studies, such actions do not qualify as clinic visits.

(Boyle decl., ¶ 14 & Exh. M.)

Cal managed care plan. California Health Care Almanac, Medi-Cal Facts and Figures: Crucial Coverage for Low-Income Californians (Feb. 2019) p.31 (https://www.chcf.org/wp-content/uploads/2019/02/MediCalFactsFiguresAlmanac2019.pdf).

[3] *See* Section III, A, 3 infra.

When implementing BIPA Section 702, California defined an FQHC and RHC "visit" more narrowly than permitted under 42 C.F.R. § 447.371(d), excluding coverage of most "other ambulatory services" it included in its State plan. Currently, California's "visit" definition includes a face-to-face encounter between an FQHC patient and a physician (defined in accord with 42 U.S.C. § 1395x(r)), physician assistant, nurse practitioner, certified nurse-midwife, clinical psychologist, licensed clinical social worker, visiting nurse, comprehensive perinatal services practitioner, a four-hour day of attendance at an adult day health care center, dental hygienist, a dental hygienist in alternative practice, a marriage and family therapist, and an acupuncturist. (WIC § 14132.100(g); Calif. State Plan, Section 3.1, Attachment 3.1-A, Limitations on Attachment 3.1-A, pp. 3c – 3e, and Attachment 3.1-B, Limitations on Attachment 3.1-B, pp. 3c – 3e.)

Relevant to this case, the pharmaceutical services covered by Medi-Cal through its State plan are not recognized as FQHC or RHC "visits." This results in reimbursement under the PPS rate that is not consistent with federal law requiring Medicaid to reimburse FQHCs a face-to-face encounter between a clinic patient and any health professional whose services are reimbursed under the state plan. The Medi-Cal Rx Transition must be enjoined until an adjustment is made to the PPS rate to include face-to-face encounters with licensed pharmacists as reimbursable "visits".

c. A change in scope of service to carve pharmacy out of an FQHC's PPS rate will by definition fail to result in reimbursement at actual and reasonable cost due to the 80% adjustment factor

State law allows an FQHC to elect to have pharmacy services reimbursed on an fee-for-service basis utilizing the current fee schedules established for those services. (WIC §§ 14132.100(k); 14105.46, 14132.01.) After a scope of service change is submitted, DHCS audits the cost report applying Medicare reasonable cost principles. At the end of the audit of the scope of service change request, before the new rate is established, the difference between the newly calculated cost per-visit rate and the current PPS per-visit rate is multiplied by an 80 percent adjustment factor (colloquially

known as the "20 percent hair cut") to arrive at an amount that is added to the current PPS rate to establish the newly adjusted PPS reimbursement rate. (Cal. State Plan, Att. 4.19-B, p. 6-P, ¶ K.6(b) & (c).) (*See* Doi decl., ¶ 16 & Exh. M, p.9.)

This 80 percent adjustment factor is not codified in WIC § 14132.100 or elsewhere, and conflicts with the requirement that the costs be determined in accordance with the Medicare reasonable cost principles in 42 C.F.R. Part 413. The 80 percent adjustment factor is also by definition inconsistent with the federal mandate requiring Medicaid to establish prospective FQHC rates based on 100 percent of their reasonable and actual costs. For this reason, the "election" provided for in section 14132.100(k) to adjust pharmacy out of an FQHC's clinic base rate as a scope-of-service change is not consistent with federal law and is effectively not an option at all.

d. The Medi-Cal fee for service rate was not designed to reimbursement providers at their actual and reasonable cost of providing the pharmacy benefit

Moreover, once pharmacy benefits are carved out of an FQHC's clinic base rate, pursuant to WIC § 14132.100(k), the available methodologies for reimbursing FQHCs for pharmacy benefits do not qualify as an APM within the meaning of 42 U.S.C. § 1396a(bb)(6), which allows state Medicaid agencies to adopt alternatives to the PPS reimbursement methodology, so long as they meet the following two conditions:

> (A) the methodology is agreed to by the State and the FQHC or RHC; and
>
> (B) the methodology results in payment to the FQHC or RHC of an amount which is at least equal to the amount otherwise required to be paid to the FQHC or RHC under the PPS methodology.

Neither of the two different sets of provisions of the California Welfare and Institutions Code that apply with respect to the dispensing of 340B drugs under Medi-Cal on a fee-for-service basis meet the requirements of an APM.

The first provision, WIC § 14105.46(d), which applies to licensed pharmacies, provides that a Covered Entity "shall bill an amount not to exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code [the 340B program], plus the

professional fee pursuant to Section 14105.45 or the dispensing fee pursuant to section 14132.01." Section 14105.45 limits reimbursement for FQHCs participating in the 340B program to an amount not to exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with 42 U.S.C. § 256b, plus the professional fee. State Plan Amendment 17-002 provides for a "professional dispensing fee" of either $13.20 or $10.05 depending on the pharmacy's total (Medicaid and non-Medicaid) annual claim volume. There has been no effort to establish determine whether the professional dispensing fees contains in State Plan Amendment 17-002 cover the actual and reasonable cost of an FQHC in providing the pharmacy benefit. (*See* Boyle decl., ¶ 9 & Exh. H (Mercer report), p.15 (only .2% of usable responses to survey regarding dispensing fee costs were received from FQHC/RHC pharmacies).)

The second provision, WIC § 14132.01 applies to nonprofit clinic dispensaries, rather than licensed pharmacies, and applies "[n]otwithstanding any other provision of law" to nonprofit FQHCs that have elected to be reimbursed for pharmaceutical goods and services on a fee-for service basis under WIC § 14132.100(k). Section 14132.01 expressly applies to FQHCs that are administering or dispensing drugs to their patients under a dispensary license issued by the California Board of Pharmacy pursuant to California Business & Professions Code §§ 4180 – 4186. (WIC § 14132.01(a).) Section 14132.01(a) provides that these clinics "shall bill and be reimbursed, as described in this section, for drugs and supplies covered under the Medi-Cal program and Family PACT Waiver Program."[4]

Section 14132.01 provides that, as to drugs administered or dispensed through a nonprofit clinic dispensary, if the clinic elects to participate in the 340B program, will be reimbursed at a "cost" defined as follows:

> For purposes of this section, "cost" means an aggregate amount equivalent to the sum of the actual acquisition cost of a drug or supply plus a clinic dispensing fee not to exceed twelve dollars ($12) per billing unit as identified in either the Family PACT Policies, Procedures, and Billing Instructions

[4] "Family PACT" is the name for the Family Planning, Access, Care, and Treatment benefit covered by Medi-Cal under WIC § 14132(aa).

> Manual, or the Medi-Cal Inpatient/Outpatient Provider Manual governing outpatient clinic billing for drugs and supplies, as applicable. For purposes of this section, "cost" for a take-home drug that is dispensed for use by the patient within a specific timeframe of five or less days from the date medically indicated means actual acquisition cost for that drug plus a clinic dispensing fee, not to exceed seventeen dollars ($17) per prescription. Reimbursement shall be at the lesser of the amount billed or the Medi-Cal reimbursement rate, and shall not exceed the net cost of these drugs or supplies when provided by retail pharmacies under the Medi-Cal program."

(WIC § 14132.01(b)(1).)

Despite the fact that the California Legislature adopted this statute in 2004, Medi-Cal has not yet implemented the statutory requirement for covered Medi-Cal drugs other than those dispensed to Family PACT beneficiaries, so again, the section 14132.01 "option" is not really an option for FQHCs.

Neither of the licensed pharmacy reimbursement methodologies described in WIC §§ 14105.45 and 14105.46, nor the clinic dispensary reimbursement requirements described in WIC § 14132.01, were developed in a manner to ensure that FQHCs would be paid in a manner that reimbursed them for the actual cost of providing pharmacy services consistent with 42 U.S.C. § 1396a(bb).

In sum, the pharmacy benefit is an optional Medicaid benefit that the State has opted to provide to Medi-Cal beneficiaries. Having elected to cover pharmacy, the State is obligated to reimburse FQHCs for these services in the manner provided for in 42 U.S.C. § 1396a(bb).

3. Federal law preempts California's attempt to garner the benefits of the 340B program for itself by depriving Covered Entities of the benefits in the name of avoiding duplicate discounts

The 340B Drug Discount Program allows FQHCs and other Covered Entities[5] that provide services to underserved areas or populations at no cost or on a sliding fee scale basis to buy certain outpatient drugs at a discount, but seek reimbursement through the patient or a third-party payer at a non-discounted price, thereby providing an additional

[5] A "covered entity" is an entity that Congress has identified as eligible for discounts under the 340B discount drug program in 42 U.S.C. § 256b(a)(4), hereafter referred to as a "Covered Entity" or "Covered Entities."

revenue stream for the covered entity. The program helps a participating FQHCs defray other operating losses, including costs incurred by providing care to under-or uninsured patients. Drug manufacturers participating in Medicaid are required to participate in the 340B Program.

In establishing the 340B discount drug program the Conference Report (H.R. Rep. No. 102-384 (II) (1992)) (Boyle decl., ¶ 9 & Exh. H) stated its intention regarding the purposes of the program, in pertinent part, as follows:

- "The Committee emphasizes that participation by a 'covered entity' in the price reductions under these agreements is completely at the option of each entity."
- "In giving these 'covered entities' access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."
- "[T]he Committee emphasizes that the bill does not prohibit the entity from dispensing a drug procured under the terms of this agreement in connection with a clinic visit and including the drug in the cost of the clinic visit for which the clinic bills the State Medicaid program. Because the State receives no separate claim for reimbursement for the prescription, the State will not claim a rebate on that unit of the drug from the manufacturer under the Medicaid rebate agreement, and the manufacturer is not required to make a price reduction twice on the same unit of drug."

The Medi-Cal Rx Transition would undermine the 340B Program by imposing the fee-for-service reimbursement methodology contained in WIC § 14105.46 on FQHCs and other 340B Covered Entities.

Section 14105.46 was added to proposed budget language. Both California's Senate and Assembly Floor analyses included a misleading description of the statutory language proposed by DHCS, implying that it was merely implementing a requirement of federal Medicaid law, and that "Federal rules require entities dispensing 340B purchased drugs to Medi-Cal enrollees to pass the discount on by only billing Med-Cal the actual acquisition cost plus the dispensing fee as contained in state statute." (Boyle decl., ¶¶ 2-4 & Exhs. A-C.) In fact, federal law contained no such requirement.

When the federal Health & Human Services ("HHS") sub-agency, the Health

Resources & Services Administration ("HRSA") initially adopted a mechanism to prevent State Medicaid Agencies from improperly collecting duplicate discounts, in 1993, it included three primary elements (see Boyle decl., ¶¶ 5 & 6 & Exhs. D & E):

1. It established a Medicaid Exclusion File and required covered entities to answer "yes" or "no" to the question of whether or not, as to Medicaid fee-for-service beneficiaries, they were dispensing 340B drugs;

2. It clarified that as to FQHCs and other Covered Entities that were dispensing drugs to Medicaid beneficiaries that were billed as part of an all-inclusive rate, there was no risk of a duplicate discount,[6] thus no special requirements or obligations on the part of either the State or Covered Entities; and

3. It initially adopted a requirement that 340B drugs be billed to Medicaid at actual acquisition cost plus a dispensing fee established by the State Medicaid Agency. This element was **retracted by HRSA on March 15, 2000** (65 Fed. Reg. 13983 at 13984 (Mar. 15, 2000) [see Boyle decl., ¶ 7 & Exh. F]).

Federal law expressly preempts State development of mechanisms to avoid 340B duplicate discounts with respect to Medicaid fee-for-service beneficiaries in 42 U.S.C. § 256b(a)(5)(A)(ii) because the HHS Secretary timely established a mechanism to prevent duplicate discounts.

In short, Congress authorized the Secretary of HHS to create an exclusive mechanism to avoid duplicate discounts on drugs purchased through the 340B program, so long as it did so in a timely manner. (42 U.S.C. §§ 256b(a)(5) & 1396r-8(a)(5).) Namely, if the Secretary [did] not establish a mechanism under section 256b(a)(5)(A) within 12 months of the date of enactment [Nov. 4, 1992], States would be permitted to adopt mechanisms to avoid duplicate discounts. (42 U.S.C. § 1396r-8(a)(5).)[7] Since

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[6] A duplicate discount occurs when a Covered Entity purchases 340B drugs from the manufacturer at a discounted price and the State later seeks a rebate from the manufacturer for the same drugs.

[7] Had the Secretary failed to adopt a mechanism, the State was permitted to require each covered entity to inform the State Medicaid Agency when it was seeking reimbursement for a 340B drug, and the State was required to "provide a means by which a covered entity shall indicate on any drug reimbursement claims form . . . that a unit of the drug that is the subject of the form is subject" to a discount under 340B, whereupon the State would be prohibited from

HRSA adopted a mechanism to prevent duplicate discounts in a timely manner, California's mechanism, as set out in WIC § 14105.46 is preempted by federal Medicaid law.[8]

Federal Medicaid law creates a preference for 340B Covered Entities, and reimbursing these entities for 340B drugs at a rate that is lower than that paid to any other Medi-Cal provider eliminates the benefit intended by Congress and obstructs the proper functioning of the 340B discount drug program.[9]

The duplicate discount avoidance mechanism adopted by HRSA required 340B Covered Entities to enroll in the Medicaid Exclusion File, indicating whether they dispensed 340B drugs to Medicaid beneficiaries, and prohibited State Medicaid Agencies from claiming rebates on drugs dispensed to Medicaid beneficiaries as to these Covered Entities.

Under the Medi-Cal Rx Transition, Covered Entities will continue to purchase prescription drugs at the 340B discounted rate and the Medi-Cal program will reimburse at the actual acquisition cost plus a nominal dispensing fee. The unilateral adoption by California of a requirement to reimburse drugs at the actual acquisition cost in order to aid in the identification of 340B drugs, and to identify 340B drugs on a claim-by-claim basis, rather than using the Medicaid Exclusion File as adopted by HRSA, not only violates the restrictions placed on States by Congress, but increases the administrative costs of operating a compliant 340B program and decreases reimbursement. The increase in costs arises primarily from the requirement of claim-by-claim identification of

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claiming a rebate with respect to such drug. ((42 U.S.C. §§ 256b(a)(5)(A)(ii) & 1396r-8(a)(5)(C)).

[8] *See* 58 Fed. Reg. 27293 May 7, 1993); initial mechanism finally adopted at 58 Fed. Reg. 34058 (June 23, 1993). (Boyle decl., ¶ 7 & Exh. F.)

[9] For-profit and other non-340B pharmacies are generally reimbursed at CMS's National Average Drug Acquisition Cost (NADAC), avoiding the administrative burdens associated with an invoice-by-invoice determination of acquisition cost (*see https://files.medi-cal.ca.gov/pubsdoco/ncpdp/pharmacy_fee_for_service_cod_faq.aspx).* 340B Covered Entities, however, are required to bill Medi-Cal at the "entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code." (California State Plan, Supplement 2 to Attachment 4.19-B, Methods and Standards for Establishing Payment Rates – Prescribed Drugs.)

340B drugs. The decrease in reimbursement arises from the requirement that Covered Entities bill at the "entity's actual acquisition cost for the drug, rather than using the generally applied National Average Drug Acquisition Cost ("NADAC"), used by other Medi-Cal providers, which is a rate that is generally higher than actual acquisition cost because it excludes 340B from the calculation. (Boyle decl., ¶ 15 & Exh. N.) The discriminatory reimbursement methodology adopted by the State in Section 14105.46 also undermines the Congressional scheme creating the 340B program, which is centered around ensuring that the financial benefit of 340B discounts accrue to the specified Covered Entities it identified in 42 U.S.C. § 256b(a)(4).

When Congress adopted the 340B program, it stated that it intended "to enable [Covered Entities] to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." (H.R. Rep. No. 102-384 (II), at 12 (1992).) It also stated its intention that that "participation by a 'covered entity' in the price reductions under these agreements is completely at the option of each entity." (H.R. Rep. No. 102-384 (II) (1992) (Boyle decl., ¶ 9 & Exh. H).)

Under both the fee-for-service duplicate discount avoidance mechanism adopted by HRSA, and under the Medicaid managed care duplicate discount avoidance mechanism established in 42 U.S.C. § 1396r-8(j), Congress established a preference under Medicaid. If the Covered Entity elected to dispense 340B drugs to Medicaid beneficiaries, the State was prohibited from claiming the benefit of a rebate on such drug. By reimbursing these drugs at actual acquisition cost, the Department is essentially improperly forcing the 340B covered entities to collect these rebates on the State's behalf. As stated by former DHCS director Toby Douglas when questioned by a reporter about the adoption of Section 14105.46, the change in the State's long-standing policy will align costs up front, calling it "a cleaner way of doing the process." This way, he said, savings will be realized from 340B discounts at the time the claim is paid, instead of

forcing the state to "chase manufacturers for rebates" up to six months later.[10] On the flip side, by paying Covered Entities only the actual acquisition cost plus a nominal dispensing fee, the State is depriving Covered Entities from the benefits of the 340B program.

For these reasons, Section 14105.46 stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress with respect to the 340B program and should be declared void as both expressly and impliedly preempted by applicable federal law.

B. Plaintiffs And Their Patients Will Suffer Irreparable Harm In The Absence Of Preliminary Relief

In a reported dated April 5, 2019, the California Legislative Analyst's Office found that health care providers, principally hospitals and community clinics that are eligible to participate in the 340B drug discount program "would experience a significant loss of earnings currently generated by the margin between what they pay for pharmacy-dispensed drugs and what they charge Medi-Cal managed care plans for those drugs" as a result of the Medi-Cal Rx Transition. (LAO Report, p.1, attached as Exh. B to Exh. I of the Doi decl.)

The LAO further found that the Medi-Cal Rx Transition could have negative impacts on care coordination and management. (LA Report, p.14.) The LAO noted that Medi-Cal managed care plans' primary responsibilities include providing care coordination and management for their members, and that the care coordination and management could be negatively impacted under the carve out in two ways:

- ***Less Timely Prescription Drug Utilization Information for Medi-Cal Managed Care Plans*.** Medi-Cal managed care plans, and/or their contracted providers, currently receive data – often in real-time – from pharmacies when their members fill their prescriptions. These data assist the managed care plan – particularly for relatively sick members enrolled in disease management programs – in coordinating their members' care. For example, by informing a managed care plan when a prescription is filled, the plan's designated care coordinator can learn whether the

[10] *See* Discount Drug Monitor, "States Seek to Limit 340B Reimbursement Under Medicaid," July 6, 2009. (Boyle decl., ¶ 16, Exh. O.)

> member is adhering to the schedule recommended for her or his prescription. … [C]ertain drugs are currently carved out of managed care. While DHCS provides FFS prescription drug utilization data to managed care plans on behalf of their members for currently carved out drugs, it is our understanding [ ] that this data does not arrive from DHCS in a timely enough manner to assist plans' care coordination activities.
>
> - ***Opioid Curtailment Programs*.** Some Medi-Cal managed care plans have proactively developed initiatives aimed at curtailing the overuse of prescription opioids, which were responsible for around 1,500 overdose deaths in the state in 2017. These programs, for example, place elevated prescribing restrictions on opioids and attempt to educate prescribers on safe opioid prescribing practices. In many counties, these initiatives have likely contributed to dramatically reducing the number and potency of opioid prescriptions among Medi-Cal members. Under the carve out, it is uncertain whether such initiatives by Medi-Cal managed care plans would continue.

(LAO Report, p.14.)

As indicated in the declaration of Ricardo Roman, Chief Financial Officer of the Family Health Centers of San Diego ("FHCSD"), a health center that provided health care services to over 200,000 patients in 2019, almost 80% of whom were at or below 100 percent of the federal poverty guideline and almost 97% of whom were at or below 200 percent of the federal poverty guideline, FHCSD used the 340B Program savings to provide affordable patient medication, HIV and Hep C patient screening and care management, expanded patient vision services, increased access to mobile medical and mental health services, and many other programs. (*See* decl. of Ricardo Roman, ¶¶ 4, 7.) If the Medi-Cal Rx Transition is allowed to occur, these patient services and programs are at risk of being reduced significantly or eliminated entirely. (*Id*., ¶ 9.) Patients will see longer wait times for appointments and decreased access to key support services such as patient-centered care coordination. (*Id*.) Additionally, there will be an impact to the ratio of provider and clinic support staff to patients, resulting in negative patient outcomes. (*Id*.) The Medi-Cal program and entire FQHC medical home/patient-centered care coordination model will have increased costs due to higher emergency room utilization, increased hospitalizations due to complications from chronic diseases (*e.g*., diabetes, congestive heart failure), and decreased ability to provide such services as diabetes patient support, medication therapy management, and expanded access to

primary care, mental health, and substance abuse treatment. (*Id*.) Strategic planning involving sustaining necessary resources to support important clinic functions that require more resources, such as outreach, education, care coordination, and diabetes support will be impacted severely. (*Id*.)

The Desert Aids Project ("DAP"), an FQHC and Ryan White grantee organization, serves over 7,000 active clients, almost a third of which are living with, affected by, or at-risk for HIV/AIDS, uses its 340B savings to continue HIV and STD testing services aimed at stopping the spread of the HIV epidemic; continue providing timely access to primary care, mental health, substance abuse, and prescription drug outpatient services for its patient population; provide medication assistance for patients who could not afford medications otherwise; pay for DAP's four infectious disease physicians; and increase services (dental, housing, community health, STI clinic, and various vocational programs). (Decl. of David Brinkman, ¶¶ 2, 6.) The Medi-Cal Rx Transition would put 30-40 jobs at risk in DAP's community health, client support services, and HIV/STD testing programs. (*Id*., ¶ 8.) The Medi-Cal program and the entire FQHC medical home/patient-centered care coordination model will have increased costs due to higher emergency room utilization, increased hospitalizations due to complications from chronic diseases (*e.g.*, HIV, Hepatitis, congestive heart failure), and decreased ability to provide such services as medication therapy management, and expanded access to primary care, mental health, and substance abuse treatment. (Id.) Strategic planning involving sustaining necessary resources to support important clinic functions that require more resources, such as outreach, education, care coordination, and STD testing will also be impacted severely. (*Id*.)

In addition, the loss of 340B savings will adversely impact patient services and programs such as having a call center, referral center, diabetes patient support, medication therapy management, medication-assisted treatment services for patients suffering from opioid use disorder, case management, transportation assistance, onsite pharmacies, pharmacy technicians, care coordinators, and in-house behavioral services,

and dental services, which will be at risk of being significantly reduced or eliminated. (Decls. of Ronald E. Castle, ¶¶ 13-16; Francisco Castillon, ¶¶ 20, 23-26; Germano decl., ¶¶ 2 &16; Constance Kirk, ¶¶ 7-9; Daniel L. Santi, ¶¶ 6 & 9.) This, in turn, puts FQHC patients at risk for increased access to care issues, as well as health problems that increase health care costs to the entire primary care medical home health care system. The loss of services, higher costs, poorer patient outcomes, and loss of employee positions are examples of irreparable injuries that will befall FQHCs, their patients, and their employees if the Medi-Cal Rx Transition is not enjoined. The effect of this pharmacy transition is a major threat to the sustainability of California's primary care safety net program. (Brinkman decl., ¶ 8; Roman decl., ¶ 9.)

C. The Balance Of Equities Tips In Plaintiffs' Favor

The balance of the equities here lies with maintaining the status quo to protect the providers on the front lines in this ongoing State of Emergency and their patients. There is simply no rational reason for driving the Medi-Cal Rx Transition forward while the State is otherwise pausing the overall transition from Medi-Cal managed care to the CalAIM program. Moreover, to the extent DHCS has begun to implement the Medi-Cal Rx Transition, it has done so without authorization from CMS and at its peril, and this activity was improper and itself should be enjoined. As noted above, DHCS recognized the harm to health centers and approved mitigation through the supplemental payment pool, but the SPP will not mitigate the harm in the short- or long-term. (*See* Germano decl.)

D. Issuance Of A Temporary Restraining Order Is In The Public Interest

The issuance of a temporary restraining order is in the public interest in order to protect the status quo, namely the ability of the health centers that are on the front line of the pandemic to continue to make care accessible to their patients, the populations most vulnerable in the pandemic. On the flip side, the State projects it will save less than three percent of the cost of providing the pharmacy benefit if it is allowed to implement the pharmacy benefit carve out from Medi-Cal managed care.

E. No Bond Should Be Required

The Ninth Circuit has found that Rule 65(c) invests the district court "with discretion as to the amount of security required, *if any.*" (*Barahona–Gomez v. Reno,* 167 F.3d 1228, 1237 (9th Cir.1999) (citing *Doctor's Assoc., Inc. v. Stuart,* 85 F.3d 975, 985 (2d Cir.1996)).) The district court may dispense with the filing of a bond when it concludes there is no realistic likelihood of harm to the defendant from enjoining his or her conduct. (*Barahona–Gomez,* 167 F.3d at 1237.) This is just such as action. Plaintiffs do not seek to upset the *status quo* but to maintain the *status quo*. If the Medi-Cal Rx Transition is enjoined, then Medi-Cal pharmacy benefits will remain just as they are now. This will not cause any injury to the State because the Medi-Cal Rx Transition has not even been approved by the Secretary. As such, any alleged monetary savings to the State are purely speculative. As plaintiffs and their patients would suffer the most harm due to the change to the provision of pharmacy benefits, and as any damage to the State is purely speculative, plaintiffs should not be required to post a bond. (*See, e.g*. *Bass v. Richardson*, 338 F.Supp. 478 (S.D.N.Y.1971) (plaintiffs not required to post injunction bond in action challenging cut-back of medical benefits by state).)

IV. CONCLUSION

For the foregoing reasons, plaintiffs request the issuance of a temporary restraining order preventing defendants from further implementation of the Medi-Cal Rx Transition, or, in the alternative to enjoin the State's Waiver extension request.

DATED: November 9, 2020

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