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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.

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

Defendants.

Case No. 2:20-CV-02171-JAM-KJN4

PLAINTIFFS' MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO DIRECTOR MICHELLE BAASS' MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT

Judge: Hon. John A. Mendez
Date: May 3, 2022
Time: 1:30 p.m.
Place: Courtroom 6

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I. INTRODUCTION

Plaintiffs' First Amended Complaint ("FAC") alleges clear and complete claims against the Director and the Centers for Medicare & Medicaid Services ("CMS") stemming from the implementation of Medi-Cal Rx. Plaintiffs have provided numerous factual allegations supporting their Section 1983 claim to enforce their right to cost-based reimbursement under federal law, which California's pharmacy fee-for-service ("FFS") system fails to provide. As Federally Qualified Health Centers ("FQHCs"), Plaintiffs are a unique type of Medi-Cal provider with a specific, congressionally mandated reimbursement standard set forth in 42 U.S.C. § 1396a(bb) ("Section 1396a(bb)"). The Director has failed to meet that standard. Had the Director considered the Section 1396a(bb) standard when the Department developed and adopted the FFS system for pharmacy services in State Plan Amendment 17-002 ("SPA 17-002"), or sought approval for Medi-Cal Rx, this litigation could have been avoided. Instead, the Director essentially admits that the Department chose to ignore federal requirements that specifically apply to FQHC reimbursement when developing SPA 17-002 and implementing Medi-Cal Rx.

Rather than address Plaintiffs' allegations, the Director takes this Court on a frolic and detour about steps that Plaintiffs can purportedly take in order to avoid the State's continuing violation of their federally secured right to reimbursement. Presumably, Plaintiffs could also hold bake sales or crab feeds in order to make up for the shortfall created by the State's implementation of Medi-Cal Rx, but that is not the point. The point is that the State has a legal obligation to comply with federal law, which includes reimbursing FQHCs for pharmacy services they provide to Medi-Cal patients. Federal law also gives FQHCs the benefit of the 340B drug discount program to ensure that FQHCs would be able to provide pharmacy services to their patients, while ensuring the State could not siphon FQHC grant funds intended for the uninsured.

As Plaintiffs state in the FAC, Medi-Cal Rx unlawfully relieves the State of its obligation to pay its fair share of Plaintiffs' costs of service while depriving them of critical funding that Congress intended FQHCs to use to close healthcare gaps and combat

inequity in medical services. Therefore, the Complaint stands. The Director's motion to dismiss must be denied.

II. LEGAL STANDARDS

The Court's role in reviewing a Rule 12(b)(6)[1] motion to dismiss is "necessarily a limited one." *Mohamed v. Jeppessen Dataplan, Inc.*, 614 F.3d 1070, 1099-1100 (9th Cir. 2010) (quoting *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)). Rather than "prematurely" decide if the plaintiff will "ultimately prevail" on their claims, courts only must evaluate whether the complaint states a claim upon which relief may be granted. *Id.* Federal courts must "take all allegations of material fact as true and construe them in the light most favorable to the moving party." *Steinle v. City and Cnty. of S.F.*, 919 F.3d 1154, 1160 (9th Cir. 2019). To avoid dismissal under Rule 12, plaintiffs need only provide "factual content [that] allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A plaintiff's complaint should not be dismissed under Rule 12 unless "a plaintiff can provide *no set of facts in support* of his claim that would entitle him to relief." *Parks Sch. of Bus., Inc. v. Symington*, 51 F.3d 1480, 1484 (9th Cir. 1995) (emphasis added). Even if the Court grants the motion, dismissal without leave to amend is proper only in "extraordinary" cases. *Broam v. Bogan*, 320 F.3d 1023, 1028 (9th Cir. 2003).

III. ARGUMENT

A. Plaintiffs Have Stated A Valid Section 1983 Claim Challenging California's Flawed Fee-For-Service Reimbursement System.

1. It is undisputed that Plaintiffs may bring a Section 1983 action to vindicate their right to reimbursement under Section 1396a(bb).

A well-pled Section 1983 claim must show that the defendant acted under the color of state law and deprived them of a right secured under federal law. *See* 42 U.S.C.

[1] The Director also references Rule 12(b)(1) in her notice and on page 11 of her brief. Because the legal standards addressed in the brief relate solely to Rule 12(b)(6), Plaintiffs likewise only address the sufficiency of the FAC under Rule 12(b)(6).

§ 1983; *West v. Atkins*, 487 U.S. 42, 48 (1988). Here, Congress "confer[red] individual rights" upon FQHCs that "plainly requires state plans to pay for services furnished by FQHCs." *Cal. Ass'n of Rural Health Clinics v. Douglas*, 738 F.3d 1007, 1013 (9th Cir. 2013) (hereafter "*CARHC*"); *see also* 42 U.S.C. § 1396a(bb) (establishing the FQHC-specific payment standard). Plaintiffs, as FQHCs, "have a private right of action to bring a § 1983 claim to enforce 42 U.S.C. § 1396a(bb)." *CARHC*, 738 F.3d at 1013. Section 1396a(bb) is clear in its requirement for the "State [to] pay 100 percent of [FQHCs'] costs" for their services. *Tulare Pediatric Health Care Ctr. v. State Dept. of Health Care Servs.*, 41 Cal. App. 5th 163, 170 (2019).

2. Plaintiffs' FAC sufficiently alleges that the State's FFS system for pharmacy services violates their right to reimbursement under 42 U.S.C. § 1396a(bb).

Plaintiffs have stated an actionable Section 1983 claim against the Director. Plaintiffs have alleged that the Director is acting under color of state law. FAC ¶ 107. Plaintiffs have also alleged that California must abide by federal Medicaid law, including Section 1396a(bb). *Id.* ¶ 55. As FQHCs, Plaintiffs must be reimbursed according to Section 1396a(bb). *Id.* ¶ 31. Plaintiffs further allege that California's FFS reimbursement method consists of two components, both of which are inadequate because they do not account for FQHCs' costs in acquiring drugs or dispensing them. *Id.* ¶ 59. Plaintiffs' allegations provide substantial support for their claim that the FFS reimbursement rate under SPA 17-002 fails to reimburse each FQHC at 100 percent of its costs as required by Section 1396a(bb). *See CARHC*, 783 F.3d at 1013.

The Director's motion to dismiss does not assert that the FAC lacks sufficient factual content to state a claim, nor can it. Rather, the Director asserts her own *differing legal interpretations* to attack the merits of Plaintiffs' Section 1983 claim. For example, the Director argues that Plaintiffs' position that "the costs and dispensing fees under SPA 17-002 are insufficient to meet the PPS rate requirements … is fundamentally misguided." Def. Br. at 7-8. Not so. It is the Director's *framing of the issue* that is fundamentally misguided for two reasons.

First, Plaintiffs have sufficiently alleged that the FFS reimbursement violates federal law because the drug costs and dispensing fees under SPA 17-002 were not designed to, and do not, reimburse FQHCs at 100 percent of their costs. Plaintiffs' allegations, taken as true, assert that Section 1396a(bb) creates the 100 percent reimbursement standard, and that standard applies to the FFS system. FAC ¶¶ 31, 60, 66.

The California Legislature chose to permit FQHCs to elect reimbursement for pharmacy services under a FFS alternative payment methodology ("APM") to the usual PPS system. *See* Cal. Welf. & Inst. Code § 14132.100(k); 42 U.S.C. § 1396a(bb)(6). An APM "can take a number of forms" so long as it meets the requirements of Section 1396a(bb)(6). *Pee Dee Health Care, P.A. v. Sanford*, 509 F.3d 204, 207 (4th Cir. 2007). California's APM allows Plaintiffs to "carve out" their pharmacy costs from their PPS rate and be reimbursed on a "fee schedule" to be established by the Director, in compliance with Federal Medicaid law. *See* Cal. Welf. & Inst. Code § 14132.100(k); 42 U.S.C. § 1396a(bb)(6)(B).

Before Medi-Cal Rx, Plaintiffs' pharmacy costs were "carved out" and reimbursed according to negotiated rates in their Managed Care Plan contracts, which met the requirements of an APM. That is no longer the case. As the Director admits, FQHCs are now "reimbursed under the specific [FFS] rate schedule applicable to pharmacy services" under Medi-Cal Rx. Def. Br. at 5:18-19. It is the Director's obligation to make certain that the State's FFS rate schedule complies with Federal Medicaid law when applied to FQHC's. Plaintiffs have alleged that the FFS rate for pharmacy services does not meet the requirements of an APM under Section 1396a(bb), *i.e.*, the 100 percent reimbursement standard, as applied to FQHCs in particular. Plaintiffs' allegations are more than sufficient to survive the Director's motion.

The FAC also explains why the FFS rates do not satisfy the requirements specific to FQHC's as to dispensing fees. The federal Covered Outpatient Drug Rule directed States to consider that 340B covered entities like Plaintiffs "may have additional costs

associated with dispensing [340B] drugs compared to a retail pharmacy." *Id.* ¶ 48. Yet, instead of considering FQHCs' drug dispensing costs as required, the Department relied on the Mercer Report, which expressly omitted FQHC costs from its analysis. *See Id.* ¶¶ 52-53.

Plaintiffs further allege how California's FFS reimbursement system under-reimburses them for their pharmacy costs in violation of federal law. *See, e.g.*, *id.* ¶¶ 61-63 (describing drug manufacturer overcharges for 340B medications that the FFS system does not reimburse); *id.* ¶¶ 58, 64 (describing how the FFS dispensing fees are artificially low because the Mercer Report excluded FQHC dispensing costs). Plaintiffs have alleged more than enough "factual content" for the Court to reasonably infer that the FFS system fails to adequately reimburse them for treating Medi-Cal patients. *Iqbal*, 556 U.S. at 678.

The Director disputes Plaintiffs' allegations on the facts – claiming that the Mercer Report adequately considered FQHC pharmacy dispensing and pharmacy costs. A resolution of these factual disputes is premature at the motion to dismiss stage.

Moreover, the Director argues the merits of Plaintiffs' claims, asserting her opinion that "the requirements of Section 1396a(bb) are simply not relevant to FFS reimbursement under SPA 17-002." Defs. Br. at 8:24-25. The Director is simply wrong, After Medi-Cal Rx, the two are directly connected. First, while the FFS rate may be sufficient for other Medi-Cal providers, as the Ninth Circuit has held, Section 1396a(bb) creates a specific reimbursement standard for FQHCs. *See CARHC*, 738 F.3d at 1013. As alleged in the FAC, because the FFS system does not account for FQHCs' specific costs, it fails to comply with Section 1396a(bb)'s reimbursement standard. *See* FAC ¶ 59. Second, Section 1396a(bb) requires that FQHCs be reimbursed at 100 percent of costs whether the FQHCs are being reimbursed under the PPS methodology (42 U.S.C. § 1396a(bb)(2)-(4)) or under an alternative payment methodology (42 U.S.C. § 1396a(bb)(6)(B)). *See Tulare Pediatric*, 41 Cal. App. 5th at 171; *see also* FAC ¶¶ 31, 59. Yet, the Director completely ignores this alternative payment methodology provision in her interpretation of Section 1396a(bb) and its applicability to the FFS system.

The Director also ignores case law that is directly contrary to her position: Section 1396a(bb) "is clear: the State must pay 100 percent of the [FQHCs'] costs for the defined services," and "the State cannot shirk its responsibility to pay health centers' full costs." *Tulare Pediatric*, 41 Cal. App. 5th at 171. Instead, the Director attempts to interpret the plain language of Section 1396a(bb) differently. But none of the cases cited by the Director hold that Plaintiffs are not entitled to 100 percent reimbursement under federal law – the cases only describe the structure and history of Section 1396a(bb). *See, e.g., Three Lower Cntys. Cmty. Health Servs., Inc. v. Maryland*, 498 F.3d 294, 297-98 (4th Cir. 2007) (discussing the legislative history of Section 1396a(bb) and the amendment to "relieve health centers from having to supply new cost data every year.") The Director cannot turn a blind eye to federal law and legal precedent in order to justify short-changing Plaintiffs under the FFS system.

In sum, Plaintiffs have stated a more than plausible Section 1983 claim under Section 1396a(bb) based on the flawed and non-compliant FFS reimbursement system as it is applied to FQHC's. *See CARHC*, 738 F.3d at 1013; *Tulare Pediatric*, 41 Cal. App. 5th at 170.

3. The PPS carve-in "option" is outside the FAC and does not cure the flaws of applying the FFS rates to FQHC pharmacy services.

The Director does not dispute any of the flaws of the FFS system alleged in the FAC. Instead, the Director argues that Plaintiffs can just avoid the FFS system – and, conveniently, the State's violations of federal law – by incorporating ("carving in") the costs of pharmacy services into their PPS per visit reimbursement rate. *See* Def. Br. at 8:6-9. The Director further argues that "it is untrue" that Medi-Cal Rx "requires Plaintiffs to receive reimbursement under the FFS fee schedule for pharmacy services approved under SPA 17-002." Def. Br. at 7-8. The Director's arguments are misguided, and again prematurely attack the merits of Plaintiffs claims, which are not at issue in this motion. *See Scheuer*, 416 U.S. at 236. Moreover, the Director's diversion to the PPS system misses the point: whether Medi-Cal Rx *requires* Plaintiffs to receive reimbursement under

the FFS system is unrelated to the Director's and CMS' failure to consider and comply with Section 1396a(bb)'s requirement in creating and adopting the FFS reimbursement rate for FQHC pharmacy services. *See* FAC ¶¶ 61-63, 66, 109-111. Indeed, the Director admits that at least some FQHCs – including Plaintiffs – are currently subject to the FFS reimbursement rate under Medi-Cal Rx. *See* FAC ¶ 41; Def. Br. at 5:18-19 (Under Medi-Cal Rx FQHC's are "reimbursed under the specific [FFS] rate schedule applicable to pharmacy services."). The California Legislature gave FQHCs the right to seek reimbursement for pharmacy service under a FFS methodology. The Director cannot veto this legislative grant, and decline to implement the FFS system in a lawful manner merely because she prefers the PPS methodology.

Indeed, even if Plaintiffs could simply "switch" to the PPS system, the Director fails to show that the PPS rate complies with Section 1396a(bb). It does not. For example, the process of carving pharmacy costs into the PPS rate requires an automatic 20 percent reduction in any rate increase, regardless of Section 1396a(bb). *See* State Plan, Att. 4.19-B, p.6P-Q, ¶¶ K(6)(b)-(c). Also, state law omits pharmacy visits as billable provider "visits." *See* Cal. Welf. & Inst. Code § 14132.100(g). Further, there is no mechanism for adjusting PPS rates in the face of escalating pharmacy costs. *See* Cal. Welf. & Inst. Code § 14132.100(e)(3) ("A change in costs is not, in and of itself, a scope-of-service change …"). Additionally, the PPS system does not comply with the timely payment requirements in 42 U.S.C. § 1396a(bb)(5) and 42 C.F.R. § 447.45(d), instead making full payment for claims three or more years after services are delivered. *See, e.g.*, *United States v. Ne. Med. Servs., Inc.*, No. C 10-1904 CW, 2014 WL 1992651, at *9 (N.D. Cal. May 13, 2014) (holding that the Director failed to meet the timely payment requirements for supplemental payments). Whether the PPS "option" would fully reimburse Plaintiffs for pharmacy services as required by federal law creates countless legal issues in itself, none of which may be determined at the pleading stage. *See Van Buskirk v. Cable News Network, Inc.*, 284 F.3d 977, 980 (9th Cir. 2002) ("Ordinarily, a court may look only at the face of the complaint to decide a motion to dismiss.").

In short, Plaintiffs' allegations are more than sufficient to state a Section 1983 claim. Accepting Plaintiffs' allegations as true, Plaintiffs have a federally secured right to reimbursement that the Director – by implementing Medi-Cal Rx – is violating with a flawed, non-compliant reimbursement system. The Director does not dispute the problems with the FFS system as applied to FQHCs, but instead focuses on a separate, reimbursement system, irrelevant to Plaintiffs' claims, and with its own deficiencies, that cannot be resolved on a pleadings motion. Accordingly, the Director's motion to dismiss Plaintiffs' first cause of action should be denied.

B. Plaintiffs Have Stated A Valid Claim For Declaratory Relief Based On Federal Preemption And The Administrative Procedure Act.

Federal law provides for declaratory relief in a case "of actual controversy" within this Court's jurisdiction. 28 U.S.C. § 2201(a). Cases arising under federal law are within federal courts' subject matter jurisdiction. *See* 28 U.S.C. § 1331. Courts may "declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." *Id.* § 2201(a).

The existence of another adequate remedy "does not preclude a declaratory judgment that is otherwise appropriate." Fed. R. Civ. P. 57. In fact, declaratory relief "may be an effective alternative to injunctive relief," as Congress "plainly intended . . . the Federal Declaratory Judgment Act [] to provide a milder alternative to the injunction remedy." *Pratt v. Wilson*, 770 F. Supp. 539, 545 (E.D. Cal. 1991) (quoting *Steffel v. Thompson*, 415 U.S. 452, 466-67 (1974)).

Here, Plaintiffs have met their burden to state a claim for declaratory relief. First, federal preemption is a valid jurisdictional basis for declaratory relief. Second, declaratory relief is a proper remedy for Plaintiffs' claims under both Section 1983 and the Administrative Procedure Act.

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1. Because they allege Medi-Cal Rx conflicts with federal law, Plaintiffs have sufficiently alleged a claim for declaratory relief.

Plaintiffs "may ordinarily seek declaratory and injunctive relief against state action on the basis of federal preemption" regardless of whether "an explicit statutory provision establishing a cause of action" exists. *Bernhardt v. L.A. Cnty.*, 339 F.3d 920, 929 (9th Cir. 2003) (quoting *Bud Antle, Inc. v. Barbosa*, 45 F.3d 1261, 1269 (9th Cir. 1994)). Indeed, the Supreme Court has held that federal courts have the equitable power to "enjoin unconstitutional actions by state and federal officers" when a plaintiff shows that "federal law immunizes him from state regulation." *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 327 (2015).

Here, Plaintiffs have met their burden to state a claim for declaratory relief based on federal preemption. Plaintiffs' claims based on Section 1396a(bb) are classic federal statute preemption of conflicting state law claims; it does not appear the Director challenges that federal preemption has been alleged with respect to these claims, only whether it applies.

With respect to the 340B claims, first, Plaintiffs allege that California established a mechanism for avoiding 340B duplicate discounts or rebates, even though it did not have the authority to do so. *See FAC* ¶¶ 77-78, 87, 90, 91. A plain reading of the 340B statute shows that a State's authority to adopt its own avoidance mechanism was conditioned on the federal government's failure to do so by November 1993. *Id.* ¶ 77; *see also* 42 U.S.C. § 1396r-8(a)(5)(C). But the federal government developed the Medicaid Exclusion File in June 1993, depriving individual States with authority to regulate 340B drug discounts or rebates. FAC ¶ 87. Nonetheless, California created its own avoidance mechanism that imposes the burden of 340B compliance upon Plaintiffs, while failing to compensate them for the cost of such compliance and depriving them of the savings that supported a variety of patient-centered services in medically underserved communities. *See Id.* ¶¶ 89-91, 93. The State's 340B duplicate discount or rebate avoidance mechanism is built into its FFS reimbursement system, which Medi-Cal Rx imposes upon Plaintiffs. *Id.* ¶ 122.

Yet, CMS approved California's FFS system despite the State's overreach into exclusive federal jurisdiction. *See id.*

Second, Plaintiffs have alleged Congress' goal in creating the 340B Program was to enable Plaintiffs (as 340B covered entities) to provide more services to more patients and Congress declared that the choice of whether to participate in 340B was exclusively at the option of the covered entity. FAC ¶ 25, 80, 81, 91 & 94. Before Medi-Cal Rx, Plaintiffs were able to fulfill Congress' goal by leveraging the savings from 340B discount prices to eliminate traditional barriers to care, such as transportation to appointments, high out-of-pocket costs, and counseling for addiction. *Id.* ¶ 98. Medi-Cal Rx requires Plaintiffs to dispense 340B drugs to Medi-Cal beneficiaries, or not dispense any drugs to them at all. *Id*. ¶¶ 87, 88. Under Medi-Cal Rx, the State itself claims the 340B savings granted by manufacturers, while providing no direct medical services to any patients. *Id*. ¶ 100. CMS still approved Medi-Cal Rx without regard to the purpose of the 340B Program, the effect of Medi-Cal Rx on patient services and access to care, and the burden on Plaintiffs. *See* FAC ¶¶ 68, 84-86. Therefore, Plaintiffs have the right to challenge CMS' actions and seek declaratory relief. *See* 5 U.S.C. §§ 702, 706; *Bernhardt,* 339 F.3d 920 at 929.

The Director's arguments that California's 340B-related regulations are not preempted lack merit. First, the Director argues that Plaintiffs failed to identify any express preemptory language in the federal statute. *See* Def. Br. at 11:20-23. The Director failed to read both the FAC and the statute. Plaintiffs did cite the relevant statutory language that "***If*** the [HHS] Secretary does not establish a mechanism . . .within 12 months of November 4, 1992, the following requirements shall apply." FAC ¶ 77; 42 U.S.C. § 1396r-8(a)(5)(C) (emphasis added). The statute's plain language conditions California's authority to regulate 340B duplicate discounts or rebates on the federal government's failure to act. But the federal government did act, and thus the State has no authority to impose further regulations on the 340B Program. *Id*. ¶ 78.

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Second, the Director conflates the general legality of fee-for-service systems with approval of California's regulation of 340B duplicate discounts or rebates. *See* Def. Br. at 13:4-21. While fee-for-service systems may be the "traditional" Medicaid reimbursement model, California's overreach into 340B regulations is not part of the "only reimbursement model specifically authorized under the Medicaid Act for pharmacy services." Def. Br. at 13:9-19.

Third, the Director misstates the law to conclude that Plaintiffs cannot seek declaratory relief on preemption grounds. The Director states that Plaintiffs must have a private right of action under 340B to challenge the State's regulations, but the Ninth Circuit has held the opposite. *See Bernhardt*, 339 F.3d at 929; *Bud Antle*, 45 F.3d at 1269. The Director cites two federal District Court cases that involved suits for declaratory relief based on challenges to statutes, not federal preemption. *See Am. Video Duplicating, Inc. v. City Nat'l Bank*, No. 220CV04036JFWJPR, 2020 WL 6882735, at *5 (C.D. Cal. Nov. 20, 2020) (denying declaratory relief for a challenge brought under the federal CARES Act); *Li'l Man in the Boat, Inc. v. City and Cnty. of S.F.*, No. 17-CV-00904-JST, 2018 WL 4207260, at *5-*6 (N.D. Cal. Sept. 4, 2018) (denying declaratory relief for a suit brought under California Business & Professions Code section 23300). Unlike the plaintiffs in *American Video* and *Li'l Man*, Plaintiffs here are seeking relief from state regulation that federal law preempts. FAC ¶¶ 122, 131.

Additionally, the Director embellishes the holding of *AIDS Healthcare Foundation v. Douglas*, 457 Fed. Appx. 676, 678 (9th Cir. 2011). There, the Ninth Circuit upheld the dismissal of the complaint because the plaintiff failed to "plausibly [plead] a claim" based on preemption. *Id.* Rather than hold that Welfare and Institutions Code section 14105.46 is categorically "not preempted" by federal law, the Ninth Circuit agreed that the plaintiffs did not plead facts "spell[ing] out" why it was preempted. *Id.* The Ninth Circuit did not analyze the arguments Plaintiffs raise here. Thus, in contrast to the *AIDS Healthcare Foundation* plaintiffs, Plaintiffs here have spelled out a plausible preemption claim. As such, the Director's motion should be denied.

2. Declaratory Relief Is A Proper Remedy for CMS' Improper Approval of SPA 17-002 And Medi-Cal Rx.

The Administrative Procedure Act ("APA") gives Plaintiffs the right to sue CMS for actions that adversely affect them. *See Douglas v. Indep. Living Ctr. of S. Cal., Inc.*, 565 U.S. 606, 614 (2012) (citing 5 U.S.C. §§ 701 et seq.) There is a "strong presumption that Congress intends judicial review" of such agency action. *Hyatt v. Office of Management and Budget*, 908 F.3d 1165, 1170-71 (9th. Cir. 2018). Under the APA, Courts have the authority to review agency actions and deem them as "arbitrary, capricious, an abuse of discretion," or otherwise contrary to a "constitutional right, power, privilege or immunity" or in excess of the agency's jurisdiction. 5 U.S.C. § 706.

Plaintiffs have stated a claim under the APA. Medi-Cal Rx ended Plaintiffs' longstanding pharmacy arrangements with Managed Care Plans, leaving them with the FFS system. FAC ¶¶ 41, 45. Plaintiffs alleged – in detail – that the FFS system must comply with the reimbursement standards of Section 1396a(bb), and that it fails to do so. *Id.* ¶¶ 46, 52-55, 59-66. Despite the inherently flawed FFS reimbursement rate as applied to FQHC pharmacy services, and without regard to the FQHC reimbursement standard Congress established, CMS approved the FFS system in SPA 17-002. *Id.* ¶¶ 70-73.

In addition to violating a federal statute, CMS violated its own regulation when it approved SPA 17-002 and the FFS system. The Covered Outpatient Drug Rule required that States provide reliable data in setting reimbursement rates for Medicaid pharmacy services. *See* FAC ¶ 47. CMS rulemaking also directed states to specifically consider the "additional costs" that 340B Covered entities tend to incur. *Id.* ¶ 48. Instead, California relied on the Mercer Report, which admitted that of the 2,562 pharmacies that responded to its survey, only one was a 340B covered entity with usable data. *Id.* ¶¶ 50, 52. Rather than study 340B Covered Entities further, California submitted data to CMS that was skewed toward non-340B entity pharmacy providers. *See Id.* ¶¶ 53-54. CMS' decision to accept skewed data in light of the rule requiring "accurate and reliable data" was therefore arbitrary and capricious. *See Id.* ¶ 70, 72; *see also Newton-Nations v. Betlach*,

660 F.3d 370, 378 (9th Cir. 2011) (describing "arbitrary and capricious" agency actions).

Moreover, California's FFS system conflicts with, and is preempted by, federal law governing the 340B Program, as discussed above. By approving Medi-Cal Rx, CMS made the same errors it did in approving SPA 17-002 because it defaults FQHC reimbursement for pharmacy into an FFS system that does not reimburse FQHCs in compliance with federal law. FAC ¶ 44, 74. Therefore, taking Plaintiffs' allegations as true, CMS acted in an arbitrary, capricious manner that is contrary to the law when it approved California's unsubstantiated FFS reimbursement method that now applies to Plaintiffs, and again when it approved Medi-Cal Rx. FAC ¶¶ 114, 122; *see also Newton-Nations*, 660 F.3d at 378.

The Director misconstrues the FAC and the law in three ways. *See* Def. Br. at 13-14. First, the Director asserts that "the Medicaid Act precludes private enforcement . . . of [Section 30(A)]" standards. *Id.* But Plaintiffs are not seeking declaratory relief for violations of the Section 30(A) standard as to the Director – they seek declaratory relief regarding the FQHC-specific reimbursement standards of Section 1396a(bb). *See* FAC ¶ 131. Second, the Director argues that the Covered Outpatient Drug Rule is a "regulation not enforceable under Section 1983." Def. Br. at 14 (citing *Save Our Valley v. Sound Transit*, 335 F.3d 932, 943-44 (9th Cir. 2003)). But Plaintiffs do not seek to "enforce" that regulation under Section 1983 against the Director – they are challenging, *inter alia*, the violation of the Covered Outpatient Drug Rule in their APA action against CMS. *See id.*; FAC ¶ 114. Finally, the Director conflates a pre-litigation "administrative remedy" with a cause of action under the APA. Def. Br. at 14:7-10; *see also Darby v. Cisneros*, 509 U.S. 137, 154 (1993) (describing the availability of an administrative remedy as a pre-litigation step where such an administrative process exists).

The Director also misapplies *Chevron* deference. *See* Def. Br. at 14-15. The Director jumps from the existence of *Chevron* deference in "SPA approvals" to the conclusion that CMS' approval of the FFS system is automatically valid. *See* Def. Br. at 14:22-23. Yet, even if an agency's decision is "entitled to *Chevron* [ ] deference, it may

still be arbitrary and capricious." *California v. U.S. Dep't. of Labor*, 76 F. Supp. 3d 1125, 1137 (E.D. Cal. 2014). The agency's decision may still be arbitrary and capricious if it "fail[s] to consider an important aspect of the problem" at hand. *Newton-Nations*, 660 F.3d at 378. This is precisely what Plaintiffs allege.

Contrary to the Director's assertions, *Chevron* deference does not bar Plaintiffs' claims. Courts do not defer to an agency's decision where Congress has "directly spoken to the precise issue" in a statute. *See CARHC*, 738 F.3d at 1013-1014 ("[W]e hold that *Chevron* deference does not apply, and we therefore do not defer to CMS's approval of the challenged SPA."); *Empire Health Fdtn. for Valley Hosp. Med. Ctr. v. Azar*, 958 F.3d 873, 884 (9th Cir. 2020) (quoting *Chevron*, 467 U.S. at 842). There is also no deference where judicial precedent has already held the particular statute "unambiguously forecloses the agency's interpretation" because Congress left "no gap for the agency to fill." *Id.* (quoting *Nt'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 982-83 (2005)).

Here, judicial precedent has established that the "clear" requirement of Section 1396a(bb) is to reimburse FQHCs at 100 percent of the allowable costs. *See Tulare Pediatric*, 41 Cal. App. 5th at 170. Plaintiffs are not "mom and pop" pharmacies subject only to the broad standards of Section 30(A). Def. Br. at 8-9 (citing *Cal. Pharmacists Ass'n v. Kent*, No. 19-CV-02999-JSW, 2020 WL 4460547, at *1 (N.D. Cal. Feb. 21, 2020). Plaintiffs are FQHCs that provide specific services that Congress mandated " a state plan must cover." *CARHC*, 738 F.3d at 1013-14; *see also* 42 U.S.C. § 1396a(bb). Therefore, *Chevron* deference does not apply.

Second, in approving SPA 17-002 and Medi-Cal Rx, CMS failed to consider the FQHC-specific reimbursement standard in Section 1396a(bb). In arguing that Section 1396a(bb) does not apply to the FFS system, the Director implicitly acknowledges that neither it nor CMS considered the mandatory reimbursement standard. *See* Def. Br. at 8-9. A failure to even consider a relevant issue is arbitrary and capricious *per se*. *Hoag Mem'l Hosp. Presbyterian v. Price*, 866 F.3d 1072, 1079-80 (9th Cir. 2017) (holding HHS'

failure to consider the equal access "substantive result" portion of Section 30(A) was arbitrary and capricious).

Third, *Chevron* does not shield CMS' actions that overstepped its jurisdiction. It is "fundamental that an agency may not bootstrap itself into an area in which it has no jurisdiction" *Adams Fruit Co., Inc. v. Barrett*, 494 U.S. 638, 650 (1990) (internal quotations omitted). Paragraph 7 of SPA 17-002 incorporated California's 340B duplicate discount or rebate avoidance regulations. FAC ¶ 87. Yet, the 340B Program is within the jurisdiction of the Health Services and Resources Administration ("HRSA"), not CMS. FAC ¶ 75. As CMS tried to "bootstrap" itself into HRSA jurisdiction, *Chevron* deference does not apply. *See Adams Fruit Co.*, 494 U.S. at 650.

In sum, Plaintiffs have stated a valid claim for declaratory relief as an additional remedy for its APA claims. The Director's arguments that overlook legal precedent and misstate Plaintiffs' allegations do not alter the factual content that, taken as true, support Plaintiffs' claims. *See Symington*, 51 F.3d 1480 at 1484.

IV. CONCLUSION

Plaintiffs have met and exceeded their initial burden to plead causes of action based on violations of complex statutory and regulatory schemes. A decision on the merits of Plaintiffs' FAC is premature at this stage, particularly given the complexity of the issues. For the foregoing reasons, the Director's motion to dismiss should be denied.

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