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IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

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 & Medicaid Services,

Defendants.

Case No. 2:20-cv-02171-JAM-KJN

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEFENDANT CHIQUITA BROOKS-LASURE'S MOTION TO DISMISS

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I. INTRODUCTION

On December 29, 2021, the Centers for Medicare & Medicaid Services ("CMS") approved a proposal from the California Department of Health Care Services ("DHCS") that, among other things, changed Medi-Cal's payment for Medicaid-covered drugs from a managed-care model to a fee-for-service model. This transition, termed Medi-Cal Rx, made California the single purchaser for Medi-Cal prescription drugs.

A group of health care providers known as federally qualified health centers ("FQHCs") oppose Medi-Cal Rx. This is because FQHCs can purchase drugs for their patients at steep discounts through the federal 340B Drug Pricing Program and, under a managed-care model, FQHCs can negotiate with managed-care plans for payments for these drugs at rates higher than those paid by California under its Medicaid state plan. Under a fee-for-service model, FQHCs can still obtain discounted drugs for their patients through the 340B Drug Pricing Program, but FQHCs are unable to generate additional revenue from the higher payments they might negotiate with managed-care plans.

Some FQHCs ("Plaintiffs") filed this lawsuit to try to thwart the Medi-Cal Rx transition, and their First Amended Complaint ("FAC," ECF 45) asserts claims against CMS under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2)(A). Their claims, however, reduce to nothing more than a hodgepodge of half-baked arguments and legal theories that fail as a matter of law.

Specifically, Plaintiffs contend that CMS violated federal law when it approved California's fee-for-service reimbursement formula for covered outpatient drugs (State Plan Amendment ("SPA") 17-0002), which was supported by a survey and report prepared by Mercer Health & Benefits LLC (the "Mercer Report"). But Plaintiffs' contentions betray a basic misunderstanding of the survey's purpose and methods, and regardless, "delv[ing] into the minutiae of the Secretary's approval [of a State Plan Amendment]," and attempting to "pick[] apart DHCS's research and finding potential flaws" is "an inappropriate exercise when reviewing agency action under the APA." *Managed Pharmacy Care v. Sebelius*, 716 F.3d 1235, 1251 (9th Cir. 2013).

Plaintiffs compound this "inappropriate exercise" by arguing that SPA 17-0002 violates 42 U.S.C. § 1396a(bb), which provides the requirements for reimbursing FQHCs that provide services to Medicaid patients. California satisfies § 1396a(bb) in the parts of its state plan that provide a

"prospective-payment system" for FQHCs, as well as any "alternative payment methodologies" under § 1396a(bb)(6). SPA 17-0002 is irrelevant for determining California's compliance with § 1396a(bb).

These meritless arguments are woven throughout Plaintiffs' overlapping and muddled causes of action. And because these theories fail as a matter of law, this action should be dismissed as to CMS.

II. BACKGROUND

A. Medicaid and the Fee-for-Service and Managed-Care Models

The Medicaid statute, enacted as Title XIX of the Social Security Act, "authorizes federal financial assistance to States that choose to reimburse certain costs of medical treatment for needy persons." *Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 650 (2003). To be eligible for federal funds, a state must submit a plan to the Secretary of Health and Human Services that meets federal requirements. 42 U.S.C. § 1396a. The Secretary has delegated to CMS the responsibility for determining whether a state plan or amendment meets federal requirements. 42 C.F.R. § 430.12(c)(2).

"States have two options for providing care to Medicaid beneficiaries: a 'fee-for-service' model and a managed-care model." *State v. Rettig*, 987 F.3d 518, 524 (5th Cir. 2021) (citing Medicaid Program; Medicaid Managed Care: New Provisions, 67 Fed. Reg. 40,989, 40,989 (June 14, 2002)). Under a fee-for-service ("FFS") model, the state pays medical providers—such as FQHCs—directly for covered services received by a Medicaid patient. *Id.* This is considered the "traditional" or "default" model. *See, e.g.*, *K.C. ex rel. Africa H. v. Shipman*, 716 F.3d 107, 110 (4th Cir. 2013); *Tenn. Ass'n of Health Maint. Orgs., Inc. v. Grier*, 262 F.3d 559, 562 (6th Cir. 2001); *Molina Healthcare of Ind., Inc. v. Henderson*, No. 06-1483, 2006 WL 3518269, at *2 (S.D. Ind. Dec. 4, 2006).

Under a managed-care model, a state pays a fee to a managed-care plan for each person enrolled in the plan, and the plan then pays providers for the services a Medicaid patient receives that are included in the plan's contract with the state. *See Rettig*, 987 F.3d at 524. To require Medicaid beneficiaries to receive services through a managed-care model, states apply to CMS for a waiver (a "Section 1915(b) Waiver") from certain statutory Medicaid requirements. *See* 42 U.S.C. § 1396n(b).

B. Federally Qualified Health Centers and the Prospective-Payment System

Some Medicaid patients receive health care services from FQHCs. FQHCs include health centers receiving federal grants under section 330 of the Public Health Service Act, 42 U.S.C. § 254b,

and certain tribal organizations. *See* 42 U.S.C. § 1396d(*l*)(2)(B); *St. Anthony Med. Ctrs. v. Kent*, No. 15-1926, 2016 WL 4192417, at *1 (E.D. Cal. Aug. 8, 2016). To participate in Medicaid, states must reimburse FQHCs for their services rendered to Medicaid patients. *See* 42 U.S.C. § 1396a(a)(10)(A); *St. Anthony Med. Ctrs.*, 2016 WL 4192417, at *1.

Specifically, "[f]rom 1989 through 2000, the federal Medicaid program required [states] to reimburse FQHCs for '100 percent . . . of [each FQHC's] costs which are reasonable.' 42 U.S.C. § 1396a(a)(13)(C) (repealed 2000)." *St. Anthony Med. Ctrs.*, 2016 WL 4192417, at *2 (quoting *Three Lower Ctys. Cmty. Health Servs., Inc. v. Maryland*, 498 F.3d 294, 297–98 (4th Cir. 2007)). Thereafter, to relieve FQHCs from having to supply new cost data every year, Congress amended the Medicaid statute in 2000 to implement a prospective-payment system ("PPS"). *Id.*

Under PPS, state Medicaid plans establish an initial year PPS reimbursement rate for each FQHC based on the FQHC's cost of providing covered services to the state's Medicaid patients in a specified base year. *Id.* This rate is adjusted annually based on the Medicare Economic Index, and it may also be adjusted to reflect a change in the FQHC's scope of services. *Id.* A state may also use "alternative payment methodologies" to reimburse FQHCs if they (1) are agreed to by the state and the FQHC, and (2) result in payment to the FQHC of an amount that is at least equal to what the FQHC would receive under the PPS. *Id.* at *2–3; *see* 42 U.S.C. § 1396a(bb)(6).

CMS approved California's current PPS framework on February 28, 2012. *See* CMS's Request for Judicial Notice ("CMS's RJN") Ex. 1 (Cal. State Plan, Attach. 4.19-B), Provision D, at pp. 6D–6E. PPS reimbursement for FQHCs is different from payment rates in the state plan that apply to other types of Medi-Cal providers, such as SPA 17-0002. *See* 42 U.S.C. § 1396a(bb)(1) ("[T]he State plan shall provide for payment for services . . . furnished by a Federally-qualified health center . . . in accordance with the provisions of *this subsection*," and outlining the PPS framework (emphasis added)).

C. The 340B Drug Pricing Program

FQHCs are considered "covered entities" under the 340B Drug Pricing Program, meaning they are among several classes of providers that receive discounts on drug purchases from pharmaceutical manufacturers. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967–71 (1992). Some FQHCs run their own inhouse pharmacies, while others contract with retail

pharmacies. *See* FAC ¶¶ 13–22. Either way, where FQHC patients are Medicaid managed-care patients, some FQHCs have negotiated with managed-care plans for reimbursement above the 340B purchase price as a means of generating additional revenue. *See, e.g.*, Castle Decl. (ECF 46-3) ¶¶ 5, 7; Curtis Decl. (ECF 46-5) ¶ 5; *see also, e.g.*, FAC ¶¶ 2, 39, 65, 97, 99.

D. State Plan Amendment 17-0002 and the Mercer Report

When a state reimburses a pharmacy provider for covered outpatient drugs dispensed to Medicaid patients under an FFS model, the reimbursement has two components: the "ingredient cost" of the drug and a "reasonable dispensing fee." *See* Medicaid Program; Covered Outpatient Drugs, 77 Fed. Reg. 5318, 5320 (Feb. 2, 2012). CMS issued a final rule on determining these components in 2016. *See* Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5170 (Feb. 1, 2016) (the "COD Rule"), *codified at* 42 C.F.R. Part 447, Subpart I §§ 447.500–.522.

Under the COD Rule, states must determine the "ingredient cost" of a drug based on its "actual acquisition cost," *i.e.*, the relevant state agency's "determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers." *See* 42 C.F.R. § 447.502. As for the "dispensing fee," CMS changed this term to "professional dispensing fee" in the COD Rule to "reinforce [CMS's] position that the dispensing fee should reflect the pharmacist's *professional* services and costs to dispense the drug product to a Medicaid beneficiary." 81 Fed. Reg. 5170, 5201 (Feb. 1, 2016) (emphasis added); *see* 42 C.F.R. § 447.502.

Like other states, California submitted a state plan amendment implementing the COD Rule, and the state plan amendment was denoted SPA 17-0002. *See* CMS's RJN Ex. 2 (SPA 17-0002, with page numbers added). In support of SPA 17-0002, California submitted the Mercer Report, detailing "outpatient pharmacy provider costs associated with purchasing and dispensing covered outpatient prescription drugs to Medi-Cal members." *See* CMS's RJN Ex. 3 (Mercer Report).

Under SPA 17-0002, the "drug ingredient cost" was defined as the lowest of several different metrics for determining the actual acquisition cost of a drug. *See* CMS's RJN Ex. 2 (SPA 17-0002), at 4 ¶ 4.[1] By contrast, for 340B "covered entities" and their contract pharmacies, the "drug ingredient cost"

[1] These were the "National Average Drug Acquisition Cost (NADAC) of the drug, or when no NADAC is available, the Wholesale Acquisition Cost (WAC) +0%," the "Federal Upper Limit (FUL)," or the "Maximum Allowable Ingredient Cost (MAIC)." *See* CMS's RJN Ex. 2 (SPA 17-0002), at 4 ¶ 4.

is the price "charged by the manufacturer at a price consistent with" the 340B Drug Pricing Program, 42 U.S.C. § 256b. *See id.* Ex. 2 (SPA 17-0002), at 5 ¶ 7(a).[2] And the "professional dispensing fee" is either $13.20 or $10.05, depending on the pharmacy's volume of claims during the prior year. *See id.* Ex. 2 (SPA 17-0002), at 4 ¶ 5.

CMS approved SPA 17-0002 on August 25, 2017. *See id.* Ex. 2 (SPA 17-0002), at 2. CMS's approval of SPA 17-0002 had no effect on California's PPS methodology for reimbursing FQHCs under 42 U.S.C. § 1396a(bb). *See generally id.* Ex. 2 (SPA 17-0002), at 1–14.

E. Medi-Cal Rx

Until recently, California's payments to providers of pharmaceutical services to Medi-Cal patients were incorporated into a managed-care model, but the state transitioned to an FFS model for pharmaceutical services by "carving" them out of the state's contracts with managed-care organizations delivering services under the state's Section 1915(b) Waiver. *See* CMS's RJN Ex. 4 (DHCS, Section 1915(b) Waiver Proposal for California Advancing and Innovating Medi-Cal (CalAim) (Excerpts) [hereinafter "Section 1915(b) Waiver App. Excerpts"]), Attach. III, at 11 (identifying "Pharmaceutical Services and Prescribed Drugs" as a "Benefit Carved Out of Managed Care").

California submitted its application for a Section 1915(b) Waiver on June 30, 2021, and CMS approved the application on December 29, 2021. *See* CMS's RJN Ex. 4 (Section 1915(b) Waiver App. Excerpts), at 1 (cover page); *id.* Ex. 5 (CMS's approval letter for California's Section 1915(b) Waiver), at 1. CMS's approval had no effect on California's PPS for reimbursing FQHCs. *See* 42 U.S.C. § 1396n(b) (providing that a Section 1915(b) Waiver does not waive the requirements of 42 U.S.C. § 1396a(bb)); *see also* CMS's RJN Ex. 4 (Section 1915(b) Waiver App. Excerpts), Section A, at 38–39 (confirming that California's Section 1915(b) Waiver does not affect the state's PPS for FQHCs).

F. Plaintiffs' Lawsuit

As discussed, Medi-Cal Rx "carved out" pharmaceutical services from the managed-care plans participating in the state's Section 1915(b) Waiver, and thus Plaintiffs can no longer negotiate with managed-care plans for reimbursement at greater than the rates provided in the state plan. *See* CMS's

[2] SPA 17-0002 provides an alternative "usual and customary" reimbursement where a "covered entity" is unable to purchase a drug pursuant to the 340B Drug Pricing Program. *See* CMS's RJN Ex. 2 (SPA 17-0002), at 5 ¶¶ 7(b), 1.

RJN Ex. 4 (Section 1915(b) Waiver App. Excerpts), Attach. III, at 11; FAC ¶¶ 2, 39, 65, 97, 99; *see also, e.g.*, Castle Decl. (ECF 46-3) ¶¶ 5, 7; Curtis Decl. (ECF 46-5) ¶ 5. Plaintiffs thus sued DHCS and CMS to attempt to upend Medi-Cal Rx. Their FAC asserts three claims against CMS.

Plaintiffs' first claim against CMS appears under their "Second Cause of Action" and alleges the agency "erroneously" approved SPA 17-0002 in violation of the APA. *See* FAC ¶¶ 112–119. Their second claim against CMS appears under their "Third Cause of Action" and alleges the agency "erroneously" approved California's Section 1915(b) Waiver containing Medi-Cal Rx, also in violation of the APA. *See id.* ¶¶ 120–28. And their third claim against CMS appears under their "Fourth Cause of Action" as a request for declaratory relief. *See id.* ¶¶ 129–33.

III. LEGAL STANDARDS

A. Federal Rule of Civil Procedure 12(b)(6)

Under Rule 12(b)(6), a federal court may dismiss a complaint or cause of action that fails as a matter of law. *See* Fed. R. Civ. P. 12(b)(6). "Dismissal can be based on the lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory." *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1990). In ruling on a motion to dismiss, the court may consider documents that are not physically attached to the complaint if they are matters of public record, subject to judicial notice, or if their authenticity is not contested and the complaint necessarily relies on them. *Lee v. City of Los Angeles*, 250 F.3d 668, 688–89 (9th Cir. 2001).

In an action asserting claims under the APA, "[t]he entire case on review is a question of law, and only a question of law. And because a court can fully resolve any purely legal question on a motion to dismiss, there is no inherent barrier to reaching the merits at the 12(b)(6) stage." *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993).

B. The Administrative Procedure Act

Under the APA, a court may set aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). This standard is met only where the plaintiff "meets a heavy burden" of showing "that 'the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so

implausible that it could not be ascribed to a difference in view or the product of agency expertise.'" *Managed Pharmacy Care*, 716 F.3d at 1244 (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). APA review is "highly deferential," "extremely narrow," and "presumes agency action to be valid." *U.S. Postal Serv. v. Gregory*, 534 U.S. 1, 6 (2001); *Short Haul Survival Comm. v. United States*, 572 F.2d 240, 244 (9th Cir. 1978). A court cannot "substitute its own judgment for that of the [agency]." *Gregory*, 534 U.S. at 7.

IV. ARGUMENT

A. Plaintiffs' second cause of action against CMS fails as a matter of law.

1. CMS's approval of SPA 17-0002 was consistent with the COD Rule.

Plaintiffs allege that CMS's approval of SPA 17-0002 was "erroneous" under the COD Rule because the Mercer Report was "insufficient," "incomplete," and "inaccurate." FAC ¶¶ 46–54, 60–66, 69–74, 114(a), (c); *see* 42 C.F.R. § 447.518(d) providing that, "[w]hen proposing changes to either the ingredient cost reimbursement or professional dispensing fee reimbursement," states "must provide adequate data such as a State or national survey of retail pharmacy providers or other reliable data other than a survey to support any proposed changes to either or both of the components of the reimbursement methodology," *i.e.*, "ingredient cost" and "professional dispensing fee").

Specifically, Plaintiffs complain that the Mercer Report failed to include the prices of 340B drugs in its survey of "ingredient costs." *See* FAC ¶¶ 46–54, 60–63; *see* CMS's RJN Ex. 3 (Mercer Report), at 80 (providing Mercer's "ingredient cost" survey, which stated, "Please submit drug purchase price invoice data from the month of June 2016. *Please exclude or flag any purchases your pharmacy made under a 340B contract.*" (emphasis added)). Plaintiffs also complain that most of the responses to Mercer's survey of "professional dispensing fees" were from "retail chain pharmacies" rather than FQHC pharmacies or other "covered entities" under the 340B Drug Pricing Program. *See* FAC ¶¶ 46–54, 64–66. Plaintiffs' contentions are meritless.

CMS reasonably determined that the Mercer Report was "adequate" under the COD Rule to support California's selection of "ingredient cost" and "professional dispensing fees" for the FFS reimbursement formula in SPA 17-0002. 42 C.F.R. § 447.518(d); *Managed Pharmacy Care*, 716 F.3d at 1251 (reversing the district court for "delv[ing] into the minutiae of [CMS's] approval [of California's

SPA], picking apart DHCS's research and finding potential flaws—an inappropriate exercise when reviewing agency action under the APA"); *see also Kennecott Greens Creek Min. Co. v. Mine Safety & Health Admin.*, 476 F.3d 946, 956 (D.C. Cir. 2007) (explaining that agency determinations "are given 'an extreme degree of deference' given that they involve complex judgments about sampling methodology and data analysis that are 'within [the agency's] technical expertise'" (quoting *Hüls Am., Inc. v. Browner*, 83 F.3d 445, 452 (D.C. Cir. 1996)) (alteration in original)); *League of Wilderness Defs. Blue Mountains Biodiversity Project v. Allen*, 615 F.3d 1122, 1130 (9th Cir. 2010) (similar).

In Mercer's survey of "ingredient costs," there was no need to gather data on the prices paid for 340B drugs because those prices are dictated by the 340B Drug Pricing Program itself. For this reason, SPA 17-0002 sets the "ingredient cost" for 340B "covered entities" and their contract pharmacies as the price "charged by the manufacturer at a price consistent with" the 340B Drug Pricing Program, 42 U.S.C. § 256b. *See* CMS's RJN Ex. 2 (SPA 17-0002), at 5 ¶ 7(a). Including the discounted prices paid by 340B "covered entities" in the survey would skew the reimbursement of non-340B pharmacies below an appropriate acquisition cost. *See* CMS's RJN Ex. 3 (Mercer Report), at 38 ("Outlier Detection"—"Mercer believes reported purchase prices of brand drugs at this great of a discount may be 340B purchased drugs, which should not be allowed to factor into an AAC survey.").

As for Mercer's survey of "professional dispensing fees," that term has a specific regulatory definition, and it does not include any and all expenses Plaintiffs can dream up and label "costs of dispensing" or "costs of providing pharmacy services." *See* 42 C.F.R. § 447.502 (defining "professional dispensing fee" to mean "the professional fee which is incurred at the point of sale or service," and "includes *only* pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary" (emphasis added)). Plaintiffs offer no concrete, factual allegations showing that FQHCs with inhouse pharmacies have higher "professional dispensing fees," as defined by 42 C.F.R. § 447.502, that are statistically significant, nor do they even offer a theory or explanation as to why or how this could be the case. Further, it appears that Plaintiffs predominantly use contract pharmacies like the ones captured by Mercer's survey. *See* FAC ¶¶ 13–22.

At any rate, the Mercer Report discloses and explains the professional-dispensing-fee data it collected and its analysis with respect to FQHCs and 340B "covered entities":

> In spite of the numerous channels of communication leveraged and extensive direct stakeholder outreach requesting participation, costs of dispensing for . . . federally qualified health center/rural health clinic (FQHC/RHC) . . . pharmacies could not be estimated because of the low number of responses for these pharmacy types. Additionally, only one pharmacy with usable response data reported to be a 340B Covered Entity, and therefore 340B Covered Entities were not analyzed separately from community retail pharmacies that were not 340B Covered Entities.

CMS RJN (Mercer Report) Ex. 3, at 4. In other words, FQHCs and other 340B "covered entities" like Plaintiffs did not respond to the survey. Having received a full and fair opportunity to participate, they cannot now be heard to complain that the survey did not represent their cost of dispensing drugs.

In sum, Plaintiffs' attacks on the Mercer Report are meritless, and they fail to show that CMS's approval of SPA 17-0002 violated the COD Rule or was otherwise "erroneous." *See generally Managed Pharmacy Care*, 716 F.3d at 1248 (noting that "Medicaid administration is nothing if not complex," and CMS "has been giving careful consideration to the ins and outs of the program" and "is the expert in all things Medicaid"); *Cal. Primary Care Ass'n v. Douglas*, No. 12-01708, 2012 WL 12930701, at *3 (N.D. Cal. May 10, 2012) ("The conclusion of the CMS that [California's] plan complies with the requirements of the Medicaid Act is entitled to substantial deference.").

2. CMS's approval of SPA 17-0002 was unrelated to the reimbursement of FQHCs under 42 U.S.C. § 1396a(bb).

Plaintiffs next complain that the reimbursement formula in SPA 17-0002 fails to reimburse them consistent with the requirements of 42 U.S.C. § 1396a(bb). *See* FAC ¶¶ 55–66, 69–74, 114(a), (c). But this argument makes no sense. Under Medicaid, it is the state's PPS (or alternative payment methodology per § 1396a(bb)(6)) that is designed and intended to reimburse FQHCs under § 1396a(bb). *See supra* Section II.B; *see also, e.g.*, *HealthproMed Found., Inc. v. Dep't of Health & Hum. Servs.*, 982 F.3d 15, 17 (1st Cir. 2020) (explaining that states "must reimburse the FQHCs . . . through a Prospective Payment System (PPS)"); *Legacy Cmty. Health Servs., Inc. v. Smith*, 881 F.3d 358, 363 (5th Cir. 2018) (explaining, "Section 1396a(bb) provides that the state is obligated to ensure that FQHCs are reimbursed for covered Medicaid services. . . . That section also sets forth the framework for assessing reimbursement amounts: the Prospective Payment System.").

In other words, California's PPS provides the reimbursement to which FQHCs are entitled under § 1396a(bb) for services to Medi-Cal patients, notwithstanding other reimbursement formulas that might

be generally applicable to other Medi-Cal providers, such as the formula in SPA 17-0002 for outpatient drugs. Nothing in SPA 17-0002 purports to change California's PPS or preclude Plaintiffs from receiving PPS reimbursement for the pharmaceutical services they provide to Medi-Cal patients.

Plaintiffs repeatedly allege that they are "forced to accept reimbursement for pharmacy services through the FFS," *i.e.*, SPA 17-0002 (*see* FAC ¶¶ 73, 93, 119, 131), but there is no support for this bald assertion in SPA 17-0002 or California's Section 1915(b) Waiver. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (holding that conclusory allegations "do not suffice" on a motion to dismiss, and courts "are not bound to accept as true a legal conclusion couched as a factual allegation"). Plaintiffs cannot ignore or refuse PPS reimbursement and then blame their self-inflicted injury on Medi-Cal Rx. And insofar as some FQHCs may have opted out of PPS for pharmacy services, DHCS represents that FQHCs can opt back in. *See* DHCS's Mem. Supp. Mot. Dismiss FAC (ECF 61-1), at 4:19–4:28, 5:18–5:22.

Notably, managed-care payments also are not designed or intended to satisfy the reimbursement requirements for FQHCs under § 1396a(bb). Rather, the Medicaid statute acknowledges that such payments may be less than the amount required under PPS, in which case the state must make up the shortfall through a supplemental "wraparound" payment. *See* 42 U.S.C. § 1396a(bb)(5); *HealthproMed*, 982 F.3d at 17; *Legacy*, 881 F.3d at 363. Once again, the requisite reimbursement for FQHCs under § 1396a(bb) is the PPS amount, and Plaintiffs still can receive that amount under Medi-Cal Rx.

3. Plaintiffs have failed to plausibly allege that CMS's approval of SPA 17-0002 violated 42 U.S.C. § 1396a(a)(30)(A).

Plaintiffs round out their second cause of action by alleging, "California failed to provide accurate and reliable data or an explanation of the cost impact to the Medicaid program when it submitted SPA 17-0002 ¶ 7 to CMS for approval." FAC ¶ 114(b); *see also id.* ¶¶ 67–74 (alleging, on information and belief, that CMS allegedly did not consider how SPA 17-0002 "would affect access to care and quality of care as required by Section 30(A)," 42 U.S.C. § 1396a(a)(30)(A)). But these allegations are far too conclusory to state any cognizable claim against CMS. *Iqbal*, 556 U.S. at 678. And for multiple reasons, Plaintiffs' vague allegations are particularly defective in the context of this case. *Id.* at 679 (noting that "whether a complaint states a plausible claim for relief" is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense").

First, this theory rehashes Plaintiffs' baseless criticisms of the Mercer Report, dispatched above. *See* FAC ¶¶ 68–74; *supra* Section IV.A.1. *Second*, this theory rests on Plaintiffs' meritless interpretation of 42 U.S.C. § 1396a(bb) as applying to SPA 17-0002, also dispatched above. *See* FAC ¶¶ 68–74; *supra* Sections II.B & IV.A.2. *Third*, Mercer thoroughly analyzed the budgetary impact on Medi-Cal of the different methods for calculating "ingredient costs" and "professional dispensing fees." *See* CMS's RJN Ex. 3 (Mercer Report), at 4, 8, 27–32.

Fourth, in approving SPA 17-0002, CMS found that California "provided data and studies to demonstrate that the acquisition cost methodology and pharmacy dispensing fees being paid are sufficient to assure that Medi-Cal beneficiaries will have access to pharmacy services at least to the extent as the general population." CMS's RJN Ex. 2 (SPA 17-0002), at 2. CMS's determination is subject not only to the APA's "highly deferential" standard of review, *see Short Haul*, 572 F.2d at 244, but also to deference under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), *see Managed Pharmacy Care*, 716 F.3d at 1247 (holding that *Chevron* deference applied to CMS's interpretation of the Medicaid statute when it approves an SPA, given the "broad and diffuse" language of Section 30(A)). Plaintiffs offer no specific, factual allegations that could set aside CMS's approval under this doubly deferential framework. *See E.E.O.C. v. Farmers Ins. Co.*, 24 F. Supp. 3d 956, 961 (E.D. Cal. 2014) (explaining that courts "must look at a complaint in light of the relevant evidentiary standard, in order to decide whether it contains sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face" (internal quotation marks and brackets omitted)).

Fifth, two federal courts already held that CMS's approval of SPA 17-0002 was consistent with the APA and Section 30(A). *See Cal. Pharmacists Ass'n v. Kent*, No. 19-2999, 2020 WL 4460547, at *4 (N.D. Cal. Feb. 21, 2020) (finding that the "approval of SPA 17-0002 was based on [CMS's] expertise and the data available, as well as a reasonable methodology in light of the requirements of Section 30(A)"); *see also Mkt. Pharmacy, Inc. v. U.S. Dep't of Health & Hum. Servs.*, No. 18-8425, 2019 WL 1423773, at *2 (C.D. Cal. Feb. 20, 2019) (finding that the plaintiffs failed to show that the "approval of California Medicaid State Plan Amendment ("SPA") 17-0002 was arbitrary and capricious and that it does not meet the 'minimal standards of rationality' as required by the APA" (citing *Troy Corp. v. Browner*, 120 F.3d 277, 283 (D.C. Cir. 1997); *Managed Pharmacy Care*, 716 F.3d at 1246)).

* * *

In sum, because the theories proffered in support of Plaintiffs' second cause of action fail as a matter of law, Plaintiffs' second cause of action must be dismissed under Rule 12(b)(6).

B. Plaintiffs' third cause of action against CMS fails as a matter of law.

1. CMS's approval of California's Section 1915(b) Waiver is unrelated to the reimbursement of FQHCs under 42 U.S.C. § 1396a(bb).

Plaintiffs' third cause of action challenges CMS's approval of California's Section 1915(b) Waiver reflecting the Medi-Cal Rx transition from a managed-care model to an FFS model for covered outpatient drugs. Specifically, Plaintiffs argue that Medi-Cal Rx "imposes the flawed reimbursement system under SPA 17-002 ¶ 7" that "deprives [them] of federally mandated reimbursement levels set forth in 42 U.S.C. § 1396a(bb)." FAC ¶¶ 122(a); *see id.* ¶¶ 69–74. Similarly, Plaintiffs aver that "Medi-Cal Rx and the flawed FFS reimbursement system will result in Medi-Cal failing to cover the costs of providing services to Medi-Cal beneficiaries and will improperly shift the costs of the FQHCs' Section 330 grants from HRSA." *Id.* ¶ 122(e); *see id.* ¶¶ 35, 45, 55, 69–74, 103.

These allegations reduce to nothing more than another rehashing of Plaintiffs' argument that the FFS reimbursement formula in SPA 17-0002 does not reimburse FQHCs as required by 42 U.S.C. § 1396a(bb). Once again, Plaintiffs fail to recognize that SPA 17-0002 was not designed or intended to reimburse FQHCs under § 1396a(bb). *See supra* Sections II.B & IV.A.2. Nothing in California's Section 1915(b) Waiver purports to change the PPS or preclude Plaintiffs from receiving PPS reimbursement for pharmaceutical services. *See* 42 U.S.C. § 1396n(b) (providing that a Section 1915(b) Waiver does not waive the requirements of § 1396a(bb); *see also* CMS's RJN Ex. 4 (Section 1915(b) Waiver App. Excerpts), Section A, at 38–39 (confirming that California's Section 1915(b) Waiver does not affect the state's PPS for FQHCs).

2. Nothing in the 340B Drug Pricing Program "preempts" Medi-Cal Rx.

Plaintiffs' third cause of action contends that Medi-Cal Rx "imposes [an] FFS reimbursement system that subjects [them] to provisions of SPA 17-002 ¶ 7 that are preempted by the federal Medicaid Exclusion File under 42 U.S.C. § 1396r-8(a)(5(C) as the exclusive mechanism for preventing duplicate discounts or rebates of 340B drugs." FAC ¶ 122(b); *see id.* ¶¶ 75–93. Relatedly, Plaintiffs allege that

Medi-Cal Rx "stands as an obstacle to achieving the purpose" of the 340B Drug Pricing Program. *Id.* ¶ 122(c); *see id.* ¶¶ 94–100. These convoluted preemption arguments are unavailing for several reasons.

First, there is no express preemption clause in 42 U.S.C. § 1396r-8(a)(5)(C). That provision merely directs states to establish a duplicate-discount avoidance mechanism in the event that the Secretary of Health and Human Services ("HHS") fails to establish one by November 4, 1992, and then lays out some basic requirements. *See* 42 U.S.C. § 1396r-8(a)(5)(C) ("If the Secretary does not establish a mechanism under section 256b(a)(5)(A) of this title within 12 months of November 4, 1992, the following requirements shall apply . . . ."). Nothing in that provision prohibits states from implementing additional requirements to avoid duplicate discounts, when used in concert with HHS's duplicate-discount avoidance mechanism. *See id.* Plaintiffs strain to portray the statute differently, inserting the word "only" in front of the clause "[i]f the Secretary does not establish a mechanism" (*see* FAC ¶ 77), but that word does not appear in the statute, and it would not create anything resembling an express preemption clause in any event. *See English v. Gen. Elec. Co.*, 496 U.S. 72, 78–79 (1990) (explaining that express preemption occurs where Congress "define[s] explicitly the extent to which its enactments preempt state law" through "explicit statutory language," making "the courts' task an easy one").

Second, Plaintiffs do not and cannot plausibly allege that "compliance with both state and federal law is impossible," as required for conflict preemption. *Boultinghouse v. Hall*, 583 F. Supp. 2d 1145, 1157 (C.D. Cal. 2008) (noting further that courts apply "a strong presumption that federal statutes do not preempt state laws"). Indeed, the Ninth Circuit has already found that the provisions Plaintiffs challenge in SPA 17-0002 do not conflict with the federal duplicate-discount avoidance provision, 42 U.S.C. § 256b(a)(5)(A). *See AIDS Healthcare Found. v. Douglas*, 457 F. App'x 676, 678 (9th Cir. 2011).[3] As the Ninth Circuit explained, "There is no actual conflict because the state and federal statutes can both easily be complied with; the state statute surely does not present an obstacle to the prevention of double discounts; and there is no indication that Congress intended to occupy the whole field in this part of the cooperative Medicaid program." *Id.*

[3] The California statute that the Ninth Circuit considered in *AIDS Healthcare*, California Welfare and Institutions Code section 14105.46, contains the same provisions as paragraph 7 in SPA 17-0002 that Plaintiffs contend are preempted. *See* FAC ¶¶ 75–93; CMS's RJN Ex. 2 (SPA 17-0002), at 5–6 ¶ 7.

Third, nothing in the 340B Drug Pricing Program requires CMS to force states to deliver pharmaceutical services to Medicaid patients through managed-care plans. Plaintiffs offer no authority for the proposition that the 340B Drug Pricing Program effected such a dramatic overhaul of Medicaid. *See* 67 Fed. Reg. 40,989, 40,989 (June 14, 2002) (noting that, "before 1982, 99 percent of Medicaid beneficiaries received Medicaid covered through fee-for-service arrangements"). Indeed, an FFS model like Medi-Cal Rx is the "traditional" or "default" Medicaid delivery model, and the use of managed-care plans typically requires a statutory *waiver* from Medicaid's requirements. *See* 42 U.S.C. § 1396n(b); *K.C. ex rel. Africa H.*, 716 F.3d at 110; *Tenn. Ass'n of Health Maint. Orgs.*, 262 F.3d at 562; *Molina*, 2006 WL 3518269, at *2. California has chosen to *carve out* pharmaceutical benefits from its Section 1915(b) Waiver, which incorporates other benefits into a managed-care model. *See* CMS's RJN Ex. 4 (Section 1915(b) Waiver App. Excerpts), Attach. III, at 11. It cannot be that California's transition to the "traditional" or "default" Medicaid model for pharmaceutical services is preempted by federal law.

3. Nothing in Medicaid requires or authorizes CMS to prohibit California from carving out pharmaceutical services from its managed-care plans participating in its Section 1915(b) Waiver program.

Similar to their flawed preemption arguments, Plaintiffs contend that "shifting all Medi-Cal pharmacy services to the FFS reimbursement system" is "contrary to the purpose of Medicaid." FAC ¶ 122(d); *see id.* ¶¶ 101–05. As discussed, however, FFS is the "traditional" or "default" Medicaid delivery model, and a requirement that Medicaid beneficiaries receive services through managed-care plans typically requires a *waiver* from Medicaid's requirements. *See supra* Sections II.A & IV.B.2.

Indeed, forcing California to use a managed-care model for pharmaceutical services (as Plaintiffs demand) would run roughshod over Medicaid's express provisions and the framework governing CMS's role in administering the cooperative program. The provision in the Medicaid statute governing managed-care-organization ("MCO") contracts, 42 U.S.C. § 1396b(m), lets state Medicaid agencies decide which state-plan benefits to cover under MCO contracts, and which benefits to cover only directly under FFS payment rules in the state plan. *See id.* § 1396b(m)(2)(A). CMS has no authority to second-guess California's decision. *Id.* Multiple states carve out pharmaceutical services from their

MCO contracts and provide such services directly on an FFS basis under the applicable payment terms set forth in their state plans, just as California has elected to do.[4]

C. Plaintiffs' fourth cause of action against CMS fails as a matter of law because declaratory relief is not an independent cause of action.

It is well established that "declaratory relief is a remedy, not a freestanding cause of action," and thus Plaintiff's fourth cause of action for declaratory relief "survives only to the extent that [their] other causes of action state a claim for relief." *Darling v. Green*, No. 12-362, 2013 WL 12132058, at *9 (C.D. Cal. Apr. 18, 2013). Thus, because Plaintiffs' claims against CMS under the APA fail as a matter of law, Plaintiffs are not entitled to declaratory relief or any other relief whatsoever.

V. CONCLUSION

For the foregoing reasons, Plaintiffs' claims against CMS must be dismissed.

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Respectfully submitted,

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[4] *See* CMS, National Medicaid Fee-For-Service (FFS) FFY 2020 Drug Utilization Review (DUR) Annual Report, at vii, *available at* https://www.medicaid.gov/medicaid/prescription-drugs/downloads/2020-dur-ffs-summary-report.pdf; Nat'l Conf. of State Legislators, *Medicaid Prescription Drug Laws and Strategies* (Aug. 27, 2021), https://www.ncsl.org/research/health/medicaid-pharmaceutical-laws-and-policies.aspx (noting that "[f]our states—Missouri, Tennessee, and West Virginia and Wisconsin—'carved out' the pharmacy benefit from MCO contracts, instead choosing to pay a traditional fee-for-service reimbursement rate").