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CHIQUITA BROOKS-LASURE
Administrator of the Centers for Medicare & Medicaid Services

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-TLN-KJN

REPLY IN SUPPORT OF DEFENDANT CHIQUITA BROOKS-LASURE'S MOTION TO DISMISS

No Hearing Per ECF 74

In their Opposition, Plaintiffs admit that—contrary to their allegations in the First Amended Complaint ("FAC")—nothing in Medi-Cal Rx "forces" them to accept the fee-for-service ("FFS") reimbursement rate for Medicaid-covered drugs in State Plan Amendment ("SPA") 17-0002. Rather, the reimbursement guaranteed to Plaintiffs and other Federally Qualified Health Centers ("FQHCs") under 42 U.S.C. § 1396a(bb) is readily available to them under the prospective-payment system ("PPS") in California's State Medicaid Plan.

So, to try to salvage their lawsuit, Plaintiffs offer up a new grievance: They now complain that adjusting their PPS rate to include Medicaid-covered drugs is not "automatic." *See* Opp. 11:1–11:7 (complaining further that "it is not Plaintiffs' burden to 'opt back in[to]' the PPS system"). But "automatic" reimbursement is not mandated by the Medicaid statute or any other federal law—nor could it be. The California Department of Health Care Services ("DHCS") cannot magically divine each FQHC's pharmacy costs and determine its PPS rate without cooperation from the entity and the disclosure of cost information. *See* CMS RJN Ex. 1 (ECF 66-3), at Pages 6D–6E; *see also St. Anthony Med. Ctrs. v. Kent*, No. 15-1926, 2016 WL 4192417, at *2 (E.D. Cal. Aug. 8, 2016).

In the end, it is now abundantly clear that this lawsuit is not really about Plaintiffs securing the reimbursement to which they are entitled under § 1396a(bb). Rather, Plaintiffs are offering up any colorable theory in a last-ditch attempt to upend Medi-Cal Rx. That is because Medi-Cal Rx prevents them from negotiating with managed-care plans for potentially *higher* reimbursement than that provided under § 1396a(bb) and the PPS. Plaintiffs' gambit is unavailing. This action should be dismissed.

1. Plaintiffs' new theory portraying FFS reimbursement as an APM is without merit.

As noted, Plaintiffs are not "forced" to accept FFS reimbursement, and California's PPS provides the reimbursement required under § 1396a(bb). Plaintiffs apparently refuse to participate in PPS for Medicaid-covered drugs, opting instead to accept the FFS rate, which they then turn around and decry as an inadequate alternative payment methodology ("APM"). This ploy fails for several reasons.

First, it is black-letter law that "a deficient pleading cannot be cured by new allegations raised in a plaintiff's response to a motion to dismiss." *Ariz. Civ. Constructors, Inc. v. Colony Ins. Co.*, 481 F. Supp. 3d 1141, 1147 (D. Nev. 2020) (citing *Schneider v. Cal. Dep't of Corrs.*, 151 F.3d 1194, 1197 n.1

(9th Cir. 1998)). Nothing in the FAC alleges that FFS reimbursement for Medicaid-covered drugs is an APM under § 1396a(bb)(6). The FAC does not even mention APMs or cite § 1396a(bb)(6).

Second, nothing in California's State Plan suggests that electing the FFS rate in SPA 17-0002 is an APM. California's APMs are expressly denoted beginning in Section E of Attachment 4.19-B of the State Plan. *See* CMS RJN Ex. 1 (ECF 66-3). Section A.6, by contrast, does not purport to be an APM, and Plaintiffs offer no support for their contrary and conclusory contention. *Id.* Ex. 1, at Page 6B; *see Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (holding that conclusory allegations "do not suffice," and courts "are not bound to accept as true a legal conclusion couched as a factual allegation").[1]

2. SPA 17-0002 does not violate § 1396a(bb) or the Covered Outpatient Drug Rule.

Plaintiffs also rehash their contention that "[t]he lack of FQHC data" in the Mercer Report violated § 1396a(bb) and the Covered Outpatient Drug ("COD") Rule, 42 C.F.R. § 447.518(d)(1). *See* Opp. 5:1–5:25. But they ignore CMS's points and authorities showing this contention is meritless.

First, the Mercer Report, COD Rule, and SPA 17-0002 concern FFS reimbursement, whereas FQHCs are reimbursed under the PPS for purposes of § 1396a(bb), so this entire line of argument is academic if not irrelevant. Further, the Opposition does not mention the "ingredient cost" component of SPA 17-0002's reimbursement formula, thus conceding there was no need to gather data on the prices paid for 340B drugs. *See* CMS Mot. (ECF 66-1), at 8:8–8:16.

As for the "professional dispensing fee" component of SPA 17-0002, Plaintiffs point out that, in response to public comments, CMS noted that "340B covered entities may have additional costs associated with dispensing these drugs compared to a retail pharmacy." 81 Fed. Reg. 5170, 5318 (Feb. 1, 2016). *Critically*, however, the COD Rule does not require that States submit data that accounts for this possible difference to be deemed "adequate" or "reliable." On the contrary, the Rule provides that "States must provide adequate data *such as* a State or national survey *of retail pharmacy providers* or other reliable data other than a survey." 42 C.F.R. § 447.518(d)(1) (emphasis added); *see also* 42 U.S.C. § 1396r-8(k)(10); 42 C.F.R. § 447.504 (defining "retail community pharmacy" to exclude any

[1] According to DHCS, electing FFS reimbursement under Section A.6 allowed FQHCs to maximize their potential "wraparound" payments under the prior managed-care regime that predated Medi-Cal Rx. *See* 42 U.S.C. § 1396a(bb)(5); DHCS's Mot. (ECF 61-6), at 5:1–5:5.

pharmacy "that dispenses prescription medications to patients primarily through . . . clinics, charitable or not-for-profit pharmacies, [or] government pharmacies").

Moreover, the term "professional dispensing fee" in the COD Rule has a specific definition and does not include any and all "additional dispensing costs" that 340B covered entities might have. *See id.* § 447.502. Plaintiffs offer no concrete, factual allegations showing that their inhouse pharmacies have higher "professional dispensing fees," or even a theory as to why or how this could be the case, and they predominantly use contract pharmacies like the ones captured by Mercer's survey. *See* FAC ¶¶ 13–22.

In sum, nothing in the COD Rule or § 1396a(bb) required CMS to reject the Mercer Report because it did not separately estimate dispensing costs for FQHCs—particularly where FQHCs and other covered entities failed even to respond to Mercer's survey, despite "numerous channels of communication leveraged and extensive direct stakeholder outreach requesting participation." CMS RJN Ex. 3, at 4. And to be clear, Plaintiffs' failure to respond to Mercer's survey is not the "self-inflicted injury" referenced in CMS's Motion. *Contra* Opp. (ECF 75), at 5:13. Rather, it is Plaintiffs' refusal to accept PPS reimbursement, and then complain they are not reimbursed as required by § 1396a(bb). *See* CMS Mot. (ECF 66-1), at 10:9. That is not a "failure to mitigate," as Plaintiffs disingenuously contend. *See* Opp. (ECF 75), at 2:4–2:7, 10:7–10:18. It is a manufactured grievance.

3. Plaintiffs' new allegations attempting to portray California's FFS reimbursement for Medicaid-covered drugs as "340B regulations" are meritless.

SPA 17-0002 includes provisions explaining how providers are reimbursed for dispensing drugs that are purchased through the 340B Drug Pricing Program. CMS RJN Ex. 2 (ECF 66-4), at 2, 5, 14. Plaintiffs attack these provisions as "340B regulations" falling outside CMS's "statutory jurisdiction [or] authority" (*see* Opp. 11:20–12:9 (quoting 5 U.S.C. § 706(2)(C))), but this new theory is baseless.

First, this theory appears nowhere in the FAC. There is no allegation or cause of action that cites § 706(2)(C), contends that SPA 17-0002 enacted "340B regulations," or asserts that CMS exceeded its statutory jurisdiction or acted *ultra vires* in approving SPA 17-0002. *See* FAC ¶¶ 112–28.

Second, even if this theory appeared in the FAC, it would fail as a matter of law. It is entirely unclear what Plaintiffs mean by averred "340B regulations" in SPA 17-0002. Nothing in SPA 17-0002 purports to "regulate" the 340B Drug Pricing Program. Plaintiffs offer no explanation, let alone

authority, to contend that the references to 340B drugs in SPA 17-0002 divested CMS of authority to approve it. Plaintiffs' sole authority—*Adams Fruit Co. v. Barrett*, 494 U.S. 638 (1990)—is not an APA case and does not concern any *ultra vires* decision or approval by a federal agency.

4. Plaintiffs' preemption theories fail as a matter of law.

Plaintiffs also plod through their theories contending that the 340B Drug Pricing Program preempts certain aspects of SPA 17-0002 and Medi-Cal Rx. Each theory fails.

First, 42 U.S.C. § 1396r-8(a)(5)(C) is not an "express" preemption clause. That provision directs States to establish a duplicate-discount avoidance mechanism in the event that the Secretary of Health and Human Services fails to establish one under 42 U.S.C. § 256b(a)(5)(A) by November 4, 1992, and then lays out some basic requirements. Nothing in § 1396r-8(a)(5)(C) expressly prohibits provisions like those in SPA 17-0002, which merely help implement federal law. *See* CMS RJN Ex. 2 (SPA 17-0002, ECF 66-4), at 7; CMS, Best Practices for Avoiding 340B Duplicate Discounts in Medicaid (Jan. 8, 2020) ("To help assist with avoiding duplicate discounts, some state Medicaid programs have elected to use the state plan amendment (SPA) process to develop parameters around the ability of covered entities and/or contract pharmacies to dispense 340B drugs to Medicaid FFS beneficiaries.").[2]

As for field preemption, the FAC contains no such theory. Nor does the Opposition attempt to develop such a theory that is meaningfully distinct from Plaintiffs' express-preemption theory. *See* Opp. 13:2–13:9 (arguing the "plain text" of § 1396r-8(a)(5)(C) "demonstrates Congress' intent for the federal government . . . to 'occupy the field' of 340B duplicate discount regulations"). The plain meaning and purpose of § 1396r-8(a)(5)(C) was to have at least some means of avoiding duplicate discounts in place by November 4, 1992—not forbid State Medicaid agencies from having any role or responsibility to ensure that they comply with federal law. As the Ninth Circuit observed in *AIDS Healthcare Foundation v. Douglas*, "there is no indication that Congress intended to occupy the whole field in this part of the cooperative Medicaid program"—*i.e.*, the "federal statutory law designed to preclude so-called double discounts." 457 F. App'x 676, 678 (9th Cir. 2011).

Further, Plaintiffs' obstacle-preemption argument fails to recognize that avoiding duplicate discounts is itself called for under the 340B Drug Pricing Program. *See* 42 U.S.C. § 256b(a)(5)(A)(i).

[2] *See* https://www.hhs.gov/guidance/sites/default/files/hhsguidance documents/cib010820.pdf.

The alleged "significant administrative burdens" Plaintiffs decry (Opp. 13:10–13:18) are a byproduct of that requirement—not an intervening impediment or obstacle to the Program.

Finally, Plaintiffs repeatedly cite a sentence from the legislative history of the 340B Drug Pricing Program, which states: "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." *See* Opp. (ECF 75), at 13:10–13:18 (citing FAC ¶ 84, which quotes H.R. Rep. No. 102-384 (II), at 12 (1992)). While this sentence outlines the intent of the 340B Drug Pricing Program, that general goal does not require or authorize CMS to force California to use managed-care-organization ("MCO") contracts to reimburse 340B "covered entities." *See* CMS's Mot. Dismiss (ECF 66-1), at 14:1–15:2 (explaining "the use of managed-care plans typically requires a statutory *waiver* from Medicaid's requirements," and the Medicaid statute "lets state Medicaid agencies decide which state-plan benefits to cover under MCO contracts"—"CMS has no authority to second-guess California's decision").

5. Plaintiffs distort the applicable legal standards.

In their effort to stave off dismissal, Plaintiffs also obfuscate the legal standards applicable to CMS's motion to dismiss. To be clear, CMS's motion does not and need not rely on any administrative "agency record" to "test any factual allegations in the complaint." *See Marshall Cty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993). Rather, because Plaintiffs' APA claims are untethered from the very decisional documents they challenge, their claims necessarily fail as a matter of law. In turn, "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." *Id.* Such is the case here.

* * *

CMS's motion to dismiss should be granted.

Dated: May 20, 2022

Respectfully submitted,

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