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FOR PATIENT ACCESS, ET AL.

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' FIRST AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Administrative Procedure Act; Section 1983

I. INTRODUCTION

1. On December 29, 2021, the Centers for Medicare and Medicaid Service ("CMS") approved California's implementation of Medi-Cal Rx, which removes the pharmacy benefit provided by the California Medicaid program ("Medi-Cal") as a covered benefit under Medi-Cal managed care. Plaintiffs Community Health Center Alliance for Patient Access ("CHCAPA") and ten (10) nonprofit Federally Qualified Health Centers ("FQHCs") bring this suit under the federal Administrative Procedure Act ("APA") and 42 U.S.C. section 1983, to challenge the approval of Medi-Cal Rx because the approval was arbitrary and capricious in that, as approved, Medi-Cal Rx violates Plaintiffs' right to reimbursement guaranteed under federal law. Therefore, Defendants Michelle Baass, Director of the Department of Health Care Services (the "Director" and the "Department") and Chiquita Brooks-LaSure, Administrator of the Centers for Medicare and Medicaid Services (the "Administrator"), must be enjoined from violating Plaintiffs' rights as secured under federal law and from causing harm to the 11.7 million Medi-Cal patients that now receive pharmacy benefits through their Medi-Cal Managed Care Plan ("MCP").

2. Medi-Cal Rx fundamentally alters the manner through which Medi-Cal patients receive their pharmacy benefits and through which FQHCs are reimbursed for providing necessary medications to their patients. As approved, Medi-Cal Rx prohibits MCPs from offering pharmacy benefits to their plan members and requires FQHCs to only prescribe medications to their patients under the voluntary 340B Drug Discount Program ("340B Program") created by Congress to benefit FQHCs, not to harm them. If Medi-Cal Rx is implemented, FQHCs will not be able to offer their patients' prescriptions at discounted prices, for which the FQHCs are reimbursed at rates negotiated with the patients' MCP. Instead, FQHCs will required to seek reimbursement directly from the Department and only on a fee-for-service ("FFS") basis as it now exists in California's State Medicaid Plan. Thus, Medi-Cal Rx turns the Medi-Cal reimbursement program for pharmacy benefits on its head. No longer will MCPs and FQHCs be able to manage and track patient drug usage and compliance, and no longer will FQHCs be able to benefit

from the savings created by prescribing drugs through the 340B Program as Congress intended. Any such savings will now go directly to the State instead. Through Medi-Cal Rx, the State skims off the cream, but leaves FQHCs with the administrative burden of compliance, and their patients stranded. Although the State's desire to control the price of prescription drugs is laudable, the State is doing so at the expense of its poorest citizens and the people who care for them. Medi-Cal Rx is a reverse Robin Hood program, which is directly contrary to the purpose of Medicaid itself. It should never have been proposed by the Department, let alone approved by CMS.

3. Yet, giving short shrift to Medi-Cal patients and the FQHCs that serve them is nothing new for the Department and CMS. Because Medi-Cal Rx requires that Plaintiffs be reimbursed only through the FFS system that now exists in California's State Medicaid Plan, Plaintiffs also bring this action to challenge fundamental deficiencies in that FFS system. The FFS system devised by the Department and approved by CMS in 2017 does not comply with the federal Medicaid laws governing reimbursement of pharmacy services furnished by FQHCs (42 U.S.C. § 1396(bb)), the laws governing the 340B Program (42 U.S.C. §§ 256b and 1396r-8(a)(5)), and CMS's regulations relating to reimbursement of Covered Outpatient Drugs (42 C.F.R. §§ 447.502 and 447.518). Plaintiffs did not rely on California's FFS system for pharmacy reimbursement prior to the approval on Medi-Cal Rx, but as Medi-Cal Rx requires them to use it now, the FFS system must be brought into compliance with federal law, especially as it applies to the reimbursement of FQHCs.

4. When it proposed State Plan Amendment 17-002 ¶ 7, ("SPA 17-002 ¶ 7") which implemented California's FFS system, the Department did not meet the most rudimentary regulatory requirement for approval by CMS. Because federal law requires that FQHCs be reimbursed at 100 percent of their costs of service, CMS required that FQHCs' pharmacy costs in particular be considered, including both the direct costs of the prescribed drugs and the indirect costs of dispensing the drugs. Yet, the Department completely failed to adequately consider those costs to FQHCs and even excluded costs

for drugs prescribed under the 340B Program from the survey and study it provided to CMS in support of the approval SPA 17-002. As such, SPA 17-002 was deficient when it was approved by CMS in 2017, and those deficiencies have come to the fore now that Medi-Cal Rx is requiring FQHCs to be reimbursed exclusively on an FFS basis for pharmacy services. As California's FFS system is not in compliance with federal law as to reimbursements for FQHCs, Medi-Cal Rx cannot go forward until it is.

5. CMS' approvals of both Medi-Cal Rx and SPA 17-002 constitute final agency actions that were contrary to federal Medicaid laws governing the 340B Program, were contrary to Plaintiffs' constitutional rights under the Supremacy Clause of the United States Constitution, and were arbitrary and capricious. Plaintiffs therefore seek an order invalidating and setting aside (1) CMS' approval of Medi-Cal Rx, and (2) CMS' approval of SPA 17-002 ¶ 7. Plaintiffs further seek an order prohibiting the Department from (1) implementing Medi-Cal Rx as to Plaintiff FQHCs, and (2) imposing the reimbursement mechanism approved by SPA 17-002 ¶ 7 upon Plaintiff FQHCs, until such time as the Department establishes a methodology for reimbursing FQHCs for pharmacy drugs and services at a federally compliant rate that covers their actual and reasonable costs without conflicting with the requirements of the 340B Program.

II. JURISDICTION AND VENUE

6. Jurisdiction in this Court is proper under 28 U.S.C. § 1331 because the causes of action arise under the Constitution and laws of the United States, specifically 42 U.S.C. § 1983 and 42 U.S.C. § 1396 *et seq*. (the "federal Medicaid statute"), 5 U.S.C. §§ 701 *et seq*. (the Administrative Procedure Act), and Article VI of the United States Constitution (the Supremacy Clause).

7. Jurisdiction is also proper in this Court under 28 U.S.C. §§ 1343(a)(3) and (4) to redress the deprivation of rights under color of State law, and to secure equitable relief of any right, privilege, or immunity secured by the Constitution of the United States or by any Act of Congress providing for the rights of persons within the jurisdiction of the United States.

8. Venue is proper in this District under 28 U.S.C. § 1391(b) because the Department's headquarters are located in Sacramento, California, and the federal District Court for the Eastern District of California is a court of competent jurisdiction under 5 U.S.C. § 703.

9. Declaratory and injunctive relief sought in this action is authorized under 28 U.S.C. §§ 2201 and 2202, 42 U.S.C. § 1983, and the federal Administrative Procedure Act, 5 U.S.C. §§ 701 *et seq*.

III. PARTIES

A. Plaintiffs

10. Plaintiffs are a coalition of non-profit community health centers and medical providers located throughout the state of California. Their mission is to provide high-quality and comprehensive health care services, at little or no-cost, to low-income, medically underserved patients that rely on the Medi-Cal program and the services of local community health clinics. Plaintiffs include 501(c)(3) non-profit corporations designated as FQHCs by the federal Health Resources & Services Administration ("HRSA") and by CMS under 42 U.S.C. § 1396d(*l*)(2). FQHCs play a critical role in providing a safety net for Medi-Cal patients and in lowering overall health care costs to the state of California by providing an alternative to expensive specialty medical services and hospital emergency room visits. As FQHCs, Plaintiffs are required by federal law to provide health care services regardless of a patients' ability to pay.

11. Plaintiff CHCAPA is a 501(c)(4) non-profit organization whose primary purpose is to promote the social welfare by working to improve access to affordable, comprehensive, high-quality health care services for Medi-Cal patients who rely on community health centers to treat their medical needs. CHCAPA's affiliate members are all FQHCs.

12. The Plaintiff health centers to this action all participate in the 340B Program, a federal program that allows "Covered Entities" such as FQHCs to purchase

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life-saving medications from drug manufacturers at a discount, provided Plaintiffs use the savings to provide more comprehensive medical care to the patients they serve.

13. Plaintiff Avenal Community Center, dba Aria Community Health Center ("Aria") is a California non-profit corporation with its principal place of business in Lemoore, California. Aria began operations in 1996 and has been designated as an FQHC since 2007. Aria provides health care services to Medi-Cal patients at 32 clinic locations in Kings, Fresno, and Tulare Counties. Aria provides pharmacy services to its patients through 66 contract pharmacies and one in-house pharmacy, and provides medications as appropriate during regular patient visits. In 2019, Aria served 32,982 patients, 72 percent of whom were Medi-Cal patients and 6.7 percent of whom had no health insurance.

14. Plaintiff Community Health Centers of the Central Coast ("CHCCC") is a California non-profit corporation with its principal place of business in Santa Maria, California. CHCCC began operations in 1978 and has been designated as an FQHC since 1993. CHCCC serves Medi-Cal patients at 30 clinic locations in San Luis Obispo and Santa Barbara Counties. CHCCC provides pharmacy services to its patients through 75 contract pharmacies and one in-house pharmacy, and provides medications as appropriate during regular patient visits. In 2019, CHCCC served 111,735 patients, 63.37 percent of whom were Medi-Cal patients and 15.05 percent of whom had no health insurance.

15. Plaintiff Family Health Centers of San Diego ("FHCSD") is a California non-profit corporation with its principal place of business in San Diego, California. FHCSD began operations in 1970 and has been designated as an FQHC since 1991. FHCSD serves Medi-Cal patients at 50 service sites in San Diego County. FHCSD provides pharmacy services to its patients through 241 contract pharmacies and one in-house pharmacy, and provides medications as appropriate during regular patient visits. In 2020, FHCSD served 160,902 patients, 57 percent of whom were Medi-Cal patients and 33 percent of whom had no health insurance.

16. Plaintiff Imperial Beach Community Clinic ("Imperial Beach") is a California non-profit corporation with its principal place of business in Imperial Beach, California. Imperial Beach began operations in 1971 and has been designated as an FQHC since 2006. Imperial Beach serves Medi-Cal patients at two clinic locations in San Diego County. Imperial Beach provides pharmacy services to its patients through 17 contract pharmacies, and provides medications as appropriate during regular patient visits. In 2019, Imperial Beach served 9,798 patients, 53.53 percent of whom were Medi-Cal patients and 8.94 percent of whom had no health insurance.

17. Plaintiff La Maestra Family Clinic ("La Maestra") is a California non-profit corporation with its principal place of business in San Diego, California. La Maestra began operations in 1990 and has been designated as an FQHC since 1997. La Maestra serves Medi-Cal patients at 16 clinic locations in San Diego County. La Maestra provides pharmacy services to its patients through 64 contract pharmacies and three in-house pharmacies, and provides medications as appropriate during regular patient visits. In 2019, La Maestra served 45,716 patients, 68 percent of whom were Medi-Cal patients and 26 percent of whom had no health insurance.

18. Plaintiff Omni Family Health ("Omni") is a California non-profit corporation with its principal place of business in Bakersfield, California. Omni began operations in 1978 and has been designated as an FQHC since 1978. Omni serves Medi-Cal patients at 36 clinic locations in Kern, Fresno, Tulare, and Kings Counties. Omni provides pharmacy services to its patients through 89 contract pharmacies and seven in-house pharmacies, and provides medications as appropriate during regular patient visits. In 2019, Omni served 131,449 patients, 71 percent of whom were Medi-Cal patients and 10 percent of whom had no health insurance.

19. Plaintiff Open Door Community Health Centers ("Open Door") is a California non-profit corporation with its principal place of business in Arcata, California. Open Door began operations in 1971 and has been designated as an FQHC since 1999. Open Door serves Medi-Cal patients at 13 clinic locations in Humboldt and Del Norte Counties.

Open Door provides pharmacy services to its patients through 16 contract pharmacies with 53 locations, and provides medications as appropriate during regular patient visits. In 2019, Open Door served 60,219 patients, 53 percent of whom were Medi-Cal patients and 5 percent of whom had no health insurance.

20. Plaintiff Shasta Community Health Center ("Shasta") is a California non-profit corporation with its principal place of business in Redding, California. Shasta began operations in 1988 and has been designated as an FQHC since 1997. Shasta serves Medi-Cal patients at six locations in Shasta County. Shasta provides pharmacy services to its patients through 35 contract pharmacies, and provides medications as appropriate during regular patient visits. In 2019, Shasta served 33,610 patients, 80.12 percent of whom were Medi-Cal patients and 8.03 percent of whom had no health insurance.

21. Plaintiff South County Community Health Center, Inc., dba Ravenswood Family Health Network ("Ravenswood") is a California non-profit corporation with its principal place of business in East Palo Alto, California. Ravenswood serves Medi-Cal patients at seven clinic locations in San Mateo and Santa Clara Counties. Ravenswood provides pharmacy services to its patients through 22 contract pharmacies and one in-house pharmacy, and provides medications as necessary during regular patient visits. Walgreens, which serve as many of Ravenswood's 340B Program contract pharmacies, indicated its intent to terminate their contracts with Ravenswood, effective December 31, 2021, because Medi-Cal Rx is set to take effective January 1, 2022, which will reduce Ravenswood contract pharmacy locations from 22 to 12. In 2019, Ravenswood served 17,216 patients, 56 percent of whom were Medi-Cal patients and 32 percent of whom had no health insurance.

22. Plaintiff United Health Centers of the San Joaquin Valley ("UHC") is a California non-profit corporation with its principal place of business in Fresno, California. UHC began operations in 1971. UHC provides health care services to Medi-Cal patients at 25 clinic locations in Fresno, Kings, and Tulare Counties. UHC provides pharmacy

services to its patients through 142 contract pharmacies and 10 in-house pharmacies. In 2019, UHC served 97,407 patients, 50 percent of whom were Medi-Cal patients and 22 percent of whom had no health insurance.

B. Defendants

23. Defendant Director Michelle Baass is sued in her official capacity as the Director of DHCS, which is, and at all relevant times was, the public agency of the State of California charged with administration of the Medi-Cal program under California Welfare and Institutions Code §§ 17020, 14000 et seq., and Title 22 of the California Code of Regulations, §§ 50000 *et seq.* Director Baass was appointed on September 10, 2021. Plaintiffs are informed and believe that Director Baass is and has been responsible for overseeing the Department's efforts to obtain federal approval for Medi-Cal Rx since her appointment. Prior to Ms. Baass' appointment, the previous Directors, were at all relevant times, responsible for the overall administration of the Medi-Cal program, including defining, approving, and communicating Medi-Cal coverage and reimbursement policies on behalf of DHCS, authorizing proposed modification to the State Medicaid Plan under provisions of applicable federal law, and ensuring the Department administers the Medi-Cal program in compliance with all applicable federal laws and regulations. The Director has the power and authority to manage and control the actions of the Department, and either actively approved, or was aware of and did not disapprove of, the Department's actions at issue in this action.

24. Defendant Administrator Chiquita Brooks-LaSure is sued in her official capacity as the Administrator of CMS, the federal agency responsible for reviewing and approving Medicaid Waiver applications and State Plan Amendments submitted by the State of California under 42 U.S.C. §§ 1315 and 1396n(b) and 42 C.F.R. §§ 430.10 *et seq.* on behalf of the federal Department of Health and Human Services ("HHS").

IV. GENERAL ALLEGATIONS

25. Medi-Cal Rx must be enjoined for several reasons. First, Medi-Cal Rx violates federal law by requiring Plaintiffs to seek reimbursement for pharmacy costs

through the Medi-Cal FFS reimbursement system, which does not comply with the federally mandated FQHC reimbursement requirements of 42 U.S.C. § 1396a(bb). Second, the FFS system that Medi-Cal Rx imposes for Medi-Cal pharmacy drugs and services is legally deficient, and CMS erroneously approved it in SPA 17-002, ¶ 7 [1]. SPA 17-002 failed to establish a reimbursement formula that considered FQHCs' actual costs in buying 340B Program medications and their costs in dispensing those medications to patients, as required by federal law. *See* 42 C.F.R. § 447 (2016); 42 U.S.C. § 1396a(bb) (governing FQHC reimbursement under Medicaid). Third, Medi-Cal Rx and SPA 17-002 violate federal law by depriving Plaintiffs of the federally granted choice to participate in the 340B Program, and subjecting them to alternative state-level 340B duplicate discounts/rebates avoidance mechanisms that are preempted by federal law. *See* 42 U.S.C. §§ 256b(a)(5)(A) and 1396r-8(a)(5)(C). Fourth, Medi-Cal Rx must be enjoined because it interferes with the 340B Program's purpose of enabling FQHCs to use their 340B Program savings to provide better health care services to underserved communities. *See* 42 U.S.C. § 256b; H.R. Rep. No. 102-384, pt. 2 at 12 (1992).

A. Background on Medicaid Requirements for Reimbursing Providers

26. Congress enacted Title XIX of the Social Security Act – better known as Medicaid – in 1965, in order to provide individual states with the funds necessary to furnish medical care to low-income and underserved people who, without public assistance, would not have access to high-quality and life-saving health care services.

27. Medicaid is jointly financed by federal and state governments and is administered by the States through State plans approved by the Secretary of HHS. 42 U.S.C. § 1396a; 42 C.F.R. § 430.0. States that choose to participate in Medicaid must comply with both the statutory requirements imposed by Medicaid and with the

[1] SPA 17-002 was approved and became part of the current, operative state plan effective April 1, 2017. *See* Cal. State Plan, Section 4.19, Attachment B, Supplement 2, https://www.dhcs.ca.gov/formsandpubs/laws/Pages/Attachment419-B.aspx.

accompanying regulations. *See Alaska Dep't of Health and Soc. Serv's. v. Ctr's. for Medicare and Medicaid Serv's.*, 424 F.3d 931, 935 (9th Cir. 2005); *see also* 42 U.S.C. § 1396c; 42 C.F.R. § 430.35. Participating States must also develop and maintain a "State plan," which serves as an agreement between the State and CMS regarding how the State administers Medicaid and assures that it will comply with all applicable federal laws and regulations. Generally, State plans describe who is covered under Medicaid, the services they receive, and how the State will reimburse healthcare providers for treating Medi-Cal patients. States may amend their plans through State plan amendments ("SPAs") by obtaining CMS approval for the changes.

28. California participates in Medicaid through Medi-Cal, which the Department administers. Cal. Welf. & Inst. Code §§ 10740, 14000, *et seq.* The Department is responsible for establishing and complying with the state plan and submitting any SPAs to CMS. *See* 42 U.S.C. § 1396a(a)(5); 42 C.F.R. §§ 430.10, 430.12, 430.14, 431.10. The Department is also required to ensure that Medi-Cal provides specific "covered services" to eligible beneficiaries and reimburses providers for their services. 42 C.F.R. § 431.10; *Cal. Ass'n of Rural Health Clinics v. Douglas*, 738 F.3d 1007, 1010 (9th Cir. 2013).

29. Each State Plan must "provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan . . . as may be necessary . . . to assure that payments are consistent with the efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area . . . ." 42 U.S.C. § 1396a(a)(30)(A) ("Section 30(A)") (emphasis added); 42 C.F.R. §§ 447.204 and 447.500(a)(5).

30. Section 30(A) requires state Medicaid agencies to consider whether Medicaid beneficiaries have access to care equal to the general insured population when setting Medicaid payment rates and to preclude states from basing Medicaid rate setting

decisions solely on budgetary factors. *Hoag Mem. Hosp. Presbyterian v. Price*, 866 F.3d 1072 (9th Cir. 2017). In other words, Section 30(A) establishes a general floor for compensating healthcare providers for treating Medi-Cal patients, to ensure that Medi-Cal patients have doctors available to provide healthcare services. Failure to consider and ensure this access renders approval of a SPA arbitrary and capricious. *See id*. at 1081.

31. While Section 30(A) sets a general standard for reimbursement for all Medi-Cal providers, 42 U.S.C. § 1396a(bb) ("Section 1396a(bb)") mandates a more specific standard for FQHCs, including Plaintiffs – that is, the "State plan shall provide payment for [FQHC] services in an amount that is equal to 100 percent" of an FQHC's actual and reasonable costs of providing services to Medicaid patients. Thus, a State plan's reimbursement method may comply with Section 30(A), but not necessarily with Section 1396a(bb).

32. As a participating state, California's State plan and reimbursement methods must comply with both Section 30(A) and Section 1396a(bb). Relevant here, California created its FFS system in SPA 17-002, which CMS approved in April 2017.

33. Federal law allows the Secretary of HHS to 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) This is commonly referred to as a "Section 1115 Waiver."

34. States may also seek a waiver of other Medicaid requirements under 42 U.S.C. § 1396n, commonly referred to as a "Section 1915(b) Waiver." Specifically, under Section 1915(b), the HHS Secretary may waive many of the state plan requirements under 42 U.S.C. § 1396a, except for expressly specified provisions that may not be waived. The key non-waivable provision relevant here is that states must reimburse FQHCs for 100 percent of their costs as required by Section 1396a(bb). *See* 42 U.S.C. § 1396n(b).

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35. Congress mandated that States fully reimburse FQHCs for the services they provide to Medicaid patients, in order to ensure that FQHCs had sufficient resources to treat Medicaid patients without using other federal grants intended to cover services to non-Medicaid patients. Indeed, Congress created FQHCs to ensure quality health care services for underserved and impoverished communities. In addition, Congress created the 340B Program, which allows FQHCs to purchase prescriptions at discounted pricing, so that they could spend their scarce resources on improving patient services instead of paying the high cost of drugs. These federal programs have worked. FQHCs have been lauded by the state and federal governments alike for the front-line and high-quality healthcare services they provide to Medicaid and Medi-Cal patients, especially during the global pandemic that continues to decimate low-income communities.

36. Despite the undisputed success of FQHCs and the federal programs that support them, the State of California and CMS have taken actions that violate the fundamental requirements of these programs and conflict with and undermine the federal objectives of providing quality health care services to underserved communities.

B. Medi-Cal Rx and Its Impact On Providers and Patients

37. In January 2019, Governor Newsom issued Executive Order N-01-19, which instructed the Department to remove pharmacy benefits from Medi-Cal beneficiaries' managed health care plans and allow the State (instead of safety net providers[2]) to utilize the benefits of their access to discounted drugs, while leaving all the compliance and administrative burdens on the safety net providers, including Plaintiffs. The Governor's Executive Order was intended to reduce the cost of prescription drugs to save the State money.

38. In 2011, CMS approved a Section 1115 Waiver for California that implemented the Medi-Cal managed care system. Under managed care, the State

[2] The safety net providers eligible to participate in the 340B Program are called "covered entities" and include certain federal HRSA grantees such as Plaintiff FQHCs. *See* 42 U.S.C. § 256b(1)(4).

contracts with MCPs to administer and reimburse the delivery of health care services. The State pays the MCP a monthly rate, called a "capitated" payment, for each Medi-Cal beneficiary enrolled in the plan. In return, the MCP assumes the risk of the cost of providing care to Medi-Cal patients enrolled in the plan. As of September 2021, approximately 83.5 percent of all Medi-Cal beneficiaries – over 11.7 million patients – were enrolled in managed care.[3]

39. The MCPs then contract with health care providers, including Plaintiffs and other FQHCs, to actually provide medical services to Medi-Cal patients at a negotiated rate. Under Medi-Cal managed care, FQHCs generally received a negotiated reimbursement rate for pharmacy drugs and services that approximates the FQHCs actual costs of providing those drugs and services, consistent with federal law's requirements for reimbursing FQHCs at 100 percent of their costs. In the event that an MCP pays an FQHC at a rate less than its cost-based prospective payment system ("PPS") rate, the State is required to pay the difference. 42 U.S.C. § 1396a(bb)(5). MCPs are not permitted to pay FQHCs less than they pay other providers for the same services. 42 U.S.C. § 1396b(m)(2)(A)(ix).

40. MCPs provide a variety of health care benefits to Medi-Cal patients, including pharmacy services. By including pharmacy services as a covered benefit alongside other medical services, doctors can more accurately coordinate patient care, ensure patients are receiving their prescribed medications and following their treatment plan, and close care gaps that would otherwise go unnoticed. For example, if a physician at Plaintiff Open Door's clinics prescribes a Lidocaine patch for chronic pain, the doctor can access real-time information regarding the patient's cost and if the patch is available for pickup. If it is not available, the doctor can easily and quickly adjust the treatment plan so the patient's needs are met. Pharmacists in turn can work directly with the

[3] *See* "Medi-Cal Monthly Eligible Fast Facts," Department of Healthcare Services, September 2021, at 10, https://www.dhcs.ca.gov/dataandstats/statistics/Pages/Fast_Facts.aspx.

patient's primary doctor to adjust patient medication and track and prevent potential substance-abuse issues. Moreover, FQHCs can serve as a one-stop-shop for patients by housing all of the patient's care providers in one place, including pharmacists. Patients can see their doctor and pick up their prescription in one trip, thereby eliminating the need for patients to make multiple trips to different providers. Many Medi-Cal patients lack reliable transportation or are unable to dedicate time to multiple errands, so the ability to pick up any prescriptions at the same time as their doctor appointment eliminates a major barrier to health care access in the State of California.

41. Even though managed care has improved patient care and health outcomes, the Department proposed Medi-Cal Rx as the program to fulfill the Governor's charge to push all Medi-Cal pharmacy services in to the FFS system.

42. California first attempted to obtain approval for Medi-Cal Rx via an amendment to its Section 1115 Waiver, with the goal to effectuate the pharmacy transition as of January 1, 2021. When that plan fell apart, on or around June 30, 2021, California sought approval for Medi-Cal Rx via a new Section 1915(b) waiver that is to take effect on January 1, 2022.

43. In addition to this lawsuit, Plaintiffs have expressed concerns about the implementation of Medi-Cal Rx on numerous occasions to each Defendant. On March 18, 2021, Plaintiffs' counsel wrote to CMS' Director of the State Demonstrations Group to provide an overview of the problems with Medi-Cal Rx. On April 16, 2021, Plaintiff CHCAPA wrote a follow-up letter to CMS describing, in detail, why Medi-Cal Rx is inconsistent with federal law and the goals of Medicaid. On May 3, 2021, Plaintiff CHCAPA submitted a public comment to the Section 1915(b) waiver application, reiterating the many shortcomings of the Medi-Cal Rx initiative and the severe consequences that it will bring upon patients and providers alike. On July 14, 2021, Plaintiff CHCAPA wrote another letter to CMS, again noting the Department's apparent attempts to avoid public input regarding Medi-Cal Rx, emphasizing the lack of an adequate reimbursement method for FQHCs. Plaintiffs included a copy of their May 3

letter in their July 14 letter to CMS. On August 27, 2021, Plaintiffs wrote another letter to CMS further describing the threat Medi-Cal Rx poses to FQHCs and Medi-Cal patients, pointing out that it is improper for California to seek CMS approval for Medi-Cal Rx under its Section 1915(b) Waiver, instead of as a substantive change to its Section 1115 Waiver authority. On December 21, 2021, Plaintiff CHCAPA wrote again to CMS regarding the deficiencies in a Supplemental Payment Pool that the State created to mitigate Plaintiffs' financial losses due to Medi-Cal Rx. Other than acknowledging receipt of Plaintiffs' first letter, CMS has never responded to Plaintiffs' concerns.

44. Instead, on December 29, 2021, CMS – the federal agency responsible for administering Medicaid – wrongfully approved Medi-Cal Rx as part of California's Section 1915(b) Waiver. As approved, Medi-Cal Rx will wreak havoc on the health care delivery and funding system that Congress created to best serve impoverished communities that lack access to traditional health care.[4] Moreover, serious questions exist as to whether California will in fact see any savings from the Medi-Cal Rx plan. A study published in July 2021's *American Journal of Managed Care* found that integrated pharmacy benefits are more cost effective than fee-for-service. And a 2019 report conducted by the Menges Group that analyzed 13 states that implemented an Rx carve-out model, found that if California adopts the same model, it "would result in a 19.4% increase in net Medi-Cal pharmacy expenditures."[5]

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[4] In October, the CEOs of the two largest not-for-profit, publicly governed health care plans in California (Inland Empire Health Plan and L.A. Care Health Plan) published an opinion piece raising concerns about care coordination. John Baackes & Jarrod McNaughton, *Put the Brakes on Deeply Flawed Medi-Cal Rx Rollout*, Los Angeles Daily New (Oct. 11, 2021),https://www.dailynews.com/2021/10/11/put-the-brakes-on-deeply-flawed-medi-cal-rx-rollout/ ("[C]arving out pharmacy benefits from managed care plans is going to hamper the care coordination that health plans have been striving to improve for a population that is already facing health inequity. Such coordination improves health outcomes by ensuring members receive their medications and avoid harmful drug interactions, and it prevents abuse.").

[5] *See id.*

45. Before Medi-Cal Rx, the market-based payment through the Medi-Cal MCP and other federal provisions, requiring that FQHCs get paid no less than other providers, ensured that Plaintiffs were reimbursed for pharmacy services in compliance with federal law. *See* 42 U.S.C. § 1396b(m)(2)(A)(ix). However, payment through the State's FFS system will result in FQHCs being underpaid, in violation of federal law. Moreover, by failing to cover the FQHCs costs of providing drugs and pharmacy services to Medi-Cal patients, Medi-Cal Rx will also result in Medicaid cost-shifting, including increasing the risk that FQHCs will be forced to use their Section 330 HRSA grants – issued to provide services to the uninsured – to subsidize the Medi-Cal program, in a manner directly contrary to Congressional intent. Most importantly, Medi-Cal Rx threatens Plaintiffs' ability to continue to provide health care services to Medi-Cal patients and threatens to deprive millions of Medi-Cal patients of reliable access to their medication.[6]

C. CMS Wrongfully Approved Medi-Cal Rx, Which Violates Federal Law by Forcing Plaintiffs into the Legally Deficient FFS Reimbursement System for Pharmacy Services.

46. California's FFS reimbursement system must comply with two important provisions of federal law. First, the Covered Outpatient Drug Rule, adopted by CMS in 2016, requires the State to base its proposed FFS reimbursement method on "reliable data" and to provide that data to CMS to support the proposed changes. 42 C.F.R. § 447.518(d). Second, the State's reimbursement mechanism is also required to comply with federal law that mandates states to reimburse FQHCs for 100 percent of their costs for treating Medi-Cal patients. 42 U.S.C. § 1396a(bb). In creating California's FFS reimbursement system, the Department failed to comply with either requirement.

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[6] Congress has recognized the negative impact of carving out pharmacy from coverage by Medicaid MCPs in connection with the adoption of the Drug Rebate Equalization Act of 2009, S. 547, 111th Congress § 2 (2009); ultimately adopted as part of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2501, 124 Stat. 119, 306-08 (2010), as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 1206, 124 Stat. 1029, 1056-57.

1. The FFS System Violates the Covered Outpatient Drug Rule Because It Failed to Account for FQHCs' Pharmacy Costs.

47. The CMS Covered Outpatient Drug Rule requires that covered entities be reimbursed for "pharmacy costs," which "include, but are not limited to, reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy." 42 C.F.R. §§ 447.518(a)(2); *id.* § 447.502 (defining "professional dispensing fee").[7]

48. The Covered Outpatient Drug Rule also requires States to provide adequate and reliable data, such as a State or National survey of retail pharmacy providers, to support any proposed changes to the reimbursement methodology for pharmacy costs. Additionally, CMS directed each state to consider the fact that "[340B] covered entities may have additional costs associated with dispensing these drugs compared to a retail pharmacy," and that the states should "consider those dispensing costs when looking at overall payment to these covered entities." Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5318 (Feb. 1, 2016) (to be codified at 42 C.F.R. pt. 447). States were required to submit the proposed change in reimbursement

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[7] The Covered Outpatient Drug Rule was not adopted under the Medicare reasonable cost provisions, which establish the minimum levels of Medicaid reimbursement for FQHCs under 42 U.S.C. § 1396a(bb); nor are they "based on such other tests of reasonableness as the Secretary prescribes in regulations under section 1833(a)(3) [42 U.S.C. § 1395l(a)(3)]." *See* 42 C.F.R. § 447.500(a). Instead, as relevant here, they were adopted under the general requirements described in 42 U.S.C. § 1396a(a)(30)(A), with regard to the efficiency, economy, and quality of care in the context of payments for covered outpatient drugs, and no analysis was undertaken by Defendants to ensure that the "pharmacy costs" definition was consistent with the requirement that both direct and indirect FQHC costs be allowed. 42 C.F.R. § 447.500(a)(5).

methodology and the supporting data to CMS through a SPA, which was subject to the formal review process. 42 C.F.R. § 447.518(d).

49. While CMS stated that the Covered Outpatient Drug Rule "does not limit states to one method or only using pharmacy invoices to determine AAC," it still required 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 when proposing any change to its ingredient cost or dispensing fee reimbursement." Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5170, 5293-5294 (Feb. 1, 2016) (to be codified at 42 C.F.R. pt. 447).

50. To comply with the Covered Outpatient Drug Rule's data requirements, the Department contracted with Mercer Government Human Services Consulting ("Mercer") to survey pharmacies as to their pharmacy costs. Mercer's survey purported to evaluate the ingredient cost and the costs to be reimbursed through a professional dispensing fee. Mercer issued its final report on January 4, 2017 (the "Mercer Report").

51. Mercer solicited data from California pharmacies through two separate surveys. One focused on data for the professional dispensing fee, and another focused on data for the ingredient costs, but expressly excluded a survey of the cost of 340B drugs.

52. Of the 5,644 pharmacies to which Mercer asserts it sent the surveys, only 2,562 – less than half – responded, most of which were retail chain pharmacies. Moreover, Mercer admitted that FQHC pharmacies only provided four responses – or 0.2 percent – and that due to the small numbers of responses, further analyses were not conducted of FQHC pharmacy costs. Furthermore, Mercer admitted that only one pharmacy with usable response data was a 340B Covered Entity. Therefore, pharmacy costs for Covered Entities' were not sufficiently studied in the Mercer Report, nor were they analyzed separately from non-340B Covered Entities like retail pharmacies, as required by the applicable federal regulations.

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53. Rather than attempt to further study FQHCs or other Covered Entities' pharmacy costs as required, Mercer disregarded FQHCs' and Covered Entities' costs entirely. California nonetheless adopted the Mercer Study's recommendations in SPA 17-002 and its proposed FFS system.

54. Thus, the FFS reimbursement system created in SPA 17-002 failed to comply with 42 C.F.R. § 447.518(d) because it did not use reliable data to demonstrate that the FFS reimbursement adequately covers Plaintiffs' reasonable pharmacy costs.

2. As It Does Not Provide for Full Reimbursement of Plaintiffs' Pharmacy Costs as Required by Law, the FFS System Violates Plaintiffs' Right to Reimbursement Under Section 1396a(bb).

55. In addition to the Covered Outpatient Drug Rule, federal law also requires that reimbursement methods adopted by California's State Plan establish FQHC payment rates on a per-visit basis at a rate that is equal to 100 percent of FQHCs' "reasonable and related costs in furnishing [FQHC] services . . . ." 42 U.S.C. §§ 1396a(bb)(1). Congress mandated this requirement for States participating in Medicaid to avoid a situation in which FQHCs were required to use their HRSA Section 330 grants to subsidize the Medicaid program.[8] Pharmacy services – and the drugs covered under California's State Plan – are among the mandatory FQHC service benefits required to be reimbursed at 100 percent of an FQHC's costs. *See* 42 U.S.C. § 1396d(a)(2)(C) (defining mandatory FQHC services); *see also* § 254b(b)(1)(V) (defining the required primary health services to qualify as a 340B Covered Entity to include pharmaceutical services).

56. Medi-Cal Rx eliminates pharmacy drugs and services as a covered benefit in MCPs and forces all Medi-Cal providers, including Plaintiffs, into the FFS reimbursement system instead. In contrast to the managed care model, the FFS system

[8] *See Three Lower Cnties. Comm. Health Svc's., Inc. v. Maryland*, 498 F.3d 294, 297-98 (4th Cir. 2007). To ensure a State does not shift the costs of Medicaid services to the health center or the Section 330 grant program, Congress provided FQHCs with a private right of action to enforce the state's FQHC payment obligations under 42 U.S.C. § 1396a(bb). *See Cal. Ass'n of Rural Health Clinics v. Douglas*, 721 F.3d 1097, 1104-07 (9th Cir. 2013).

reimbursement method consists of two pieces: the "actual acquisition cost" and a "professional dispensing fee." *See* Cal. Welf. & Inst. Code § 14105.46; *id.* § 14105.45(b)(2)(B); Cal. State Plan, Attachment 4.19-B, Supplement 2 at ¶ 7.

57. "Actual acquisition cost" means that, as to 340B drugs, "a covered entity is required to bill and will be reimbursed 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**." Cal. Welf & Inst. Code § 14105.46(d) (emphasis added). Manufacturer overcharges[9] in excess of the statutory 340B price, shipping costs, and distributer or wholesaler markup that are part of the cost of acquisition, are not reimbursed under this formula. The dispensing fee does not cover these acquisition-related costs.

58. The dispensing fee amounts are set forth in a statute and the State Plan. The professional dispensing fee is fixed at either $10.05 or $13.20 per claim, depending on the clinic's annual claim volume. Cal. Welf. Inst. Code § 14105.45(b)(2)(B); Cal. State Plan, Attachment 4.19-B, Supplement 2 at ¶ 5. Plaintiffs are limited to these specific amounts for reimbursement because of their status as covered entities. *See id.* § 14105.46; Cal. State Plan, Attachment 4.19-B, Supplement 2 at ¶ 7.

59. Both portions of the FFS system are inadequate under Section 1396a(bb)'s requirements. The "actual acquisition cost" does not account for the various fees and additional charges Plaintiffs must pay in order to physically obtain a given medication. Additionally, the dispensing fee amounts were created without considering FQHCs' costs in dispensing drugs to Medi-Cal patients.

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[9] 340B covered entities cannot sue manufacturers for overcharges but must rely on the Alternative Dispute Resolution ("ADR") mechanism established by Congress in 2010 as part of the Patient Protection and Affordable Care Act. *See* Pub. L. No. 111-148, § 7102(a), 124 Stat. 823 (2010), codified at 42 U.S.C. § 256b(d)(3)); *Astra USA, Inc. v. Santa Clara Cty*, *Cal.*, 563 U.S. 110 (2011). While this ADR mechanism was to be established "[n]ot later than 180 days after the date of enactment of the Patient Protection and Affordable Care Act," it was only finalized more than 10 years later on January 13, 2021, and has since been enjoined as to Eli Lilly and Company, and is the target of additional drug manufacturer litigation.

a. The FFS Reimbursement Does Not Reflect FQHCs' Entire Cost of Purchasing 340B Drugs.

60. The FFS system adopted in SPA 17-002 caps reimbursement for the "actual acquisition cost" for 340B drugs at the same price as the amount "as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code." This is problematic for several reasons.

61. First, the Department failed to conduct any survey to determine the actual cost to providers for 340B purchases. The Mercer Study survey template stated that the respondent should "exclude or flag any purchases your pharmacy made under a 340B contract." Thus, the final Mercer study recommendations did not include FQHCs' entire costs of purchasing drugs, such as shipping or distributer or wholesaler markups. Consequently, this omission ensured that no data would be available to determine whether the Department would in fact reimburse covered entities like Plaintiffs at a level and amount that covered the drug's entire purchase price.

62. Second, the Department's reimbursement mechanism fails to address manufacturer overcharges for 340B drugs, which would be borne entirely by the covered entity, not by the program purportedly covering the drugs. According to a 340B Report from HRSA, "[f]our of the five manufacturers that HRSA audited in fiscal year 2021 had adverse findings and were required to repay entities for overcharges."[10] Yet the Department failed to account for situations that some Plaintiffs have faced where they are charged more than the 340B "ceiling price" to acquire a 340B drug, but are reimbursed as though they paid the "actual" discounted price. *See* 42 U.S.C. § 1396a(bb).

63. Since FQHCs have long had no functioning mechanism to challenge manufacturer overcharges for 340B, as described in footnote 9, under the Department's

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[10] *See* Tom Mirga, *HRSA Audit Finds Drug Maker and Subsidiary Overcharged 340B Providers*, 340B Report (Dec. 2, 2021), https://340breport.com/hrsa-audit-finds-drug-maker-and-subsidiary-overcharged-340b-providers/; *see also* HRSA FY 21 Manufacturer Audit Results at https://www.hrsa.gov/opa/program-integrity/audit-results/fy-21-manufacturer-audit-results.

methodology, Medi-Cal's costs would be borne by providers, including Plaintiffs, in violation of Section 1396a(bb).

b. The FFS Dispensing Fee Does Not Reflect FQHCs' Costs in Providing Drugs to Their Patients.

64. The Department also relied on the Mercer Report's incomplete data to establish the dispensing fee portion of the FFS system, approved in SPA 17-002. As a result of the Department's disregard of the federal mandate to consider FQHCs' and Covered Entities' higher costs, the resulting dispensing fees reflect an artificially low, unrepresentative average of retail pharmacy costs. In adopting the dispensing fees in SPA 17-002, the Department shirked its responsibility to "develop methodologies that ensure that . . . 340B entities are reimbursed adequately." *See* Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5318 (Feb. 1, 2016) (to be codified at 42 C.F.R. pt. 447).

65. The managed care system enabled California to avoid answering for its flawed FFS reimbursement with respect to Plaintiffs because the MCPs reimbursed Plaintiffs at a negotiated rate consistent with federal law. Therefore, Plaintiffs have not been required to accept the inherently defective FFS rate for providing pharmacy services to Medi-Cal patients. By eliminating MCP coverage of pharmacy care, Medi-Cal Rx now pushes Plaintiffs into the FFS system, requiring them to accept reimbursement amounts that were not developed as required by federal law.

66. Because SPA 17-002 did not consider FQHC costs under the 100-percent reimbursement standard of Section 1396a(bb) in creating the FFS dispensing fees or actual acquisition costs, Plaintiffs are informed and believe, and thereon allege, that the FFS reimbursement rate does not satisfy the clear federal requirement that Plaintiff FQHCs be reimbursed for 100 percent of their costs. SPA 17-002 is therefore unenforceable as applied to Plaintiffs and similarly situated FQHCs, and thus must be enjoined.

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3. CMS Wrongfully Approved SPA 17-002 Without Regard to the Potential Impact on Access to Care and Quality of Care as Required by Section 30(A).

67. As noted above, Section 30(A) requires that each state's Medicaid plan must assure that payments to providers are sufficient to enlist enough providers so that care and services are available under the plan, at least to the extent that such care and services are available to the general population in the geographic area.

68. Plaintiffs are informed and believe and thereon allege that, in approving SPA 17-002, CMS did not consider how paying FQHCs less than their costs for drugs and pharmacy services, or how its application of an extremely costly and burdensome claim-by-claim process on 340B covered entities, while compensating covered entities for dispensing services at the same rate as providers not similarly burdened, would affect access to care and quality of care as required by Section 30(A). SPA 17-002 is therefore unenforceable as applied to Plaintiffs and similarly situated FQHCs, and thus must be enjoined.

4. As They Did Not Comply with Federal Law, CMS Wrongfully Approved Both SPA 17-002 and Medi-Cal Rx.

69. Before the Department could adopt the new dispensing fee based on the Mercer Report, it required federal approval. *See, e.g.*, Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5170 (Feb. 1, 2016) (to be codified at 42 C.F.R. pt. 447). On or around May 30, 2017, the Department submitted the proposed SPA 17-002 to CMS, seeking approval of the dispensing fees.

70. Plaintiffs are informed and believe that the Department failed to disclose to CMS that the underlying data supporting the dispensing fees in SPA 17-002 did not reflect FQHCs' costs, which the Covered Outpatient Drug Rule required States to consider. Plaintiffs are further informed and believe that the Department did not explain whether or how it had ensured that the $10.05 and $13.20 per claim fully reimbursed FQHCs' costs as required by 42 U.S.C. § 1396a(bb).

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71. Instead, in its submission to CMS, the Department merely stated that it did not agree with "some commenters'" concerns that the "professional dispensing fees may not cover their costs of dispensing," or that it created any concerns for Medi-Cal patients to access medical care.

72. CMS accepted the Department's representations at face value. In a letter dated August 25, 2017, CMS stated that it was approving SPA 17-002, including the faulty reimbursement mechanisms, effective April 1, 2017. In its approval letter, CMS inaccurately stated that the Department "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," ignoring Mercer's own admitted deficiencies in the survey data.

73. The data supporting SPA 17-002 did not consider FQHCs' or 340B Covered Entities' costs, and CMS failed to ensure that the resulting reimbursement method satisfied the federally mandated reimbursement standard. CMS' approval of SPA 17-002 in the face of these serious deficiencies was arbitrary, capricious, an abuse of discretion, and contrary to law. Accordingly, Plaintiffs cannot be forced to accept reimbursement for pharmacy services through the FFS created by SPA 17-002.

74. Because Medi-Cal Rx mandates the inherently flawed FFS system previously approved in SPA 17-002, CMS' approval of Medi-Cal Rx is also arbitrary, capricious, an abuse of discretion, and contrary to law, and therefore must be enjoined.

D. The FFS System Described in SPA 17-002, ¶ 7, Conflicts With Federal Law Governing the 340B Program and Is Thus Preempted and Unenforceable.

1. HRSA Adopted the Medicaid Exclusion File as the Exclusive Mechanism for Avoiding "Duplicate Discounts or Rebates" on 340B Medications.

75. The 340B Drug Pricing Program is a drug-discount program established by Congress in 1992 and administered by the HHS Secretary. The Secretary delegated oversight of the 340B Program to the HRSA. *See* Statement of Organizations, Functions,

and Delegations of Authority, 58 Fed. Reg. 19,137-02 (Apr. 12, 1993). FQHCs are "covered entities" intended to benefit from the 340B Program. 42 U.S.C. § 256b(a)(4)(A).

76. Under the 340B Program, savings on drugs dispensed to Medicaid patients occur in one of two ways. A covered entity may purchase 340B drugs from the manufacturer at a discounted rate and use the savings for patient-care related purposes; or alternatively, a State may seek a rebate from the manufacturer on non-340B drugs. To avoid a situation in which manufacturers sell 340B drugs at a discounted rate to a covered entity and the State then seeks a rebate on the same drugs, federal law prohibits covered entities from requesting a discount on a 340B drug if the drug is "subject to the payment of a rebate to the State."[11] The 340B statute refers to this as the prohibition on duplicate discounts or rebates. 42 U.S.C. § 256b(a)(5)(A).

77. Congress charged the HHS Secretary with the task of establishing a mechanism to ensure that Covered Entities comply with the duplicate discount or rebate prohibition by November 4, 1993. 42 U.S.C. § 1396r-8(a)(5)(C). Simultaneously, Congress conditioned individual States' authority to adopt a duplicate discount avoidance mechanism only if HHS' failed to act by November 4, 1993. In other words, only "if the [HHS] Secretary does not establish a mechanism" by the statutory deadline would State Medicaid Agencies have authority do so. *Id.*

78. The Secretary of HHS delegated the task to HRSA, which adopted a duplicate discount or rebate prohibition mechanism within the statutory timeframe, on June 23, 1993, thus precluding a state's enforcement of its own alternative mechanism. *See* 58 Fed. Reg. 34058.

79. The duplicate discount or rebate prevention mechanism HRSA adopted is known as the Medicaid Exclusion File ("MEF"), which serves as "the official data source

[11] A 340B drug is not "subject to the payment of a rebate to the State" once the covered entity complies with HRSA's duplicate discount avoidance mechanism described in 42 U.S.C. §§ 256b(a)(5)(A)(ii).

to determine whether 340B drugs are billed to Medicaid in order to prevent duplicate discounts."[12] The whole purpose of the MEF is to serve as a platform for covered entities to record their election as to whether or not to use 340B drugs for Medicaid beneficiaries, which determines whether drugs are subject to a manufacturer's payment to the State or not. If the covered entity elects to dispense 340B drugs to Medicaid beneficiaries, the drugs are not "subject to the payment of a rebate to the State" under 42 U.S.C. § 256b(a)(5)(A)(i).

80. The MEF duplicate discount avoidance system achieves Congress' legislative intent to minimize the administrative burden on covered entities with respect to identification of 340B drugs dispensed to Medicaid beneficiaries, while also providing freedom of choice on the part of participating providers as to whether to shoulder the administrative and compliance burdens of the program. H.R. Rep. No. 102-384, pt. 2 (1992).

81. The MEF does not require identification of 340B drugs on individual Medicaid claims, nor does it require billing Medicaid at the 340B price. Yet, these burdens will now be placed on covered entities as a result of CMS' approval of SPA 17-002, ¶ 7.

82. Moreover, the MEF allows covered entities to choose whether to purchase and dispense 340B drugs in Medicaid or not, as HRSA noted in 2014 on the federal 340B website.[13] HRSA's instructions are consistent with Congress' intent that "participation by a 'covered entity' in the price reductions under these [340B] agreements is completely at the option of each entity." 102 H. Rpt. 384, part 2. The MEF allows State Medicaid programs to know which entities are using 340B drugs for Medicaid patients, and which are not. By electing to dispense 340B drugs within the MEF, the drugs are, by operation

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[12] *See Clarification on Use of the Medicaid Exclusion File*, Health Resources and Services Administration, Dec. 12, 2014.

[13] *Id.* ("At registration, covered entities inform HRSA whether [they] will purchase and dispense 340B drugs to their Medicaid patients ('carve-in') or whether they will purchase drugs for their Medicaid patients through other mechanisms ('carve-out').").

of law, no longer "subject to the payment of a rebate to the State" within the meaning of 42 U.S.C. § 256b(a)(5)(A), and a covered entity may be reimbursed by Medicaid for the drug.

83. In setting 340B drug reimbursement at a rate different from other providers, California violates the prohibition on State-level alternative duplicate discount avoidance mechanisms. As described by the Department, California's 340B covered entities are required to "identify claims where Medi-Cal beneficiaries receive 340B purchased drugs . . . [i]n order to comply with federal law claims must be filled out correctly to prevent 'duplicate discounts'."[14] This statement is directly contrary to the exclusivity requirements of federal law, only permitting states to adopt alternative mechanisms if HRSA had failed to act in a timely manner, which it did not. 42 U.S.C. §§ 256b(a)(5)(A)(ii) and 1396r-8(a)(5)(C).

84. Adoption of an impermissible state-level duplicate discount avoidance mechanism is unavoidable if a State adopts a 340B-specific reimbursement methodology based on the statutory 340B ceiling price. Any such reimbursement methodology would render nonsensical Congress' limitations regarding adoption of duplicate discount avoidance mechanisms, since claims would need to be identified on a claim-by-claim basis, the 340B ceiling price would need to be disclosed on claim forms, audits and resolution of disputes regarding 340B pricing would need to be provided and paid for outside of the exclusive dispute resolution mechanisms described in 42 U.S.C. § 256b(d)(3), and both the State and CMS would become enmeshed in the administration of the 340B program, as to which only HRSA has been delegated administrative authority.

85. Finally, and perhaps most significantly, allowing state-level reimbursement mechanisms tied to the 340B ceiling price would turn the question of whether the drug was "subject to the payment of a rebate" or not, within the meaning of 42 U.S.C.

[14] https://www.dhcs.ca.gov/provgovpart/Pages/DrugRebateFAQ.aspx#30

§ 256b(a)(5)(A)(i), on its head. While the MEF permits the covered entity to elect whether a drug provided to a Medicaid patient is subject to a rebate, California's SPA 17-002 instead subjects *all* drugs to a rebate, which allows the State to collect drug savings at the expense of covered entities.

86. As such, CMS' approval of SPA 17-002, ¶ 7, is preempted by federal law, and Plaintiffs request an order from the court holding unlawful and setting aside CMS' approval of SPA 17-002, ¶ 7, and enjoining Defendants from implementing it.

2. HRSA's Medicaid Exclusion File Preempts California's Own 340B-Specific Requirements for FQHCs.

87. HRSA's timely creation of the MEF deprived California of authority to create a duplicate discount or rebate avoidance scheme, but the State did exactly that in 2009 by adopting two statutes governing 340B drugs that directly conflict with the MEF.[15] These two statutes were incorporated into paragraph 7 of California SPA 17-002, which addressed the manner of reimbursement of covered entities and their contract pharmacies under 42 C.F.R. § 447.518(a)(1)(i) and (ii) of the Covered Outpatient Drug Rule. CMS' approval of paragraph 7 of SPA 17-002 was inconsistent with and preempted by federal law.

88. In contrast to the MEF, California Welfare & Institutions Code section 14105.46(b) purports to *require* 340B Covered Entities to "dispense only 340B drugs to Medi-Cal beneficiaries." This requirement is directly contrary to HRSA's 2014 instruction to covered entities that participation in the 340B Program itself was purely voluntary, just as Congress intended.

89. In addition, Section 14105.46(d) provides: "A covered entity shall bill an amount not to exceed the entity's actual acquisition cost for the drug, as charged by the

[15] HRSA provided guidance in 1993 directing 340B Covered Entities to bill no more than the entity's actual acquisition cost plus a dispensing fee to avoid duplicate discounts. HRSA retracted that guidance in 2000, but it did not abrogate the MEF as the exclusive 340B duplicate discount avoidance mechanism.

manufacturer at a price consistent with Section 256b of Title 42 of the United States Code plus the professional fee pursuant to Section 14105.45 or the dispensing fee pursuant to Section 14132.01." Sections 14105.46(b) and (d) are California's mechanism for preventing duplicate discounts or rebates on 340B drugs in the FFS system. First, the Department ensures that FQHCs will only dispense discounted medications to Medi-Cal patients by mandating it. Cal. Welf. & Inst. Code § 14105.46(b). Then, the Department only reimburses FQHCs at the statutory maximum, excluding other actual costs such as manufacturer overcharges and shipping charges.

90. These statutes conflict with the MEF and are therefore preempted for two reasons. First, California did not have the authority to create a duplicate discount avoidance mechanism because federal law gave HHS exclusive jurisdiction to do so if it acted within a certain time, which it did. *See* 42 U.S.C. § 1396r-8(a)(5)(C).

91. Second, California eliminated Plaintiffs' choice of whether to participate in the 340B Program, including the administrative burdens that accompany it, by instead mandating that Plaintiffs only provide 340B drugs to Medi-Cal patients. *See* Cal. Welf. & Inst. Code § 14105.46(b). The administrative burdens of participating in the 340B Program include, for example, a cumbersome claim-by-claim analysis and self-audit to identify each claim where a Medi-Cal patient received a 340B medication. The Department has mandated claim-by-claim self-audits of compliance with § 14105.46, requiring significant staffing and administrative costs. Tellingly, it issued these "self-audit" demands in the middle of the COVID-19 pandemic, when Plaintiffs' pharmacy staffs were struggling to ensure the vaccination of their patients and dealing with staffing shortages. Plaintiffs might accept these administrative burdens if they received the benefit of the savings generated by participation in the 340B Program, but Medi-Cal Rx both denies them the choice to opt in or opt out of the 340B Program for Medi-Cal and deprives them of any savings they can leverage to better serve their patients.

92. Under managed care, mandatory 340B participation was of minimal concern because the market reimbursement rate from the MCPs adequately covered

Plaintiffs' costs of complying with the self-audit. However, the FFS reimbursement system does not factor Plaintiffs' administrative costs into either the actual acquisition cost or the dispensing fee for pharmaceuticals, and thus the reimbursement rate is inadequate to reimburse FQHCs for 100 percent of costs as required by federal law.

93. Because Medi-Cal Rx forces Plaintiffs into the FFS system, it forces Plaintiffs to comply with preempted and unenforceable state regulations of the 340B program, and to shoulder the cost of the onerous administrative burdens while passing the 340B Program savings onto the State. Thus, enforcement of SPA 17-002 and Medi-Cal Rx must be enjoined because the FFS system and California's regulatory scheme are inconsistent with and preempted by HRSA's duplicate discount or rebate avoidance mechanism established by federal law.

E. Medi-Cal Rx Must Be Enjoined Because It Undermines The Purpose of the 340B Program by Depriving Plaintiffs of Funds Necessary to Provide Better Services to More Eligible Patients.

94. Congress created the 340B program for the express purpose of enabling covered entities like Plaintiffs 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).

95. The 340B Program accomplishes Congress' goals by requiring, as a condition of participating in Medicaid, that pharmaceutical manufacturers sell outpatient drugs at a discounted price to covered entities like Plaintiffs. According to HRSA, sales of 340B medications totaled approximately $29 billion in 2019. Generally, covered entities saved between 25 and 50 percent of the total amount of money they would have spent on non-340B priced medications.

96. Plaintiff FQHCs utilize the 340B Program savings to provide better services to more patients. These services include treating conditions that HRSA has identified as priorities and which are more prevalent among the communities that FQHCs serve,

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including HIV, diabetes, asthma, mental health conditions, substance abuse, hypertension, and heart disease.[16]

97. Under Medi-Cal managed care, covered entities, including Plaintiffs, purchase 340B medications at the discounted price, and the MCPs reimburse them at a negotiated, generally market-based, price. While the negotiated reimbursement rate is higher than the 340B price, FQHCs do not "profit" from the 340B Program. Instead, Plaintiffs are required by law to invest every penny of 340B savings into providing more services to their patients who face numerous barriers to accessing basic health care services. 42 U.S.C. §§ 254b(e)(5)(A) and 254b(k)(3)(I); 45 C.F.R. § 75.308(a), and 45 C.F.R. pt. 75, Subpart E.

98. Plaintiffs are leveraging their savings from 340B discounts to do exactly as Congress intended. For example, Plaintiff Omni passes 340B savings onto its patients by subsidizing costs for medical services, including prescription medications, to reduce out-of-pocket costs for patients who need to save every dollar possible to cover their basic life necessities. Plaintiff Shasta has used its 340B savings to provide free transportation services to patients who need help getting to and from their doctors' appointments, eliminating a simple yet often insurmountable barrier for some of Shasta's Medi-Cal patients. Shasta also covers 100 percent of the cost of medications it provides to its patients who are homeless and could not afford their medication, no matter how

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[16] *See* Jennifer L. Rodis, Alexa Sevin, Magdi H. Awad, et al., *Improving Chronic Disease Outcomes Through Medication Therapy Management in Federally Qualified Health Centers*. 8 J. Primary Care Community Health 4, 324-31 (2017), https://journals.sagepub.com/doi/10.1177/2150131917701797; Jennifer L. Rodis, Tracy R. Capesius, et al., *Pharmacists in Federally Qualified Health Centers: Models of Care to Improve Chronic Disease*, 16 Preventing Chronic Disease (2019), https://doi.org/10.5888/pcd16.190163; Nat'l Coalition on Health Care and the Inst. for Healthcare Improvement, Curing the System: Stories of Change in Chronic Illness Care (May 2002), https://www.kpwashingtonresearch.org/application/files/7216/3131/0280/act_report_may_2002_curing_the_system.pdf. *See also* HRSA, 2020 Uniform Data System Report for California Health Center Program; UDS Report Table 6A: Selected Diagnoses and Services Rendered; https://data.hrsa.gov/tools/data-reporting/program-data/state/CA/table?tableName=6A.

necessary it is for their health. Plaintiff Open Door uses its 340B savings to combat opioid addiction through its Medication Assistance Program. The 340B Program allows Open Door to acquire Suboxone, a scientifically-proven treatment that helps patients overcome and manage opioid addiction, and to provide counseling and support services to help keep patients from relapsing.

99. Medi-Cal Rx changes everything. By forcing Plaintiffs to be reimbursed under FFS for pharmacy services, Plaintiffs will no longer receive the savings from purchasing 340B discounted drugs, which they were required to apply to patient services. Instead of the negotiated reimbursement from an MCP, the Department will only pay Plaintiffs the 340B drug price (which it incorrectly assumes is "actual acquisition cost"), plus a dispensing fee in the FFS system. As discussed above, the FFS reimbursement system did not account for FQHC or 340B covered entities' costs in providing pharmacy services to their patients, or that FQHCs might be overcharged for 340B drugs. Thus, Plaintiffs will be deprived of an adequate reimbursement rate and savings that Congress created for them to reinvest into better serving their patients.

100. Medi-Cal Rx allows the State of California to benefit from the 340B Program at the expense of the underserved patients Congress sought to help. Because it directly interferes with the purpose of the federal 340B Program, Medi-Cal Rx and SPA 17-002, upon which it relies, are preempted by federal law and must be enjoined.

F. CMS' Approval of Medi-Cal Rx Via a 1915(b) Waiver Violates Federal Law Because Medi-Cal Rx Is Inconsistent with the Purposes of Medicaid.

101. As part of the 1915(b) Waiver approval process, CMS is required to determine, in approving such a waiver, that it, among other things, that "the State's proposed program or activity meets the requirements of the [Medicaid] Act . . . ." 42 C.F.R. § 430.25(g)(1).

102. In California's 1915(b) waiver proposal, the impact of its approval of Medi-Cal Rx, as set forth in the proposal's Attachment III, is described as "the carve-out of pharmacy services billed on a pharmacy claim" for the purpose of reducing State

expenditures." Although the State claims savings of $6.9 billion in managed care costs, it fails to identify the amount of the cost-shift to the fee-for-service system. In an earlier fiscal projection by the State, the estimated managed care pharmacy savings and related managed care administration savings was projected to be $5.82 billion annually, but the fee-for-service pharmacy costs were projected to be $5.65 annually. The Department also expected savings related to non-hospital 340B clinics (*i.e.*, Plaintiffs and other FQHCs and clinics) to be $147,000,000 annually. Thus, even assuming alleged cost-savings is a valid basis for making sweeping changes to the Medi-Cal program, the amount of the savings as represented to CMS in connection with the waiver only told half the story.

103. More importantly, CMS' approval of the Medi-Cal Rx provision of the 1915(b) Waiver was made in full awareness that California lacks, and has taken no steps to adopt, an FFS reimbursement mechanism that complies with 42 U.S.C. § 1396a(bb) with respect to FQHC pharmacy services. The approval was also inappropriate in that by shifting 11.7 million new Medi-Cal into the FFS system, CMS would significantly undermine the scope and quality of care available to Medi-Cal beneficiaries by failing to provide for adequate reimbursement for FQHC pharmacy services, shifting Medicaid's costs to the HRSA-administered Section 330 grant funds, and forcing FQHCs to comply with the improper State-level duplicate discount avoidance mechanism set forth in SPA 17-002, ¶ 7, and thus undermining the HRSA-administered 340B program, as more fully described above.

104. CMS's approval of Medi-Cal Rx of the 1915(b) Waiver was improper under the laws relating to approval of 1915(b) Waivers, in that the waiver is contrary to the purposes of the Medicaid Act. Instead of enabling high-quality medical services for those who cannot otherwise afford it, Medi-Cal Rx ensures that patients receiving care at FQHCs would receive less care, and care of lesser quality, in the midst of a global pandemic.

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105. As such, CMS' approval of Medi-Cal Rx in the 1915(b) waiver was arbitrary, capricious, an abuse of discretion, and contrary to applicable law. Plaintiffs therefore request that the court hold unlawful and set aside CMS's approval of the 1915(b) waiver as to the pharmacy carve-out described on page 206 of the Waiver Proposal and on Attachment III of the Proposal.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION

(42 U.S.C. § 1983 against Director Baass)

For Violations of Plaintiffs' Right to Reimbursement Under 42 U.S.C. § 1396a(bb)

106. Plaintiffs incorporate by reference each of the previous paragraphs set forth above as if fully alleged herein.

107. Defendant Baass, in her official capacity as Director of DHCS, is a person acting under the color of state law.

108. While acting under color of state law, the Director's conduct described above has deprived Plaintiffs of rights guaranteed under federal law by implementing Medi-Cal Rx, notwithstanding the flawed SPA 17-002 FFS reimbursement method, which established a reimbursement mechanism without regard to whether it reimburses FQHCs in a manner consistent with 42 U.S.C. § 1396a(bb).

109. Specifically, the Director's development, approval, and implementation of Medi-Cal Rx will result in inadequate reimbursement to Plaintiffs in violation of federal law because:

a) Medi-Cal Rx will require all of Plaintiffs' pharmacy services to be reimbursed through the FFS system established by SPA 17-002;

b) The FFS system as approved did not account for FQHCs' actual and reasonable costs in purchasing medications and providing pharmacy services, and therefore the FFS method does not accurately reflect Plaintiffs' costs in providing those services; and

c) The Director has failed or refused to ensure that the dispensing fees are sufficient to cover Plaintiffs' actual and reasonable costs in providing pharmacy services, in violation of 42 U.S.C. § 1396a(bb).

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110. Defendant's conduct is an actual and proximate cause of Plaintiffs' harm and Plaintiffs have an express private right of action to protect them from such harm and enforce their right to reimbursement under 42 U.S.C. § 1396a(bb). *See Cal. Ass'n of Rural Health Clinics*, 783 F.3d at 1013.

111. Plaintiffs are entitled to injunctive relief prohibiting the Director from implementing Medi-Cal Rx with respect to FQHC pharmacy services until such time as the Director can demonstrate that the reimbursement system under Medi-Cal Rx reimburses FQHCs for providing pharmacy services in compliance with 42 U.S.C. § 1396a(bb).

SECOND CAUSE OF ACTION

(Administrative Procedure Act against Administrator Brooks-LaSure)

For Erroneous Approval of SPA 17-002

112. Plaintiffs incorporate by reference each of the previous paragraphs set forth above as if fully alleged herein.

113. The Administrator's conduct in approving California's SPA 17-002 ¶ 7 in April 2017 constitutes final agency action with respect to the dispensing fees and FFS reimbursement method at issue in this action.

114. The Administrator's acts to approve SPA 17-002 ¶ 7 were arbitrary, capricious, and an abuse of discretion, and/or not in accordance with federal law, and are unsupported by substantial evidence because:

a) California relied on insufficient and incomplete analyses of pharmacy service costs that excluded FQHCs and 340B providers' higher costs, contrary to the Covered Outpatient Drug rules resulting in a dispensing fee that fails to reimburse to Plaintiffs at the level required by federal law as set forth in 42 U.S.C. § 1396a(bb).

b) California failed to provide accurate and reliable data or an explanation of the cost impact to the Medicaid program when it submitted SPA 17-002 ¶ 7 to CMS for approval, and thus the Administrator did not have sufficient evidence on which to approve the SPA.

c) CMS approved the FFS method in SPA 17-002 ¶ 7 despite the admitted incomplete and inaccurate data in the Mercer Report, which omitted FQHC pharmacy services costs upon which the FFS reimbursement amounts were based.

115. Plaintiffs have suffered a legal wrong and/or are adversely affected by the Administrator's arbitrary, capricious, or otherwise unsupported and erroneous approval of SPA 17-002 ¶ 7, because Plaintiffs will not be reimbursed at the appropriate levels under the FFS system, and Plaintiffs' mission and mandate to provide health care to impoverished and underserved patients will suffer as a result.

116. The approval of SPA 17-002 ¶ 7 is not wholly committed to the agency's discretion because Congress enacted statutory requirements and standards for reimbursing Plaintiffs, including 42 U.S.C. § 1396a(bb), that the Administrator is aware of and is obligated to observe.

117. No other adequate remedy exists for Plaintiffs to seek judicial review of the Administrator's or CMS' actions to approve SPA 17-002 ¶ 7.

118. No federal statute requires the exhaustion of any administrative remedy prior to pursuing injunctive and declaratory relief in this Court.

119. Plaintiffs are entitled to injunctive relief to prevent the enforcement of the SPA 17-002 ¶ 7 and its FFS reimbursement methods as to Plaintiffs, until such time as the Director and the Administrator can demonstrate that California's FFS reimbursement system will adequately reimburse FQHCs for their costs.

THIRD CAUSE OF ACTION

(Administrative Procedure Act against Administrator Brooks La-Sure)

For Erroneous Approval of Medi-Cal Rx, Which Relies on an FFS Reimbursement System That Contradicts Federal Law

120. Plaintiffs incorporate by reference each of the previous paragraphs set forth above as if fully alleged herein.

121. The Administrator's conduct in approving California's 1915(b) Waiver Application constitutes final agency action with respect to approving Medi-Cal Rx.

122. The Administrator's act to approve of Medi-Cal Rx is arbitrary, capricious, an abuse of discretion, and/or not in accordance with federal law, and is unsupported by substantial evidence because:

a) Medi-Cal Rx is inconsistent with federal law because it imposes the flawed FFS reimbursement system under SPA 17-002 ¶ 7, which deprives Plaintiffs of federally mandated reimbursement levels set forth in 42 U.S.C. § 1396a(bb).

b) Medi-Cal Rx imposes a FFS reimbursement system that subjects Plaintiffs to the 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.

c) Approving Medi-Cal Rx was contrary to federal law because the initiative stands as an obstacle to achieving the purpose of the 340B Program.

d) Approving Medi-Cal Rx and shifting all Medi-Cal pharmacy services to the FFS reimbursement system reduces patients' access to high-quality medical services, which is contrary to the purpose of Medicaid.

e) Adopting 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 to the FQHCs' Section 330 grants from HRSA, grants to provide services to the uninsured.

123. Furthermore, the Administrator has failed or refused to consider relevant information provided by Plaintiffs, demonstrating that Medi-Cal Rx should be denied or delayed because it fails to comply with federal law. Nonetheless, the Administrator approved Medi-Cal Rx.

124. Plaintiffs have suffered a legal wrong and/or are adversely affected by the Administrator's arbitrary, capricious, or otherwise unsupported and erroneous approval of Medi-Cal Rx because it imposes the defective FFS system created by SPA 17-002 ¶ 7 upon Plaintiffs, depriving Plaintiffs of their right to federally mandated reimbursement rates, subjecting them to invalid and preempted state regulations of the 340B program, and impeding their mission to provide health care to impoverished and underserved patients.

125. The approval of Medi-Cal Rx is not wholly committed to the agency's discretion because Congress enacted statutory requirements and standards for Section 1915(b) Waivers, State Plan Amendments, and FQHC reimbursements, all of which the Administrator is obligated to observe.

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126. No other adequate remedy exists for Plaintiffs to seek judicial review of the Administrator's or CMS' actions to approve Medi-Cal Rx.

127. No federal statute requires the exhaustion of any administrative remedy prior to pursuing injunctive and declaratory relief in this Court.

128. Plaintiffs are entitled to injunctive relief to prevent the implementation of Medi-Cal Rx until such time as the Director and the Administrator can demonstrate that the delivery system under Medi-Cal Rx will adequately reimburse FQHCs for their costs and that it will no longer impede FQHCs from fulfilling Congress' goals of the 340B Program to "stretch scarce federal dollars" to provide more services to more patients.

FOURTH CAUSE OF ACTION

(Declaratory Relief against All Defendants)

129. Plaintiffs incorporate by reference each of the previous paragraphs set forth above as if fully alleged herein.

130. An actual and justiciable controversy has arisen and now exists between the parties relating to the issue of whether Medi-Cal Rx and the FFS reimbursement system, created by SPA 17-002 ¶ 7, comply with federal law as to FQHCs and the Covered Outpatient Drug Rule. Plaintiffs assert that Defendants knew or should have known that Medi-Cal Rx will underfund Plaintiffs contrary to federal law, and subject Plaintiffs to invalid and preempted State Plan provisions by forcing Plaintiffs into an FFS reimbursement system that does not comply with federal law. Plaintiffs further assert that the financial implications of Medi-Cal Rx create a conflict with federal law by impeding the goals of the federal 340B Program, and thus that Medi-Cal Rx is contrary to the purpose of Medicaid generally.

131. Pursuant to 28 U.S.C. § 2201, Plaintiffs request this Court to declare that the Administrator's approval of Medi-Cal Rx and SPA 17-002 ¶ 7 is invalid, unlawful, and preempted by federal law, and that the Director may not lawfully implement the changes. Plaintiffs further seek a declaratory judgment confirming that (1) Medi-Cal Rx wrongfully forces Plaintiffs into the FFS system that CMS wrongfully approved via SPA 17-002 ¶ 7;

(2) that CMS failed to require that FQHC costs in providing pharmacy drugs and services, be covered in developing the FFS reimbursement system for FQHC pharmacy drugs and services, before it approved SPA 17-002 ¶ 7; (3) that SPA 17-002 ¶ 7 subjects Plaintiffs to State Plan provisions that are inconsistent with, and preempted by, the laws governing the 340B Program and Medicaid; (4) that CMS' approvals of Medi-Cal Rx and SPA 17-002 ¶ 7 are therefore void as preempted by federal law; (5) that the provisions of Medi-Cal Rx and SPA 17-002 ¶ 7 are therefore unenforceable as applied to Plaintiffs; (6) that Medi-Cal Rx impermissibly undermines the purpose of Medicaid, as well as the 340B Program and associated congressional intent to "stretch scarce federal resources as far as possible" to provide more services to more patients, by depriving FQHCs of critical funding it reinvests into patient care; and (7) that because of the conflict Medi-Cal Rx creates with federal law, Medi-Cal Rx and the SPA 17-002 FFS reimbursement scheme it relies upon, cannot be enforced as to Plaintiffs until such time as CMS receives adequate assurance from the Director that the reimbursement method under Medi-Cal Rx adequately reimburses Plaintiffs for providing pharmacy drugs and services in a manner consistent with 42 U.S.C. § 1396a(bb) and the Covered Outpatient Drug Rule.

132. No administrative appeal process or other administrative remedy is available to Plaintiffs and/or CHCAPA's members, as applicable, to challenge CMS' approval of or the Department's implementation of Medi-Cal Rx and SPA 17-002 ¶ 7.

133. All of the said injuries are great, immediate, and irreparable, for which damages at law are inadequate, and for which Plaintiffs and/or CHCAPA's members, have no plain, adequate, or speedy relief at law or otherwise.

VI. PRAYER FOR RELIEF

For the reasons stated above, Plaintiffs respectfully request that the Court grant the following relief:

1. That an injunction issue, enjoining the Director from implementing Medi-Cal Rx with respect to FQHCs in the absence of a reimbursement method that adequately funds FQHCs in accordance with federal law;

2. For judicial declarations described above establishing the legal rights and obligations of the parties;

3. For costs of litigation and reasonable attorneys' fees, as provided by 28 U.S.C. § 2412(d) and 42 U.S.C. § 1988.

4. Such further and additional relief as the Court deems just and proper.

DATED: December 30, 2021

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