HANSON BRIDGETT LLP
KATHRYN E. DOI, SBN 121979
ANDREW W. STROUD, SBN 126475
500 Capitol Mall, Suite 1500
Sacramento, California 95814
Telephone: (916) 442-3333
Facsimile: (916) 442-2348
Email: kdoi@hansonbridgett.com
Email: astroud@hansonbridgett.com

REGINA M. BOYLE, SBN 164181
LAW OFFICE OF REGINA M. BOYLE
Post Office Box 163479
5531 7th Avenue
Sacramento, CA 95816-9479
Telephone: (916) 930-0930
Email: rboyle@cliniclaw.com

Attorneys for Plaintiffs
COMMUNITY HEALTH CENTER ALLIANCE
FOR PATIENT ACCESS, ET AL.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

COMMUNITY HEALTH CENTER ALLIANCE FOR PATIENT ACCESS; AVENAL COMMUNITY HEALTH CENTERS; COMMUNITY HEALTH CENTERS OF THE CENTRAL COAST; FAMILY HEALTH CENTERS OF SAN DIEGO; IMPERIAL BEACH COMMUNITY CLINIC; LA MAESTRA FAMILY CLINIC; OMNI FAMILY HEALTH; OPEN DOOR COMMUNITY HEALTH CENTERS; SHASTA COMMUNITY HEALTH CENTER; SOUTH COUNTY COMMUNITY HEALTH CENTER, INC.,

Plaintiffs,

v.

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

Defendants.

Case No.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

I. INTRODUCTION

1. In the era of COVID-19, community health centers designated as Federally-qualified health centers ("FQHCs") are on the front lines of providing services to the low income communities suffering the most from the pandemic. On the health care front, the State of California was planning to transition to a new health care delivery system for Medi-Cal but those plans have been set back by the pandemic. Instead, the Medi-Cal program has determined it needs to extend its authority from the federal government to provide health care services to Medi-Cal beneficiaries through Medi-Cal managed care by another year, rather than transition to a new system. However, at the same time the State is asking the federal government to allow it to maintain the status quo due to the pandemic, the State is also asking the federal government to carve the FQHC pharmacy benefit out of Medi-Cal managed care, a move that would strike a major financial blow to FQHCs that are already reeling from the impacts of the pandemic. If the FQHC pharmacy benefit carve-out is implemented on January 1, 2021 as requested by the State, then vital funds that Congress intended to go to FQHC's in order to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive health care services to low income communities, will be diverted to the State instead. The front lines will be broken.

2. Not only is this unsound as a matter of public policy, but the FQHC pharmacy benefit carve-out proposed by the State is prohibited by law as well because: (a) the State did not comply with the notice and comment requirements in making its untimely request to the federal government for permission to effectuate the carve-out; (b) the State still does have in place a means for reimbursing FQHCs for their actual and reasonable costs of providing pharmacy services outside of Medi-Cal managed care, as required by federal law; and (c) the State is prohibited from indirectly obtaining rebates for drugs covered by the 340B pharmacy reimbursement program with respect to FQHCs that have registered with the Medicaid Exclusion File.

/ / /

3. This action is brought by FQHCs seeking to enjoin the State's FQHC pharmacy benefit carve-out from Medi-Cal managed care because the State's request for federal approval of the carve-out is fundamentally flawed and because there is no reimbursement mechanism in place that meets basic requirements of federal Medicaid law. If implemented, FQHCs will be unable to fulfill their congressional mandate of providing health care services to low income communities at a time when those communities need their services the most. Without the court's immediate intervention, the plaintiff FQHCs and their patients will suffer irreparable injury because they will no longer be able to provide health care services that are desperately needed by the communities they serve. It is critical that low income communities have access to affordable healthcare as Congress intended, especially in the midst of a global pandemic.

II. SUMMARY OF THE CASE

4. California's Medicaid program, known as Medi-Cal, provides a "safety net" that ensures the State's poor have access to basic health care services. FQHCs and rural health clinics ("RHCs") in California provide comprehensive, culturally competent, quality primary health care services to medically underserved communities and vulnerable populations, and are America's "safety net" health care providers at more than 2,000 health care delivery sites. Health centers have an established tradition of providing care for people underserved by America's health care system: the poor, uninsured, and homeless; minorities; migrant and seasonal farmworkers; public housing residents; and people with limited English proficiency.

5. FQHCs, including the plaintiff FQHCs, are health centers that receive federal grants under Section 330 of the Public Health Services Act (42 U.S.C. § 254b). Section 330 requires that FQHC's be located in areas designated as medically-underserved, *i.e*., areas with insufficient health care providers for their population, and FQHC's must treat all patients regardless of their ability to pay for those services.

6. By qualifying to receive a Section 330 grant, health centers are designated as FQHCs. This is a payment designation entitling the health centers to enhanced

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

7. Beginning in 2011, the State implemented Medi-Cal managed care through a waiver authorized by Section 1115 of the Social Security Act. Under Medi-Cal managed care, the State enters into contracts with Medi-Cal managed care [health] plans ("MCPs") to pay the MCP a monthly rate for each Medi-Cal beneficiary enrolled in the plan. In return for this "per-member-per-month" or "capitated" payment, the MCP is "at risk" for the cost of Medicaid-covered health care services provided to Medi-Cal beneficiaries assigned to the plan. The MCP, in turn, enters into contracts with providers, including FQHCs, to provide Medi-Cal services to patients at a capitated rate. At the end of each fiscal year, the FQHC submits a reconciliation request, which reconciles the capitated payments received from the MCPs, as well as any interim payments received from the Medi-Cal program, with the amount that the FQHC would have received if it had been paid the PPS rate for the visits for the year. In 2018, 82% of Medi-Cal beneficiaries were covered by and receiving services through a Medi-Cal managed care plan.[1]

---

[1] California Health Care Almanac, Medi-Cal Facts and Figures: Crucial Coverage for

8. One of the benefits that has been provided through Medi-Cal managed care plans in California since 2011 is the pharmacy benefit. The State is authorized to provide the pharmacy benefit via Medi-Cal managed care through a federally-approved mechanism known as the Medi-Cal managed care 1115 Waiver Demonstration Project (the "Waiver"). The negotiated reimbursement rate FQHCs receive for pharmacy services via the Waiver approximates the FQHCs actual costs of providing the pharmacy benefit consistent with the federal law governing FQHC reimbursement.

9. On January 7, 2019, Governor Gavin Newsom issued an executive order (EO N-01-19) that directed the Department of Health Care Services (the "Department") to transition all pharmacy services from Medi-Cal managed care to a fee-for-service benefit by January 2021 (the "Medi-Cal Rx Transition" or "pharmacy benefit carve-out"). However, the State has not yet received federal approval to implement the Medi-Cal Rx Transition, and the State did not even seek such approval until September 16, 2020, when it submitted an untimely request to extend the Waiver for a year through the end of 2021. In addition, the Department ran roughshod over the regulatory requirements for notice and the opportunity to be heard, misrepresented the dramatic and devastating fiscal impact of the changes on FQHCs, and requested approval of the modification request despite the lack of consistency with the fundamental purposes to be served by 1115 Waiver Demonstration Projects.

10. If the FQHC pharmacy benefit is carved out of Medi-Cal managed care and is instead reimbursed via the FQHC's PPS rate or the fee-for-service or "FFS" rate that was established based on the costs of providing pharmacy services for other (non-FQHC) providers, then FQHCs will no longer be reimbursed at a rate approximating their actual costs of providing pharmacy services. This result is not consistent with the Medi-Cal program's obligations under federal law to pay its fair share of the cost of providing FQHC services to Medi-Cal beneficiaries. Paying FQHCs less than cost will reduce the

---

Low-Income Californians (Feb. 2019) p.31 (https://www.chcf.org/wp-content/uploads/2019/02/MediCalFactsFiguresAlmanac2019.pdf).

FQHCs' ability to continue to provide the quality of care and access to care for patients who rely on FQHCs for their primary care. The Medi-Cal managed care plans, which are responsible for managing the cost and quality of the health care of their assigned members, also oppose the Medi-Cal Rx Transition because it impedes the health plans' ability to manage a patient's care by disconnecting the pharmacy benefit from the remainder of the patients' primary care.[2]

11. In acknowledgment of the adverse impact of the Medi-Cal Rx Transition on FQHCs and their patients, the State agreed to create a supplemental payment pool of $105 million (half State-half federal funds), which would be available between July 1, 2020 and June 30, 2021, to compensate FQHCs for the loss of revenue resulting from the Medi-Cal Rx Transition. Unfortunately, this supplemental payment pool has proven to be inadequate because (1) it is only approved for the current fiscal year, (2) since the fiscal year is half over, only $52.5 million (half State-half federal funds) remains available for distribution between January 1, 2021 and June 30, 2021; (3) it has proven difficult, if not impossible, to administer the pool in an equitable manner, and (4) the pool is not an adequate substitute for compliance with the requirements of federal law regarding reimbursement of FQHCs described in 42 U.S.C. § 1396a(bb).

12. By letter dated April 13, 2020, trade associations representing Medi-Cal managed care plans, public hospitals, safety net hospitals, children's hospitals, and primary care clinics sent a letter to the Secretary of the California Health and Human Services Agency requesting a delay in the implementation of Medi-Cal Rx in light of the strain and uncertainty created by the COVID-19 pandemic. The members of these trade associations – the Local Health Plans of California, California Association of Health Plans, California Association of Public Hospitals and Health Systems, California Primary Care Association, Private Essential Access Community Hospitals, and California Children's Hospital Association – collectively service the vast majority of the

[2] California Legislative Analyst's report entitled "Analysis of the Carve Out of Medi-Cal Pharmacy Services From Managed Care" ("2019 LAO Report"), p.14.

approximately 13 million Californians enrolled in Medi-Cal. In the April 13, 2020 letter, these trade associations asked that the Department of Health Care Services pause ongoing planning activities and re-evaluate the feasibility of implementing the Medi-Cal Rx Transition on January 1, 2021.

13. On September 23, 2020, plaintiff Community Health Center Alliance for Patient Access ("CHCAPA"), a 501(c)(4) trade association representing the interests of FQHCs, sent a letter to the defendants requesting the opportunity to discuss a long-term solution to the FQHC underpayment issues that will occur if the Medi-Cal Rx Transition occurs on January 1, 2021, as planned. CHCAPA raised the concern that the current PPS and FFS payment of the FQHC pharmacy benefit were inconsistent with federal law and noted the deficiencies in the Department's Waiver extension request. The parties met and conferred on September 29 and September 30, 2020, and CHCAPA's counsel provided a list of potential solutions to defendants on September 30, 2020, but on October 5, 2020, defendants declined to consider or discuss the potential long-term solutions identified by CHCAPA.

14. Plaintiffs seek declaratory and injunctive relief to prevent implementation of the carve-out of the FQHC pharmacy benefit from Medi-Cal managed care on the grounds that the Department followed a fatally flawed process in seeking the Waiver extension, particularly with respect to the impact of the Medi-Cal Rx Transition on FQHCs, and because the pharmacy transition contained in the Waiver extension request is invalid as to the Medi-Cal Rx Transition for FQHCs, as the resulting PPS and FFS reimbursement to FQHCs would not be consistent with federal law.

III. JURISDICTION AND VENUE

15. This action arises under federal statutory law, specifically, 42 U.S.C. § 1983 and 42 U.S.C. § 1396 *et seq*. (hereafter, the "Medicaid statute"). This action also arises under Article I (the Appropriations Clause) and Article VI (the Supremacy Clause) of the United States Constitution.

/ / /

16. This Court is vested with jurisdiction under 28 U.S.C. § 1331 because this action arises under the laws of the United States, including the Supremacy Clause of the United States Constitution and federal Medicaid law. This Court is also vested with jurisdiction under 28 U.S.C. § 1343(a)(3) and (4) to redress the deprivation 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.

17. Venue is proper in this district under 28 U.S.C. § 1391(b).

18. The declaratory and injunctive relief sought in this action is authorized under 28 U.S.C. §§ 2201 and 2202 and 42 U.S.C. § 1983.

IV. THE PARTIES

A. The Plaintiffs

19. The plaintiffs are a 501(c)(4) organization that represents the interests of community health centers and the medically-underserved populations that the health centers serve, as well as 501(c)(3) non-profit corporations designated as FQHCs, located throughout the State of California. The mission of each individual plaintiff is to provide primary health care services and to serve as a safety-net provider for medically underserved populations. FQHCs play a critical role in containing health care costs as they serve as an alternative to hospital emergency rooms for the poor and uninsured. All FQHCs are required by federal law to provide health care services regardless of a patient's ability to pay.

20. Plaintiff **Community Health Center Alliance for Patient Access ("CHCAPA")** is a 501(c)(4) whose primary purpose is to promote the social welfare by working to improve access to affordable, comprehensive, quality health care by the medically underserved populations served by community health centers. CHCAPA's affiliate members are FQHCs.

21. Plaintiff **Avenal Community Health 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 by the United States Department of Health & Human Services' Health Resources and Services Administration ("HRSA") and the Centers for Medicare and Medicaid Services ("CMS") as a Federally-qualified health center, as defined for purposes of the Medicaid program in 42 U.S.C. section 1396d(l)(2), since 2003. Aria provides FQHC services to eligible Medi-Cal beneficiaries at 32 locations in Kings, Fresno, and Tulare Counties. Aria currently provides pharmacy services to Medi-Cal beneficiaries via 66 contract pharmacies and one in-house pharmacy, as well as dispensing drugs as part of its patient visits. In calendar year 2019, Aria provided services to 32,982 patients, 72% of which were Medi-Cal patients and 6.7% of which were uninsured.

22. 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 has been designated by HRSA and CMS as a Federally-qualified health center, as defined for purposes of the Medicaid program in 42 U.S.C. section 1396d(l)(2), since 1993. CHCCC provides FQHC services to eligible Medi-Cal beneficiaries at 32 locations in San Luis Obispo and Santa Barbara Counties. CHCCC currently provides pharmacy services to Medi-Cal beneficiaries via 75 contract pharmacies and one in-house pharmacy, as well as dispensing drugs as part of its patient visits. In calendar year 2019, CHCCC provided services to 111,735 patients, 63.37% of which were Medi-Cal patients and 15.05% of which were uninsured.

23. 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 by HRSA and CMS as a Federally-qualified health center, as defined for purposes of the Medicaid program in 42 U.S.C. section 1396d(l)(2), since 1991. FHCSD provides FQHC services to eligible Medi-Cal beneficiaries at 45 locations in San Diego County. FHCSD currently provides pharmacy services to Medi-Cal beneficiaries via 170 contract pharmacies and one in-house pharmacy, as well as dispensing drugs as part of its patient visits. In calendar

year 2019, FHCSD provided services to 149,244 patients, 59% of which were Medi-Cal patients and 31% of which were uninsured.

24. 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 by HRSA and CMS as a Federally-qualified health center, as defined for purposes of the Medicaid program in 42 U.S.C. section 1396d(l)(2), since 2006. Imperial Beach provides FQHC services to eligible Medi-Cal beneficiaries at two locations in San Diego County. Imperial Beach currently provides pharmacy services to Medi-Cal beneficiaries via 17 contract pharmacies and no in-house pharmacies, as well as dispensing drugs as part of its patient visits. In calendar year 2019, Imperial Beach provided services to 9,798 patients, 53.53% of which were Medi-Cal patients and 8.94% of which were uninsured.

25. 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 by HRSA and CMS as a Federally-qualified health center, as defined for purposes of the Medicaid program in 42 U.S.C. section 1396d(l)(2), since 1997. La Maestra provides FQHC services to eligible Medi-Cal beneficiaries at 16 locations in San Diego County. La Maestra currently provides pharmacy services to Medi-Cal beneficiaries via 64 contract pharmacies and three in-house pharmacies, as well as dispensing drugs as part of its patient visits. In calendar year 2019, La Maestra provided services to 45,716 patients, 68% of which were Medi-Cal patients and 26% of which were uninsured.

26. 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 by the HRSA and CMS as a Federally-qualified health center, as defined for purposes of the Medicaid program in 42 U.S.C. section 1396d(l)(2), since 1978. Omni provides FQHC services to eligible Medi-Cal beneficiaries at 36 locations in Kern, Fresno, Tulare, and Kings Counties. Omni currently provides

pharmacy services to Medi-Cal beneficiaries via 82 contract pharmacies and four in-house pharmacies, as well as dispensing drugs as part of its patient visits. In calendar year 2019, Omni provided services to 131,449 patients, 71% of which were Medi-Cal patients and 10% of which were uninsured.

27. 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 by HRSA and CMS as a Federally-qualified health center, as defined for purposes of the Medicaid program in 42 U.S.C. section 1396d(l)(2), since 1999. Open Door provides FQHC services to eligible Medi-Cal beneficiaries at 15 locations in Humboldt and Del Norte Counties. Open Door currently provides pharmacy services to Medi-Cal beneficiaries via 16 contract pharmacies with 53 locations and no in-house pharmacies, as well as dispensing drugs as part of its patient visits. In calendar year 2019, Open Door provided services to 60,219 patients, 53% of which were Medi-Cal patients and 5% of which were uninsured.

28. **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 by HRSA and CMS as a Federally-qualified health center, as defined for purposes of the Medicaid program in 42 U.S.C. section 1396d(l)(2), since 1997. Shasta provides FQHC services to eligible Medi-Cal beneficiaries at six locations in Shasta County. Shasta currently provides pharmacy services to Medi-Cal beneficiaries via 35 contract pharmacies and no in-house pharmacies, as well as dispensing drugs as part of its patient visits. In calendar year 2019, Shasta provided services to 33,610 patients, 80.12% of which were Medi-Cal patients and 8.03% of which were uninsured.

30. 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 began operations in 2001 and has been designated by HRSA and CMS as a Federally-

qualified health center, as defined for purposes of the Medicaid program in 42 U.S.C. section 1396d(l)(2), since 2001. Ravenswood provides FQHC services to eligible Medi-Cal beneficiaries at seven primary locations in San Mateo County. Ravenswood currently provides pharmacy services to Medi-Cal beneficiaries via 22 contract pharmacies and one in-house pharmacy, as well as dispensing drugs as part of its patient visits. In calendar year 2019, Ravenswood provided services to 17,216 patients, 56% of which were Medi-Cal patients and 32% of which were uninsured.

B. The Defendants

31. Defendant William Lightbourne is the Director of DHCS and, in that capacity, is 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 and authorizing proposed modifications of the State Medicaid Plan under the provisions of the applicable federal law. (Cal. Welf. & Inst. Code § 14100.1; 22 Cal. Code of Regs. § 50004.) Defendant Lightbourne, in his capacity as Director of DHCS, has the power and authority to manage and control the actions of DHCS, and either actively approved or was aware of and did not disapprove the actions of DHCS described in this complaint. Defendant Lightbourne is sued in his official capacity.

32. Defendant DHCS is, and at all times mentioned herein was, a part of the executive branch of the State of California. DHCS is the single State agency charged with the administration of the Medi-Cal program. (Cal. Welf. & Inst. Code §§ 10720, 14000 et seq.; 22 Cal. Code of Regs., §§ 50000 et seq.) Defendant Lightbourne, in his official capacity as Director of DHCS, and DHCS are collectively referred to as "DHCS".

V. BACKGROUND

A. Federal Medicaid Law

33. In 1965, Congress enacted Title XIX of the Social Security Act, more generally referred to as The Medicaid Act, to provide States with funding to furnish medical assistance to individuals "whose income and resources are insufficient to meet the costs of necessary medical services." (42 U.S.C. §§ 1396 *et. seq*.; *Wilder v. Va.*

Hosp. Ass'n (1990) 496 U.S. 498, 502.) The Medicaid program authorizes federal financial support to States for medical assistance to low income persons who are aged, blind, disabled, or members of families with dependent children. The program is jointly financed by the federal and State governments and administered by the States, with the federal financial participation level accounting for between approximately 50 and 83 percent generally, with a maximum of 100 percent payment by the federal government for certain Indian Health Service health centers and hospitals (42 C.F.R. § 433.10).

34. A State's participation in Medicaid is voluntary, but when a State chooses to participate, it must comply with the provisions of the Medicaid Act and its implementing regulations. (*Alaska Dept. of Health and Social Servs. v. Centers for Medicare and Medicaid Servs.* (9th Cir. 2005) 424 F.3d 931, 935.) Each State administers its Medicaid program through a single State agency, which is charged with the responsibility of establishing and complying with the State's Medicaid plan (the "State Plan") that, in turn, must comply with the provisions of the applicable federal Medicaid law. (42 U.S.C. § 1396a(a)(5); 42 C.F.R. §§ 430.10 & 431.10.) To the extent that services are provided through a demonstration project under Section 1115 of the Social Security Act (42 U.S.C. § 1315), federal financial participation is not available for changes to a demonstration or a demonstration extension until approved by CMS. (42 C.F.R. § 431.412.)

35. A State participating in the Medicaid program must cover certain mandatory benefits. (*See* 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(1)-(5), (7), (17), (21); 42 C.F.R. §§ 440.210, 440.220.) Other Medicaid benefits are optional at the discretion of each State. (*See* 42 C.F.R. § 440.225.)

36. Mandatory benefits include the Rural Health Clinic ("RHC") services described in 42 U.S.C. § 1396d(a)(2)(B), added by Congress in 1977 (P.L. 95-210). (42 U.S.C. § 1396d(a)(2)(B) and 1396d(l)(1).) RHCs are federally-approved clinics that provide services in rural, underserved areas. In 1989, Congress created the Medicaid FQHC services benefit described in 42 U.S.C. § 1396d(2)(C), defining it in substantially the same manner as the Medicaid RHC benefit. FQHCs are federally-approved health

centers that serve medically under-served populations or areas. (42 U.S.C. §§ 254b(a)(1), 1396a(2)(C), 1396d(l)(1)-(2), 1395x(aa)(2), (4).)

37. The FQHC benefit is defined as including the *Medicare* RHC services described in 42 U.S.C. § 1395x(aa)(1) when furnished to an individual as a patient of an FQHC, and "any other ambulatory services offered by a Federally-qualified health center and which are otherwise included in the plan". (42 U.S.C. §§ 1396d(a)(2)(C); 1396d(l)(2); and 1395x(aa)(1)(A)-(C).)

38. The Medicare and Medicaid definitions of an FQHC require, as a precondition to eligibility for certification as an FQHC, compliance with the requirements applicable to health centers under 42 U.S.C. § 254b. (42 U.S.C. §§ 1395x(aa)(4) and 1396d(l)(2)(B).) Section 254b requires health centers to provide specified services, "either through the staff and supporting resources of the center or through contracts or cooperative arrangements", including "pharmaceutical services as may be appropriate for particular centers". (42 U.S.C. § 254b(a)(1)(A) and (b)(1)(A)(i)(V).)

39. In describing the difference between the optional "clinic" benefit (42 U.S.C. § 1396d(a)(9)) and the FQHC services benefit (42 U.S.C. § 1396d(a)(2)(C)), CMS has clarified that the Medicaid FQHC benefit includes coverage of services provided by community providers under contract. (CMS, "Frequently-Asked Questions (FAQs): Federal Funding for Services 'Received Through' an IHS/Tribal Facility and Furnished to Medicaid Eligible American Indians and Alaska Natives (SHO #16-002)(January 18, 2017).)

40. FQHCs are eligible to participate in the 340B Drug Pricing program (42 U.S.C. §§ 256b and 1396r-8) ("340B Program"), which requires drug manufacturers to provide discounts on outpatient prescription drugs to certain safety net health care providers specified in statute, known as Covered Entities.[3] Covered Entities include

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

FQHCs, AIDS Drug Assistance Programs, and certain disproportionate share hospitals. The 340B Program helps these designated hospitals and clinics provide more care to additional patients. The 340B ceiling price – the maximum amount a drug manufacturer can charge a Covered Entity for a given drug – is equal to the Average Manufacturer Price (AMP) minus the Unit Rebate Amount, both set by the Centers for Medicare & Medicaid Services (CMS). Covered Entities purchase 340B drugs at a price that is at least 23.1 percent below AMP for brand name drugs; 13 percent below AMP for generic drugs; and 17.1 percent below AMP for clotting factor and pediatric drugs. In 2018, total sales in the 340B Program were approximately $24 billion. Covered Entities saved between 25 to 50 percent on what they would have otherwise paid for covered outpatient drugs. [4]

41. Many 340B Covered Entities do not operate in-house pharmacies. Because the requirements to obtain a pharmacy license are complex and operating a pharmacy can be expensive, many Covered Entities choose not to "expend precious resources to develop their own in-house pharmacies."[5]

42. Federal Medicaid law also requires State Medicaid plans to provide for payment for the FQHC and RHC services described in Sections 1396d(a)(2)(B) and (C) in accordance with per-visit, prospective payment system described in Section1396a(bb). (42 U.S.C. § 1396a(a)(15).) There are no federal Medicaid regulations defining an FQHC "visit". The RHC "visit" is defined for purposes of Medicaid as a face-to-face encounter between a clinic patient and any health professional whose services are reimbursed under the State plan." (42 C.F.R. § 447.371(d); *see also* CMS Publ. 45, State Medicaid Manual, Ch. 4, § 4231(B).) Drugs dispensed under the 340B Program by FQHCs

/ / /

---

[4] HRSA Fiscal Year 2021 Justification of Estimates for Appropriations Committees, pg. 294 (https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2021.pdf).

[5] HRSA Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1006).

through these contract pharmacy arrangements are considered to be dispensed by the FQHC, and are FQHC services within the meaning of 42 U.S.C. § 1396d(a)(2)(C).

43. The State's Medicaid Plan must be submitted to the Secretary of the United States Department of Health and Human Services ("Secretary") for approval and must describe the policies and methods to be used to set payment rates for each type of service included in the State Plan. (42 C.F.R. §§ 430.10 & 447.201(b).) Changes to the State Plan may not be implemented by a State prior to being approved by the Secretary; the Secretary delegates approval authority to the Centers for Medicare and Medicaid Services ("CMS"). (42 C.F.R. § 430.12.) CMS may approve or disapprove the submitted amendment, or it may request more information before making a determination. (42 C.F.R. § 430.16.) The Ninth Circuit has "held, unambiguously, that "the State [is] obligated to submit and obtain approval of its [State Plan Amendment] before implementation." (*California Association of Rural Health Clinics v. Douglas, supra*, 738 F.3d at 1018, *quoting Developmental Services Network v. Douglas* (9th Cir. 2011) 666 F.3d 540, 544-46.)

44. Under Section 1115 of the Social Security Act, the Secretary may waive certain Medicaid requirements for an approved "experimental, pilot, or demonstration project" that the Secretary finds "is likely to assist in promoting the objectives of" the Medicaid Act. (42 U.S.C. § 1315.) As is the case with State plan amendments, waiver applications, extension and material changes to benefits require the Secretary's prior approval. No federal financial participation is generally available for changes to the demonstration that have not been approved by CMS. (42 C.F.R. § 431.412(d).)

45. Unlike a State plan amendment, however, 1115 waiver applications and extension requests cannot be submitted by the State Medicaid Agency, but "must be sent from the Governor of the State to the Secretary," submission through a delegate is not permitted. (42 U.S.C. § 1315(e) & (f); 42 C.F.R. § 431.412(c); *see also* 77 Fed. Reg. 11678, 11685 [CMS rejected a request to allow the submitting party of a demonstration

/ / /

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

46. Applications to extend statewide demonstration projects under Sections 1115(a) and (e) must be submitted "[d]uring the 6-month period ending 1 year before the date the waiver . . . would otherwise expire, must be submitted by the chief executive officer of the state – not a delegate, and must meet certain other requirements. Applications by a state's chief executive officer under Section 1115(f) for approval of an extension of a waiver, "shall be submitted to the Secretary at least 120 days prior to the expiration of the current period of the waiver project." (42 U.S.C. § 1315(f).)

B. California's Medicaid Program

47. California participates in the Medicaid program through the California Medical Assistance Program, also known as Medi-Cal, and has designated DHCS as the agency responsible for its administration. (*See* Cal. Welf. & Inst. Code §§ 10720, 14000 et seq.; 22 Cal. Code of Regs., §§ 50000 et seq.)

48. Medi-Cal generally reimburses providers for delivering covered benefits in two ways. The first is a "fee for service" process whereby the Department determines whether the healthcare services were covered and furnished to an eligible beneficiary, and, if so, pays the service providers directly. Alternatively, the Department administers Medi-Cal through various managed care models operated by public and private entities under contract. State Medicaid Agencies are permitted to implement a managed care delivery system using three basic types of federal authorities: (1) State plan authority under 42 U.S.C. § 1396u–2 ("State Plan Model"); (2) waiver authority under 1396n(a) and (b) (a "1915 Waiver"); or (3) waiver authority under 42 U.S.C. § 1315 ("1115 Waiver").

49. The Department administers California's Medicaid program in part pursuant to a Section 1115 waiver that permits states to enact certain pilot projects in their Medicaid programs. (42 U.S.C. § 1315.) California's 1115 Waiver is referred to as the "California Medi-Cal 2020 Demonstration Project, Number 11-W-00193/9" (the "Waiver").

/ / /

50. Medicaid managed care plans generally provide healthcare services to Medicaid enrollees through subcontracted providers. Unlike a traditional fee-for-service model, under a managed care program, the health maintenance organizations, generally referred to as Medicaid managed care organizations or "MCOs", enter into comprehensive risk contracts with the state.[6] A comprehensive risk contract is a risk contract between the State and an MCO that covers comprehensive services, that is, inpatient hospital services and any of the following services, or any three or more of the following services: (1) Outpatient hospital services; (2) Rural health clinic services; (3) Federally Qualified Health Center (FQHC) services; (4) Other laboratory and X-ray services; (5) Nursing facility (NF) services; (6) Early and periodic screening, diagnostic, and treatment (EPSDT) services; (7) Family planning services; (8) Physician services; or (9) Home health services. (42 C.F.R. § 438.2.)

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

C. California's 1115 Waiver For Medi-Cal Managed Care

52. As noted above, under Section 1115 of the Social Security Act, the Secretary may waive certain Medicaid requirements for an approved "experimental, pilot, or demonstration project" that the Secretary finds "is likely to assist in promoting the objectives of" the Medicaid Act. (42 U.S.C. § 1315.)

53. In 2010, the Department obtained the Centers for Medicare and Medicaid Services' ("CMS") approval to remove its State Medicaid plan provisions requiring enrollment in Medicaid managed care (Attachment 3.1-F), and moved Medicaid managed

[6] *See* 42 U.S.C. § 1396b(m) (defining MCOs); 42 C.F.R. § 438.1(a) (rules regarding MCOs and state contracts).

care into the California Medi-Cal 2020 1115 Demonstration (the "Waiver"). The benefits that are covered by MCO plans are described in Attachment N to the Waiver. The Waiver currently identifies as MCO covered benefits the mandatory FQHC benefit (42 U.S.C. § 1396a(2)(C)) and the optional pharmacy benefit (42 U.S.C. § 1396a(a)(10), 1396d(a)(12) 1396d(a)(54), 1396r-8(d); 42 C.F.R. § 440.120).

54. Following the end of the waiver period, the Department intended to implement California Advancing and Innovating Medi-Cal ("CalAIM"), a multi-year initiative to implement overarching policy changes across all Medi-Cal delivery systems. As part of CalAIM, DHCS intended to transition all existing managed care authorities into one consolidated 1915(b) California managed care waiver, and propose an 1115 waiver with other program authorities. In 2019 and early 2020, the Department conducted stakeholder engagement for both CalAIM and the 1115 and 1915(b) waiver renewals. In May 2020, DHCS announced the delay of CalAIM, due to the impact of COVID-19. Because of the delay of CalAIM, the Department determined to submit a 12-month extension request to CMS for the Medi-Cal 2020 waiver, to ensure continuation of important programs prior to their eventual transitions under CalAIM. (*See* https://www.dhcs.ca.gov/provgovpart/Pages/medi-cal-2020-waiver.aspx (as of Aug. 23, 2020).)

55. On July 22, 2020, the Department issued a Notice of Proposed Extension, giving the public notice of the intended request for the 12-month extension. The July 22, 2020 Notice of the Proposed Extension provides: "This proposal is intended to extend the current structure and objectives of the programs listed above **with no changes to** eligibility, **benefits** or cost sharing for beneficiaries. … DHCS expects that this 12-month extension will not increase federal or state expenditures and may result in a net decrease in managed care expenditures due to intended changes to the capitated benefits schedule for Medi-Cal managed care." [Emphasis added.]

56. In explaining why it is seeking the extension, the Department says, "It is essential for the stability of the state's health care systems, particularly during the

pandemic, that the current Medi-Cal 2020 Section 1115 waiver provisions be extended for one year to December 31, 2021."

57. Ironically, while purporting to seek stability for the state's health care systems, particularly during the pandemic, the State is simultaneously pulling the financial rug out from under FQHCs and their patients by implementing the Medi-Cal Rx Transition, saving money by failing to reimburse FQHCs for the actual cost of providing the pharmacy benefit to Medi-Cal beneficiaries.

58. The evidence of the financial impact to FQHCs and other safety-net providers is reflected in the State's description of how it will achieve budget neutrality in extending the 1115 Waiver contained in its Draft Medicaid Section 1115 Waiver Demonstration Extension Request, dated July 22, 2020, p.37:

> Finally, the state projects that the overall budget impact of this 12-month waiver demonstration extension will not be significant to the federal government. The state is implementing a pharmacy benefit carve-out that is expected to result in a net decrease in managed care expenditures due to intended changes to the capitated benefits schedule for Medi-Cal managed care. The projected savings is estimated to be $5.5 to $6 billion due to the pharmacy benefit carve-out, clearly offsetting any additional funding provided to sustain the Whole Person Care pilots, the DMC-ODS, and the GPP/SNCP and the Dental Transformation Initiative. In addition, while the PRIME activities that are currently funded under Medi-Cal 2020 are transitioning to the QIP authority, the dedicated funds for these activities are also offset by the pharmacy benefit carve-out. In sum, we expect federal expenditures to decrease, rather than increase, during the course of the 12-month extension period.

In short, the State is projecting a $5.5 to $6.0 billion savings associated with the pharmacy transition. FQHCs are estimated to provide pharmacy benefits to roughly six percent of the Medi-Cal population. Six percent of $5.5 to $6.0 billion is $330 to $360 million. Thus, the State is projecting that FQHCs will lose $330 to $360 million in revenue as a result of the Medi-Cal Rx Transition.

59. The 1115 Waiver's terms and conditions state that "**[c]hanges related to** eligibility, enrollment, **benefits**, enrollee rights, **delivery systems**, **reimbursement methodologies**, cost sharing, evaluation design, federal financial participation (FFP), sources of non-federal share funding, budget neutrality, and **other comparable program**

elements specified in these STCs must be submitted to CMS as amendments to the demonstration." [Emphasis added.]

60. The State's removal of the pharmacy benefit from the current 1115 Waiver requires an approved amendment. For the reasons set forth below, any approval of the pending 1115 Waiver extension request to remove the pharmacy benefit would be defective because the Waiver extension request is procedurally deficient and untimely. The State cannot implement material changes to its 1115 Waiver, such as the removal of the pharmacy benefit, prior to federal approval. (*See California Association of Rural Health Clinics v. Douglas*, 738 F.3d 1007 (9th Cir. 2013) [the State must submit and obtain approval of a State Plan amendment before implementation]; *Dev. Serv. Network v. Douglas*, 666 F.3d 540, 544-46 (9th Cir. 2011) [same].)

D. <u>The Waiver Extension Request Was Procedurally Deficient And Untimely</u>

61. Public notice in connection with an 1115 Waiver, including an extension request, is required to include a description of the proposed health care delivery system, including benefits coverage, and how such provisions vary from the State's current features. The Department has not adequately addressed the impact of the proposed changes in the waiver's coverage of either the pharmacy or FQHC benefits that are currently reimbursed in large part through managed care under the waiver.

62. The extension request, as summarized by the Department in both its July 22, 2020, Draft for Public Comment entitled "Medicaid Section 1115 Waiver Demonstration Extension Request" and in the July 22, 2020, Tribal Notice of Proposed Change to the Medi-Cal Program addressing the proposed 12-month extension request for the waiver, fails to adequately describe significant changes in the benefits to be provided under the waiver, reflects a failure to consider the negative impact of these changes on the health care safety net, and with respect to the Tribal Notice, includes erroneous representations regarding the impact of the changes proposed in the extension to the FQHC and pharmacy benefits currently covered through Medi-Cal managed care plans under the waiver.

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

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

64. Yet, the Legislative Analyst's Office has warned that the impact of the proposed transition of the pharmacy services benefit from MCO coverage to fee-for-service reimbursement would result in significant losses in revenues for safety net providers, including FQHCs.[7] That this misrepresentation of no impact to FQHCs by the State would be made in the Public Notice completely undermines the purpose of the notice requirement.

65. Furthermore, the extension does not serve an experimental or demonstration purpose within the meaning of Section 1315. As conceived, experimental projects were "expected to be selectively approved by the Department [of Health & Human Services] and to be those which are designed to improve the techniques of administering assistance." (S. Rep. No. 1589, 87th Cong., 2d Sess. 19, reprinted in 1962 U.S.C.C.A.N. 1943, 1962.) It is not clear how the extension will advance any such purpose, nor would it. On April 13, 2020, a coalition of associations representing Medi-Cal managed care plans, hospitals, and health centers sent a letter to the Health & Human Services Secretary asking for a one-year delay in the implementation of the Medi-Cal Rx Transition due to unresolved clinical issues, the stresses and pressures of COVID-19 on health centers, unresolved issues relating to implementing pharmacy carve-outs for the California Children's Services program and the medically-fragile children it serves, and confusion and disruption to care of patients.

---

[7] 2019 LAO Report, supra footnote 1, at p.1 ("In addition, health care providers, principally hospitals and community clinics that are eligible to participate in the 340B drug discount program, would experience a significant loss of earnings currently generated by the margin between what they pay for pharmacy-dispensed drugs and what they charge Medi-Cal managed care plans for those drugs.").

66. These deficiencies, together with rushed public comment schedule (proposed extension announced on Wednesday, July 22 with two public hearings: Friday, August 7 and Monday, August 10), deprived providers and patients from notice and opportunity to comment on the scope and nature of the negative impact of the proposed changes on their ability to provide Medi-Cal covered services to their patients. Moreover, although the State apparently received 271 comments from the public, it has not made those comments publicly available and mischaracterized at least one comment letter that objected to the Medi-Cal Rx Transition in its submission to CMS for approval (a comment letter submitted by plaintiffs).

67. The State also submitted its Waiver extension request untimely. Section 1115 requires that requests to extend a waiver project must be submitted **at least 120 days** prior to the expiration of the current period of the waiver project. The Special Terms and Conditions of the current 1115 waiver further state that a request to amend the demonstration must be submitted to CMS for approval no later than 120 days prior to the planned date of implementation of the change and may not be implemented until approved. The 120-day advance application requirement is contained in 42 U.S.C. § 1315(f)(1) and cannot be waived. Yet the Department submitted its application for an extension of the 1115 Waiver on September 16, only **106 days** prior to the December 31 expiration date of the 1115 Waiver.

68. Finally, section 1115 requires that waiver applications and extension requests "be sent from the Governor of the State to the Secretary," submission through a delegate is not permitted. (42 U.S.C. § 1315(e) & (f); 42 C.F.R. § 431.412(c); *see also* 77 Fed. Reg. 11678, 11685 [CMS rejected a request to allow the submitting party of a demonstration extension to include a Governor's designee, stating that "[w]e need to have an assurance that the demonstration is fully supported by State law and State executive authority."]. In this case, the 1115 waiver extension request was sent under a cover letter signed by the Chief Deputy Director of Health Care Programs/State Medicaid

/ / /

Director, not by the Governor of the State of California. Accordingly, a proper request has not been submitted.

69. The State must be enjoined from moving forward with the Medi-Cal Rx Transition until it has engaged in a transparent and procedurally proper process for amending the 1115 Waiver to carve out the pharmacy benefit and acknowledged and addressed its intendent repercussions on safety net providers and their patients.

70. To the extent that the Department views CMS as having the authority to extend timelines due to the COVID-19 crisis, such flexibility could not conceivably be used as to the Medi-Cal Rx transition amendment in the present situation, where it will likely have a significant negative impact on the principal providers of health care services to minority and poor populations that have experienced the highest mortality rates under this pandemic.

E. If The Pharmacy Benefit Is CarvedOut Of Medi-Cal Managed Care, The Remaining Options For Reimbursing FQHCs For The Pharmacy Benefit Are Not Designed To Reimbursement At Their Actual Costs As Required By Federal Law

71. If the pharmacy benefit is carved-out of Medi-Cal managed care, the remaining options for reimbursing FQHCs for the pharmacy benefit are (1) carving the pharmacy benefit into the FQHC's prospective payment system rate, and (2) reimbursement at the generally-applicable Medi-Cal fee-for-service payment rate paid to non-FQHC Medi-Cal providers. For the reasons explained below, neither of these payment mechanisms is consistent with the federal requirement that FQHCs be reimbursed their actual and reasonable costs of providing FQHC services.

1. Under federal law, FQHCs must be reimbursed their actual and reasonable costs of providing services to Medicaid beneficiaries

72. In 1989, recognizing the central role of FQHCs in caring for the Medicaid population and recognizing that state Medicaid programs typically paid less than 70% of

/ / /

/ / /

the cost of care,[8] Congress enacted special payment provisions to ensure that Medicaid programs fully covered the cost for FQHCs to provide "covered" services to their Medicaid patients. This payment protection was essential to the financial stability of health centers since, as a condition of their Section 330 grant, health centers must, for all intents and purposes, contract with their state Medicaid programs. Without these payment protections, State Medicaid Agencies would be permitted to force health centers to use funding intended by Congress to subsidize care for the uninsured, principally their Section 330 grant funds, to subsidize their Medicaid services. In order to prevent this diversion of federal grant funds by State Medicaid programs, Congress adopted the federal requirements that are at the heart of this action.

73. Accordingly, since 1989, Congress has imposed, and currently imposes, special requirements for payments states must make to FQHCs for Medicaid-covered services they provide to Medicaid recipients. Section 6404 of OBRA required reimbursement of FQHCs at "100 percent of [each FQHC's] costs which are reasonable and related" to the provision of Medicaid-covered services to Medicaid beneficiaries. In passing this "100 percent" requirement, Congress sought to prevent diversion of Section 330 grant funds by State Medicaid Agencies that failed to cover the actual cost of purportedly covered services. The report of the House Budget Committee accompanying the 1989 legislation describes this payment guarantee as follows:

> Medicaid payment levels to Federally funded health centers cover less than 70 percent of the costs incurred by the centers in serving Medicaid patients. The role of [health centers] . . . is to delivery comprehensive primary care services to underserved populations or areas without regard to ability to pay. To the extent that the Medicaid program is not covering the cost of treating

---

[8] H.R. Rep. No. 101-247, at 392, reprinted in 1989 U.S.C.C.A.N. 2118, stating that –

> The Subcommittee on Health and the Environment heard testimony that may that, on average, Medicaid payment levels to Federally-funded health centers cover less than 70 percent of the costs incurred by the centers in serving Medicaid patients. . . .To the extent that the Medicaid program is not covering the cost of treating its own beneficiaries, it is compromising the ability of the centers to meet the primary care needs of those without any public or private coverage whatsoever.

> its own beneficiaries, it is compromising the ability of the centers to meet the primary care needs of those without any public or private coverage.
>
> . . . To ensure that Federal PHS Act grant funds *are not used to subsidize health center or program services to Medicaid beneficiaries*, States would be required to make payment for these [FQHC] services at 100 percent of the costs which are reasonable and related to the cost of furnishing these services.

(H.R. Rep. No. 101-247, at 392-93, reprinted in 1989 U.S.C.C.A.N. 2118-19 [emphasis added].)

74. In December 2000, in section 702 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act ("BIPA") of 2000, Congress changed the methodology for FQHC reimbursement from a retrospective to a prospective payment system ("PPS"). What did not change was the fundamental underlying policy of ensuring that FQHCs are reimbursed 100 percent of their cost of treating Medicaid patients.

75. Under BIPA, FQHCs are to be reimbursed at a "per-visit" rate for providing Medicaid covered services to Medicaid beneficiaries. The Medicaid RHC services and the FQHC services benefits are defined in substantially the same manner. These services include physician services, services provided by physician assistants, nurse practitioners, clinical psychologists, clinical social workers, and services and supplies "incident to" such services as would otherwise be covered if furnished by a physician or as an incident to a physician's services. In addition to these Medicare "core" services,[9] any other ambulatory service included in a State's Medicaid plan is considered a covered FQHC service, if the FQHC offers such a service. (42 U.S.C. § 1396d(a)(2)(C); CMS Publ. 45, Ch. 4, § 4231(B).)[10]

---

[9] The FQHC services incorporated into the Medicaid FQHC benefit through 42 U.S.C. § 1396d(l)(2) as described in Medicare's 1395x(aa)(1)(A)-(C). These services are generally referred to as the Medicare "core" FQHC services, and must be reimbursed by Medicaid when provided by an FQHC regardless of whether they are generally covered outside of an FQHC in its State Medicaid plan

[10] https://www.cms.gov/regulations-and-guidance/guidance/manuals/paper-based-manuals-items/cms021927.

76. The California Court of Appeal recently reinforced the need for the State to comply with federal law, holding that, consistent with the plain language of 42 U.S.C. § 1396a(bb)(2), the Department "**must pay** 100 percent of [an FQHC's] costs for . . . services." (*Tulare Pediatric, supra,* 41 Cal.App.5th at p. 171 [emphasis added].) In its opinion, the *Tulare Pediatric* court further held that the State's efforts to do otherwise was the precise type of behavior "Congress sought to avoid: pay[ing] a health center less than the center's full cost of treating Medicaid beneficiaries, [thereby] creating a risk [the] clinic will use Public Health Services Act grant funds to subsidize Medicaid beneficiaries." (*Id*., at p. 171.)

2. California's methodology for reimbursing FQHCs using a PPS rate is not consistent with federal law with respect to the pharmacy benefit

a. California's failure to recognize visits with licensed pharmacists as a billable PPS visit is inconsistent with federal law

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

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

78. When implementing BIPA Section 702, California defined an FQHC and RHC "visit" more narrowly than permitted under 42 C.F.R. § 447.371(d), excluding coverage of most "other ambulatory services" it included in its State plan. Currently, California's "visit" definition includes a face-to-face encounter between an FQHC patient and a physician (defined in accord with 42 U.S.C. § 1395x(r)), physician assistant, nurse practitioner, certified nurse-midwife, clinical psychologist, licensed clinical social worker,

visiting nurse, comprehensive perinatal services practitioner, a four-hour day of attendance at an adult day health care center, dental hygienist, a dental hygienist in alternative practice, a marriage and family therapist, and an acupuncturist. (Cal. Welf. & Inst. Code, § 14132.100(g); Calif. State Plan, Section 3.1, Attachment 3.1-A, Limitations on Attachment 3.1-A, pp. 3c – 3e, and Attachment 3.1-B, Limitations on Attachment 3.1-B, pp. 3c – 3e.)

79. Relevant to this case, the pharmaceutical services covered by Medi-Cal through its State plan are not recognized as FQHC or RHC "visits." This results in reimbursement under the PPS rate that is not consistent with federal law requiring Medicaid to reimburse FQHCs a face-to-face encounter between a clinic patient and any health professional whose services are reimbursed under the state plan.

b. California's limitations on when FQHCs can request a recalculation of their PPS rates prevent adjustments when drug costs increase are inconsistent with federal law

80. Under the PPS rate applicable to FQHCs, rather than a health center submitting a claim for each service provided (commonly known as the "fee-for-service" or "FFS" payment method) and being reimbursed different amounts according to the particular service rendered, each visit by a Medicaid beneficiary is reimbursed at the same flat rate. This per-visit rate is required to reflect the average cost of providing services to Medicaid patients over a given period of time.

81. Specifically, federal Medicaid law requires rates to be set for entities approved as FQHCs after 2000 as follows:

> (bb) Payment for services furnished by Federally-qualified health centers and rural health clinics.
>
> > (2) Fiscal year 2001— . . . for services furnished on and after January 1, 2001, during fiscal year 2001, the State plan shall provide for payment for such services in an amount (calculated on a per visit basis) that is equal to 100 percent of the average of the costs of the center or clinic of furnishing such services during fiscal years 1999 and 2000 which are reasonable and related to the cost of furnishing such services . . . [.] (*See* 42 U.S.C. § 1396a(bb)(2).)

(*See* 42 U.S.C. § 1396a(bb)(2).)

82. These PPS rates once set for FQHCs that were in existence prior to 1999, must be adjusted pursuant to federal law. Specifically:

> (3) Fiscal year 2002 and succeeding fiscal years— . . . for services furnished during fiscal year 2002 or a succeeding fiscal year, the State plan shall provide for payment for such services in an amount (calculated on a per visit basis) that is equal to the amount calculated for such services under this subsection for the preceding fiscal year—
>
> > (A) increased by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) applicable to primary care services (as defined in section 1395u(i)(4) of this title) for that fiscal year; and
> >
> > (B) adjusted to take into account any increase or decrease in the scope of such services furnished by the center or clinic during that fiscal year.

(*See* 42 U.S.C. § 1396a(bb)(3).)

83. The California State plan further provides with respect to rate setting for existing facilities:

> (a) Beginning on January 1, 2001, the prospective payment reimbursement rate for an FQHC . . . was equal to 100 percent of the average reported cost-based reimbursement rate per visit for fiscal years 1999 and 2000 for the FQHC . . ., as determined in accordance with cost reimbursement principles for allowable costs explained in 42 CFR Part 413, as well as, Generally Accepted Accounting Principles. For each FQHC . . . the prospective payment reimbursement rate for the first fiscal year was calculated by adding the visit rate for fiscal years 1999 and 2000, and then dividing the total by two.

(Cal. State Plan, Att. 4.19-B, p. 6-D, ¶ D.2.a.)

84. After an FQHC's PPS rate is set, it is adjusted annually for inflation by the Medicare Economic Index ("MEI"). (Cal. Welf. & Inst. Code, § 14132.100(d).) In 2019, the MEI was 1.9%. The only other time an adjustment is made is when an FQHC experiences one of nine qualifying events set forth in California Welfare & Institutions Code section 14132.100(e)(2) and the State Plan. These nine qualifying events are:

/ / /

(A) The addition of a new FQHC service that is not incorporated in the baseline PPS rate, or a deletion of an FQHC service that is incorporated in the baseline PPS rate.

(B) A change in service due to amended regulatory requirements or rules.

(C) A change in service resulting from relocating or remodeling an FQHC.

(D) A change in types of services due to a change in applicable technology and medical practice utilized by the center or clinic.

(E) An increase in service intensity attributable to changes in the types of patients served, including, but not limited to, populations with HIV or AIDS, or other chronic diseases, or homeless, elderly, migrant, or other special populations.

(F) Any changes in FQHC services or the provider mix of an FQHC or one of its sites.

(G) Changes in operating costs attributable to capital expenditures associated with a modification of the scope of any of the FQHC services, including new or expanded service facilities, regulatory compliance, or changes in technology or medical practices at the center or clinic.

(H) Indirect medical education adjustments and a direct graduate medical education payment that reflects the costs of providing teaching services to interns and residents.

(I) Any changes in the scope of project approved by HRSA.

(Cal. Welf. & Inst. Code, § 14132.100(e)(2)(A)-(I); Cal. State Plan, Att. 4.19-B, pp. 6-M to 6-O, ¶ K.2(a)-(i).).)

85. These qualifying events are intended to account for changes in the "type, intensity, duration, or amount of services, or any combination thereof" of services that are provided during an average visit. (Cal. Welf. & Inst. Code, § 14132.100(e)(3)(c); Cal. State Plan, Att. 4.19-B, p. 6-M, ¶ K.1(a) to (d).). Put another way, these provisions provide for an adjustment to an FQHC's per visit rate when the average of providing the defined set of FQHC services has changed due to changes in the type, intensity, duration or amount of FQHC services during the prior fiscal year. State and federal law require the Department, in such an instance, to adjust the FQHC's PPS rate.

/ / /

86. If an FQHC experiences at least one qualifying event and meets four additional conditions, the FQHC "may apply for an adjustment to its per-visit rate based on a change in the scope of services provided by the FQHC" pursuant to California Welfare & Institutions Code section 14132.100(e)(1) and Cal. State Plan, Att. 4.19-B, p. 6-M, ¶ K.).

87. The four additional conditions set forth in section 14132.100(e)(3) and the State Plan expressly provide that a change in costs alone is not enough to qualify an FQHC for a rate change:

> (3) A change in costs is not, in and of itself, a scope-of-service change, unless all of the following apply:
>
> > (A) The increase or decrease in cost is attributable to an increase or decrease in the scope of services defined in subdivisions (a) and (b), as applicable.
> >
> > (B) The cost is allowable under Medicare reasonable cost principles set forth in Part 413 (commencing with Section 413) of Subchapter B of Chapter 4 of Title 42 of the Code of Federal Regulations, or its successor.
> >
> > (C) The change in the scope of services is a change in the type, intensity, duration, or amount of services, or any combination thereof.
> >
> > (D) The net change in the FQHC's or RHC's rate equals or exceeds 1.75 percent for the affected FQHC or RHC site. For FQHCs and RHCs that filed consolidated cost reports for multiple sites to establish the initial prospective payment reimbursement rate, the 1.75-percent threshold shall be applied to the average per-visit rate of all sites for the purposes of calculating the cost associated with a scope-of-service change. “Net change” means the per-visit rate change attributable to the cumulative effect of all increases and decreases for a particular fiscal year.

(Cal. Welf. & Inst. Code, section 14132.100(e)(3); *see also* Cal. State Plan, Att. 4.19-B, p. 6-M, ¶ K.1.)

88. Under this statutory framework, an increase in drug costs in and of itself would not qualify for a rate change under section 14132.100(e) because it is not a qualifying event and does not constitute a change in the type, intensity, duration, or amount of services, but rather is a change in costs alone, which does not, in and of itself,

constitute a scope-of-service change. The net cost of prescription drugs -- meaning sticker price minus manufacturer discounts -- for all brand-name drugs in the United States rose more than three times faster than the rate of inflation over the course of a decade, according to a study published in the Journal of the American Medical Association.[11] Without the ability to adjust their rate when drug costs increase, FQHCs are prevented from being reimbursed their actual and reasonable costs.

c. California's process for adjusting PPS rates conflicts with federal law because it limits adjustments to only 80 percent of the per visit increase in costs

89. After a scope of service change is submitted, the Department audits the cost report applying Medicare reasonable cost principles. At the end of the audit of the scope of service change request, before the new rate is established, the difference between the newly calculated cost per-visit rate and the current PPS per-visit rate is multiplied by an 80 percent adjustment factor (colloquially known as the "20 percent hair cut") to arrive at an amount that is added to the current PPS rate to establish the newly adjusted PPS reimbursement rate. (Cal. State Plan, Att. 4.19-B, p. 6-P, ¶ K.6(b) & (c).)

90. This 80 percent adjustment factor is not codified in Welf. & Inst. Code § 14132.100, and conflicts with the requirement that the costs be determined in accordance with the Medicare reasonable cost principles in 42 C.F.R. Part 413.) The 80 percent adjustment factor is also inconsistent with the federal mandate requiring Medicaid to establish prospective FQHC rates based on 100 percent of their reasonable and actual costs.

/ / /

/ / /

/ / /

/ / /

/ / /

[11] https://jamanetwork.com/journals/jama/article-abstract/2762310

3. The Medi-Cal fee-for-service reimbursement for pharmaceutical services is not intended to reimburse FQHCs their actual and reasonable cost of providing the pharmacy benefit

a. The Medi-Cal pharmacy benefit generally

91. California's State Medicaid plan (the "State plan") describes Medi-Cal's covered services in Section 3. Section 3 includes a description of Medi-Cal's coverage of the optional pharmacy benefit permitted under 42 U.S.C. § 1396a(a)(12).

92. Specifically, Section 3, Attachments 3.1-A and 3.1-B, of the State plan include coverage of "***Prescribed drugs***, dentures, prosthetic devices, and hearing aids; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist" as permitted by 42 U.S.C. § 1396a(a)(12). [Emphasis added.] Page 1 of Attachment 3.1-B specifically states that "[t]he following ambulatory services are provided."

93. Prescribed drug services are thus "other ambulatory services" included in the State plan and, to the extent furnished by an FQHC, must be reimbursed in the manner provided for in 42 U.S.C. § 1396a(bb).

94. California currently reimburses Medi-Cal providers for the pharmacy benefit in one of two ways – Medi-Cal managed care or fee-for-service.

95. In Medi-Cal managed care, California includes the pharmacy benefit in the capitated (per-member-per-month) rate that it pays the health plans, and which, in turn, the health plans negotiate with the provider. Reimbursement for the drugs is based on rates established via the Medi-Cal managed care plans' negotiations with the providers.

96. Alternatively, California reimburses providers on a fee-for-service basis. Two different sets of provisions of the California Welfare and Institutions Code apply with respect to the dispensing of 340B drugs under Medi-Cal.

97. California Welfare and Institutions Code section 14105.46(d) provides that a Covered Entity "shall bill an amount not to exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code [the 340B program], plus the professional fee pursuant

to Section 14105.45 or the dispensing fee pursuant to Section 14132.01." Section 14105.45 limits reimbursement for FQHCs participating in the 340B program to an amount not to exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with section 256b of title 42 of the United States Code, plus the professional fee. State Plan Amendment 17-002 provides for a "professional dispensing fee" of either $13.20 or $10.05 depending on the pharmacy's total (Medicaid and non-Medicaid) annual claim volume.

98. Section 14132.01 applies to nonprofit clinic dispensaries, rather than licensed pharmacies, and applies "[n]otwithstanding any other provision of law" to nonprofit FQHCs that have elected to be reimbursed for pharmaceutical goods and services on a fee-for service basis under Welfare & Institutions Code § 14132.100(k).

99. Section 14132.01 expressly applies to FQHCs that are administering or dispensing drugs to their patients under a dispensary license issued by the California Board of Pharmacy pursuant to California Business & Professions Code §§ 4180 – 4186. (Welf. & Inst. Code § 14132.01(a).) Section 14132.01(a) provides that these clinics "shall bill and be reimbursed, as described in this section, for drugs and supplies covered under the Medi-Cal program and Family PACT Waiver Program."[12] (Despite the fact that the California Legislature adopted this statute in 2004, Medi-Cal has not yet implemented the statutory requirement for covered Medi-Cal drugs other than those dispensed to Family PACT beneficiaries.)

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

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

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

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

(Cal. Welf. & Inst. Code § 14132.01(b)(1).)

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

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

b. Reimbursement of the FQHC pharmacy benefit as an Alternative Payment Methodology to the PPS rate

103. California statutory law provides for reimbursement of pharmacy services under an Alternative Payment Methodology ("APM"), within the meaning of 42 U.S.C. § 1396a(bb)(6), which permits State Medicaid Agencies to adopt alternatives to the PPS reimbursement methodology, so long as they meet the following two conditions:

(A) the methodology is agreed to by the State and the FQHC or RHC; and

(B) results in payment to the FQHC or RHC of an amount which is at least equal to the amount otherwise required to be paid to the FQHC or RHC under the PPS methodology.

104. As amended in 2009, the FQHC reimbursement sections of the current State plan excludes reimbursement of most "optional benefits" including community

/ / /

pharmacy drugs and services. This results in the FQHC pharmacy benefit being treated not as an FQHC optional benefit, but rather as a non-FQHC benefit.

105. Section 4.19 of the State plan sets out the State plan's provisions relating to reimbursement of FQHC services, stating that "ATTACHMENT 4.19-B describes the methods of payment and how the agency determines the reasonable cost of the services (for example, cost reports, cost or budget reviews, or sample surveys)."

106. Attachment 4.19-B, which the Department has stated "describes the methods of payment and how the agency determines the reasonable cost of the [covered FQHC] services", states the following at page 6B - 6B.1:

> **C. Services Eligible for Reimbursement Under This Amendment**
>
> 1. (a) Services eligible for prospective or alternative payment reimbursement are covered benefits described in Section 1905(a)(2)(C) of the Act that are furnished by an FQHC and services described in Section 1905(a)(2)(B) of the Act that are furnished by an RHC. The services furnished will be reported to DHCS annually, in a format prescribed by DHCS.
>
> (b) **Optional services that are furnished by an FQHC and RHC within the scope of subparagraph C.1(a), or any other provision of this State Plan, are covered only to the extent that they are identified in the State Plan segments titled, "Limitations on Attachment 3.1-A" and "Limitations on Attachment 3.1-B" on pages 3 through 3e, effective July 1, 2016."**

107. The cited limitations pages include no references to the manner of reimbursement of the optional pharmacy benefit when provided by an FQHC or RHC. In other words, these pharmacy benefits are not covered as part of the FQHC benefit. This State plan modification was made unilaterally by the Department, and was not the result of a change in either State or Federal law relating to FQHCs. Furthermore, it is inconsistent with Welfare & Institutions Code § 14132.100(a) and (b), which recognize that the FQHC and RHC services described in 42 U.S.C. § 1396d(a)(2)(B) and (C) are "covered benefits" under the Medi-Cal program.

108. While Welfare & Institutions Code § 14132.100(k) recognizes that an FQHC or RHC may "elect" to have pharmacy services reimbursed on a fee-for-service basis, utilizing the current fee schedules established for those services," the Department has

failed to establish a fee schedule consistent with its obligations for implementation of Alternative Payment Methodologies under 42 C.F.R. § 1396a(bb)(6).[13] CMS has confirmed that while State Medicaid Agencies may reimburse FQHCs based on an Alternative Payment Methodology, it has a continuing obligation to ensure that the payments under this system, in this case the "current fee schedules" utilized to reimburse FQHCs for pharmaceutical services, result in a payment that is not less than the FQHC would be paid under a PPS methodology.

109. In short, the non-managed care fee schedules described in Welfare & Institutions Code §§ 14132.01, 14105.45 and 14105.46 do not provide for a methodology that reimburses FQHCs for pharmaceutical services in the manner required by section 1396a(bb).

F. Federal Law Preempts California's Attempt To Garner The Benefits Of The 340B Program For Itself By Depriving Covered Entities Of The Benefits In The Name Of Avoiding Duplicate Discounts

110. Congress authorized the Secretary of HHS to create an exclusive mechanism to avoid duplicate discounts on drugs purchased through the 340B program, so long as it did so in a timely manner. (42 U.S.C. § 256b(a)(5) and 42 U.S.C. § 1396r-8(a)(5).) The HHS's Health Resources & Services Administration ("HRSA") adopted a mechanism to prevent duplicate discounts in a timely manner.[14] As a result, defendants

/ / /

[13] Specifically, 42 U.S.C. § 1396a(bb)(6), which defines "alternative payment methodologies," provides as follows:

> Notwithstanding any other provision of this section, the State plan may provide for payment in any fiscal year to a Federally-qualified health center for services described in section 1396d(a)(2)(C) of this title or to a rural health clinic for services described in section 1396d(a)(2)(B) of this title in an amount which is determined under an alternative payment methodology that--
>
> (A) is agreed to by the State and the center or clinic; and
>
> (B) results in payment to the center or clinic of an amount which is at least equal to the amount otherwise required to be paid to the center or clinic under this section.

[14] *See* 58 Fed. Reg. 27293 May 7, 1993); initial mechanism finally adopted at 58 Fed. Reg. 34058 (June 23, 1993).

lack the authority to adopt their own mechanisms via implementation of California Welfare & Inst. Code § 14105.46.

111. California Welfare & Inst. Code § 14105.46 improperly adopts an alternative mechanism to avoid duplicate discounts in violation of federal Medicaid law. Furthermore, federal Medicaid law creates a preference for 340B Covered Entities, and reimbursing these entities for 340B drugs at a rate that is lower than that paid to any other Medi-Cal provider eliminates the benefit intended by Congress and obstructs the proper functioning of the 340B discount drug program.[15]

112. The duplicate discount avoidance mechanism adopted by HRSA required 340B Covered Entities to enroll in the Medicaid Exclusion File, indicating whether they dispensed 340B drugs to Medicaid beneficiaries, and prohibited State Medicaid Agencies from claiming rebates on drugs dispensed to Medicaid beneficiaries as to these Covered Entities. HRSA further was granted authority to develop a mechanism to prevent duplicate discounts. HRSA initially exercised that authority to require the Covered Entities to bill Medicaid at the actual acquisition cost plus a reasonable dispensing fee for these drugs. HRSA retracted this requirement in 2000.[16]

113. Under the Medi-Cal Rx Transition, Covered Entities will continue to purchase prescription drugs at the 340B discounted rate and the Medi-Cal program will

---

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

[16] *See* 65 Fed. Reg. 13984 (March 15, 2000); *see also* OIG Report entitled "State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs," (June 2011) at page i, stating that "In 1993, HRSA directed covered entities to bill State Medicaid agencies at actual acquisition cost (AAC) for 340B-purchased drugs. In 2000, HRSA issued new guidance directing covered entities to instead refer to State Medicaid agencies' policies for applicable billing policies."

reimburse at the actual acquisition cost plus a nominal dispensing fee. The unilateral adoption by California of a requirement to reimburse drugs at the actual acquisition cost in order to aid in the identification of 340B drugs, rather than using the Medicaid Exclusion File as adopted by HRSA, not only violates the restrictions placed on states by Congress, but increases the administrative costs of operating a compliant 340B program and decreases reimbursement. The increase in costs arises primarily from the requirement of claim-by-claim identification of 340B drugs. The decrease in reimbursement arises from the requirement that Covered Entities bill at the "entity's actual acquisition cost for the drug, rather than using the generally applied National Average Drug Acquisition Cost ("NADAC"), used by other Medi-Cal providers, which is a rate that is generally higher than actual acquisition cost. The discriminatory reimbursement methodology adopted by the State in Section 14105.46 alsoundermines the Congressional scheme creating the 340B program, which is centered around ensuring that the financial benefit of 340B discounts accrue to the specified Covered Entities it identified in 42 U.S.C. § 256b(a)(4).

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

115. Under both the fee-for-service duplicate discount avoidance mechanism adopted by HRSA in 1993, and under the Medicaid managed care duplicate discount avoidance mechanism established in 42 U.S.C. § 1396r-8(j), Congress established a preference under Medicaid. If the Covered Entity elected to dispense 340B drugs to Medicaid beneficiaries, the State was prohibited from claiming the benefit of a rebate on such drug. By reimbursing these drugs at actual acquisition cost, the Department is essentially improperly forcing the 340B covered entities to collect these rebates on the

State's behalf. As stated by former DHCS director Toby Douglas when questioned by a reporter about the adoption of Section 14105.46, the change in the State's long-standing policy will align costs up front, calling it "a cleaner way of doing the process." This way, he said, savings will be realized from 340B discounts at the time the claim is paid, instead of forcing the state to "chase manufacturers for rebates" up to six months later.[17] On the flip side, by paying Covered Entities only the actual acquisition cost plus a nominal dispensing fee, the State is depriving Covered Entities from the benefits of the 340B program.

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

VI. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

(Declaratory Relief)

The Medi-Cal Rx Transition Cannot Take Place In The Absence Of A Transparent Public Process That Complies With The Laws Governing 1115 Waivers

117. Plaintiffs reallege and incorporate by reference each of the previous allegations set forth in this petition and complaint set forth above as if set forth in full herein.

118. An actual and justiciable controversy has arisen and now exists between the parties relating to the issue of whether the Department may implement the Medi-Cal Rx Transition when its request for obtaining federal approval for this material change was submitted untimely, involved a deficient public comment process, lacked transparency, contained material misrepresentations regarding the impact of the amendments to the Waiver on FQHCs, and mischaracterized FQHC comments

[17] *See* Discount Drug Monitor, "States Seek to Limit 340B Reimbursement Under Medicaid," July 6, 2009.

submitted during the DHCS public comment period. Plaintiff contends that these deficiencies prohibit the Medi-Cal Transition Rx from being implemented and defendants contend that they do not.

119. The Department's pending request for an extension of the 1115 Medi-Cal managed care Waiver that includes an amendment to the existing Waiver to carve-out the pharmacy benefit cannot be approved and implemented and violates due process because it was submitted less than 120 days before the termination date of the existing Waiver, because the Department's notice falsely stated that there would be no impact on FQHCs, and because the Department grossly mischaracterized the FQHCs' objection to the waiver extension request in its summary of comments submitted to CMS.

120. The Federal Declaratory Judgment Act empowers federal courts to declare the rights and other legal relations of any interested party seeking such declaration, and also provides authority for further necessary and appropriate relief based on its declaratory judgments. Plaintiffs are interested parties.

121. Plaintiffs have no adequate remedy at law and Rule 57 of the Federal Rules of Civil Procedure provides that the existence of another adequate remedy does not preclude a judgment for declaratory relief in cases where it is appropriate. In addition, the court may order a speedy hearing of an action for a declaratory judgment and may advance it on the calendar. Each is appropriate in this matter.

122. A declaratory judgment is necessary to ensure that the State complies with federal law, as required by the Supremacy Clause, in moving the pharmacy benefit out of Medi-Cal managed care into a fee-for-service or prospective payment system reimbursement methodology in a manner consistent with 42 U.S.C. § 1396a(bb).

123. Plaintiffs and their patients will suffer immediate adverse impact if the pharmacy benefit is moved out of Medi-Cal managed care into a fee-for-service or prospective payment system reimbursement methodology that is not consistent with 42 U.S.C. § 1396a(bb), as will occur on January 1, 2021 in the absence of intervention by

/ / /

this court. Therefore, the controversy between plaintiffs and the Department is imminent and a declaratory judgment is necessary to resolve the rights and duties of the parties.

124. In order to maintain the status quo, plaintiffs also seek an injunction that prevents the Department from implementing the Medi-Cal Rx Transition as part of its request to extend the 1115 Waiver due to the defects in its request to amend the Waiver.

125. Plaintiffs have no administrative remedy, or any plain, speedy, or adequate remedy at law, and unless relief is granted as prayed, the Department will move forward with the Medi-Cal Rx Transition.

126. Plaintiffs also request recovery of attorneys' fees pursuant to 42 U.S.C. § 1988.

SECOND CLAIM FOR RELIEF

(Declaratory Relief)

The Medi-Cal Rx Transition Cannot Take Place In The Absence Of A Reimbursement Mechanism That Reimburses Health Centers At 100 Percent Of Their Actual Costs For Pharmacy Services

127. Plaintiffs reallege and incorporate by reference each of the previous allegations set forth in this petition and complaint set forth above as if set forth in full herein.

128. An actual and justiciable controversy has arisen and now exists between the parties relating to the issue of whether the Department may implement the Medi-Cal Rx Transition as to FQHCs in the absence of a reimbursement methodology that either ensures reimbursement of FQHCs for their full costs as part of their Prospective Payment System rate, paid on a per visit rate for visits with pharmacists, or via an Alternative Payment Methodology that ensures payment of these services at 100 percent of their actual costs on a fee-for-service basis, as required by federal law.

129. The Federal Declaratory Judgment Act empowers federal courts to declare the rights and other legal relations of any interested party seeking such declaration, and also provides authority for further necessary and appropriate relief based on its declaratory judgments. Plaintiffs are interested parties within the meaning of the Act.

130. Plaintiffs have no adequate remedy at law and Rule 57 of the Federal Rules of Civil Procedure provides that the existence of another adequate remedy does not preclude a judgment for declaratory relief in cases where it is appropriate. In addition, the court may order a speedy hearing of an action for a declaratory judgment and may advance it on the calendar. Each is appropriate in this action.

131. A declaratory judgment is necessary to ensure that the State complies with federal law, as required by the Supremacy Clause, in moving the pharmacy benefit out of Medi-Cal managed care into a fee-for-service or prospective payment system reimbursement methodology in a manner consistent with 42 U.S.C. § 1396a(bb).

132. Plaintiffs and their patients will suffer immediate adverse impacts if the pharmacy benefit is moved out of Medi-Cal managed care into a fee-for-service or prospective payment system reimbursement methodology that is not consistent with 42 U.S.C. § 1396a(bb), as will occur on January 1, 2021 in the absence of intervention by this court. When the Medi-Cal Rx Transition goes into effect on January 1, 2021, the plaintiff FQHCs will be immediately impacted and will suffer irreparable injury by not being able to receive reimbursement for these services at their actual cost. The FQHCs' patients will also be adversely affected because services will be reduced when the FQHCs' revenue is slashed due to the pharmacy transition. Finally, the FQHCs' Section 330 grant monies will immediately begin to subsidize the Medi-Cal program once the Medi-Cal program begins to underpay the FQHCs for the cost of providing these services. Therefore, the controversy between plaintiffs and the Department is imminent and a declaratory judgment is necessary to resolve the rights and duties of the parties.

133. In addition, an injunction is necessary to maintain the status quo as to the present pharmacy benefit while this court resolves the rights and duties of the parties. Plaintiffs seek an injunction that prohibits the Department from implementing the pharmacy benefit carve-out unless and until the Department puts into place a mechanism for reimbursing FQHCs their actual costs of providing pharmacy services outside of Medi-Cal managed care as required by law.

134. Plaintiffs have no administrative remedy, or any plain, speedy, or adequate remedy at law, and unless relief is granted as prayed, the Department will move forward with the Med-Cal Rx Transition.

135. Plaintiffs also request recovery of attorneys' fees pursuant to 42 U.S.C. § 1988.

THIRD CLAIM FOR RELIEF

(Declaratory Relief)

The Pharmacy Transition Violates Federal Law, Which Prohibits The State From Seeking Rebates Where Covered Entities Have Registered With The Medicaid Exclusion File

136. Plaintiffs reallege and incorporate by reference each of the previous allegations set forth in this petition and complaint set forth above as if set forth in full herein.

137. Under federal law, a State is prohibited from seeking rebates on drugs when a covered entity has registered as participating in the 340B Medicaid Exclusion File.

138. The Pharmacy Transition is inconsistent with the law as to who has priority to benefit from 340B savings – covered entities or the State.

139. An actual and justiciable controversy has arisen and now exists between the parties relating to the issue of whether the State is prohibited from implementing the Pharmacy Transition in order to obtain rebates on drugs dispensed by Plaintiffs and their in-house or contract pharmacies when the Plaintiffs have registered with the 340B Medicaid Exclusion File. Plaintiffs contend that for these reasons the State is prohibited from implementation of the pharmacy benefit carve-out and defendants contend that it is not.

140. The Federal Declaratory Judgment Act provides that a court may declare the rights and other legal relations of any interested party seeking a declaration in a case of actual controversy within its jurisdiction, whether or not further relief is or could be

/ / /

sought. (42 U.S.C. § 2201.) Plaintiffs are interested parties within the meaning of the Act.

141. A declaratory judgment is necessary to ensure that the intent of Congress in adopting the 340B Program is followed and to prevent the violation of federal law.

142. In addition, injunctive relief is necessary to prevent irreparable harm to the Plaintiffs and their patients that will occur if the Medi-Cal Rx transition is implemented.

143. Plaintiffs have no administrative remedy, or any plain, speedy, or adequate remedy at law, and unless relief is granted as prayed, DHCS will move forward with the Medi-Cal Rx Transition.

144. Plaintiffs also request recovery of attorneys' fees pursuant to 42 U.S.C. § 1988.

FOURTH CLAIM FOR RELIEF

(Injunctive Relief)

Enjoining Defendants From Proceeding With The Medi-Cal Rx Transition

145. Plaintiffs reallege and incorporate by reference each of the previous allegations set forth in this petition and complaint set forth above as if set forth in full herein.

146. Plaintiffs will suffer irreparable harm if defendants proceed with the Medi-Cal Rx Transition before complying with federal law as to its implementation in the manner alleged herein and before defendants establish a reimbursement methodology that either ensures reimbursement of FQHCs for their full costs as part of their Prospective Payment System rate, paid on a per visit rate for visits with pharmacists, or via an Alternative Payment Methodology that ensures payment of these services at 100 percent of their actual costs on a fee-for-service basis, as required by federal law, and until defendants develop a means of complying with federal law as to plaintiffs and their in-house or contract pharmacies that have registered with the 340B Medicaid Exclusion File.

/ / /

147. If not enjoined by this Court, defendants will proceed with the Medi-Cal Rx Transition in derogation of plaintiffs' rights under federal law as guaranteed through the Supremacy Clause.

148. Plaintiffs have no plain, speedy, and adequate remedy at law. Damages are indeterminate or unascertainable and, in any event, would not fully redress any harm suffered by plaintiffs because they are unable to engage in legally protected activity due to California's enforcement of the Medi-Cal Rx transition.

FIFTH CLAIM FOR RELIEF

(Violation Of 42 U.S.C. § 1983)

149. Plaintiffs reallege and incorporate by reference each of the previous allegations set forth in this petition and complaint set forth above as if set forth in full herein.

150. Defendant Lightbourne is a state actor and his conduct in his official and individual capacity is subject to 42 U.S.C. §§ 1983 and 1988.

151. Acting under color of State law, Defendant Lightbourne has proximately caused the violation of plaintiffs' rights guaranteed under the United States Constitution and federal law by seeking to deny Plaintiffs their federally secured reimbursement for the FQHC pharmacy benefits at their actual and reasonable costs; by doing so without providing any replacement benefit; and by denying Plaintiffs due process of law in so acting.

152. Plaintiffs are entitled to declaratory and injunctive relief requiring Defendant Lightbourne, in his official capacity, to immediately cease and desist from implementing the Medi-Cal Rx Transition unless and until the State complies fully with federal law, including providing plaintiffs due process of law. Plaintiffs are also entitled to attorneys' fees and costs incurred in this action to vindicate their federal rights.

WHEREFORE, Plaintiffs pray for relief as follows:

/ / /

/ / /

VII. PRAYER FOR RELIEF

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

1. That a declaration issue declaring that the Medi-Cal Rx Transition from Medi-Cal managed care to fee-for-service reimbursement for FQHC pharmacy services cannot occur because the State's submission of the 1115 Waiver extension request seeking to amend the Waiver to carve-out pharmacy was untimely, the State's request was not submitted by the Governor and is therefore null and void, the notice regarding the impact of the Waiver on FQHCs contained material misrepresentations, and the Department's summary of the comments submitted by the FQHCs to the Medi-Cal Rx Transition in its Waiver extension request was grossly inaccurate and did not address the objections of the FQHCs.

2. That a declaration issue declaring that the Medi-Cal Rx Transition from Medi-Cal managed care to fee-for-service reimbursement for FQHC pharmacy services cannot occur until there is either an approved Alternative Payment Methodology to reimburse FQHCs for these services at their actual costs, or there is a mechanism for adjusting an FQHCs' prospective payment system rate in the face of wildly variable year-to-year drug costs.

3. That a declaration issue declaring that the State's 80% adjustment to the rate increase determined to be due to an FQHC following the audit of a change in scope-of-service request is a violation of 42 U.S.C. § 1396a(bb) and is null and void.

4. That a declaration issue declaring that State cannot reimburse FQHCs pursuant to Welfare and Institutions Code section 14105.46 in the name of avoiding duplicate discounts such that the so the State can claim the benefit of the discount on 340B drugs provided to beneficiaries of State health care programs if the Covered Entity has informed HRSA at the time of registration for the Medicaid Exclusion File that it will dispense 340B drugs to its 340B patients.

/ / /

5. That an injunction issue enjoining the Department from implementing the Medi-Cal Rx Transition due to the Department's material failure to comply with the notice and comment requirements of the 1115 Waiver extension process, the Department's failure to timely submit its request to amend the existing Waiver to carve-out pharmacy benefits, and the Department's failure to submit the request under the proper agent of the State.

6. That an injunction issue enjoining the Department from implementing the Medi-Cal Rx Transition away from Medi-Cal managed care and towards fee-for-service reimbursement for FQHC pharmacy services until there is either an approved Alternative Payment Methodology to reimburse FQHCs for these services at their actual costs, or there is a mechanism for including actual costs in the FQHCs' prospective payment system rate and FQHCs are reimbursed on a per visit basis for face-to-face encounters with pharmacists.

7. That an injunction issue enjoining the State from reimbursing FQHCs pursuant to Welfare and Institutions Code section 14105.46 in the name of avoiding duplicate discounts such that the so the State can claim the benefit of the discount on all 340B drugs provided to beneficiaries of State health care programs if the Covered Entity has informed HRSA at the time of registration for the Medicaid Exclusion File that they will dispense 340B drugs to their 340B patients.

8. That defendants' actions violated plaintiff's' rights secured under federal law and the United States Constitution such that plaintiffs are the prevailing parties on their claims and are entitled to be awarded their costs of litigation, including reasonable attorneys' fees as permitted under 42 U.S.C. § 1988.

/ / /

/ / /

/ / /

/ / /

/ / /

9. That the Court grant plaintiffs such further and additional relief as the Court may deem just and proper.

DATED: October 29, 2020

HANSON BRIDGETT LLP

By: /S/ Kathryn E. Doi
KATHRYN E. DOI
ANDREW W. STROUD
Attorneys for Plaintiffs

DATED: October 29, 2020

LAW OFFICES OF REGINA M. BOYLE

By: /S/ Regina M. Boyle
REGINA M. BOYLE
Attorney for Plaintiffs