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California Primary Care Association*

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF CALIFORNIA**

COMMUNITY HEALTH CENTER
ALLIANCE FOR PATIENT ACCESS, *et*
al.,

Plaintiffs,

vs.

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

Defendants.

Case No. 2:20-CV-02171-DAD

**MOTION FOR ADMIN. RELIEF
FOR LEAVE TO FILE AMICUS CURIAE
BRIEF BY CALIFORNIA PRIMARY
CARE ASSOCIATION REGARDING
DEFENDANTS' MOTIONS TO DISMISS;
PROPOSED AMICUS CURIAE BRIEF**

(filed pursuant to Civ. L. Rule 233)

Judge: Hon. Dale A. Drozd

[motions submitted on 4/19/22 and pending]

1 By this motion pursuant to Civil Local Rule 233,¹ the California Primary Care Association
 2 (“CPCA”) respectfully requests leave of court to file an amicus curiae brief in the above-
 3 captioned action regarding the motions to dismiss filed by the defendants Michelle Baass
 4 (“DHCS”) and Chiquita Brooks LaSure (“CMS”) and opposed by plaintiffs Community Health
 5 Center Alliance For Patient Access et al. (“CHCAPA”).

6 CPCA’s amicus brief supports no party but seeks to provide relevant and useful
 7 information to assist the Court in adjudicating the motions before it. Counsel for the parties in this
 8 action have been notified of this application. Counsel for CHCAPA consents to the filing of
 9 CPCA’s amicus brief; counsel for DHCS does not oppose, and counsel for CMS takes no
 10 position. *See* Declaration of Long X. Do ¶3, attached hereto.

11 INTERESTS OF THE PROPOSED AMICUS CURIAE

12 CPCA was first conceived in September 1993, when a group of federally funded
 13 community health centers in California came together with common concerns related to emerging
 14 state and federal health reforms. Traditional safety-net providers recognized the urgent need to
 15 form a viable, statewide organization that could work to secure the position of community-based
 16 providers through the transition to Medi-Cal managed care. CPCA was founded with a mission to
 17 (1) promote, advocate and facilitate equal access to quality health care for individuals and
 18 families in local and surrounding California communities through organized primary care clinics
 19 and clinics networks which strive to empower individuals and families served; (2) seek to
 20 maintain cost effective, affordable services; recognize cultural diversity and, where appropriate,
 21 implement services to meet the linguistic and cultural needs of the population; and (3) organize
 22 collectively to strengthen alliances, articulate and address community needs, and maximize
 23 networking opportunities. Today, CPCA represents more than 1,300 not-for-profit community
 24 health center sites and regional clinic associations who provide comprehensive, quality health
 25
 26

27 ¹ There are no rules that govern the filing of amicus curiae briefs in the district courts.
 28 Accordingly, CPCA makes this motion pursuant to Civil Local Rule 233.

1 care services, particularly for low-income, uninsured, and underserved Californians, who might
2 otherwise not have access to health care.

3 The issues raised by defendants' motions to dismiss directly bear upon the interests and
4 work of CPCA on behalf of itself and its members.

5 HOW CPCA CAN ASSIST THE COURT

6 There is no rule governing the appearance of an amicus curiae in the federal district
7 courts. Nevertheless, "[d]istrict courts have inherent authority to appoint or deny amici" as
8 derived from Federal Rule of Appellate Procedure ("FRAP") 29. *Jin v. Ministry of State Sec.*, 557
9 F. Supp. 2d 131, 136 (D.D.C. 2008) (internal quotations omitted). "District courts frequently
10 welcome amicus briefs from non-parties concerning legal issues that have potential ramifications
11 beyond the parties directly involved or if the amicus has 'unique information or perspective that
12 can help the court beyond the help that the lawyers for the parties are able to provide.'" *NGV
13 Gaming, Ltd. v. Upstream Point Molate, LLC*, 355 F. Supp. 2d 1061, 1067 (N.D. Cal. 2005)
14 (citation omitted). Though not directly applicable here, CPCA's proposed amicus brief generally
15 conforms to the content, form, and page limitation requirements of FRAP 29.

16 CPCA believes it offers a perspective that can help the Court to understand the purposes
17 and the present and historical industry practices surrounding the Medi-Cal pharmacy
18 reimbursement issues present in this case. Such broader context can illuminate the practical
19 implications on community health centers of DHCS's transition from the Medi-Cal managed care
20 reimbursement scheme to the Medi-Cal Rx program that imposes Medi-Cal fee-for-service
21 ("FFS") on community health centers that seek reimbursement of covered pharmacy benefits.
22 CPCA's amicus brief therefore could help the Court in evaluating application of the state and
23 federal statutes that are raised in the parties' briefing. This helpful information is not otherwise
24 presented in any of the parties' briefing to date.

25 //

26 //

27 //

28 ///

CONCLUSION

For the foregoing reasons, CPCA respectfully urges the Court to GRANT its application for leave to file an amicus curiae brief and thereupon order that the amicus curiae brief submitted concurrently herewith be filed in this action.

Respectfully submitted,

Dated: January 24, 2023.

ATHENE LAW, LLP

By: /s/ Long X. Do

LONG X. DO

Attorneys for CALIFORNIA PRIMARY CARE
ASSOCIATION

ATHENE LAW LLP

DECLARATION OF LONG X. DO

I, Long X. Do, hereby declare:

1. I am attorney licensed and in good standing to practice law in the State of California. I am counsel for the California Primary Care Association (“CPCA”). I make this declaration in support of CPCA’s administrative motion for leave to file an amicus curiae brief in the above-captioned action. Unless otherwise indicated, the matters stated herein are of my personal knowledge and, if called as a witness, I could and would testify to their truth.

2. On behalf of CPCA, I emailed counsel of record for all parties in this action on January 12, 2023. I informed counsel of CPCA’s intention to file an amicus curiae brief that takes no position on the defendants’ pending motions to dismiss but provides background information about the 340B program and the Medi-Cal Rx transition that CPCA believes could be helpful to the Court. I asked that counsel respond with their clients’ position on CPCA’s administrative motion for leave to submit such an amicus curiae brief.

3. Counsel for plaintiffs Community Health Center Alliance For Patient Access et al. responded that they consent to filing of CPCA’s amicus brief. Counsel for the state defendants, Department of Health Care Services et al., responded and indicated the state defendants “will not oppose” the filing of CPCA’s amicus brief. And counsel for the federal defendants, the Centers for Medicare and Medicaid Services et al., responded and indicated they “take no position.”

I declare under penalty of perjury of the laws of the United States and the State of California that the foregoing is true and correct. Executed this 24th day of January 2023 in Takoma Park, Maryland.


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15 MICHELLE BAASS, Director of the
16 California Department of Health Care
17 Services; CHIQUITA BROOKS-LASURE,
18 Administrator of the Centers for Medicare and
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19 Defendants.

Case No. 2:20-CV-02171-DAD

**AMICUS CURIAE BRIEF IN SUPPORT
OF NO PARTY BY CALIFORNIA
PRIMARY CARE ASSOCIATION
REGARDING DEFENDANTS' MOTIONS
TO DISMISS**

(filed pursuant to Civ. L. Rule 233)

Judge: Hon. Dale A. Drozd

[motions submitted on 4/19/22 and pending]

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Robert L. Murry, “The Secret of Community Health Centers? They Deliver Superior Outcomes,” Nat’l Ass’n Comm. Health Ctrs. (Dec. 28, 2022)..... 3

INTRODUCTION

Amicus curiae the California Primary Care Association (“CPCA”) takes no position on the motions to dismiss filed by defendants in this matter, but it is confident that additional information presented herein but absent from the parties’ briefing will benefit the Court’s broader understanding of the important issues that are at stake. By this brief, CPCA wishes to give further context to the 340B program and how it operated in tandem with the Medi-Cal managed care program to enable community health centers to maintain and expand critical health care services to California’s neediest communities and most underserved patients. CPCA also will explain the real-world impact of the Medi-Cal Rx transition away from Medi-Cal managed care on community health centers’ ability to care for their patients and what can or is being done about it.

The Court is faced with important questions of federal and state statutory interpretation involving several federal and state aid programs. While such legal questions are paramount and dispositive, CPCA emphasizes that resolution of the pending motions cannot be done in a vacuum. Rather, resolving the legal questions here must take full account of the impact on real lives that are served by CPCA’s community health centers. CPCA accordingly urges the Court to give full consideration to this amicus brief as it adjudicates defendants’ motions.

INTERESTS OF AMICUS CURIAE

CPCA was first conceived in September 1993, when a group of federally funded community health centers in California came together with common concerns related to emerging state and federal health reforms. Traditional safety-net providers recognized the urgent need to form a viable, statewide organization that could work to secure the position of community-based providers through the transition to Medi-Cal managed care. CPCA was founded with a mission to (1) promote, advocate and facilitate equal access to quality health care for individuals and families in local and surrounding California communities through organized primary care clinics and clinics networks which strive to empower individuals and families served; (2) seek to maintain cost effective, affordable services; recognize cultural diversity and, where appropriate, implement services to meet the linguistic and cultural needs of the population; and (3) organize collectively to strengthen alliances, articulate and address community needs, and maximize

1 networking opportunities. Today, CPCA represents more than 1,300 not-for-profit community
2 health centers and regional clinic associations who provide comprehensive, quality health care
3 services, particularly for low-income, uninsured, and underserved Californians, who might
4 otherwise not have access to health care.

5 DISCUSSION

6 **A. Community Health Centers for Decades Have Delivered Vital Community-Based** 7 **Care to an Underserved Population.**

8 Community health centers (an umbrella term that includes federally qualified health
9 centers) were created under President Lyndon B. Johnson’s “War on Poverty” in 1965. They
10 served to address the untreated health problems within low-income neighborhoods and thereby
11 mitigate the economic burdens on these under-served communities. Health centers maintained an
12 “open door” policy to provide care to all regardless of their ability to pay. *See* [Brad Wright, “Who](#)
13 [Governs Federally Qualified Health Centers?” 38 J. Health Polit. Pol’y Law 27, 28 \(2013\).](#)

14 Community health centers today are community-based and patient-directed organizations
15 that serve populations with limited access to health care. These include low-income populations,
16 the uninsured, those with limited English proficiency, migrant and seasonal farmworkers,
17 individuals and families experiencing homelessness, and those living in public housing. Health
18 centers have provided and continue to provide comprehensive, culturally competent, quality
19 primary health care services to medically underserved communities and vulnerable populations.
20 There are almost 1,400 health centers nationwide, operating 14,500 sites in rural and urban
21 locations and serving as the primary medical home for over 30 million people (including one in
22 five Californians). *See* [CPCA, Community Health Centers 2021 State Profile](#).

23 The effectiveness of community health centers is undeniable. Researchers have found that
24 these health centers improve access for hard-to-reach and underserved populations, provide
25 continuous and high-quality primary care, and reduce the use of costlier providers of care, such as
26 emergency departments and hospitals. *See* Michelle Proser, “Deserving the Spotlight: Health
27 Centers Provide High-Quality and Cost-Effective Care,” 28 J. Ambul. Care Mgmt. 321 (Oct-Dec.
28

2005). Community health centers cover more than 25 percent of all primary care visits for the nation's low-income population and generate \$24 billion in annual savings. [Nat'l Ass'n Comm. Health Ctrs., "Community Health Centers: The Local Prescription for Better Quality and Lower Costs" \(March 2011\).](#) Health centers also achieve better outcomes on many standard clinical quality metrics, providing more preventive services than other primary care providers. For instance, rates of good control of high blood pressure and diabetes are better in health centers than the national average. *See* [Robert L. Murry, "The Secret of Community Health Centers? They Deliver Superior Outcomes," Nat'l Ass'n Comm. Health Ctrs. \(Dec. 28, 2022\).](#)

B. The Confluence of 340B Savings and Medi-Cal Managed Care was Indispensable to Community Health Center Operations.

Given the charitable nature of their services, health centers operate on razor thin margins and need to maximize every dollar of revenue or grant funding that comes to them. Federal law requires that funds received, regardless of their source, must be used to further the purpose and mission of the community health center. 42 U.S.C. §254b(a)(5)(D).

All community health centers rely on a variety of financial resources, and an important one has been the savings generated under the 340B drug discount program and maximized through participation in Medi-Cal managed care. Community health centers like other health care providers participate in Medi-Cal managed care through provider contracts with health plans. The contracts establish the Medi-Cal patient population for which the community health center will be responsible and, importantly, set the reimbursement rate for covered services provided to that population. The negotiated rates generally track market rates and can yield net funds to the extent the rates are higher than the cost of providing a service. Because community health centers can obtain drugs at a discount under the 340B program, they can leverage such discounts to generate additional funds to provide comprehensive services beyond the reach of the Medi-Cal program. This historical industry practice was eliminated by the introduction of the Medi-Cal Rx program, but it had been entirely consistent with the 340B program. As explained below, transition to the Medi-Cal Rx program is having significant deleterious impact on community health centers'

ability to serve their patients.

1. The 340B Program is Designed to Maximize and Leverage Community Health Center Revenue to Expand Services to Their Patients.

The 340B program is the result of the 1990 Medicaid drug rebate program, which required drug manufacturers to sell their drugs to state Medicaid programs at discounted rates. *See* Kathryn R. Watson, “340b Bedfellows: How Community Health Centers Can Successfully Contract with Chain Pharmacies to Expand Access to Needed Medicine,” 25 ANNALS HEALTH L. 1, 3 (2016) (“Watson”). To compensate, drug manufacturers raised prices for others. *Id.*

Pursuant to section 340b of the Public Health Service Act (codified at 42 U.S.C. §256b), Congress created the 340B program to create a pathway for certain types of health care providers, including health centers, known as “covered entities,” to be eligible to purchase drugs at a significant discount. According to Congress, safety net providers experienced over a thirty percent increase in the price of outpatient drugs in 1991, relative to previous years where increases averaged closer to six percent. *See id.* (citing H.R. Rep. no. 102-384, pt. 2, at 12 (1992)). Essentially, pharmaceutical manufacturers were shifting the cost of the Medicaid drug rebate program on to health care providers, and this shift threatened to bankrupt safety net providers whose patients were disproportionately uninsured and underinsured. *Id.*

Under the 340B program, drug manufacturers that participate in Medicaid and wish to have their drugs covered as a program benefit must provide a reduced 340B price to “covered entities” for direct purchase. *See* 42 U.S.C. §256b(a)(1). 340B “covered entities” thus could purchase covered drugs for their patients at reduced prices. The program’s design is “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” *See* H.R. Rep. no. 102-384, pt. 2, at 12 (1992). Accordingly, the 340B program aims to promote broader access to affordable medications for underprivileged patients.

There are requirements for participation in the 340B program. To ensure discounted 340B drugs are dispensed consistent with the purpose of the 340B program, covered entities are prohibited from reselling or otherwise transferring a covered 340B drug to anyone who is not a

1 patient of that covered entity. 42 U.S.C. §256b(a)(5)(B). Furthermore, because drug
2 manufacturers who already give discounts under the 340B program may also participate in
3 Medicaid programs, the 340B program requires states to ensure that such manufacturers are not
4 subject to duplicate discounting of their drugs. *See id.* at §256b(a)(5)(A). Intended as a flexible
5 and vital lifeline for safety-net providers, the savings achieved through the program enabled
6 health centers to increase access to critical patient services. In fact, the Health Resources &
7 Services Administration (the federal regulator overseeing the 340B program) has explained that it
8 is entirely up to the covered entities how they benefit from the savings:

9 HRSA agrees that the intent of the 340B program was to permit the covered
10 entities to stretch scarce Federal resources, and that the benefit of the program
11 was intended to accrue to the covered entities. However, the covered entity is free
12 to negotiate how it chooses to use any such funds as it sees fit.

13 Notice Regarding 340B Drug Pricing Program – Contract Pharmacy Services, 75 Fed. Reg.
14 10272-01 at 10277 (Mar. 5, 2010).

15 Accordingly, community health centers that maximized the savings under the 340B
16 program through Medi-Cal managed care were in full compliance with program requirements.
17 What is more, maximizing 340B savings was effective and necessary to serving the important
18 community benefits that are the essence of community health centers' missions.

19 A recent survey revealed that more than half of community health centers nationwide have
20 an in-house pharmacy while most others contract for pharmacy services to serve their patients.
21 *See* [Nat'l Ass'n Comm. Health Ctrs., 340B: A Critical Program for Health Centers \(June 13, 2022\)](#).
22 Participating in the 340B program allows community health centers to provide affordable
23 discounted or free medications to their uninsured and underinsured patients. Community health
24 centers estimated that between 10 to 50 percent of their patients would go without needed
25 medications but for the 340B program. *Id.* Particularly, patients with diabetes, heart disease, and
26 behavioral health needs rely on these drugs, and the community health centers that participate in
27 the 340B program report increased access for low-income and rural patients to medically
28 necessary drugs and pharmacy services. *Id.* Funds generated through 340B program savings also

1 expand comprehensive clinical and enabling services that otherwise may not be provided, such as
2 non-billable services and providers and care coordination or enabling services. *Id.* One rural
3 community health center in California used 340B program savings to purchase a new medical van
4 to serve homeless patients, offer competitive salaries to staff to retain critical frontline providers,
5 and upgrade technology and facilities that serve patients. *See CaliforniaHealth+ Advocates, 340B*
6 *Drug Discount Program - Community Health Centers Depend on It* (2019).

7 **2. The Transition to Medi-Cal Rx Is Harming Patient Services.**

8 Community health centers in California depended upon and generated millions in
9 operating revenues from 340B savings and participation in Medi-Cal managed care. The use of
10 these funds is not restricted so long as health centers use every penny to serve patients and
11 improve services. Such flexibility means health centers can be creative in how they use their
12 funds and target gaps in services to their patient populations. For instance, community health
13 centers used the savings to pay for ancillary services such as paying staff to extend pharmacy
14 hours, providing anger management classes & substance use support groups, and linking patients
15 to services that the health centers do not provide, like food and housing assistance. The funds also
16 helped pay for non-billable services such as home visits, assistance with immigration paperwork,
17 paying for behavioral health and primary care visit on the same day, and prescription eyeglasses.
18 Other services supported by these funds include free medications to patients experiencing
19 homelessness, coverage of drug costs for those unable to afford their co-payments, free
20 transportation vouchers, free nutrition classes, and extended pharmacy hours.

21 There are obvious negative impacts by the transition to Medi-Cal Rx. No longer are
22 pharmacy drugs and services covered under Medi-Cal managed care, which means community
23 health centers cannot maximize the savings generated through the 340B program. Rather, as the
24 parties have explained, reimbursement for the same pharmacy drugs and services afforded to
25 community health centers under the Medi-Cal Rx program is significantly less than Medi-Cal
26 managed care. To put it bluntly, Medi-Cal Rx has eliminated the 340B savings that community
27 health centers had depended upon to shore up operations and sustain or expand services to their
28 patients. There are concrete consequences on patients.

1 The loss of 340B savings is frustrating, if not thwarting, community health centers' ability
 2 to increase access to health care for the communities they serve. A recent survey estimated that 22
 3 health centers in California will have to reduce hours, or in other words, health centers across the
 4 state will reduce 1,024 hours on a weekly basis. *Id.* Plans to open 36 health centers will have to be
 5 abandoned for lack of funding, and 20 existing health centers will have to close at least one site.
 6 *See CaliforniaHealth+ Advocates, 340B Drug Discount Program, supra.*

7 Clinical services also will contract due to the cut-off of funds that otherwise are generated
 8 from 340B savings. *Id.* Health centers cannot subsidize low cost or free medications to low-
 9 income patients; will have to eliminate nutrition and diet programs, population health and chronic
 10 care management projects, and education and outreach campaigns; and close food pantries and
 11 legal aid clinics. *Id.* Health centers in California also will have to close in-house pharmacies or
 12 eliminate pharmacy services all together that provide free to low-cost drugs to patients. *Id.*

13 **C. There is Yet No Effective Backstop to Shore Up the Loss in 340B Savings Funds.**

14 The California Legislature is cognizant of the impact of the 340B savings loss on
 15 community health centers. Working with health center advocates, the Legislature and the
 16 Governor approved a state budget bill for the 2020-21 fiscal year that included creation of a non-
 17 hospital 340B clinics Supplemental Payment Pool ("SPP"). *See* A.B. 80, ch. 12, Stats. 2020 §59
 18 (enacting Cal. Welf. & Inst. Code §14105.467). DHCS has obtained approval of a State Plan
 19 Amendment (no. 21-0015) that would effectively fund the SPP with \$105 million, made available
 20 to FQHCs that demonstrate "additional level of engagement to integrate, coordinate health care,
 21 and manage the array of beneficiary health complexities." *See* [SPA 21-0015](#) (CMS approved
 22 Sept. 15, 2022, effective Jan. 1, 2022). Although thus far only available to FQHCs but not all
 23 community health centers, the SPP is intended be used to allocate moneys to offset the losses of
 24 340B savings that resulted from the transition to the Medi-Cal Rx program.

25 While the SPP is a positive step toward helping community health centers to maintain
 26 services despite the Medi-Cal Rx transition, it is likely not enough to prevent contraction of
 27 services. First, DHCS thus far has only allocated \$105 million to the SPP, which is based on
 28 survey data from 2019 that sought to estimate the financial consequences of the transition to

1 Medi-Cal Rx. More recent data collected by CPCA indicates that the loss may be as high as \$205
 2 million annually. See [CaliforniaHealth+ Advocates, FY22-23 California State Budget](#)
 3 [Supplemental Payment Pool Augmentation \(April 11, 2022\)](#). The SPP therefore may not fully
 4 shore up the huge gaps in services that are resulting from the Medi-Cal Rx transition.

5 Furthermore, while the Legislature and Governor have been willing to fund the SPP,
 6 political winds and budget conditions may change in the future that could result in underfunding
 7 or no funding for the SPP. While the 340B savings losses under the Medi-Cal Rx transition are
 8 permanent, there is no guarantee that the SPP funding will be renewed on a year-to-year basis.

9 Finally, no funds from the SPP have been disbursed to community health centers, even
 10 though the Medi-Cal Rx transition was implemented in January 2022. Implementation of the SPP
 11 program must be approved by CMS through a State Plan Amendment, and that approval was
 12 received in September for FQHCs but not all community health centers. Meanwhile, community
 13 health centers have been able to fill in budget holes through emergency funding associated with
 14 the COVID pandemic. Those funding sources are going away with the end of the declaration of a
 15 state of emergency. The full impact of the 340B savings losses therefore will be felt in 2023, and
 16 yet there is no timeline or guarantee that SPP funds will be disbursed anytime soon.

17 While community health centers are optimistic that the SPP will help to offset some of the
 18 losses of services to their patients, the SPP alone is not adequate to ameliorate all the harm caused
 19 by the Medi-Cal Rx transition. There simply is no adequate solution to the loss of 340B savings.

20 CONCLUSION

21 While CPCA takes no position on the motions before this Court, it hopes the Court fully
 22 appreciates the broader context of the issues that are presented in this amicus brief.

23 Respectfully submitted,

24 Dated: January 24, 2023.

ATHENE LAW, LLP

By: /s/ Long X. Do

LONG X. DO

Attorneys for CALIFORNIA PRIMARY CARE
 ASSOCIATION