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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

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

Judge: Hon. Dale A. Drozd

[filed pursuant to Court's order on 2/14/23, docket no. 86]

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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

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

DISCUSSION

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

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

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

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

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 Indispensible 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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CONCLUSION

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

Respectfully submitted,

Dated: February 14, 2023.

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