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UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

COMMUNITY HEALTH CENTER ALLIANCE FOR PATIENT ACCESS, *et. al.*; Plaintiffs, v. MICHELLE BAASS, Director of the California Department of Health Care Services; CHIQUITA BROOKS-LASURE, Administrator of the Centers for Medicare and Medicaid Services, Defendants.	CASE NO. 2:20-CV-02171-DAD-KJN ***AMICUS CURIAE* BRIEF OF NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS** Judge: Hon. Dale A. Drozd

I. INTRODUCTION

The National Association of Community Health Centers ("NACHC") 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, NACHC wishes to give further context to the 340B program and current challenges for covered entities across the nation. FQHCs in California are experiencing devastating losses with the combination of Medi-Cal Rx transition away from Medi-Cal managed care and the nine drug manufacturers that are illegally limiting access to 340B priced drugs at contract pharmacies. NACHC will explain the importance of this Court's decision and the potential harm on underinsured and uninsured patients.

The Court is faced with important questions of federal and state statutory interpretation involving several federal and state aid programs. NACHC wants to stress that this decision can have national implications, and urge the Court to take into consideration other determining factors that can have a negative impact on covered entities around the country.

NACHC respectfully request the Court to give full consideration to this *amicus* brief as it adjudicates defendants' pending motions.

II. INTERESTS OF *AMICUS CURIAE*

The National Association of Community Health Centers (NACHC) was founded in 1971 to promote efficient, high quality, comprehensive health care that is accessible, culturally and linguistically competent, community directed, and patient centered for all. NACHC is a national, nonprofit organization whose primary objective is to further, through extensive education, training, and advocacy, the mission and purpose of Federally Qualified Health Centers ("FQHCs or community health centers"). FQHCs are community-based, patient-directed nonprofit clinics that play a vital role in our nation's health care safety net by providing primary and other health care and related services- including pharmaceutical services- to medically underserved populations throughout the nation and its territories, regardless of a patient's ability to pay for services.

III. DISCUSSION

A. Congress Created the 340B Program to Enable Covered Entities to Expand Health Care Services in Communities with Vulnerable Patients.

The 340B Drug Pricing Program requires drug manufacturers to provide discounts on covered outpatient drugs purchased by covered entities for those manufacturers to have their products covered by Medicare and Medicaid. The 340B Program is designed to reduce drug costs for certain classes of safety net providers enumerated in the 340B statute, including FQHCs, that care for medically underserved and vulnerable populations. Since 1992, covered entities, like FQHCs, have relied on 340B savings, to help offset the costs to safety net providers of furnishing uncompensated and undercompensated care. In creating 340B, Congress acknowledged the critical role safety-net providers play in the lives of low-income and rural Americans. The 340B program furthers its legislative objective to enable covered entities "to stretch scare Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), 12 (1992). Both law and regulation require FQHCs to reinvest all 340B savings into activities that further their mission of expanding access to care for the medically underserved. 42 U.S.C. § 254b(5)(D). Any savings, or "nongrant income," the 340B Program generates for FQHCs is derived directly from the statutorily-mandated and defined discount pricing scheme that, by placing a non-discretionary duty on manufacturers to offer discount drugs to covered entities, costs taxpayers nothing.

1. Congress Historically Recognized the Importance of Community Health Centers having Adequate Resources to Provide Access to Affordable Health Services and Medications.

A health center is required by Section 330 to, among other things: (1) serve an area or population designated by the Secretary to be medically underserved; (2) have a community-based board of directors (i.e. a majority of its directors must be patients of the center "who, as a group, represent the individuals being served by the center . . ."); (3) provide primary health care services, including "pharmaceutical services as may be appropriate for particular centers," and related services; (4) provide enabling services such as outreach and transportation, education, and patient

case management; (5) participate in Medicaid; and (6) serve all residents of its community and make all of its "required" and "additional" services equally available to all of its patients, regardless of any individual's ability to pay for them. See 42 U.S.C. § 254b(a), (b), (j), (k). Section 330 grant funds are appropriate to cover or subsidize the cost of services to *un*insured or *under*insured individuals who are unable to pay for them. 42 U.S.C. § 254b(e)(5)(A). Section 330 grant funds are not to be used as a subsidy for private or public health insurance programs, such as Medicaid. To prevent such a subsidy, health centers are statutorily (a) required to "make every reasonable effort to collect appropriate reimbursement for its costs in providing health services to persons who are entitled to insurance benefits," including Medicaid. id. at § 254b(k)(3)(F). For the same reason, FQHCs are prohibited from giving discounts on their services absent a patient's inability to pay. Id. at § 254b(k)(3)(F), (G).

The purpose of the FQHC designation (first established in 1989) and the associated payment right in Medicaid—is to "ensure that health centers receiving funds under [Section 330] would not have to divert Public Health Services Act funds to cover the cost of serving Medicaid patients." Three Lower Counties Community Health Services v. Maryland, 498 F.3d 294, 297–98 (4th Cir. 2007) (citing H.R. Rep. No. 101- 247, at 392–93, reprinted in 1989 U.S.C.C.A.N. 2118–19). This is accomplished through a requirement that states reimburse 100 percent of each FQHC's reasonable costs in furnishing covered ambulatory services to Medicaid beneficiaries. Consolidated Appropriations Act, 2001, Pub. L. 106-554, (Dec. 21, 2000), codified at 42 U.S.C. § 1396a(bb) (requiring states to pay each FQHC a prospective per-visit payment rate based on its historical costs in base years and with annual adjustments for inflation and changes in scope of services). Given the purpose and history of the FQHC designation in Medicaid and Medicare, it should come as no surprise that FQHCs appear first on the statutory list of provider types that qualify as "covered entities" eligible to purchase discounted drugs under the 340B Program. 42 U.S.C. § 256b(a)(4)(A). Those discounts complement and reinforce each FQHC's statutory duty to make all its services equally available to all its patients, regardless of any individual patient's ability to pay for them. It is the intersections of the 340B program, 330 grant funding, and Medicaid reimbursement that enables health centers to satisfy their mission and provide services

to the most vulnerable patients.

2. The 340B Program is Indispenable to Help Community Health Centers Offset the Costs of Furnishing Uncompensated and Undercompensated Care.

Community Health Centers, on the front lines of caring for our nation's most vulnerable patients, use 340B discounts to support their missions of increasing access to care, improving health outcomes, and fortifying the nation's safety net. Many of the programs and services that covered entities support with 340B savings are critical to treating the whole patient, but are not reimbursed by public or private insurance, and are often most needed by patients who lack insurance altogether. Many 340B safety-net providers do not have the financial resources necessary to bear the additional costs of drugs for financially needy patients. For some covered entities, 340B Program revenue has meant the difference between remaining in operation or closing. This Program generates savings that are reinvested in the health center to meet the unique needs of their communities like dental, behavioral health, specialty care, translation services, food banks, housing support, and co-pay assistance programs. Across the country, health centers serve 17.5 million people living in poverty, 2.9 million people 65 and older, 18.5 million people of minority background, and 1.3 million people experiencing homelessness. *See* Nat'l Ass'n Comm. Health Ctrs., *340B: A Critical Program for Health Centers* (June 13, 2022). In 2020, more than 90% of health center patients were at or below 200% of the Federal Poverty Level (FPL). *Id.* 340B savings create the ability for health centers to keep their doors open when they need flexible funding to meet the unique needs of their communities.

Health centers provide access to affordable medication to millions of uninsured and underinsured patients through pharmacy services. According to NACHC's most recent 340B Report, patients with diabetes, heart disease, and behavioral health needs rely on medications purchased through the 340B program more than patients with other conditions. *See* Nat'l Ass'n Comm. Health Ctrs., *340B: A Critical Program for Health Centers* (June 13, 2022). These were the top three disease states treated at health centers with medications purchased through 340B, followed by HIV/AIDS and respiratory illness. *Id.* The 340B Program extends beyond just affordable medication, it's also the comprehensive and community-based services that are integral

to improving patient health outcomes.

For example, a health center patient with diabetes who has access to 340B program discounts may benefit from affordable access to insulin and other needed medication, and also benefits from access to regular primary care, a clinical pharmacist to aid with medication management, a nutrition program to optimize their diet, and education to help the patient manage their diabetes. Combining these services leads to improved patient health and, by doing so, reduces the long-term cost and burden of disease progression on the health system.

The current, and ongoing, loss of 340B savings due to the transition to Medi-Cal Rx will ultimately impact health centers' ability to maintain adequate access to critical services for California's most vulnerable patients. Without this flexible revenue, health centers will become more reliant on federal and state funding to fill the gaps or be forced to reduce services and/or their valuable workforce. Under the Medi-Cal Rx transition, the 340B savings that health centers depended on will flow back into the state's budget and is not guaranteed to be reinvested in the Medicaid program, or to improve access to affordable health care. As California health centers will continue to stay true to their mission, it is the devastating impact on their patients that will have long-term implications.

B. California Community Health Centers are Experiencing Devastating Financial Losses Due to Ongoing Disputes with Drug Manufacturers and Contract Pharmacies.

Since September 2020, nine of the nation's largest pharmaceutical companies implemented new restrictions that they would no longer allow covered entities (including FQHCs) to purchase their covered outpatient drugs at 340B program discount prices when those drugs would be shipped to a covered entity's contract pharmacy. The manufacturers' abrupt about-face, after decades of shipping FQHCs' purchases of 340B-priced drugs to their contract pharmacies- during a global pandemic and recession- is not only callous, but also a clear violation of 340B statutory requirements and the binding pharmaceutical pricing agreements ("PPAs") manufacturers have with HHS. Both the statute, codified at 42 U.S.C. § 256b, and the PPAs (which simply incorporate 340B statutory requirements) require that manufacturers "offer each covered entity covered

outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1). Indeed, the documented refusal by these manufacturers to make their covered outpatient drugs available to covered entities at or below 340B ceiling prices when shipped to a contract pharmacy is an emulation of the examples of "knowing and intentional" overcharging given by HHS, by way of illustration, in its civil monetary penalty ("CMP") regulations, 42 CFR § 10.11(b).

Unfortunately, since 2021, covered entities have watched over 10 lawsuits challenge HRSA's authority to enforce the 340B statute and hold manufacturers accountable for jeopardizing vulnerable patients' access to affordable medications and health care services. From 1996 until late 2020, manufacturers sold their drugs to covered entities at 340B discounted prices when shipped to contract pharmacies. When Congress enacted the 340B statute, it was aware of the existing legal framework for distributing drugs. It became abundantly clear after passage of the 340B statute in 1992 that, if covered entities could not acquire drugs through bill to/ship to arrangements, many of them—those lacking in-house pharmacies—would never have been able to participate in the 340B Program, even though they clearly met the eligibility criteria established by Congress.

Providers of health care—like community health centers—must ensure that their patients have access to a pharmacy to fill their prescriptions. Some providers own and operate their own in-house pharmacies. Through contract pharmacies, uninsured and under-insured covered entity patients get their prescriptions at convenient locations, often at a greatly reduced or no cost. Community Health Centers care for increasing numbers of patients with chronic conditions managed primarily through prescription drugs. With discounted drugs no longer available at covered entities' contract pharmacies, many covered entity patients lost access to lifesaving medications.

Similar to the State, drug manufacturers cite concerns with duplicate discounts and diversion as their motivation to restriction shipments of 340B drugs to contract pharmacies. Namely, HRSA was delegated the authority to develop a duplicate discount avoidance mechanism under (42 U.S.C. 254b(a)(5)(a)(ii)) and this is the Medicaid Exclusion File. Congress, in 42

U.S.C. § 256b(a)(5)(A)(ii), only permits states to establish a mechanism to ensure that covered entities ensure that 340B drugs are not subject to improper rebate claims by states "[i]f the Secretary does not establish a mechanism within 12 months (i.e., by November 3, 1992)". Only in this case, would the requirements of 42 USCS § 1396r-8(a)(5)(C) (permitting state duplicate avoidance mechanisms) apply. We urge the Court to review the statutory requirements and existing processes in place to prevent duplicate discounts and diversion at California covered entities. Instead of implementing Medi-Cal Rx, the State could have taken action under the 340B statute to strengthen existing policies and procedures to minimize the risk of duplicate discounts and diversion.

Manufacturer policies restricting shipments of 340B drugs to contract pharmacies have already harmed covered entities and the vulnerable patients that they serve. As of 2021, more than half of community health centers rely on contract pharmacy networks to increase access for patients, considering that reliable transportation is often a barrier to care. *See* Nat'l Ass'n Comm. Health Ctrs., *340B: A Critical Program for Health Centers* (June 13, 2022). Per patient costs will increase dramatically if these providers are burdened with covering the full price of manufacturers' drugs. Many covered entities that have relied on 340B participation lack the financial resources necessary to bear the additional costs of drugs for indigent patients.

Looking at the future of the 340B program for California FQHCs, there are great concerns on the double impact of the ongoing contract pharmacy restrictions and the transition to Medi-Cal Rx. Since late 2021, Community Health Centers have navigated an additional four drug manufacturers - including Merck, Gilead, and Boehringer Ingelheim- restricting access to life-saving medications at the same time the Medi-Cal Rx transition went into effect. FQHCs outside of California are experiencing devastating financial losses based on the contract pharmacy restrictions alone. With the additional layer for California covered entities losing 340B savings on managed care prescriptions, NACHC urges the Court to consider the impact on safety-net providers while working to address conditions exacerbated by the COVID-19 Pandemic.

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IV. CONCLUSION

While NACHC 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.

Dated: February 14, 2023

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