

June 17, 2025

The Honorable Mehmet Oz, MD Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services 7500 Security Boulevard Baltimore, MD 21244 Thomas J. Engels Administrator Health Resources and Services Administration 5600 Fishers Lane, Rockville, MD 20852

Dear Administrators Oz and Engels,

On behalf of the 1,496 Community Health Centers (CHCs) nationwide, thank you for your support and commitment to the mission of CHCs and the vital care they provide for 32.5 million patients. I write today to highlight the critical importance of the 340B program, which enables CHCs to provide access to low-cost drugs and comprehensive services to their patients. The 340B landscape has changed significantly over the past five years and continues to evolve. Navigating these dynamics has been difficult for health centers and has impacted patient care. As you develop additional policies and guidance on the program, please consider the impacts of 340B changes, including shifts to a rebate model, would have on CHCs.

As you know, Community Health Centers are the best, most innovative, and resilient part of our nation's health system. For sixty years, health centers have provided high-quality, comprehensive, affordable primary and preventive care. In addition to medical services, CHCs provide dental, behavioral health, pharmacy, vision, and other essential health services to America's most vulnerable, medically underserved communities in urban, rural, suburban, frontier, and island communities.

Since its establishment thirty-two years ago, the 340B program has been essential to health centers and their patients. Unlike other covered entities, health centers are required to invest every penny of 340B savings into activities that expand access for their patients by law and regulation. As a result, CHCs are good stewards of these savings and truly embody the original intent of Congress that the program should enable safety-net organizations to "stretch scarce federal resources."

Due to ambiguity in the law, significant legal and operational challenges have decreased access to the program in recent years. NACHC has worked independently and in coalition with other stakeholders, including some unlikely partners, to push for common-sense reforms to the program to ensure stability and predictability and reorient the program back to true safety-net providers. However, thus far, those reforms have been elusive. The growth in the program has led some pharmaceutical companies to restrict access to drugs and propose major shifts to the program, including changing it to a rebate model.

As the Administration develops additional guidance on the 340B program, I want to reiterate our continued concern about the significant challenges a rebate model would impose on health center pharmacies, given the thin financial margins of health centers and the lack of sufficient capital to

purchase drugs at higher prices upfront. A rebate program would be detrimental to health centers' financial viability and limit patient access to low-cost drugs. CHCs could not sustain their 340B programs if discounts were converted to rebates, as a rebate model would:

- 1) Create significant cash-flow issues, as CHCs would have to purchase all drugs at full price upfront, then wait months to receive the rebate and
- 2) Add a large administrative burden to request and track rebate payments on each unit of drug dispensed.

Many 340B-covered entities' pharmacies, including health centers, operate with a physical inventory. They seek to ensure they have the medications their patients need, highlight any recurring inventory issues, reduce waste, and identify differences between inventory and actual stock. Additionally, health centers operate on razor-thin financial margins while serving some of the most vulnerable, lower-income populations. Health centers serve 1 in 3 people in poverty, and health center patients are four times more likely to have income at or below the Federal Poverty Level (FPL). Half of health center patients have Medicaid coverage, nearly 20% lack insurance, and 11% of patients receive Medicare coverage. Health centers provide healthcare services to all patients and evaluate patients, both those without insurance and those underinsured, on a sliding fee scale to help lower the cost they pay for services based on family size and income.

Health center entity-owned and contract pharmacies offer prescription assistance programs to help patients with lower incomes afford their medications. Additionally, CHCs offer co-pay assistance programs, which lower patients' costs when acquiring their prescriptions at the pharmacy. Health centers put their patients first, stretching their scarce federal resources as far as possible while discounting services to ensure healthcare remains affordable and accessible to all their patients. More than half of community health centers operate with margins below 5%, and 11 million patients were served by health centers operating with negative margins in 2022. These facts show that forcing a rebate model would not be economically or financially feasible for health center pharmacies. Allowing manufacturers to implement a rebate model would fundamentally change the intent and practice of the 340B Program. Health center 340B pharmacies should not lose the ability to purchase drugs with an up-front discount through the 340B program.

Alongside the possibility of a rebate model, we would also welcome an opportunity to discuss the recent Executive Order (EO) titled "Lowering Drug Prices by Once Again Putting Americans First." Specifically, Section 7 of the EO requires CHCs receiving future Section 330 grants to offer insulin and EpiPen products to low-income patients at or below the 340B price. This includes not only uninsured patients but also underinsured individuals, which is defined as those with high-deductible health plans or high out-of-pocket drug costs.

We appreciate the administration's keen interest in lowering drug prices for Americans. As you know, CHCs are locally governed organizations that are required by law and policy to reinvest

¹ https://dclcorp.com/blog/inventory/physical-inventory-count/#:~:text=Physical%20inventory%20counts%20can%20help,help%20to%20improve%20customer%20satisfact

² https://www.nachc.org/wp-content/uploads/2023/07/Community-Health-Center-Chartbook-2023-2021UDS.pdf

https://data.hrsa.gov/tools/data-reporting/program-data/national/table?tableName=Full&year=2022

⁴ https://www.nachc.org/wp-content/uploads/2023/07/Community-Health-Center-Chartbook-2023-2021UDS.pdf

340B savings back into patient care. The program contributes to health centers' operating margin by enabling them to focus savings on areas that will be most meaningful for patients, such as lower drug prices through a sliding fee scale or health care services that otherwise would not be supported.

NACHC would welcome the opportunity to discuss how the new policy will be implemented and how new requirements will intersect with existing requirements that are placed on CHCs and other stakeholders, such as Pharmacy Benefit Managers (PBMs). For example, Section 330 of the Public Health Service Act requires CHCs to maximize their reimbursement from payors, and the EO could put health centers in non-compliance with PBMs that do not allow pharmacies to waive or reduce co-pays, in direct contradiction with this EO. Additionally, we believe new administrative elements should be placed on PBMs rather than CHCs, such as detailing patients' progress toward meeting their deductibles. Lastly, we encourage the Administration to consider issuing regulations preventing payers from blocking health centers from sliding co-pays for uninsured and underinsured patients, either more broadly or for insulin and injectable epinephrine specifically, to ensure continued access to these life-saving drugs.

We appreciate the Administration's inclusion of CHCs in the Make America Healthy Again agenda. Health centers' ability to continue to participate in the 340B program is essential to our financial viability so that we can continue serving this nation's most vulnerable patients. We look forward to continuing to work with the Administration to lower prescription drug prices for all Americans and appreciate your consideration of our feedback. Should you have any questions about our comments, please feel free to contact Joe Dunn, Chief Policy Officer, at jdunn@nachc.org or at (703) 244-3799.

Sincerely,

Kyu Rhee, MD, MPP Chief Executive Officer