ADVOCATES FOR COMMUNITY HEALTH

Testimony for the Record
Submitted to the
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
for the Hearing on
"Oversight of 340B Drug Pricing Program"
June 4, 2024

Thank you for holding this hearing, "Oversight of 34B Drug Pricing Program," to examine recent trends and developments within the 340B Program. We offer this testimony to share our perspective on the trends and developments from the perspective of community health centers. In our view, the 340B program is being eroded – not by health centers, but by other actors in the field whose actions are hindering the provision of health care for the underserved.

Advocates for Community Health (ACH) is a national membership organization comprised of leading federally qualified community health centers (CHCs) focused on health equity and innovation to drive health care systems, policies, and health programs. Our members provide high-quality, comprehensive primary health care, mental health services, preventive care, and social services to over two million people living in under-resourced communities.

ACH supports reform of the 340B program so that health centers can continue to leverage the program to their patients' benefit. We support increased accountability and transparency and believe comprehensive reform can set the program on a path to long-term stability. However, as we hope you hear from many today, **significant decreases in 340B revenue for health centers is not an acceptable outcome of 340B reform**.

Health Centers Exemplify the Purpose of the 340B Program

The 340B program enables community health centers to meet their mission, and without it, the nation's largest and strongest primary care network would falter**.** As required by Section 330 of the Public Health Service Act, CHCs are committed to serving all individuals regardless of their insurance status or availability to pay. As opposed to other covered entity types, which can charge facility fees, get support from 1115 waiver dollars, and receive other add-on payments, CHCs have no other flexible funding streams to support their mission to serve everyone in their communities. 340B remains one of precious few sources of support for the care we provide – and it doesn't use a dime of taxpayer dollars to do it.

The 340B program helps CHCs serve as health care lifelines for millions of Americans. By allowing the purchase of drugs at a discounted price, 340B program savings enable CHCs to

serve a patient population with disproportionately complex health and social needs.[1] As required by law and regulation, and as core to health centers' mission, CHCs reinvest every dollar of program income back into patient care and support. CHCs are proud to re-invest 340B savings into initiatives like medication adherence programs, outreach workers for hard-to-reach populations, enrollment assisters and navigators to ensure health insurance access, and population health projects that improve individual and community health. Health center participation in the 340B program exemplifies the intent behind the creation of the program: to maximize federal investment and expand care to underserved communities as effectively as possible.

Health Centers are Losing Access to 340B Savings

Contract Pharmacy Restrictions

Under current federal guidance, 340B covered entities are permitted to dispense 340B drugs to patients through contracting with external pharmacies. These arrangements are particularly helpful in rural communities, where health centers may be farther apart, and access to a local pharmacy is a better way to facilitate patient access to care. This is also crucial for health centers without an in-house pharmacy, as establishing and maintaining such operations is costly and resource intensive.

Unfortunately, this networked, access-oriented approach – that has worked well for CHCs and their patients for over a decade – is under threat. Currently, dozens of drug manufacturers are unlawfully limiting access to contract pharmacy services through burdensome restrictions, prohibiting access to care for vulnerable populations, with 13 placing restrictions on community health centers. The contract pharmacy arrangements that do remain are often set up to overcompensate pharmacies and do not allow for maximum accrual of savings to the benefit of patient care.

Furthermore, patients who rely on medications exclusively available through specialty pharmacies face unique access challenges. These are often not located near a covered entity, and medications must be dispensed to patients from pharmacies in alternative locations or through mail order. Restrictions on contract pharmacies without special protections for specialty pharmacies would endanger access to specialty medicines with the support of a clinical pharmacist. We support reform that offers community health centers and their patients access to all pharmacy arrangements necessary to ensure patient access to affordable medications.

Discrimination from Insurers and PBMs

Pharmacy benefit managers (PBMs) and insurance companies impose policies that dramatically reduce health center savings from the 340B program. For example, they may treat 340B

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

providers differently than other providers in terms of reimbursement, participation in standard or preferred networks or inventory management systems, or they may interfere in a patient's choice to receive drugs from a 340B pharmacy. This behavior reduces health centers' savings from the program and impacts the provision of patient care.

Medicaid Restrictions

Many states are forcing health centers to "carve out" their Medicaid patients from 340B through regulation or state law, resulting in a significant loss of savings in states across the country. States can then claim the Medicaid drug rebate on these products and add the revenue to state coffers, without any legal guardrails on how that funding is used.

Health Centers Need Protection Now

ACH is an ardent supporter of increased transparency and accountability in the 340B program; we believe that the lack of transparent, reliable information around this program and its impact on covered entities has contributed to its instability. For this reason, in 2022, ACH developed a proposal to ensure that participating entities can access the benefits of the program, while ensuring greater accountability and transparency.

This proposal creates a new opt-in subset of 340B called "340C."[2] Entities can opt-in to 340C, through which they receive protections from the actions that are reducing their savings, and in return are required to reinvest all savings into the populations they serve, submit annual reports on such savings, and undergo regular compliance audits with meaningful sanctions. 340C is completely voluntary; anyone who participates in 340B may choose to participate in 340C. The proposal maintains key provisions of the original 340B program, including the prime vendor, certification processes, and a prohibition on resale of drugs.

If entities opt to participate in 340C, they are subject to detailed accountability and transparency standards, including the following:

- Any funds generated shall be reinvested into program operations, patient care, and other community benefits, as determined by the covered entity leadership and governing board, to the populations served.
- Entities shall submit annual reports attesting to these requirements.
- Participants are subject to risk-based audits of records that establish their compliance.

In return for agreeing to these standards, entities will have access to:

- Reimbursement at wholesale acquisition cost (WAC) for all Medicaid drugs,
- Protection against discriminatory network and reimbursement actions by health insurers and PBMs, which undermine the intent of the 340B program, and

[2] https://advocatesforcommunityhealth.org/wp-content/uploads/2024/05/White-Paper-340C-Proposal-May-2024-1.pdf

- Unlimited use of contract pharmacies as necessary.

Under our 340C proposal, we recommend entities submit annual reports to HRSA that include community benefit as reported on the health center's IRS form 990, and evidence of tangible benefit to patients, which could include critical staffing, service expansion, infrastructure investments and/or access to medications, among other initiatives.

Position on Related Legislation

Advocates for Community Health has endorsed HR 7635, the 340B Pharmaceutical Access to Invest in Essential, Needed Treatments & Support (PATIENTS) Act of 2024. This legislation, introduced by Representative Doris Matsui (D-CA-7), would ensure access to contract pharmacies for 340B covered entities.

Advocates for Community Health does **NOT** support the 340B Affording Care for Communities and Ensuring a Strong Safety-Net Act (340B ACCESS Act) in its current form. This legislation was recently introduced by Representatives Larry Bucshon, MD (R-IN-08), Buddy Carter (R-GA-01), and Diana Harshbarger (R-TN-01), and we believe it would result in an unacceptable reduction in the value of the 340B program to health centers, which would restrain their ability to care for patients and continue expanding access to care for those most in need.

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We appreciate the opportunity to provide comments. For more information, please contact me at apearskelly@advocatesforcommunityhealth.org and Stephanie Krenrich, our Senior Vice President Policy and Government Affairs, at skrenrich@advocatesforcommunityhealth.org.

Sincerely,

Amanda Pears Kelly
Chief Executive Officer
Advocates for Community Health