



December 9, 2024

The Honorable John Thune
The Honorable Debbie Stabenow
The Honorable Shelley Moore Capito
The Honorable Tammy Baldwin
The Honorable Jerry Moran
The Honorable Ben Cardin

United States Senate

Dear Senators,

As concerned stakeholders with a deep commitment to transparency, accountability, and equitable health care access for the individuals, families and vulnerable communities we serve, the Black Women's Health Imperative (BWHI) and the undersigned organizations are writing to express our desire to help Congress arrive at comprehensive reforms to the 340B Drug Pricing Program.

The stated purpose of the 340B program – to stretch scarce federal resources as far as possible, reach more eligible patients, and provide more comprehensive health services – is intended to advance equitable health access for vulnerable Americans. However, today, the program falls short for far too many patients.

While a number of legislative proposals have been put forth, several gaps remain in addressing key challenges. As Congress considers 340B program reform, **we urge closer consideration of comprehensive, holistic approaches that hold all 340B-eligible providers to the same standard as the federal grantees who have served as good stewards of the program and their communities since its inception.** To maximize its full potential and to provide access so sorely needed, 340B reform must: standardize transparency, reporting, and accountability requirements; encourage covered entities to act as faithful stewards of the program and of true safety-net communities; and ensure patient access and affordability when they are treated by 340B providers.

Background

340B was created to help safety-net providers more effectively care for vulnerable communities and low-income, uninsured, and underinsured patients. For three decades, federally qualified health centers (FQHCs) and other so-called “federal grantees” like Ryan White HIV clinics have used 340B savings for uncompensated care for these communities, ensuring access to PrEP for

patients in need and reinvesting funds into the unique needs of their communities including dental care, behavioral health, co-pay assistance programs, and more.

As a condition of their federal funding, these grantees must invest all of their revenue, which includes any profits generated by their participation in 340B, back into the communities they serve. As a result, they continue to be exemplary stewards of the 340B program. **However, the requirements for federal grantees, as conditions of their HRSA grants, do not apply to 340B hospitals. Consequently, the program has fallen short of fulfilling its original intent despite its exponential growth in the last three decades.**

340B is today the second-largest federal drug program after Medicare Part D, reaching \$66 billion in 2023; nearly 80% of these funds flow to hospitals,¹ which are in no way subject to these requirements and are therefore able to maximize profits from 340B without reducing costs for patients. At the same time, some 340B hospitals sue patients for medical debt, expand outpatient facilities and pharmacy networks in wealthy areas, and shutter clinics in low-income and rural communities.

The fundamental misalignment between hospital and federal grantee requirements in the program is directly responsible for 340B's inability to fulfill its mission in *all* the communities it's meant to serve.

Standardize 340B Program Transparency & Accountability Requirements

Grantees like FQHCs and HIV clinics are required to report their general revenue, which includes profits from 340B, and re-invest funds into programs that advance patient health and expand care and services. **Congress should take learnings from these providers and require all 340B participants to report how much 340B revenue they receive and how it is allocated – and demonstrate concrete community impact through expansion of services or increased charity care.** Hospitals should also work with advocates for, and representatives of, the communities they serve to determine the needs of their patients that can be met utilizing 340B funds.

This would go a long way to addressing the lack of transparency that allows 340B to grow among hospitals without benefiting the communities it's intended to serve. It should also be paired with increased oversight: **Congress must reinforce the federal government's ability to hold hospitals accountable and keep the program on track through regulations, audits, and enforcement actions.**

To date, hospitals have taken advantage of this lack of oversight to capture 340B revenue from nearly any patient that walks through their doors, without commensurate benefit to those patients. 340B-eligible prescriptions are often determined by third-party administrators (TPA), data consultants contracted by covered entities, that help maximize 340B profits by "defining" nearly anyone who's ever visited a certain hospital as a "340B patient" and thus making their

¹ <https://www.hrsa.gov/opa/updates/2023-340b-covered-entity-purchases>

prescriptions eligible for a discount.² At no point is a patient made aware of their 340B status, making it impossible for them to receive tangible benefit from the program.

Reforms should prioritize the provision of meaningful care to the patient within this 340B “patient definition” framework by clarifying the opaque program rules that have led to the program’s abuse and expansion. **We must also maintain flexibility and consideration for patients treated at rural facilities and by grantees**, who may have different needs (e.g., telehealth) and are already subject to more substantial accountability around 340B funds.

Prioritize True Safety-Net Providers & Underserved Communities in 340B

340B’s failure to link program eligibility for hospitals with demonstrable benefit to patients has diluted the program’s core safety-net focus over time. **Congress should consider reforming hospital qualification criteria for participating in 340B to ensure the program most benefits the facilities treating large numbers of uninsured, underinsured, and low-income patients.**

The program also allows hospital systems to expand their 340B profitability through the operation of “child site” facilities, often outpatient physician offices acquired by hospitals through vertical integration. These facilities access 340B through their affiliation with the parent hospital, without any requirements to care for low-income communities, expand services for low-income patients, or even provide medicines at low or no cost. In fact, studies show that nearly half of child sites were located in ZIP codes where median household incomes were significantly higher than that of the parent site.³ Reporting from the *Wall Street Journal* and others have shown how this works in practice, with large systems like Henry Ford Health in Michigan taking advantage of 340B by registering outpatient facilities in wealthy areas under “parent” sites in lower-income areas.⁴ **Congress should use targeted hospital eligibility reforms to require child sites improve access in the low-income areas that are at the heart of 340B’s mission.**

Similar reforms should be applied to hospitals’ vast networks of “contract pharmacy” locations, which are also typically expanded into wealthy areas rather than pharmacy deserts.⁵

Ensure Underserved Communities Can Access Affordable Care & Medication

At its core, the 340B program should ensure low-income individuals are able to afford their care and medications and access the services they need. Yet, several major 340B systems and their dozens of child sites fail to provide adequate charity care commensurate with their 340B earnings. According to the *Wall Street Journal*, some large 340B hospital systems are among the hospitals with the lowest charity care rates.⁶ Recent reporting has also shown how 340B institutions like Allina Health, which operates in Minnesota and Western Wisconsin, actively

² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10986201/>

³ <https://avalere.com/insights/340b-hospital-child-sites-and-contract-pharmacy-demographics>

⁴ <https://www.wsj.com/articles/340b-drug-discounts-hospitals-low-income-federal-program-11671553899>

⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9206190/>

⁶ <https://www.wsj.com/articles/340b-drug-discounts-hospitals-low-income-federal-program-11671553899>

engage in predatory debt collection and litigation – even from patients eligible by law for free care.^{7,8}

This is clearly inconsistent with 340B's intent as medical debt today affects one in 12 Americans,⁹ disproportionately communities of color, people with disabilities, and other marginalized communities. **Patient-centered 340B reform should ensure hospitals are held accountable to provide adequate levels of charity care and financial assistance to their patients as a condition of their 340B participation and must include protections from predatory medical debt collection.**

Patients at 340B facilities should be prevented from incurring such high costs in the first place when providers purchase steeply discounted 340B medications. Federal grantees are subject to statutory limits through their HRSA grants on what they can charge patients, but similarly strong requirements are not in place for 340B hospital systems. A more direct approach that standardizes discount-sharing can ensure that patients can access affordable medications – regardless of what kind of 340B entity they seek care from. **Any serious 340B reform effort must address the core issue of patient affordability by requiring 340B medicines be provided to low-income patients at an affordable price based on a sliding fee scale**, which should be made clear to patients at the clinic and at the pharmacy counter and should apply at all child site and contract pharmacy locations.

Congress Must Take Meaningful, Comprehensive Action to Address All 340B Challenges

Meaningful 340B reform must be comprehensive and thoroughly address all the program's shortcomings, from transparency and accountability to affordability at the pharmacy counter. The federal grantees who have been good stewards of 340B funds for the past three decades provide a clear path forward for these efforts.

One of the underlying principles that guides quality, patient-centered healthcare – the acceptance that a patient is an expert on their own experience – applies to patient-centered policy. Communities of color, rural communities, and others that 340B was intended to serve are well aware of their needs and willing to communicate their experiences within the healthcare system, and it is essential that Congress listen. As advocates for these communities who can benefit from 340B, we look forward to having a seat at the table as Congress considers reforms.

Sincerely,

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Black Women's Health Imperative

ADAP Advocacy Association
Association of American Indian Physicians

⁷ <https://www.nytimes.com/2023/06/01/business/allina-health-hospital-debt.html>

⁸ <https://www.nytimes.com/2022/09/24/business/nonprofit-hospitals-poor-patients.html>

⁹ <https://www.healthsystemtracker.org/brief/the-burden-of-medical-debt-in-the-united-states/>

BlackDoctor.Org
CancerCare
Community Access National Network
Council on Black Health
HIV+Hepatitis Policy Institute
Mom Congress
MANA, A National Latina Organization
NAACP
National Council of Negro Women
National Hispanic Council on Aging
Prevent Blindness
Preventive Cardiovascular Nurses Association

cc: Dr. Bill Cassidy, Chair, Senate Committee on Health, Education, Labor & Pensions
Sen. Bernie Sanders, Ranking Member, Senate Committee on Health, Education, Labor
& Pensions