

October 30, 2020

Lamar Alexander
Chair
Senate Health, Education, Labor and Pensions Committee
428 Senate Dirksen Office Building
Washington DC 20510

Mr. Greg Walden
Ranking Member
House Energy and Commerce Committee
2322 Rayburn House Office Building
Washington, DC 20515

Sent by email to 340B@help.senate.gov and 340B@mail.house.gov

RE: Recommendations for Strengthening and Preserving the 340B Drug Pricing Program

Dear Senator Alexander and Representative Walden,

Howard Brown Health appreciates the opportunity to provide input on how to improve the 340B Drug Pricing Program. Howard Brown writes today to tell you that 340B is not only working, but working well, to allow Federally Qualified Health Centers (FQHCs) to provide critical health services for vulnerable patient populations and ensure that they have continued access to care. 340B is more critical than ever in light of the challenges and financial strain we have incurred in response to the COVID-19 pandemic. Howard Brown does not believe legislation to change the 340B program is needed, however, in order to improve the current program, we encourage Congress to use its oversight powers to ensure that the Department of Health and Human Services (HHS) is enforcing the 340B statute and using its existing authority to penalize manufacturers not meeting their 340B statutory obligations.

Howard Brown is the largest LGBTQ health center in the Midwest, serving over 38,000 patients across twelve clinic locations in Chicago. As a FQHC, Howard Brown provides comprehensive, high quality and affordable care—including primary care, behavioral health, mental health services, HIV/STI prevention, elder services and community outreach initiatives—to all of our patients, regardless of ability to pay. Through these programs, Howard Brown fulfills its mission of eliminating health disparities and improving health outcomes experienced by LGBTQ individuals.

Congress created the 340B Program in 1992 to allow safety net providers, including FQHCs to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services”—without spending taxpayer dollars. The 340B program plays a huge part in FQHCs’ ability to achieve their mission. FQHCs are community-based, patient-directed, non-profit or public organizations whose central mission is to ensure access to care for all individuals, regardless of ability to pay. FQHCs, are required by federal law, regulation, and mission to invest every penny of 340B savings into activities that advance their charitable mission.

At Howard Brown, we reinvest the savings from our 340B Program to improve health outcomes for our patient population in many different ways, including:

- Expanded clinical capacity: Prior to becoming a FQHC in 2015, Howard Brown was a small agency with two adult clinics and a drop-in space for homeless adolescents. After becoming eligible to participate in the 340B Program, Howard Brown has transformed into a citywide network of 12 clinical sites, including dentistry and psychiatry services, as well as robust clinical services for homeless youth. The 340B program played a large role in Howard Brown’s significant expansion, which has allowed us to increase access by reaching a far greater number of patients, including the over 38,000 patients we served last year.
- Comprehensive wrap-around support services: The 340B Program has made it possible for Howard Brown to provide high quality and affirming services to our more vulnerable patients. This includes essential and holistic wrap-around support services—such as social support groups, HIV case management, and substance use programs—to help patients achieve optimal health outcomes. One such program is in.power program, which provides STI screening and care, case management, support groups, legal advocacy, and clinical services to survivors of sexual violence.
- Access to affordable medications for people living with HIV/AIDS: In 2019, we provided primary care and support services for 5,477 patients living with HIV, 82% of whom have achieved viral suppression. Given the high cost of HIV medications, the availability of reduced price medication through the 340B program has been a lifesaver for many Howard Brown patients living with HIV.

Below, we offer several general comments and recommendations regarding the 340B program based on our own experiences and concerns with this critical program.

1. Protect and preserve the 340B program. Congress should clarify that the 340B program’s mission is intended to increase scarce federal resources to safety net providers and to eligible patients

2. Prohibit PBMs and for-profit companies from discriminating against FQHCs or one of their contract pharmacies in 340B drug reimbursement. PBMs have been attempting to negotiate lower reimbursement rates for 340B priced drugs compared to non-340b counterparts. This goes against the mission of the 340B program. Lowering reimbursement rates results in transferring the 340B savings from FQHCs to for-profit companies instead.
3. Stop manufacturers from violating the 340B Statute. We remain extremely concerned that Eli Lilly, AstraZeneca, and Sanofi recently began denying 340B pricing to FQHCs for drugs dispensed through community pharmacy arrangements. These actions violate the law and jeopardize our ability to provide needed care to patients with low incomes. Manufacturers have a statutory obligation to offer drugs at 340B prices to all eligible FQHCs and there is no exception that allows manufacturers to deny pricing based solely on where the drugs are shipped. Allowing this to stand will encourage these and other drug companies to expand pricing restrictions to a wider range of vital drugs. We urge Congress to ensure that HHS enforces the 340B statute by immediately using its existing authority to stop these manufacturers' unlawful actions.
4. Prevent turning 340B into a rebate program. There is an effort by drug companies to overhaul the longstanding 340B discount model and replace it with a rebate system. This new system would make it significantly more difficult and expensive for all FQHCs, including ours, to access 340B savings and could result in denial of 340B pricing. For the program's entire history, pursuant to published HRSA guidance, manufacturers have provided access to 340B pricing through discounts at the time of purchase, not back-end rebates. The new rebate model would require covered entities to pay exorbitant prices for drugs in the hope that they would receive a rebate at a later point in time. It would also give drug companies complete control over when and under what circumstances the statutorily required 340B discount would be provided. We urge Congress to keep pressure on HHS to stop manufacturers from moving forward with a rebate model without prior approval or, at the very least, until guidance has been issued, subject to public notice and comment.
5. Put a mechanism in place for MCO duplicate discounts. Congress should clarify that MCO Medicaid 340B savings are meant to go to covered entities. States must have mechanisms in place to prevent MCO duplicate discounts.

6. HRSA should have authority to make rulemaking decision as it relates to 340B program. We encourage Congress to ensure that HHS uses its existing authority to address the recent actions taken by drug companies that are in violation of the law and seek to undermine the 340B program and to protect the 340B Program so that FQHCs can continue to provide high quality care to all our patients.

In closing, we thank you for your consideration of our comments, and for your efforts to support the 340B program. If you have any questions, please contact Tim Wang, Director of Policy and Advocacy, at timothyw@howardbrown.org.

Sincerely,



David Ernesto Munar
President and CEO