



AMERICA'S ESSENTIAL HOSPITALS

July 6, 2023

The Honorable Cathy McMorris Rodgers
Chair
House Energy and Commerce Committee

The Honorable Mike Crapo
Ranking Member
Senate Finance Committee

Submitted electronically via drugshortages@mail.house.gov

Dear Chair McMorris Rodgers and Ranking Member Crapo:

Thank you for your interest in understanding the impact of drug shortages and for your leadership in finding equitable solutions.

America's Essential Hospitals is the leading champion for hospitals and health systems dedicated to high-quality care for all, including those who face financial and social barriers. Our more than 300 member hospitals serve communities where millions of individuals live below the poverty line and lack health insurance. These hospitals not only care for marginalized and at-risk patients but also operate critical trauma centers, provide specialty care, and contribute significantly to training the next generation of the health care workforce. Despite making up only 5 percent of hospitals nationally, our hospitals operate a third of the nation's level I trauma centers, 40 percent of burn care beds, and more than a quarter of pediatric intensive care beds, and they train nearly three times more physicians than other U.S. teaching hospitals.¹

Given their safety net mission and the challenges they face, essential hospitals heavily rely on federal support to fulfill their vital role. These hospitals operate on margins approximately 60 percent lower than other U.S. hospitals and provide a disproportionate share of uncompensated care. With three-quarters of their patients uninsured or covered by Medicaid or Medicare, and only a fraction supported by commercial insurance, essential hospitals truly form the backbone of the nation's health care safety net.²

In this context, drug shortages impose significant burdens on hospitals serving that safety net role, especially those with a high proportion of Medicaid and uninsured patients.

¹ Clark D, Ramiah K, Taylor J, et al. *Essential Data 2022: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2020 Annual Member Characteristics Survey*. America's Essential Hospitals. <https://essentialdata.info>. Accessed June 30, 2023.

² Ibid.

These hospitals already confront multiple challenges, including limited resources, complex patient needs, purchasing power constraints, staffing and workload pressures, and health disparities.

It is critical that we recognize the role these hospitals play as community anchors and work together to find solutions that mitigate the effect of drug shortages on vulnerable patient populations. By targeting the unique challenges essential hospitals face, we can ensure equitable access to quality care for all individuals, regardless of their socioeconomic status or insurance coverage.

The 340B Drug Pricing Program plays a positive and crucial role in helping our member hospitals improve access to drugs and health care by:

- **Stretching scarce resources further:** The 340B program allows safety net providers to purchase medications at discounted prices, resulting in significant cost savings. These savings enable essential hospitals to allocate their limited resources more efficiently and effectively. They can redirect funds towards patient care, including by expanding services, enhancing medication management programs, investing in technology, or hiring additional staff members.
- **Increasing medication availability:** By accessing medications at reduced prices through the 340B program, essential hospitals can maintain a more consistent supply of essential drugs, even during periods of drug shortages. This ensures that patients receive necessary treatment without interruptions, minimizing adverse health outcomes and improving overall care quality.
- **Expanding pharmacy services:** Many essential hospitals participating in the 340B program have on-site pharmacies or affiliated pharmacy programs. These pharmacies play a crucial role in managing medication inventories, coordinating with suppliers, and implementing strategies to mitigate the effect of drug shortages. They can work closely with health care providers to identify alternative medications, manage inventory levels, and educate patients about medication options.
- **Enhancing patient assistance programs:** Essential hospitals can reinvest cost savings obtained through the 340B program in patient assistance programs, benefiting people who face economic and social hardships. Essential hospitals can establish or expand medication assistance funds, prescription discount programs, or patient navigation services. These initiatives help patients afford their medications, ensuring that financial barriers do not prevent them from accessing necessary treatments during drug shortages.

There is no evidence that the 340B program affects drug shortages. In fact, the FDA has never found a connection between the 340B program and drug shortages. Accounting for an extremely small share of national drugs sales, 340B drugs have a minimal effect on the market, and the sale of 340B drugs would not affect pricing in a way that could create a drug shortage. Furthermore, to the extent there are shortages on drugs largely used on the inpatient side, those drugs are not 340B eligible. Also, where manufacturers offer generic drugs at prices equal to or lower than 340B discounted prices, 340B pricing does not apply.

As enacted by Congress, the 340B program also includes inflationary penalties similar to the Medicaid rebate program, raising the 340B discount if manufacturers raise the price of a drug faster than inflation. Research has shown that this policy supports access; it effectively slows drug increases not only for drugs sold to 340B providers but also for drugs sold to all purchasers. This has resulted in significant savings to the Medicare program—\$7 billion from 2013 to 2017.³

While the 340B program provides important and necessary support, mitigating drug shortages requires a multifaceted approach involving various stakeholders. These efforts include improving supply chain resilience, enhancing communication between manufacturers and health care providers, implementing effective shortage management protocols, and advocating for policies that prioritize patient access to essential medications.

By leveraging the benefits of the 340B program and implementing comprehensive strategies, essential hospitals can navigate the challenges of drug shortages more effectively, ensuring that their patients, especially those facing economic and social hardships, receive the quality care they deserve.

Despite the crucial role the 340B program should continue to play in preserving access to drugs, America's Essential Hospitals has grave concerns regarding current threats to the program. These threats, particularly the restrictions drug manufacturers imposed on contract pharmacies, significantly affect patients in need, and undermine essential hospitals' ability to provide vital care, manage the drug supply chain, and plan for future needs.

Drug manufacturers' unlawful and widespread imposition of contract pharmacy restrictions hinders essential hospitals' ability to provide affordable medications and care for the under-resourced patients who rely on them, which undermines the program's effectiveness.

Contract pharmacies play a crucial role in expanding the 340B program's reach and impact. The Health Resources and Services Administration recognizes that 340B covered entities may elect to dispense 340B drugs to patients through contract pharmacy services. These arrangements allow essential hospitals to extend their services to underserved communities, remote areas, and patients who face transportation challenges or other social drivers of poor health. In addition, an increasing number of specialty drugs are available only through specific specialty pharmacies with which hospitals must contract to access those drugs. By imposing restrictions on contract pharmacies, in blatant violation of current law, drug manufacturers are directly harming vulnerable patients who depend on the 340B program for affordable access to necessary medications. This also contributes to drug shortages and affects the supply chain for all providers.

³ Dickson S. Association Between the Percentage of US Drug Sales Subject to Inflation Penalties and the Extent of Drug Price Increases. *JAMA Network Open*. 2020;3(9):e2016388. <https://doi.org/10.1001/jamanetworkopen.2020.16388>. Erratum in: *JAMA Network Open*. 2020;3(10):e2026259. Accessed July 6, 2023.

Furthermore, these restrictions not only impose administrative burdens and additional costs on safety net providers but also divert resources from patient care and hinder essential hospitals' ability to provide comprehensive services to their communities.

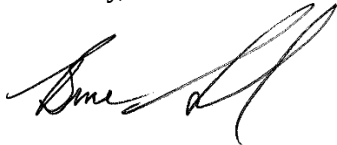
We urge lawmakers to address the threats to the 340B program as part of the larger effort to secure the drug supply chain and act to protect essential hospitals' ability to use contract pharmacies. By doing so, we can ensure that uninsured and underinsured patients have equitable access to affordable medications and that essential hospitals can continue their vital mission of providing quality care to underserved populations.

We respectfully ask you, as leaders in Congress, to support and champion efforts to safeguard the integrity of the 340B program and the communities and health care providers who rely on it. Your support is crucial in preserving this vital program and ensuring that all patients receive the medications they need to lead healthy lives.

Thank you, and we look forward to your continued efforts in supporting access to affordable medications and quality health care for all.

America's Essential Hospitals appreciates the opportunity to provide these comments. If you have questions, please contact Jason Pray, vice president of legislative affairs, at 202.412.2491 or jpray@essentialhospitals.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Bruce Siegel". The signature is fluid and cursive, with a long horizontal stroke at the end.

Bruce Siegel, MD, MPH
President and CEO
America's Essential Hospitals