

GREATER NEW YORK HOSPITAL ASSOCIATION

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July
Twenty-Five
2023

The Honorable John Thune
United States Senate
511 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
United States Senate
731 Hart Senate Office Building
Washington, DC 20510

The Honorable Shelley Moore Capito
United States Senate
172 Russell Senate Office Building
Washington, DC 20510

The Honorable Tammy Baldwin
United States Senate
141 Hart Senate Office Building
Washington, DC 20510

The Honorable Jerry Moran
United States Senate
521 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ben Cardin
United States Senate
509 Hart Senate Office Building
Washington, DC 20510

Dear Sens. Thune, Stabenow, Capito, Baldwin, Moran, and Cardin:

On behalf of the more than 150 public and private not-for-profit hospitals and health systems in four states that make up the membership of the Greater New York Hospital Association (GNYHA), we appreciate this opportunity to respond to your June 16 Request for Information.

There is a significant imbalance in the way the 340B Drug Pricing Program (340B Program or Program) is discussed and understood in the public sphere, which is perhaps a byproduct of the tension between the profit-making imperative that drives publicly traded, for-profit drugmakers and the mission of safety net institutions to serve their communities. That tension is unavoidable in a system that seeks to provide resources to mission-based organizations without using Federal funds. But that is the whole point of the 340B Program.

Our main, overarching response to your request is that balance is necessary—whether it is with respect to 340B covered entities’ use of contract pharmacies, transparency initiatives, or program integrity enhancements. The pendulum has swung too far in the direction of drugmakers and too far away from the safety net providers that the law is intended to help.

The Program is an essential tool for safety net hospitals that are challenged to develop sustainable financial strategies that support the provision of health care to the underserved. These hospitals



GNYHA is a dynamic, constantly evolving center for health care advocacy and expertise, but our core mission—helping hospitals deliver the finest patient care in the most cost-effective way—never changes.

experience significant shortfalls in Medicare and Medicaid reimbursement relative to their operating costs. In New York, we estimate that Medicare covers 84% of hospital costs, while Medicaid only covers 61%.¹ On average, 70% of hospital discharges and 60% of outpatient visits are covered by these government payers. Only some institutions are in the position to offset these shortfalls by negotiating favorable rates with commercial payers. Exacerbating this situation are the financial impacts of the COVID-19 emergency, combined with extraordinary, unremitting increases in labor costs, among other stressors. In a 2022 survey of New York hospitals' financial condition, 85% reported either negative or unsustainable operating margins (below 3%).²

Now more than ever, the 340B Program is a lifeline for safety net hospitals seeking to provide services to their communities. Unfortunately, the Program—and by extension the hospitals and patients it supports—is under attack.

We understand that you are not inclined to take a position on the legal questions raised by certain pharmaceutical manufacturers' attempts to impose restrictions on 340B covered entities that the 340B statute itself does not contain. But as you consider ways to improve the 340B Program's integrity and stability, it is important to understand the context of the legal battle.

In mid-2020 near the height of the COVID-19 “first surge” in New York, GNYHA members began receiving notices from certain pharmaceutical manufacturers purporting to impose limits on their use of contract pharmacies to distribute discounted medications. Later that year the US Department of Health and Human Services Office of the General Counsel issued an advisory opinion informing manufacturers that such policies were impermissible, saying, “Certain manufacturers’ newfound and unilateral refusal to sell drugs through contract pharmacies is at odds with the structure and intended operation of the statute.”³

The manufacturers persisted, and in May 2021 the Health Resources and Services Administration (HRSA) issued violation letters to the companies, putting them on notice that they could be subject to civil monetary penalties for overcharges.⁴ Litigation ensued.

As the lawsuits work their way through the system, more and more manufacturers have started to restrict contract pharmacy arrangements, increasing their profits while safety net hospitals' 340B

¹ *Critical Condition: New Yorkers are Losing Access to Care as a Fiscal Crisis Hammers Hospitals Statewide*, Joint Association Survey Results, December 2022, available at <https://www.gnyha.org/tool/joint-hospital-association-survey-results-report/>.

² *Ibid.*

³ U.S. Department of Health and Human Services, Office of General Counsel. *Advisory Opinion 20-6 on Contract Pharmacies Under the 340B Program*. Washington, DC: HHS, 2020. https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf (Accessed July 19, 2023)

⁴ Health Resources and Services Administration. "Program Integrity, HRSA Correspondence to Stakeholders." <https://www.hrsa.gov/opa/program-integrity>. (Accessed July 19, 2023)

savings plummet.⁵ For this and other reasons we believe balance must be restored in the way we collectively understand the Program and in the types of policies that are developed to enhance its integrity and stability. We offer the below comments for your consideration.

Contract Pharmacy Arrangements Should be Supported, not Undermined.

The use of contract pharmacies allows covered entities to expand access to medications in their communities while maintaining their 340B savings. Legislation is necessary to support these efforts.

The list of manufacturers that are imposing limits on covered entities' contract pharmacy arrangements is long and growing, and they are taking advantage of an arguable lack of clarity in the law. Legislation is needed to clarify that the 340B statute requires pharmaceutical manufacturers to deliver discounted drugs to covered entities, regardless of how they are dispensed, and to prohibit them and other third parties from imposing administrative conditions on covered entities' use of contract pharmacies to distribute drugs to patients or otherwise discriminate against 340B covered entities.

Additional Transparency Initiatives are Unnecessary.

There is already a panoply of requirements that GNYHA members—all non-profit organizations—must meet to demonstrate their commitment to community benefit and their entitlement to tax exemption. While we believe much of the public comment around this issue is misguided, it is important to note that there are strident calls to increase disclosures of how tax-exempt hospitals meet their community benefit obligations. This is an area in flux.

It would be burdensome and redundant to add another layer of disclosure specific to the uses of 340B savings. Non-profit hospitals should not be required to undertake additional tracking, documentation, and analysis of how they use their savings on top of existing disclosure requirements.

That said, GNYHA supports efforts to enhance voluntary transparency measures, such as the American Hospital Association's "340B Good Stewardship Principles."⁶ Such efforts help hospitals communicate the value of the Program to their communities and beyond. In that and other contexts, hospitals have reported using their 340B savings for a wide range of activities, from providing free vaccines and financial assistance to uninsured patients for outpatient drugs, to

⁵ 340B Health reported as of June 2023, twenty-one drugmakers had imposed such restrictions. [https://www.340bhealth.org/files/Contract Pharmacy Financial Impact Report July 2023.pdf](https://www.340bhealth.org/files/Contract_Pharmacy_Financial_Impact_Report_July_2023.pdf). Accessed July 20, 2023

⁶ American Hospital Association. "340B Hospital Commitment to Good Stewardship Principles." <https://www.aha.org/initiativescampaigns/2018-09-13-340b-hospital-commitment-good-stewardship-principles>. Accessed July 20, 2023.

transportation for patients for follow-up appointments, to supporting the maintenance of essential services in their communities such as obstetrics and substance use disorder treatment services.⁷

Program Integrity Enhancements Must be Balanced.

While we agree that compliance with the 340B statute's requirements and conditions is important, we believe the focus on covered entities, almost to the exclusion of other parties, is inappropriate and a missed opportunity. HRSA requires covered entities to maintain certain records and undergo audits, which may give rise to corrective action plans. Oversight of drug manufacturers, by comparison, is scant. Any program integrity enhancements should focus on this gap: Drugmakers' program integrity requirements should parallel those of covered entities, including in the quantity of audits they undergo. They should include efforts to monitor and guard against manufacturers' unilateral imposition of burdensome requirements and restrictions on covered entities.

We further agree that duplicate discounts are inappropriate and should be avoided. We have commented on various proposals to combat duplicate discounts put forth by HRSA over the years, including regarding contract pharmacy arrangements. We have generally argued that the state Medicaid programs are in the best position to establish effective processes to avoid duplicate discounts for both fee-for-service and Medicaid managed care drugs. States and covered entities should work together to establish such processes to identify and manage 340B drugs by, for example, requiring the use of a billing modifier.

We hope these comments are helpful as you consider ways to improve the 340B Program, which is vital to safety net hospitals and the patients and communities they serve. Thank you for giving us the opportunity to provide input.

Sincerely,



Laura M. Alfredo
Executive Vice President,
Legal, Regulatory, and Professional Affairs
and General Counsel

⁷ Brief of Thirty-Seven State and Regional Hospital Associations as Amici Curiae in *American Hospital Association, et al v. Becerra*. Available at <https://www.gnyha.org/wp-content/uploads/2023/07/20-1114tsac37StateAndRegionalHospitalAssociations.pdf>.