Illinois Health and Hospital Association

July 27, 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 Benjamin L. Cardin
United States Senate
509 Hart Senate Office Building
Washington, DC 20510

Dear Senators Thune, Stabenow, Moore Capito, Baldwin, Moran and Cardin:

On behalf of our more than 200 hospitals and nearly 40 health systems, including over 100 member hospitals that participate in the 340B Drug Pricing Program (340B program), the Illinois Health and Hospital Association (IHA) appreciates the opportunity to comment on this bipartisan request for information on the 340B program. Since 1992, the 340B program has allowed healthcare providers to stretch scarce federal resources, allowing them to better serve their patients and communities.

Consistent with Congress' intent, Illinois' 340B hospitals use the savings achieved through the 340B program to provide direct access to healthcare services and medicines for underserved patients, and to support a variety of initiatives that increase access to healthcare services in their communities. For example, one of our hospitals established a mobile clinic program that provides school physicals to children living in low-income and underserved communities, regardless of a family's ability to pay. Another Illinois hospital used savings from the 340B program to create a dialysis center that primarily serves low-income patients. Others use 340B savings to provide free colonoscopies and mammograms, free transportation to medical appointments, and oral health services through mobile dental vans.

The 340B program has been especially important for Illinois' Safety Net Hospitals. These hospitals predominantly serve patients enrolled in Medicare or Medicaid, two

1151 East Warrenville Rd.
P.O. Box 3015
Naperville, IL 60566
630.276.5400

700 South 2nd St.
Springfield, IL 62704
217.541.1150

499 South Capitol St. S.W.
Suite 410
Washington, DC 20003
630.276.5645

833 West Jackson Blvd.
Suite 610
Chicago, IL 60607
312.906.6150

www.team-iha.org

programs that chronically underpay hospitals. At the same time, drug prices have gone up, with a recent report by the Department of Health and Human Services (HHS) finding that between July 2021 and July 2022, drug prices increased by an average of 31.6% for over 1,200 drugs – many of which are used to treat cancer and other chronic conditions.[1] These staggering price increases chip away at the savings hospitals use to care for their communities. Further, these price increases come at a time when hospitals are still building back, both economically and operationally, from the COVID-19 pandemic.

The IHA welcomes this opportunity to address how the 340B program continues to be an immense value to communities across Illinois and the nation. We welcome the opportunity to work with Congress to ensure that the 340B program continues to benefit patients and communities, while preventing any cuts to the program that would jeopardize patient access to care.

Question: What specific policies should be considered to ensure HRSA can oversee the 340B program with adequate resources? What policies should be considered to ensure HRSA has the appropriate authority to enforce the statutory requirements and regulations of the 340B program?

Through the Affordable Care Act, the Health Resources and Services Administration (HRSA) has the authority to resolve disputed claims between 340B providers and drug manufacturers through the Administrative Dispute Resolution (ADR) process. The ADR process is meant to adjudicate disputes that occur when a drug manufacturer overcharges a 340B provider for covered 340B drugs. Unfortunately, the ADR process has yet to be fully implemented; IHA believes allowing HRSA to implement this process the way Congress intended is a necessary first step before any new enforcement authorities are considered.

Full implementation of the ADR process would be helpful in addressing recent actions drug manufacturers have taken to limit or deny 340B pricing through arrangements with community and specialty pharmacies (contract pharmacies). Since 2020, several large drug manufacturers have restricted or denied 340B hospitals' access to statutorily required 340B prices for drugs purchased through contract pharmacies. This is in clear violation of the law because these drug manufacturers are overcharging 340B hospitals for these covered drugs by intentionally limiting or denying access to 340B prices.

According to the American Hospital Association (AHA), the actions of these drug manufacturers have resulted in 340B Critical Access Hospitals experiencing average annualized losses of over $500,000 and 340B Disproportionate Share Hospitals (DSH) experiencing average annualized

[1] https://aspe.hhs.gov/reports/prescription-drug-price-increases

losses of nearly $3 million.[2] These financial losses impede the ability of 340B hospitals to improve patient access by limiting coordination with local pharmacies to provide necessary drugs in the communities in which patients live. It also reduces the resources hospitals have to fulfill the intent of the 340B program of stretching scarce federal resources to increase access to care.

Drug manufacturers, however, do benefit from these restrictions. They pocket the additional revenue stemming from overcharging hospitals, and there is no expectation that this additional revenue will be used to expand access to drugs for patients or be reinvested into communities. Drug manufacturers must be held accountable to the legal requirements that 340B drugs be sold at a discounted price, and full implementation of the ADR process will allow HRSA to enforce this requirement.

The IHA strongly urges HRSA to finalize its most recent 340B ADR proposed rule, which will allow 340B hospitals and other participating covered entities the ability to bring forth disputed claims for administrative review before the panel. Simultaneously, while HRSA has the authority to oversee the 340B program, IHA recommends Congress ensure HRSA has the tools it needs to conduct that oversight.

Question: What specific policies should be considered to establish consistency and certainty in contract pharmacy arrangements for covered entities?

Congress should clarify and codify protections for contract pharmacy arrangements in the Federal 340B statute. HRSA has recognized the importance of contract pharmacies in the 340B program since 1996, expanding access to lifesaving drugs by allowing patients to fill their prescriptions in their communities. Further, the ability to work with contract pharmacies allows 340B hospitals to get their patients drugs that may not otherwise be available. **Congress should take action to provide clarity, codifying protections for contract pharmacies to remove ambiguity in this space. Such action will allow HRSA to exercise its enforcement authority and preserve access through contract pharmacies for the patients and communities served by 340B hospitals.**

HRSA should also continue to enforce the law and hold drug companies accountable by using its existing enforcement authority to impose civil monetary penalties against drug companies violating the law. While HRSA has attempted to exercise its authority in this capacity, several drug companies filed lawsuits across the country challenging HRSA's authority to protect these contract pharmacy arrangements. At least one court of appeals has sided with the drug companies, holding that HRSA lacks the needed authority to penalize drug companies for restricting access to 340B drugs sold at contract pharmacies (see *Sanofi Aventis U.S. LLC v. HHS*,

[2] https://www.aha.org/2022-11-14-survey-brief-drug-companies-reduce-patients-access-care-limiting-340b-community-pharmacies

58 F.4th 696, 700 (3d Cir. 2023)). **Again, codifying protections that explicitly allow 340B covered entities to distribute drugs through contract pharmacies will strengthen HRSA's enforcement authority, and protect the 340B program and the patients it serves.**

Question: What specific policies should be considered to ensure that the benefits of the 340B program accrue to covered entities for the benefit of patients they serve, not other parties?

As stated above, we strongly urge Congress to codify the use of contract pharmacies as a lawful and critical part of the 340B program. This law should ensure that drug companies cannot condition, restrict or deny 340B pricing for drugs regardless of the manner in which those drugs are dispensed or administered to patients.

Additionally, we believe Congress can play an important role in overseeing and regulating pharmacy benefit manager (PBM) practices. Specifically, PBMs often participate in discriminatory 340B pricing, forcing hospitals to accept lower and discriminatory reimbursement rates. In other words, 340B hospitals forgo the savings they should realize through the 340B program in order to ensure patient access to drugs through PBM pharmacy networks.

In Illinois, the legislature passed Public Act 102-0778[3] which established protections for 340B covered entities contracting with PBMs, third-party payers, and Medicaid managed care organizations. These protections ensure contracts between 340B covered entities and the aforementioned payers may not contain provisions that result in reimbursement, fees, or adjustments that treat a 340B covered entity differently than a non-340B covered entity. The Act also includes additional protections around patient choice, network protections, and a catchall anti-discrimination provision.

While Illinois has protections in place to prevent discriminatory 340B pricing, such practices as well as other harmful policies remain prevalent in many parts of the country, and continue to enrich PBMs at the expense of 340B hospitals.[4]

Therefore, IHA urges Congress to hold PBMs accountable by:

- Prohibiting nationwide PBM policies that provide differential reimbursement to 340B providers and non-340B providers (discriminatory pricing);
- Prohibiting PBMs from steering patients away from 340B pharmacies to pharmacies that they own, denying the ability of 340B entities to earn program savings; and
- Prohibiting PBMs from engaging in "white bagging" or "brown bagging" policies that jeopardize patient safety and undermine access to 340B discounts for providers and their patients.[5]

[3] https://www.ilga.gov/legislation/publicacts/fulltext.asp?Name=102-0778
[4] https://www.jdsupra.com/legalnews/new-supreme-court-ruling-affirms-state-2371638

Question: What specific policies should be considered to implement commonsense, targeted program integrity measures that will improve the accountability of the 340B program and give healthcare stakeholders greater confidence in its oversight?

HRSA already utilizes its authority to conduct over 200 audits of 340B covered entities every year. These audits are rigorous and require hospitals to maintain several years of auditable records, as well as policies and procedures to mitigate against issues like diversion of drugs to ineligible patients and duplicate discounts. Any findings of noncompliance result in hospitals working in good faith with HRSA to take corrective action and come into compliance with program rules.

Drug manufacturers are also permitted to conduct audits of 340B hospitals in certain instances in coordination with HRSA, but hospitals have no ability to audit drug manufacturers. There are numerous examples of drug companies violating program rules and requirements, such as overcharging hospitals, denying 340B pricing for certain drugs, and arbitrarily placing drugs in limited distribution. **Congress should mandate that HRSA provide hospitals and other covered entities the same ability to audit drug manufacturers.**

Congress should also mandate that HRSA increase the number of annual audits of drug companies, bringing more parity to their oversight efforts. Specifically, while HRSA performs over 200 audits of 340B covered entities each year, they perform on average less than six audits annually for drug manufacturers. More equitable oversight will ensure all 340B program participants are abiding by programmatic rules and requirements.

Question: What specific policies should be considered to ensure transparency to show how 340B healthcare providers' savings are used to support services that benefit patients' health?

Illinois' 340B hospitals are required under both state and federal law to report a variety of information to demonstrate the care they provide to underserved populations. On a federal level, hospitals report uncompensated care, charity care and other benefits provided to the communities they serve through both the Medicare cost reports and the IRS 990 form required for tax-exempt organizations. According to the AHA, the most recent IRS 990 data show that 340B hospitals alone provide nearly $68 billion in community benefits.[6]

In Illinois, all hospitals are required to report the amount of charity care they provide to the Illinois Department of Public Health, and nonprofit hospitals are required to submit community benefit reports to the Illinois Office of the Attorney General, data which support their tax exempt status. In fact, the most recent data show that Illinois' 340B hospitals provide almost $700 million in charity care. Further, Illinois 340B hospitals are committed to AHA's 340B

[5] https://www.aha.org/system/files/media/file/2022/05/aha-white-bagging-infographic.pdf
[6] https://www.aha.org/2022-06-07-2022-340b-hospital-community-benefit-analysis

Hospital Commitment to Good Stewardship Principles,[7] pledging to communicate the value of the 340B program, disclose estimated 340B savings, and continue rigorous internal oversight.[8]

While 340B hospitals are engaged and committed to transparency, drug companies are not required to report any information about how they set their prices or when they have implemented a policy that restricts access to 340B pricing. Such transparency in decision-making would mitigate arbitrary and egregious price increases for drugs that are critical and lifesaving for patients, while also ensuring federal and state governments are aware of drug manufacturer actions that may unilaterally and illegally hinder the 340B program. **We urge Congress to develop policies that increase oversight of drug companies to better ensure transparency in pricing practices and adherence to the requirements of the 340B program.**

Thank you again for the opportunity to share our comments with you and your colleagues on the value of the 340B program. IHA looks forward to working with you to ensure that the 340B program continues to provide access to necessary drugs and services for patients in the communities our 340B hospitals serve.

Sincerely,

A.J. Wilhelmi
President & CEO
Illinois Health and Hospital Association

[7] https://www.aha.org/initiativescampaigns/2019-10-03-hospitals-have-committed-340b-principles
[8] https://www.aha.org/initiativescampaigns/2018-09-13-340b-hospital-commitment-good-stewardship-principles