July 28, 2023

Senator Tammy Baldwin
141 Hart Senate Office Building
Washington, D.C. 20515

Senator Shelley Moore Capito
172 Russell Senate Office Building
Washington, D.C. 20515

Senator Ben Cardin
509 Hart Senate Office Building
Washington, D.C. 20515

Senator Jerry Moran
521 Dirksen Senate Office Building
Washington, D.C. 20515

Senator Debbie Stabenow
731 Hart Senate Office Building
Washington, D.C. 20515

Senator John Thune
511 Dirksen Senate Office Building
Washington, D.C. 20515

Dear Senators:

On behalf of the Alliance for Integrity and Reform of 340B (AIR340B), thank you for the opportunity to share our perspective regarding steps Congress can take to improve health care outcomes within underserved communities.

AIR340B is comprised of patient advocacy groups, clinical care providers, biopharmaceutical innovators, and other interested parties who are concerned the 340B Drug Pricing Program has transformed in ways that move it farther from its original purpose, which is to be a program primarily focused on providing discounts on drugs to true safety-net providers caring for America's vulnerable or uninsured patients. Instead, as several economists and other experts have demonstrated, the 340B program is distorting markets and driving up costs for all Americans without contributing to its safety-net mission. While the 340B program can be a powerful tool for health equity, program loopholes must be addressed to put patients over profits, once and for all.

Consistent with AIR340B's mission, we recommend policy changes addressing the program's overarching lack of oversight, accountability, and transparency. Our full recommendations are outlined below.

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

Currently, there are no requirements or 340B protections in place to ensure low-income and uninsured patients receive discounted medicines from 340B hospitals or their contract pharmacies. A recent GAO examination determined that almost half of the studied 340B hospitals (14 out of 30) do not provide discounts to low-income, uninsured patients at the hospital's contract pharmacies.[1] Of serious concern, almost one-fifth of the studied 340B hospitals reported not providing discounts to low-income, uninsured patients at the hospital's *in-house* pharmacies.[2] In fact, many contract pharmacies may often charge patients a drug's full retail price because pharmacies are not obligated to share the discount with patients in need.

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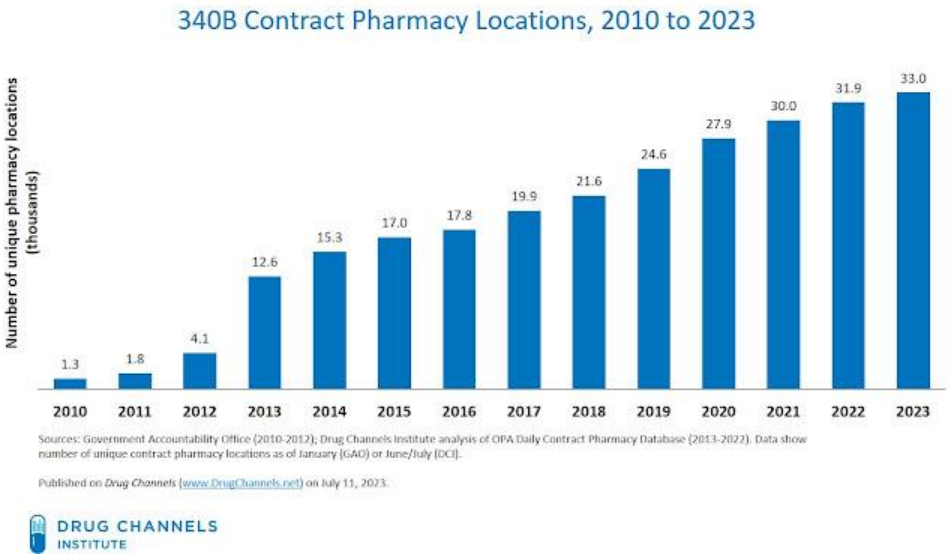
[1] *340B Drug Discount Program: Information about Hospitals That Received an Eligibility Exception as a Result of COVID-19* .; 2023. Accessed July 23, 2023. https://www.gao.gov/assets/gao-23-106095.pdf

[2] *Ibid*.

Adding to the evidence that these pharmacies are not reaching low-income, uninsured patients, several studies[3][4][5] confirm the expansion of contract pharmacies tends to be in less diverse, higher income neighborhoods and not in medically underserved areas (MUAs). Independent government watchdogs have reported that when disproportionate share hospitals (DSHs) use contract pharmacies, it is common for pharmacies to not apply 340B discounts for uninsured patients.[6]

AIR340B is concerned with the lack of benefit provided by these pharmacies to patients, especially considering the significantly increasing role pharmacies are playing in the program. One recent analysis determined there are over 33,000 unique contract pharmacy locations as of June 2023 with over 194,000 contractual relationships and over 9,500 340B covered entities.[7]

**Figure One:**




Moreover, large corporations dominate this market. The nation's three largest pharmacy benefit managers (PBMs) — CVS Health, Express Scripts, and OptumRx—maintain over 43,000 of these covered entity relationships. Including Walgreens and Walmart, over 75% of contract pharmacy relationships are controlled by these five for-profit companies.[8]

AIR340B requests that Congress revisits the role of contract pharmacies entirely, especially when it comes to their partnerships with 340B hospitals. We question whether these pharmacies help improve access to medicines for low-income and uninsured patients. At a minimum, Congress should consider the following:

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[3] 340B – A missed opportunity to address those that are medically underserved. Xcenda.com. Published November 18, 2021. Accessed July 19, 2023. https://www.xcenda.com/insights/340b-and-health-equity-medical-underserved-areas
[4] 340B Hospital Child Sites and Contract Pharmacy Demographics. Avalere Health. Published April 18, 2022. https://avalere.com/insights/340b-hospital-child-sites-and-contract-pharmacy-demographics
[5] Nikpay S, Gracia G, Geressu H, Conti R. Association of 340B Contract Pharmacy Growth With County-Level Characteristics. wwwajmccom. 2022;28. Accessed July 19, 2023. https://www.ajmc.com/view/association-of-340b-contract-pharmacy-growth-with-county-level-characteristics
[6] Contract Pharmacy Arrangements in the 340B Program Report (OEI-05-13-00431) 02-04-2014. oig.hhs.gov. Accessed July 19, 2023. https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp
[7] See Fein AJ, Ph.D. EXCLUSIVE: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market. Accessed July 19, 2023. https://www.drugchannels.net/2023/07/exclusive-for-2023-five-for-profit.html
[8] *Ibid*.

- Contract pharmacies should be required to be located in medically underserved and otherwise vulnerable communities. This will help ensure 340B reaches those patients the program is intended to serve.
- Hospitals should be required to use a sliding fee scale for 340B medications administered to low-income patients hospitals and their contract pharmacies. This will help ensure vulnerable patients receive a discount on their medicines if they are treated at a 340B hospital.

***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?***

For-profit pharmacy expansion in 340B has opened the door for pharmacy benefit managers (PBMs) to profit off the program. PBM-owned, for-profit pharmacies — like those operated by or affiliated with CVS Health, Express Scripts and OptumRx — continue to increase their participation in 340B despite clear indicators that patients are not benefiting from their expansion into the program.

Since 2010, the Health Resources and Service Administration (HRSA) has allowed covered entities to have an unlimited number[9] of "contract pharmacy arrangements" under 340B. Since then, we have seen exponential growth of contract pharmacy arrangements, including with for-profit, PBM-owned specialty pharmacies. In just four years, there has been a 1,006[10] increase in contract pharmacy arrangements between 340B entities and specialty pharmacies.

Exponential growth of the program has lent itself to 340B becoming a virtual "cash cow" for many covered entities and their contract pharmacies, generating an estimated $13 billion[11] in gross profits from 340B-purchased retail medicines in 2020 alone. It is estimated that over half[12] of these profits are concentrated within four corporations — Walgreens, Walmart, Accredo, and CVS Health. Alarmingly, two of these companies are associated with a PBM, demonstrating the substantial profit PBMs can generate through 340B.

Especially concerning is that despite evidence that DSH hospitals and contract pharmacies are profiting, the only data[13] that exists on whether patients see benefits from 340B suggests that in most cases, they do not.

Reevaluating how the program has grown is crucial for its future — including the role PBMs have played in that growth. To stop PBMs from leeching off the program, Congress must take steps to revisit the role of contract pharmacies in the program since PBMs and pharmacies are largely one in the same.

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

For health care stakeholders to have confidence in the effectiveness of the 340B program, Congress must take on a greater role in program oversight by implementing measures to address current loopholes allowing bad actors to exploit 340B.

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[9] Contract Pharmacy Services | HRSA. www.hrsa.gov. https://www.hrsa.gov/opa/implementation-contract
[10] Vandervelde A, Erb K, Hurley L. *For-Profit Pharmacy Participation in the 340B Program OCTOBER 2020*. Accessed July 27, 2023. https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf
[11] *Ibid.*
[12] Phrma.org. Accessed July 27, 2023. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/BRG_For-Profit-Pharmacy-Participation-in-the-340B-Program_Infographic.pdf
[13] Digital Scholar M, Paul D, Morgan I, et al. *The 340B Program, Contract Pharmacies and Hospitals: An Examination of the First 25 Years of Their Increasingly Complex Relationship the 340B Program, Contract Pharmacies and Hospitals: An Examination of the First 25 Years of Their Increasingly Complex Relationship*.; 2018. Accessed July 27, 2023. https://mds.marshall.edu/cgi/viewcontent.cgi?article=1204&context=mgmt_faculty

Unfortunately, there is a gap between the eligibility criteria for certain types of facilities' participation in the 340B program and the mission Congress established for the program. The metric generally used to qualify 340B hospitals is based on an inpatient measure of low-income insured patients and does not account for the uninsured patients a hospital treats. Eligibility is also not tied to the degree to which a hospital provides free or discounted care to low-income patients who qualify for its charity care program. Reevaluation of hospital eligibility criteria is needed to ensure the 340B program is meeting its intended purpose and aiding those hospitals providing a true safety net function by serving high numbers of low-income uninsured patients.

More clearly defining a 340B patient will help determine when hospitals can obtain 340B discounts – ensuring program growth is concentrated in the vulnerable communities the program was created to protect. In 2015, HRSA released a proposed omnibus guidance[14], addressing several issues, including the definition of a 340B eligible patient. Under the proposed guidance HRSA's revised patient definition would state that:

- Simply providing a referral from a covered entity to an outside provider was insufficient to qualify the drugs prescribed by the outside provider for a 340B discount;
- Dispensing or infusion of outpatient drugs to an individual at a covered entity would not be enough to establish the individual was a patient of the covered entity;
- Employees of a covered entity are not considered to be 340B patients unless they otherwise meet the patient definition; and
- A provider merely having privileges or credentials at a covered entity would not be enough to demonstrate a patient treated by that provider is a patient of the covered entity.

These clarifications would have been an important initial step toward increasing oversight and accountability in the 340B drug discount program.

Additionally, reforms are needed to curb the financial incentives driving 340B hospitals to acquire community-based physician practices, particularly given the substantial increase in health care costs associated with the site of care shifting from physician offices to hospital facilities in the last decade.

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

We are concerned that the benefits of the program are not accruing to vulnerable patients. Study after study demonstrates that a large portion of 340B hospitals fail to provide an adequate amount of charity care to justify their participation in the 340B program. Instead, 340B hospitals are often not reinvesting program revenue back into patients who need it most.

In 2022, AIR340B released an analysis of charity care levels at 340B DSH hospitals. Charity care is defined as free or discounted health care provided to patients who qualify for a hospital's charity care program and are considered low income. According to the analysis, 65% of 340B DSH hospitals[15] provide less charity care than the national average for all hospitals, including for-profit hospitals. Additionally, 25% of 340B DSH hospitals provide charity care that represents less than 1% of their total operating costs.

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[14] 340B Drug Pricing Program Omnibus Guidance. Federal Register. Accessed July 27, 2023. https://www.federalregister.gov/documents/2015/08/28/2015-21246/340b-drug-pricing-program-omnibus-guidance

[15] AIR340B. *Left Behind: An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Drug Pricing Program*.; 2022. Accessed July 27, 2023. https://340breform.org/wp-content/uploads/2022/02/AIR340B_LeftBehind_2022.pdf

Similarly, an analysis from the Lown Institute found that 77% of nonprofit hospitals evaluated[16] spent less on charity care and community investment than the estimated value of their tax breaks. The vast majority of the worst offenders under this analysis are also 340B hospitals.

To ensure the benefits of the 340B program are reaching the vulnerable patients 340B covered entities treat, the following should be pursued.

- Public reporting of hospital involvement in the 340B program including:
    - What percentage of 340B discounts go directly to patients through lowering their out-of-pocket costs?
    - How much money is a hospital making from 340B?
    - How much of a hospital's total operating costs go toward charity care?
- Clear guidance and standards identifying 340B hospital eligibility.
- Hospitals should be required to use a sliding fee scale for 340B medications administered to low-income patients at 340B hospitals and their contract pharmacies. This will help ensure vulnerable patients receive a discount on their medicines if they are treated at a 340B hospital.

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Thank you for the opportunity to provide comments on these important issues. Should you have any questions or need more information, please contact Bob Dold at bdold@forbes-tate.com or (202) 638-0125.

Sincerely,

Bob Dold
AIR340B

[16] Lown Institute. Nonprofit hospitals receive billions more in tax breaks than they invest in their communities. Lown Institute Hospital Index. Accessed July 27, 2023. https://lownhospitalsindex.org/2023-fair-share-spending/