March 29, 2024

Senator John Thune
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Washington, D.C. 20515

Senator Debbie Stabenow
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Senator Shelley Moore Capito
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Senator Tammy Baldwin
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Senator Jerry Moran
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Senator Ben Cardin
509 Hart Senate Office Building
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Dear Senators:

On behalf of the Alliance for Integrity and Reform of 340B (AIR340B), thank you for the opportunity to provide feedback on the SUSTAIN 340B Act Discussion Draft and Supplemental RFI regarding steps Congress can take to ensure the 340B program is being used to lower the cost of medicines for patients in underserved communities.

AIR340B comprises patient advocacy groups, clinical care providers, biopharmaceutical innovators, and other interested parties who are concerned the 340B Drug Pricing Program continues to stray ever farther from its original purpose as a true safety net program focused on expanding access to discounted medicines for vulnerable and uninsured patients.

AIR340B commends the Senators' collective efforts to find bipartisan solutions to the issues plaguing the 340B program. We have always supported greater transparency, accountability, and oversight of the program to ensure it directly supports access for vulnerable patients. We appreciate that the discussion draft covers several important policy issues and that the supplemental request seeks further input on limiting use of contract pharmacies in the program. We believe, if left unaddressed, the unrestrained growth of contract pharmacies will continue to help hospitals, pharmacy benefit managers (PBMs), and large pharmacy chains profit from the program without ensuring low-income and other vulnerable patients benefit.

Consistent with the mission of AIR340B, we recommend the following policies be addressed to improve program integrity and ensure existing program abuses are addressed so that patients are benefiting from the 340B program, as intended.

Recommendation #1: True accountability in 340B requires a clear, statutory patient definition.

The statutory definition of a covered entity "patient" under 340B is crucial to the program's implementation. However, the definition of this term has been a consistent source of confusion and abuse in the 30 years since it was first conceived. AIR340B believes more clearly defining a covered entity patient will help determine when hospitals can obtain 340B discounts, ensuring program use is concentrated in the vulnerable communities the program was created to serve.

The Health Resources and Services Administration's (HRSA's) proposed 2015 guidance on the definition of a patient would have been a first step toward the accountability and transparency needed in the program.[1] Congress should consider similar elements for a statutory patient definition to be applied on a prescription-by-prescription basis. For example:

- An individual must receive a drug at an authorized dispensing location that is: (i) ordered or prescribed by a covered entity provider as a result of an in-person health care service furnished by the provider at a covered entity location registered in the Office of Pharmacy Affairs; and (ii) directly related to that health care service;
- A covered entity provider must be an employee or independent contractor of the covered entity, such that the covered entity bills for and is responsible for the services furnished by the 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;
- The individual is described in a category of individuals within the scope of, and receives a health care service that is within the scope of, the covered entity's federal grant, project, designation or contract;
- The health care service and the drug prescribed as a result of that service are reimbursed as "outpatient" items and services; and
- The individual has an ongoing relationship with the covered entity, such that the covered entity creates and maintains auditable health care records demonstrating: (i) compliance with the elements of the patient definition; (ii) responsibility for the individual's care; and (iii) that the covered entity has provided a health care service to the individual through an in-person visit at a registered covered entity location within 12 months following the visit that resulted in the prescription for the drug.

Recommendation #2: Any reform to the 340B program must include a requirement that low-income and uninsured patients receive discounted medicines from 340B hospitals and their contract pharmacies.

There are currently no requirements or 340B protections in place to ensure low-income and uninsured patients receive discounted 340B medicines from participating hospitals or their contract pharmacies.

[1] 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

Unfortunately, this crucial loophole in the 340B program is not adequately addressed in this discussion draft, continuing to create opportunities for 340B hospitals, PBMs, and contract pharmacies to generate significant profits at the expense of vulnerable patients.

A recent study from the Government Accountability Office found roughly half of 340B hospitals do not provide discounts to vulnerable patients at their contract pharmacies.[2] This is the third government report to draw the same conclusion regarding the "inappropriate treatment of low-income, uninsured patients."[3] One in-depth analysis of contract pharmacies found the vast majority of patients receive "zero or close to zero" discounts on the cost of their medicines, meaning that despite the massive discounts that 340B covered entities receive, most 340B patients effectively pay the full retail price of their medicines.[4]

To ensure the benefits of the 340B program are reaching vulnerable patients:

- All 340B covered entities should be required to pass through a share of their 340B discounts to low-income and uninsured patients by directly lowering patient out-of-pocket costs for medicines.
- Program eligibility should be contingent on a covered entity's establishment of a sliding fee scale for medicines prescribed to low-income and uninsured patients. This recommendation builds on requirements for child site and contract pharmacies contained in the SUSTAIN discussion draft.

Recommendation #3: 340B reforms should aim to improve access and affordability for patients, not simply expand the size of the program. Requiring manufacturers to provide unlimited discounts to tens of thousands of contract pharmacies only helps PBMs and pharmacy chains, not patients.

AIR340B has consistently expressed strong opposition to any legislative proposal that requires pharmaceutical manufacturers to offer 340B-discounted drugs to any and all pharmacies contracted to dispense 340B medicines. Rather than helping to direct discounts to vulnerable patients, these requirements enable national pharmacy chains and PBMs to continue earning profits off a vital safety net program.

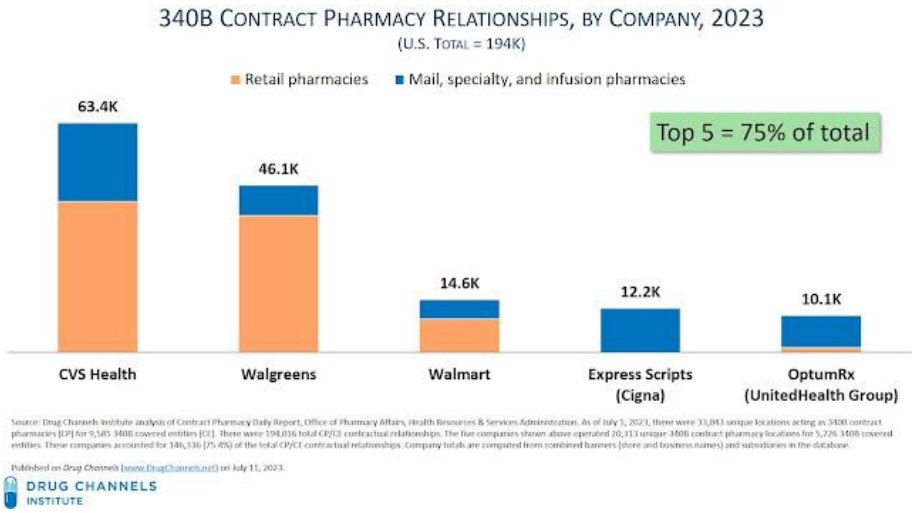
Contract pharmacies earn profit margins on 340B drugs that are three times larger than those of independent clinics dispensing non-340B drugs.[5] Those profits, combined with historically weak federal oversight, have spurred rampant growth in the use of contract pharmacies. The number of contract

[2] 340B Drug Discount Program: Information about Hospitals That Received an Eligibility Exception as a Result of COVID-19 .; 2023. Accessed March 19, 2024. https://www.gao.gov/assets/gao-23-106095.pdf
[3] EXCLUSIVE: The 340B Program Reached $54 Billion in 2022—Up 22% vs. 2021. Accessed March 19, 2024. https://www.drugchannels.net/2023/09/exclusive-340b-program-reached-54.html
[4] Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?. Accessed Marrch 19, 2024. https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/are-discounts-in-the-340b-drug-discount-program-being-shared-with-patients-at-contract-pharmacies.pdf
[5] For-Profit Pharmacy Participation in the 340B Program. Accessed March 19, 2024. https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf

pharmacies grew by roughly 3,200% from 2009 to 2022, following non-binding guidance from HRSA that enabled 340B entities to contract with an unlimited number of pharmacies.[6] Today, more than 33,000 pharmacy locations – half the entire U.S. pharmacy industry – are contracted to dispense 340B medicines, and the majority of these pharmacies are owned by PBMs.[7] Consequently, the 340B program has ballooned to become the nation's second-largest federal prescription drug program, second only to Medicare Part D.[8] Forecasts also show that at the program's current rate of growth, drug purchases under the 340B program will likely surpass purchases under Medicare Part D by 2028.[9]

The nation's three largest PBMs – CVS Health, Express Scripts, and OptumRx – along with Walgreens and Walmart control more than 75% of 340B contract pharmacy relationships. [10] Moreover, recent analysis finds contract pharmacies captured $10 billion in 340B funds in 2023 alone, padding profits for these for-profit companies instead of supporting vulnerable patients.[11]

Figure One



Critically, research shows the unchecked growth of contract pharmacies has been "concentrated in affluent and predominately white communities," not in the medically underserved areas these

[6] Ranking Member Cassidy Seeks Information from Major Contract Pharmacies as Part of Ongoing 340B Investigation. Accessed March 19, 2024. https://www.help.senate.gov/ranking/newsroom/press/ranking-member-cassidy-seeks-information-from-major-contract-pharmacies-as-part-of-ongoing-340b-investigation
[7] EXCLUSIVE: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market. Accessed March 19, 2024. https://www.drugchannels.net/2023/07/exclusive-for-2023-five-for-profit.html
[8] 340B Program at a Glance. Accessed March 19, 2024. https://media.thinkbrg.com/wp-content/uploads/2022/12/06082105/340B-Program-at-a-Glance-2022_clean.pdf
[9] 340B Program at a Glance. Accessed March 19, 2024. https://media.thinkbrg.com/wp-content/uploads/2024/01/12123932/340B-Program-at-a-Glance_2024-FINAL-CLEAN.pdf
[10] EXCLUSIVE: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market. Accessed March 19, 2024. https://www.drugchannels.net/2023/07/exclusive-for-2023-five-for-profit.html
[11] 340B Program at a Glance. Accessed March 19, 2024. https://media.thinkbrg.com/wp-content/uploads/2022/12/06082105/340B-Program-at-a-Glance-2022_clean.pdf

pharmacies are meant to support.[12] As former Congressman Ed Towns and Dr. Ben Chavis, former Executive Director of the National Association for the Advancement of Colored People, recently wrote, 340B entities "are happy to use their branches in poor areas to get 340B drugs into the pipeline, but then re-route these medicines throughout the hospital network to be sold at full price to patients of all income levels."[13]

To ensure the 340B program serves patients, rather than corporate profits, any reform should:

- Address the outsized, pernicious role of PBMs in the 340B program. Congress should revisit the role of contract pharmacies entirely, especially when it comes to their partnerships with 340B hospitals, as in many cases PBMs and contract pharmacies are largely one in the same.
- Reject proposals that would require manufacturers to offer 340B-discounted medicines to any contract pharmacy that a covered entity demands. These mandates would only spark further uncontrolled growth in the program and undermine efforts to introduce much-needed transparency and accountability.
- Require that contract pharmacies be located in medically underserved or otherwise vulnerable communities. This will help ensure 340B discounted medicines reach the patients the program is meant to serve.

Recommendation #4: Proposed transparency requirements for covered entities are an important step forward, but more is needed to capture impacts of the 340B program on patient costs.

Reporting requirements for 340B covered entities are vital for the program's success, and AIR340B commends the Senators for proposing requirements that covered entities regularly submit data on the number of individuals who receive drugs at 340B prices, expenditures on charity care, patient demographics, contract pharmacy partnerships and total 340B discounts realized. However, to ensure the 340B program benefits patients, covered entities should also be required to disclose the percentage of 340B discounts that go directly to patients by lowering their out-of-pocket costs.

Additionally, for patients and providers to have any confidence in the effectiveness of the 340B program, Congress must assume a greater oversight role by implementing measures to close loopholes that allow bad actors to exploit this safety net program. For instance, a reevaluation of hospital eligibility criteria is needed to ensure the 340B program meets its intended purpose of aiding hospitals that serve large numbers of low-income and uninsured patients. Reforms are also needed to curb the financial incentives that drive 340B hospitals to acquire community-based physician practices, particularly given the substantial increases in health care costs that come with shifting from physician offices to hospital facilities.

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[12] Assessment of US Pharmacies Contracted With Health Care Institutions Under the 340B Drug Pricing Program by Neighborhood Socioeconomic Characteristics. Accessed March 19, 2024. https://jamanetwork.com/journals/jama-health-forum/fullarticle/2793530

[13] The Atlanta Voice, "Patients Over Profit Congress Can Improve 340B." https://theatlantavoice.com/ben-chavis-ed-towns/