PRI CENTER FOR MEDICAL ECONOMICS AND INNOVATION

ISSUE BRIEF

Good Intentions Gone Awry: The Case of the 340B Program

Wayne Winegarden

NOVEMBER 2022

A Pacific Research Institute Publication

Good Intentions Gone Awry: The case of the 340B program
Wayne Winegarden
November 2022

Pacific Research Institute
680 E. Colorado Blvd. #180
Pasadena, CA 91101
Tel: 415-989-0833
Fax: 415-989-2411
www.pacificresearch.org

Download copies of this study at www.pacificresearch.org.

Contents

Executive Summary

The overly complex 340B program is doubling in size every three years or so, an unsustainable rate of growth. This extreme growth magnifies the program's inherent flaws causing harm to the broader healthcare landscape and the vulnerable patient groups 340B is supposed to be helping. Fundamental reforms to the program are required. This *Issue Brief* describes how the program's key flaws are causing the observed adverse outcomes and suggests policy reforms that can rectify these problems.

Fundamentally, a core problem with the 340B program is that covered entities do not need to demonstrate that at-risk patients' outcomes are improving. And, while many covered entities do important work, many entities, particularly too many 340B hospitals, are providing less charitable care than the average institution but are reaping the higher revenues 340B enables.

To address this problem, reforms should impose stricter qualification standards that ensure the generous 340B discounts are only available to those institutions achieving the program's goals. 340B healthcare providers and hospital systems should have demonstrable evidence that the organization is serving the intended low-income populations before having the ability to purchase medicines at the discounted levels. In particular, the Medicaid qualification requirements should be increased due to the expansion of Medicaid to many middle-class families that the Affordable Care Act enabled.

Another problem is the program's lax and ineffective oversight that is enabling entities that do not qualify for 340B status to become 340B institutions. Further, the program's lack of transparency means that there is insufficient information regarding the profits covered entities generate from the program and how they generate that money. Consequently, meaningful transparency requirements on 340B covered entities are urgently needed. These include implementing better verification processes to ensure that only eligible entities receive the 340B discount on medicines. They should also include transparent reporting requirements that detail the profit that covered entities, particularly the disproportionate share hospitals, receive and how much charity care the hospitals provide both at the main hospital and all satellite clinics that are also allowed to participate in 340B. In those cases where the transparency requirements reveal that the covered entities are not meeting the program's goals, those entities should be ineligible for 340B discounts.

The radical expansion of the number of contract pharmacies that covered entities can work with has created a loophole that is also worsening outcomes. The number of contract pharmacies has grown by more than 4,000 percent between 2010 and 2020. Contract pharmacies earn significantly higher margins (an estimated 72 percent profit margin) when dispensing 340B medicines. Unfortunately, contract pharmacies do a poor job of ensuring that the 340B discounts are only provided to the eligible population. Further, the expansion of contract pharmacies is mostly occurring in rich neighborhoods not lower income areas, and the out-sized profits contract pharmacies are earning off the 340B program is diverting resources that should be supporting the targeted patients.

To address the problems created by the exploitation of the contract pharmacy provisions, comprehensive 340B reform should limit contract pharmacies to locations where underserved communities live. Further, covered entities should be required to justify their pharmacy relationships with respect to how a proposed contract pharmacy enhances the covered entities' ability to meet the stated goals of the 340B program.

Finally, reforms should target the large number of market distortions that are harming patients. These adverse consequences arise through several pathways. The need to cover the growing demand for 340B discounts, as well as the myriad number of other concessions demanded by industry middlemen, has driven up the list prices of medicines by nearly 35 percent over the last six years even though the revenues that manufacturers receive (referred to as net

prices) have declined by nearly 9 percent. Consequently, the 340B program contributes to higher out-of-pocket drug costs for too many patients because their costs are tied to the inflated list prices. Uninsured patients, unlike all other payers, must pay list prices for their medicines and insured patients must pay their co-insurance costs that are typically based on list prices.

The 340B program also creates adverse incentives that can increase costs in other areas of the healthcare system. For example, the industry consolidation incented by the large 340B profits convert lower-cost independent practices (e.g., oncology practices) into hospital affiliated practices that typically charge significantly higher costs for medical services and decrease patient choice.

Minimizing these market distortions require reforms that ensure patients directly benefit from the lower prices. Such reforms include ensuring that the out-of-pocket costs for vulnerable patient populations are limited to nominal payments, not the over-inflated list prices. Further, the 340B discount should only be recognized if these expansions and acquisitions are in qualified at-risk areas serving the defined at-risk population.

Introduction

The 340B program, contrary to its stated purpose, has become an obstacle to affordable healthcare. 340B is rife with abuse and adverse incentives that increase costs for patients including the very patients the program is supposed to help. Since there are scant signs that the program's double-digit rates of growth are diminishing, these adverse consequences will persist and continue to harm the broader healthcare landscape.

340B's fundamental problem is its overly complex structure. It is a classic example of fixing a government-created problem with a new government program that ultimately generates an entirely new set of challenges that must be managed. In this case, 340B was supposed to fix the unintended consequences that arose when Medicaid's best price rule was introduced in 1990. Prior to the best price rule, drug manufacturers would provide free medicines to clinics serving at-risk populations. Under the best price rule, continuing these giveaways meant that the "best price" on these medicines was zero. It is impossible for any manufacturer to supply the entire Medicaid population with free medicines and remain a viable business. Not surprising, manufacturers withdrew this support.

The 340B program creates a means for these healthcare facilities (referred to as covered entities) to receive medicines at discounted prices once again. Drug manufacturers participating in the 340B program are required to sell their medicines to covered entities at the statutorily determined price that often exceeds a 50 percent discount to the market price and in some cases brings the net price of a medicine down to one penny. The expectation is that these lower prices will help the covered entities provide at-risk populations with more affordable healthcare. Should a manufacturer reject the offer to sell medicines to covered entities on the cheap, then federal law states that Medicaid will stop covering that medicine. The threat of being banned from Medicaid creates an offer that drug manufacturers cannot refuse.

> "340B's fundamental problem is its overly complex structure.

Improving vulnerable populations' access to medicines is clearly important but the structure of the 340B program is fundamentally flawed, which has caused the program to inflict more harm than good. Achieving 340B's goal of helping vulnerable patients receive healthcare does not require the program to include more than one-half of all hospitals in the country and allow them to generate 340B profits from all their patients with no limits on how that money is spent. Reforms to 340B's structure are sorely needed, consequently.

The purpose of this *Issue Brief* is to link the well documented problems of 340B to the flaws in its design and suggest specific policy reforms that could lessen the program's unnecessary costs and improve its ability to serve the intended at-risk population. An understanding of 340B's problems begins with an understanding of the adverse incentives driving its accelerated growth.

340B is on an Accelerated Growth Path

The federal statute governing 340B provides limited guidance regarding how the program is administered, and it does not require covered entities to provide the discounted drugs solely to people who are truly in need. Since covered entities can prescribe the discounted medicines purchased through the 340B program to anyone who receives medical care at their facilities, including patients who have insurance and pay full price for the medicines, the 340B program creates a very large regulatory-driven profit opportunity.

Examining the profit opportunity as it relates to cancer drugs, an analysis of drug pricing at 340B hospitals by Gal (2021) found that "340B hospitals have a higher drug margin on Medicare patients" that provides "a handsome profit from Medicare patients for 340B hospitals."[1] Further, "the data shows that commercial insurers are charged 3.8 times the acquisition price of oncology drugs to 340B hospitals, making the 340B hospital profit for treating commercial patients with cancer truly remarkable.[2]

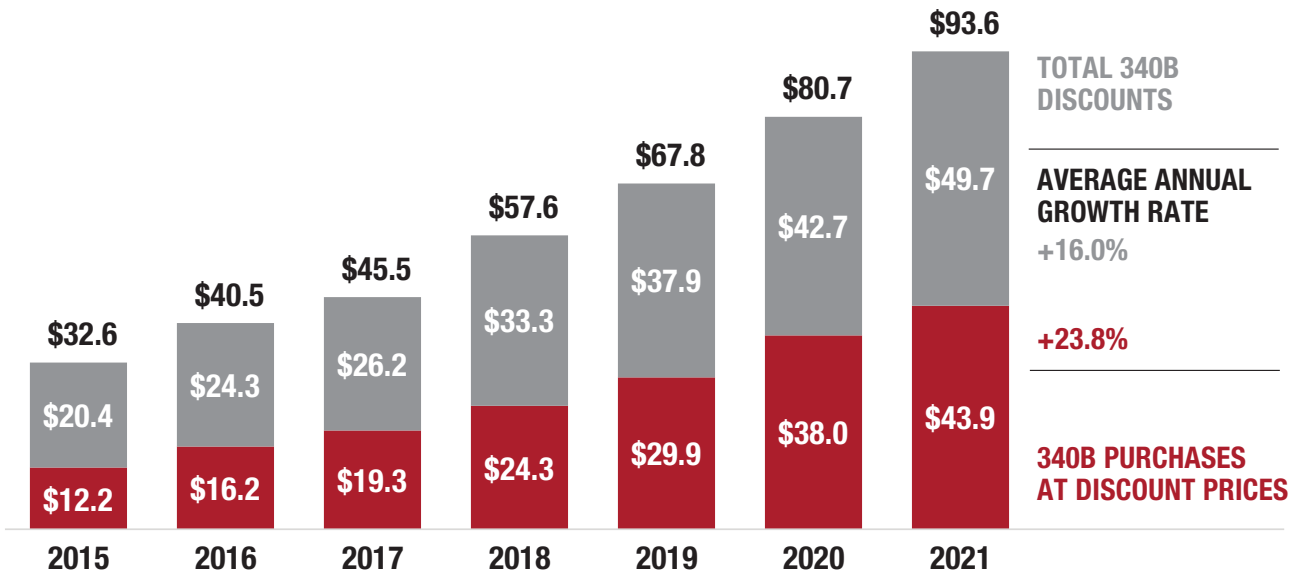
These large profit opportunities arise because 340B hospitals pocket the difference between their costs, which are based on the extremely discounted price for medicines, and their payer reimbursements (either Medicare, employer plans, or commercial insurers), which reflect drugs' undiscounted prices.

For instance, Medicare would typically pay a hospital $1,060 in reimbursement for a drug with an average sales price (ASP) of $1,000, enabling the hospital to earn a 6 percent return on administering the drug. If that hospital were a 340B institution, the entity's costs could be around $500 for the drug and its reimbursement from Medicare would be $1,060. Thus, in this case, 340B enables hospitals to earn revenues that are more than nine times higher than the revenues that a non-340B hospital can earn for administering the exact same drug.

"Thus, in this case, 340B enables hospitals to earn revenues that are more than nine times higher than the revenues that a non-340B hospital can earn for administering the exact same drug.

Thanks to the Affordable Care Act (ACA), which expanded the size of the Medicaid population (the share of Medicaid inpatients served is used to determine institutional eligibility), the number of hospitals that qualify for 340B status exploded along with the number of covered entities – particularly hospitals. The program's growth has also been accelerated by 2010 guidance from the Health Resources and Services Administration (HRSA) that expanded the number of contract pharmacies a covered entity could work with. The broader availability of a large profit opportunity has fueled the program's explosive growth, which is illustrated in Figure 1.

FIGURE 1
Total Purchases of 340B Drugs at Discount Prices and Total 340B Discounts, 2015 - 2021

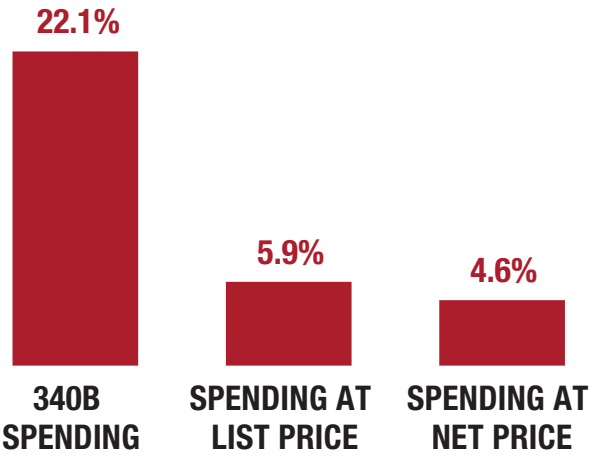


Source: Drug Channels

The red bars in Figure 1 track the growth in the 340B program based on the total amount of drugs sold valued at discounted prices. Back in 2015, total 340B covered entities purchased $12.2 billion worth of drugs, which was a $20.4 billion discount from the cost of these drugs valued at their list price ($32.6 billion). Since 2015, 340B purchases valued at their discount prices have grown 23.8 percent annually and reached $43.9 billion in 2021. This equaled a $49.7 billion discount from the full cost of the drugs at their list price, which was $93.6 billion.

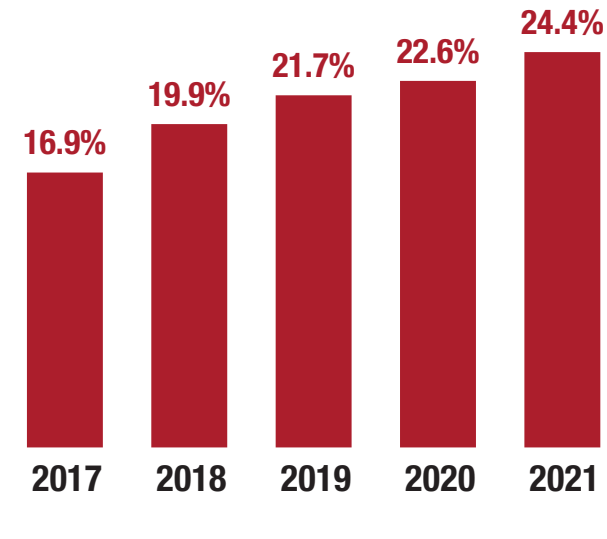
This exceptional revenue growth of the 340B program can also be visualized by comparing its growth to the growth in overall pharmaceutical spending, see Figure 2. Figure 2 compares the 5-year compound average annual growth rate (CAGR) between purchases of 340B drugs compared to total pharmaceutical spending valued at list prices and net prices (total spending net of all discounts, including 340B discounts, that reflect the actual cost of the drugs to the healthcare system).[3] Figure 2 illustrates that the average annual growth in drug spending via the 340B program is four to five times faster than the growth in overall pharmaceutical spending. Due to years of accelerated growth, 340B spending increased from an already high 7.0 percent of total pharmaceutical spending valued at list prices in 2016 to 12.1 percent of total pharmaceutical spending valued at list prices in 2021.

FIGURE 2
Compound Average Annual Growth Rate 340B Spending Compared to Total Pharmaceutical Spending, 2016 - 2021



Source: Drug Channels and IQVIA

FIGURE 3
340B Discounts as a Percent of Total Manufacturer Discounts and Rebates



Source: Author calculations based on Drug Channels data

Another way to demonstrate 340B's excessive growth is to compare the value of the 340B program's discounts to the total discounts and rebates paid by pharmaceutical manufacturers. This comparison is presented in Figure 3. Figure 3 demonstrates that the manufacturer provided 340B discounts now account for one-quarter of the total value of discounts manufacturers pay.

As Drug Channels noted, "the 340B Drug Pricing Program is now unambiguously the second-largest government pharmaceutical program, based on net drug spending. But unlike such programs as Medicare Part D and Medicaid, 340B lacks a regulatory infrastructure, well-developed administrative controls, and clear legislation to guide the program."[4]

The accelerated growth and large size of 340B discounts are troubling. When 340B spending was focused tightly on the core targeted healthcare facilities, the program's inherent flaws created negligible adverse consequences. The significant expansion of the program, when coupled with its inherent flaws, has led to large systemic costs such that the program is now fundamentally unsustainable. Broad based reforms that return the program to its original size and intention are required, consequently. These reforms should directly address the specific problems the program is now creating.

Improving Outcomes for At-Risk Patients Should Be Required

Perhaps the most disconcerting problem of 340B is the costs patients are bearing as a direct result of the program. Starting with the problems for uninsured patients, according to Gal (2021),

> the data shows that hospitals are charging cash-paying patients roughly the same as the median commercial prices (1.02 times).
>
> This observation is obviously problematic. About eight percent of the U.S. population was uninsured in 2019 and the mandate of the 340B designated hospitals certainly includes providing affordable care to this segment. (In fact, 340B institutions' main response to criticism is that they use the 340B economics to address the uninsured). The idea that they charge these patients the same 3.8 times their purchase price does not fit with this mission.[5]

Charging commercial prices to uninsured patients is problematic because, as Gal (2021) notes, uninsured patients are typically considered to be part of the at-risk population that 340B is designed to help. When these patients pay the commercial prices that do not reflect the large 340B discounts the hospital received, an opportunity to help at-risk patients has been lost. In fact, based on the Gal (2021) study, their drug costs could have been reduced by up to the entire 380 percent mark-up relative to the covered entity's actual costs. Rather than alleviating the drug costs for the uninsured, these hospitals are using 340B discounts to pad their own bottom lines.

The flaws in 340B can also increase costs for patients on Medicare or with commercial insurance. According to a 2015 Government Accountability Office (GAO) study examining the impact on Medicare patients,

> in both 2008 and 2012, per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at 340B DSH hospitals than at non-340B hospitals. This indicates that, on average, beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other hospitals in GAO's analysis. For example, in 2012, average per beneficiary spending at 340B DSH hospitals was $144, compared to approximately $60 at non-340B hospitals. The differences did not appear to be explained by the hospital characteristics GAO examined or patients' health status.[6]
>
> The GAO further explains that these outcomes are consistent with a financial incentive at hospitals participating in the 340B program to prescribe more drugs or more expensive drugs to Medicare beneficiaries. Unnecessary spending has negative implications, not just for the Medicare program, but for Medicare beneficiaries as well, who would be financially liable for larger copayments as a result of receiving more drugs or more expensive drugs. In addition, this raises potential concerns about the appropriateness of the health care provided to these beneficiaries.[7]

The GAO analysis supports the notion that 340B's incentive to increase overall drug spending is occurring in practice. Not only does this drive-up overall healthcare spending, but it harms insured patients by raising their out-of-pocket costs.

Then there is the issue of charity care. Being a hospital that is a 340B covered entity (referred to as a disproportionate share hospital), it logically follows that 340B hospitals should be spending more money on charity care than the average hospital. Logical, but wrong. Winegarden (2021) examined hospital data from the Centers for Medicare

and Medicaid Services' (CMS) Healthcare Provider Cost Reporting Information System (HCRIS). This data

> provides operational and financial information on hospitals that include each hospital's cost of charity care. Benchmarking each hospital's net income and charity care spending to net patient revenues, the hospitals in the CMS database devoted 2.03 percent of their net patient revenues toward charitable care in 2017. However, leveraging the list of the current 340B covered entities maintained by the Health Resources & Services Administration, the Office of Pharmacy Affairs 340B OPAIS, charitable spending as a share of net patient revenues by 340B hospitals was a smaller 1.66 percent.[8]

These results are consistent with the findings of AIR340B, which has examined the relative amount of charity care provided by 340B hospitals relative to the industry average for the past eight years.[9] According to the 2022 report,

> The findings of this analysis demonstrate that the 340B program includes many hospitals that provide minimal charity care. In fact, for one-quarter (25 percent) of the 340B hospitals studied, charity care represents less than one percent of hospital operating costs ... These hospitals provide a level of charity care that is far below the 2.9 percent national average for all short-term acute care hospitals, regardless of 340B status. An additional 40 percent of the 340B hospitals studied provide charity care that represents between 1 percent and 2.9 percent of operating costs. In total, about two-thirds (65 percent) of 340B hospitals provide less charity care than the national average for all hospitals, including for-profit hospitals.[10]

Making this result more troubling, and consistent with the GAO's findings, 340B hospitals are more profitable according to Winegarden (2021), which noted that

> evaluating each hospital's net income relative to net revenue demonstrates that the profitability (or excess of revenues over costs for non-profit hospitals) of 340B hospitals was 37 percent larger (6.25 percent compared to 4.55 percent) at 340B hospitals compared to the average of all hospitals.[11]

The combination of less charity care and greater profitability indicate that too many hospitals that are not pursuing the program's goals are qualifying for 340B status. In these instances, 340B is simply a revenue subsidy for hospitals that, on net, is harming patients by increasing their costs. Given this clear evidence that 340B drug discounts are being offered to institutions that are not advancing the goal of expanding care to vulnerable populations, reforms should impose stricter eligibility requirements for 340B, particularly for disproportionate share hospitals.

SOLUTION: Eligibility for 340B discounts need tightening by imposing stricter qualification standards. 340B healthcare providers and hospital systems should have demonstrable evidence that the organization serves the intended low-income populations on an outpatient basis and meets a minimum charity care threshold before having the ability to purchase medicines at the discounted levels.

In particular, the Medicaid qualification requirements should be increased due to the expansion of Medicaid to many middle-class families that was promoted by the Affordable Care Act, and it should factor in both inpatient and outpatient care.

Fix 340B's Lax and Ineffective Oversight

In another examination of the 340B program, the GAO found that the program's oversight and "HRSA's processes do not provide reasonable assurance that participating nongovernmental hospitals meet eligibility requirements. … Given these weaknesses, some nongovernmental hospitals that do not appear to meet the statutory requirements for program eligibility are participating in the 340B Program and receiving discounted prices for drugs for which they may not be eligible."[12]

In addition to the lax oversight, restrictions on how the subsidies can be used and reporting requirements, particularly for disproportionate share hospitals, are permissive. For instance, "340B DSH hospitals are not required to use 340B savings to serve vulnerable populations, nor are they required to report how 340B revenues are used."[13] Due to these inadequate reporting requirements, it is unknown whether disproportionate share hospitals use their 340B profits to increase care for the targeted population or if these resources are simply used for other purposes.

When hospitals spend the profits generated from the 340B program on anything other than expanding care to vulnerable populations, then, regardless of the value of the expenditures, they violate the purpose of the 340B program. The data demonstrating that 340B hospitals devote relatively fewer resources toward charity care indicate that these institutions are not using their 340B resources to expand care to the targeted patient groups. Instead, far too much of the program's resources are simply subsidizing profitable hospitals rather than helping these institutions expand care.

Ensuring that the uses of 340B resources are consistent with the program's intention begins with demanding greater transparency from 340B covered entities.

SOLUTION: As an overarching goal, greater transparency requirements on 340B covered entities should be adopted. These include implementing better eligibility verification processes with robust standards, such as those suggested by the GAO (2019) to ensure that only eligible entities receive the 340B discount on medicines. Those covered entities not meeting the program's requirements should be ineligible for 340B discounts.

Additionally, reporting requirements for hospitals and covered entities should be adopted that detail the amount of profit they receive from the 340B program, and the payer mix of the patients generating these prescriptions.

Close The Contract Pharmacy Loophole That Is Worsening Outcomes

The contract pharmacy guidance was adopted because many smaller clinics that served the targeted population qualified for the program but were too small to have in-house pharmacies. To help these healthcare providers participate in the program, the original contract pharmacy provision was created. This provision allowed entities without an in-house pharmacy to contract with one outside pharmacy.

The ability to work with multiple contract pharmacies was granted by HRSA bureaucrats, not Congress, through guidance in 2010 and allows covered entities to establish an unlimited number of contract pharmacy relationships. The elimination of any control over how many contract pharmacies a covered entity can use has led to many unwanted consequences.

Pharmacies want to gain 340B contract pharmacy status because, like covered entities, the designation is incredibly profitable. According to a BRG study of contract pharmacies participation in the 340B program, "the average profit margin on 340B medicines commonly dispensed through contract pharmacies is an estimated 72 percent, compared with just 22 percent for non-340B medicines dispensed through independent pharmacies."[14] It is not just high margins; the high margins translate into large dollar revenues. According to BRG, "340B covered entities and their contract pharmacies generated an estimated $13 billion in gross profits on 340B purchased medicines in 2018, which represents over 25 percent of the total gross profits on brand medicines realized by all providers that dispense or administer medicines."[15]

The combination of attractive margins and unlimited contracting ability caused the number of pharmacy arrangements to explode. A 2022 JAMA study tracked the growth of contract pharmacies both before and after the removal of any controls over an entity's number of contract pharmacies. The authors found that "the percentage of pharmacies contracting with a 340B institution pre-expansion (2006-2009) grew minimally (1.2% to 1.7%) …. Post expansion (2011-2019) growth accelerated overall (5.9% to 29.9%) and among retail (5.7% to 32.6%), specialty (5.3% to 24.7%), and mail-order (4.5% to 20.5%) pharmacies."[16]

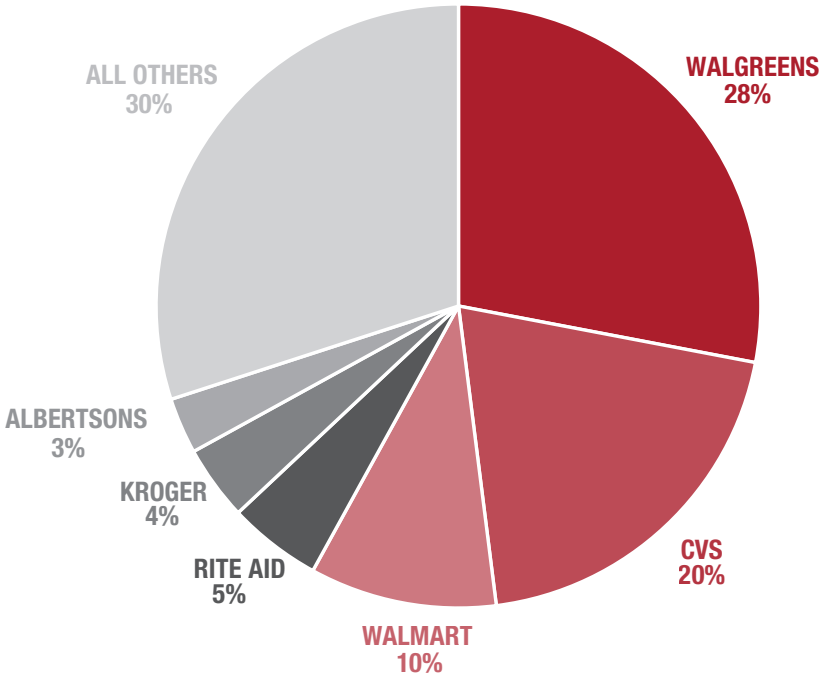
Supporting the JAMA analysis, the BRG study documented that,

> between April 1, 2010, and April 1, 2020, the number of contract pharmacy arrangements increased from 2,321 to 100,451—a 4,228 percent increase…. Today, more than 27,000 individual pharmacies (almost one out of every three pharmacies) participate in the 340B program as contract pharmacies, including virtually all the major national and regional chains, such as Walgreens, Walmart, CVS, Rite-Aid, Kroger, Albertsons, Costco, and many more. Hospitals enrolled in the 340B program contract on average with twenty-two distinct pharmacies, and the largest contract pharmacy networks include over 250 pharmacies, some of which are thousands of miles away from the 340B covered entity.[17]

In response to the decades-long dramatic growth in contract pharmacy arrangements enabled by HRSA's administrative overreach, some manufacturers are limiting their shipments of 340B drugs to contract pharmacies. This has led to multiple lawsuits that are working their way through the courts.

Not only are major retailers participating as contract pharmacies, but the outsized profit opportunity for contract pharmacies is mostly subsidizing these major retailers that clearly do not require government support. According to Drug Channels 2020 data on contract pharmacies, 70 percent of the contract pharmacy locations are part of major chains and three major retailers (Walgreens, CVS, and Walmart) account for 58 percent of all locations, see Figure 4.

FIGURE 4
340B Contract Pharmacy Locations by Company, 2020
(Total Contract Pharmacy Locations: 27,928)



Source: Drug Channels

Adding to these concerns, the 340B contract pharmacy program has a poor track record of ensuring program integrity. For instance, most of the expansion in contract pharmacies has not occurred in the neighborhoods where the targeted populations live. The 2022 JAMA analysis found that

> from 2011 to 2019, the share of 340B retail pharmacies in socioeconomically disadvantaged and primarily non-Hispanic Black and Hispanic/Latino neighborhoods declined, even though the share of all retail pharmacies (i.e., 340B and non-340B) in socioeconomically disadvantaged and racial and ethnic minoritized neighborhoods increased slightly ….
>
> Although the percentage of 340B pharmacies in the lowest income neighborhoods declined by 5.6%, the percentage of non-340B pharmacies in the same neighborhoods increased by 1.3% …. In contrast, though the percentage of 340B pharmacies in the highest income neighborhoods increased by 5.0%, the percentage of non-340B pharmacies in the same neighborhoods increased by 1.5%....[18]

The results of the JAMA study are consistent with the perverse incentives of the 340B program. Expanding contract pharmacies to wealthier neighborhoods expands the profitability of the program because patients in wealthier areas are more likely to have commercial or Medicare insurance. Commercial insurance and Medicare reimburse covered entities at the full price even though the costs to the covered entities are significantly discounted. The contract pharmacies are, consequently, more likely to earn their 72 percent profit margin when dispensing drugs from wealthier neighborhoods.

Contract pharmacies also do a poor job of ensuring that the 340B discounts are only provided to the eligible population, in part because large pharmacies serve a broad population that includes the patients of 340B entities as well as patients from non-340B institutions. It is often difficult to distinguish between these groups of patients, which causes drug diversion – the practice of giving patients of non-340B entities the 340B discount – to be a large problem at contract pharmacies. Citing HRSA audits of contract pharmacies, the GAO documented that 66 percent of the drug diversions HRSA discovered between 2012 and 2017 occurred at contract pharmacies.[19]

The exponential expansion of the contract pharmacy program is troubling, consequently, because the expansion is occurring mostly in rich neighborhoods not lower income areas, contract pharmacies do a poor job maintaining the 340B program's integrity. The out-sized profits contract pharmacies are earning off the 340B program is diverting resources that should be supporting the targeted patients. Consequently, reforms to the contract pharmacy program are desperately needed.

SOLUTION: Congress should implement contract pharmacy legislation as part of reforms to the overall 340B program. Putting contract pharmacy requirements in statute without other substantial program reforms could reward HRSA's overreach without helping patients.

As part of the comprehensive reform, contract pharmacies should be limited to areas convenient to the at-risk patients the 340B program should be serving. Further, covered entities should be required to justify their pharmacy relationships with respect to how the proposed contract pharmacy enhances the covered entities' ability to meet the stated goals of the 340B program.

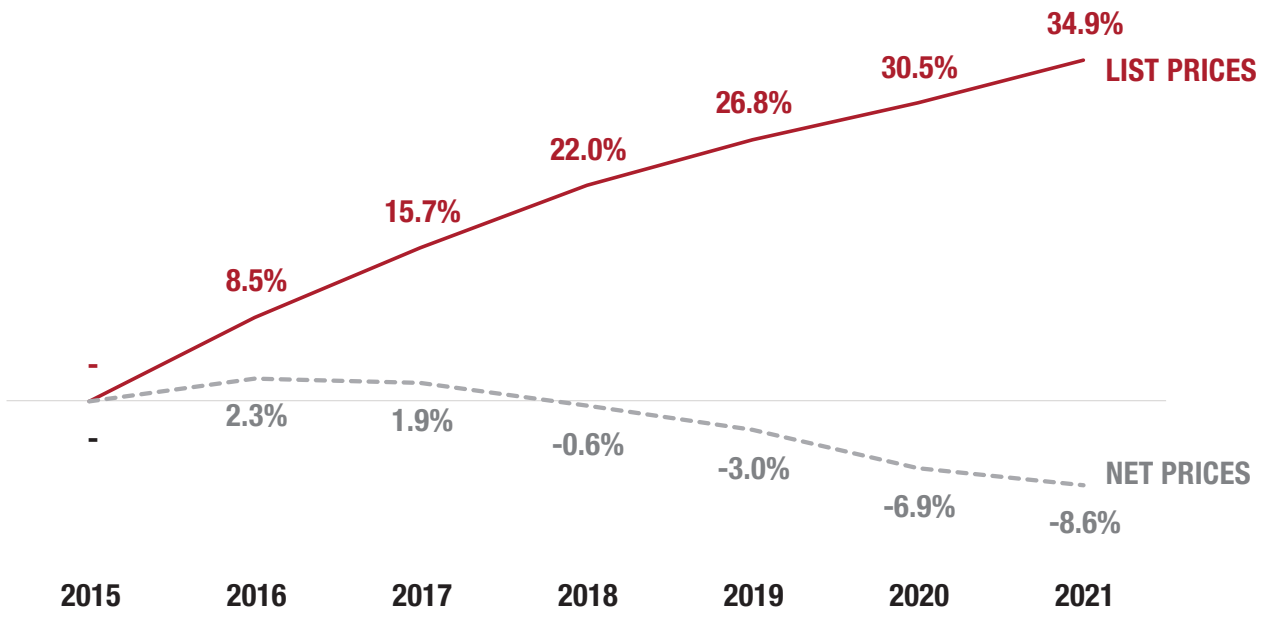
Fix the 340B Market Distortions That Are Increasing Patient Costs

The adverse impacts from the 340B discount program are not confined to the participants in the program. Instead, 340B is imposing large costs on the broader pharmaceutical market. Even back in 2011, prior to the enormous growth over the past decade, the GAO warned that

> as the number of covered entities enrolled in the 340B program increases and more drugs are purchased at 340B prices, there is the potential for unintended consequences, such as cost-shifting to other parts of the health care system.[20]

This cost shifting occurs in many ways. One example is the impact discounts have on the overall pricing environment. The need to cover the growing demand for 340B discounts, as well as the myriad number of other concessions demanded by industry middlemen, has driven up the list prices of medicines even though the revenues that manufacturers receive (referred to as net prices) have been declining. These trends are illustrated in Figure 5.

FIGURE 5
Cumulative Growth in List Prices for Large Manufacturers Compared to Cumulative Change in Net Prices for Large Manufacturers
2016 - 2021



Source: Author calculations based on data from Drug Channels

Over the six-year period between 2016 and 2021 the list prices for innovative drugs from large manufacturers rose nearly 35 percent but the net prices – the prices received by manufacturers – declined by nearly 9 percent. The growth in discounts, such as 340B discounts, explains the diverging trends. What this means is that the revenues 340B entities (along with industry middlemen) have been receiving are growing at the expense of manufacturers. Therefore, the resources to invest in future innovations are being constrained.

At the same time uninsured patients, who must pay the gross prices for medicines even though no other payer does, are paying more. Even costs for insured patients are increased because their co-insurance costs are typically tied to the rising list prices not the more systemically relevant net prices. Consequently, due to its impact on driving up gross prices to fund the 340B discounts, the 340B program directly increases the out-of-pocket drug costs for too many patients. It is important to note that these cost impacts are separate from the incentive for covered entities to prefer higher-cost drugs to lower-cost drugs or the incentive to prescribe more expensive medicines, which also raise costs on patients.

The 340B program also creates adverse incentives that can increase costs in other areas of the healthcare system. For example, the large profits offered by the 340B program has incentivized industry consolidation. This incentive is particularly strong with respect to independent oncology practices. These independent practices do not qualify for 340B discounts but if a 340B hospital purchases the practice, then, as part of the larger institution, the practice does qualify for the discounts. Due to the high cost of oncology medicines, the profit opportunity from transforming the practice into a 340B qualified institution is large. However, hospital practices typically charge significantly higher costs for cancer treatment services than independent practices. Therefore, transforming the independent practice into a division of the hospital system decreases patient choice and increases overall healthcare spending.
Beyond the reforms that target the program to the at-risk populations it is designed to help, reforms should be adopted that ensure patients directly benefit from the lower prices.

SOLUTION: Addressing these cost shift problems is straightforward. First, because the program is intended to help vulnerable patient populations, it should be required that 340B lower income patients' costs are capped at a nominal cost sharing level.

Second, for purposes of the 340B program, hospital expansions and practice acquisitions should only be recognized if these facilities are in qualified at-risk areas and treat a substantial share of vulnerable patients on an outpatient basis.

Conclusion

A famous quote attributed to Herbert Stein states "if something cannot go on forever, it will stop". The unsustainability of 340B's current trajectory is evident, indicating that the generosity of the program will have to stop.

In response to 340B's limitless benefits to covered entities and contract pharmacies, many drug manufacturers are attempting to impose their own controls of contract pharmacy abuse. These efforts have resulted in litigation that is making its way through the courts.[21] Consistent with 340B's common theme, the smaller organizations serving vulnerable patient populations (aka, the intended beneficiaries of the program) suffer the most from the rising uncertainty and potential restrictions.

Whether the manufacturer's actions are ultimately judged by the courts to be right or wrong, they never should have been necessary. Government programs should be implemented with the proper focus and oversight to ensure they address the targeted problem with as few adverse side effects as possible.

The time has come to hold 340B to this standard. Congress should right-size this program so that it targets true safety net providers and the low-income patients they serve. This would allow the program to fulfill its intended purpose without harming the broader healthcare system.

Endnotes

1 Gal A "Examining Hospital Price Transparency, Drug Profits, & the 340B Program" Community Oncology Alliance (COA), September 2021, https://communityoncology.org/wp-content/uploads/2021/09/Moto-COA-340B_Hospital_Markups_Report.pdf.

2 Ibid.

3 Total pharmaceutical spending at list prices and net prices are from: "The Use of Medicines in the U.S. 2022: Usage and Spending Trends and Outlook to 2026" IQVIA Institute, April 2022, https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-use-of-medicines-in-the-us-2022/iqvia-institute-the-use-of-medicines-in-the-us-2022.pdf.

4 Fein, A "The 340B Program Climbed to $44 Billion in 2021—With Hospitals Grabbing Most of the Money" Drug Channels, August 15, 2022, https://www.drugchannels.net/2022/08/the-340b-program-climbed-to-44-billion.html (accessed October 12, 2022).

5 Gal A "Examining Hospital Price Transparency, Drug Profits, & the 340B Program" Community Oncology Alliance (COA), September 2021, https://communityoncology.org/wp-content/uploads/2021/09/Moto-COA-340B_Hospital_Markups_Report.pdf.

6 "Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals" Government Accountability Office, June 2015, GAO-15-442, https://www.gao.gov/assets/gao-15-442.pdf.

7 Ibid.

8 Winegarden W "Profiting from 340B: A review of charity care and financial performance at 340B hospitals" Pacific Research Institute Center for Medical Economics and Innovation, November 2021, https://medecon.org/wp-content/uploads/2021/11/340B-Study_FinalWeb.pdf.

9 The most recent report is, Left Behind: An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Drug Pricing Program" AIR340B, February 2022, https://340breform.org/wp-content/uploads/2022/02/AIR340B_LeftBehind_2022.pdf.

10 Left Behind: An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Drug Pricing Program" AIR340B, February 2022, https://340breform.org/wp-content/uploads/2022/02/AIR340B_LeftBehind_2022.pdf.

11 Winegarden W "Profiting from 340B: A review of charity care and financial performance at 340B hospitals" Pacific Research Institute Center for Medical Economics and Innovation, November 2021, https://medecon.org/wp-content/uploads/2021/11/340B-Study_FinalWeb.pdf.

12 "340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements" Government Accountability Office, December 2019, GAO-20-108, https://www.gao.gov/assets/gao-20-108.pdf.

13 Mulligan K "The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments" USC Schaeffer Center for Health Policy and Economics" October 14, 2021, https://healthpolicy.usc.edu/research/the-340b-drug-pricing-program-background-ongoing-challenges-and-recent-developments/#:~:text=Yet%20despite%20large%20340B%20sales,how%20340B%20revenues%20are%20used..

14 Vandervelde A, Erb K, and Hurley L "For-Profit Pharmacy Participation in the 340B Program" BRG, October 2020, https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf.

15 Ibid.

16 Lin JK, Li P, Doshi JA, Desai SM "Assessment of US Pharmacies Contracted With Health Care Institutions Under the 340B Drug Pricing Program by Neighborhood Socioeconomic Characteristics" *JAMA Health Forum*, 2022, 3(6): e221435. doi:10.1001/jamahealthforum.2022.1435

17 Vandervelde A, Erb K, and Hurley L "For-Profit Pharmacy Participation in the 340B Program" BRG, October 2020, https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf.

18 Lin JK, Li P, Doshi JA, Desai SM "Assessment of US Pharmacies Contracted With Health Care Institutions Under the 340B Drug Pricing Program by Neighborhood Socioeconomic Characteristics" *JAMA Health Forum*, 2022, 3(6): e221435. doi:10.1001/jamahealthforum.2022.1435

19 "Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement" Government Accountability Office, June 2018, GAO-18-480, https://www.gao.gov/assets/gao-18-480.pdf.

20 "Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement" Government Accountability Office, September 2011, GAO-11-836, https://www.gao.gov/assets/gao-11-836.pdf.

21 See: Ryan White Clinics 340B, https://rwc340b.org/update-on-340b-contract-pharmacy-litigation-decisions-issued-in-four-manufacturer-lawsuits/.

About the Author

Wayne Winegarden, Ph.D., is a Sr. Fellow in Business & Economics, Pacific Research Institute, as well as the Director of PRI's Center for Medical Economics and Innovation.

Dr. Winegarden's policy research explores the connection between macroeconomic policies and economic outcomes, with a focus on fiscal policy, the health care industry, and the energy sector. As Director of the Center for Medical Economics and Innovation, Dr. Winegarden spearheads research and advances policies that support the continued viability and vitality of the U.S. biomedical and pharmaceutical industries to the benefit of patients and overall economic growth.

Dr. Winegarden's columns have been published in the *Wall Street Journal, Chicago Tribune, Investor's Business Daily, Forbes.com,* and *USA Today.* He was previously economics faculty at Marymount University, has testified before the U.S. Congress, has been interviewed and quoted in such media as CNN and Bloomberg Radio, and is asked to present his research findings at policy conferences and meetings.

Dr. Winegarden is also the Principal of an economic advisory firm that advises clients on the economic, business, and investment implications from changes in broader macroeconomic trends and government policies. Clients have included Fortune 500 companies, financial organizations, small businesses, and trade associations. Previously, Dr. Winegarden worked as a business economist in Hong Kong and New York City; and a policy economist for policy and trade associations in Washington D.C. Dr. Winegarden received his B.A., M.A., and Ph.D. in Economics from George Mason University.

About PRI

The Pacific Research Institute (PRI) champions freedom, opportunity, and personal responsibility by advancing free-market policy solutions. It provides practical solutions for the policy issues that impact the daily lives of all Americans, and demonstrates why the free market is more effective than the government at providing the important results we all seek: good schools, quality health care, a clean environment, and a robust economy.

Founded in 1979 and based in San Francisco, PRI is a non-profit, non-partisan organization supported by private contributions. Its activities include publications, public events, media commentary, community leadership, legislative testimony, and academic outreach.

Center for Business and Economics

PRI shows how the entrepreneurial spirit—the engine of economic growth and opportunity—is stifled by onerous taxes, regulations, and lawsuits. It advances policy reforms that promote a robust economy, consumer choice, and innovation.

Center for Education

PRI works to restore to all parents the basic right to choose the best educational opportunities for their children. Through research and grassroots outreach, PRI promotes parental choice in education, high academic standards, teacher quality, charter schools, and school-finance reform.

Center for the Environment

PRI reveals the dramatic and long-term trend toward a cleaner, healthier environment. It also examines and promotes the essential ingredients for abundant resources and environmental quality: property rights, markets, local action, and private initiative.

Center for Health Care

PRI demonstrates why a single-payer Canadian model would be detrimental to the health care of all Americans. It proposes market-based reforms that would improve affordability, access, quality, and consumer choice.

Center for California Reform

The Center for California Reform seeks to reinvigorate California's entrepreneurial self-reliant traditions. It champions solutions in education, business, and the environment that work to advance prosperity and opportunity for all the state's residents.

Center for Medical Economics and Innovation

The Center for Medical Economics and Innovation aims to educate policymakers, regulators, health care professionals, the media, and the public on the critical role that new technologies play in improving health and accelerating economic growth.

Free Cities Center

The Free Cities Center cultivates innovative ideas to improve our cities and urban life based around freedom and property rights – not government.

PACIFIC RESEARCH INSTITUTE

www.pacificresearch.org

MAILING ADDRESS
PO Box 60485
Pasadena, CA 91116

Tel 415-989-0833

SACRAMENTO OFFICE
2110 K Street, Suite 28
Sacramento, CA 95816
Tel 916-389-9774

PASADENA OFFICE
680 E. Colorado Blvd., Suite 180
Pasadena, CA 91101
Tel 626-714-7572

CONNECT WITH US

facebook.com/pacificresearchinstitute

@pacificresearch

youtube.com/pacificresearch1

www.linkedin.com/company/pacific-research-institute

pacificresearchinstitute