

Addressing the Problems of Abuse in the 340B Drug Pricing Program

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Introduction

Named for section 340B of the Veterans Health Care Act of 1992, the 340B program was designed to fix a snafu created by the 1990 Medicaid Drug Rebate Program. The 1990 legislation required any pharmaceutical manufacturer that wanted its drugs covered by Medicaid to enter into a rebate program agreement.

The Medicaid program provides health coverage to low-income adults, children, pregnant women, and people with disabilities. Over 68 million people are currently enrolled in Medicaid, 71 million if enrollees in the Children's Health Insurance Program (CHIP) are also included.¹ In total, nearly 22 percent of the U.S. population is currently covered by one of these programs, making them the main public health insurance programs in the U.S. today.

Under the terms of the drug rebate agreements, manufacturers are required to provide Medicaid with the "best price" available to any other purchaser when selling medicines to Medicaid patients – also referred to as the *best price requirement*.² While the 1990 Medicaid Drug Rebate Program was seemingly a way to reduce costs for the large Medicaid population, it also created adverse, but unintended, consequences.

Prior to the 1990 Act, manufacturers, as part of the companies' charitable programs, were offering safety-net providers (health care providers that primarily serve vulnerable populations, such as low-income patients who are uninsured) large discounts on their purchases of medicines. Under the Medicaid drug rebate program, if manufacturers continued to offer these large discounts to safety-net providers, then those discounts would be included as part of Medicaid's best available price calculations, and thus available nationwide.

While providing help to a select group of needy patients was possible before the creation of the Medicaid drug rebate program, extending these loss-inducing prices to the entire Medicaid population was simply unsustainable. Therefore, the unintended consequence of the 1990 legislation was to significantly increase the costs on drug manufacturers if they continued to extend these sizable discounts to safety-net providers – the discounts would then have to be applied to the much larger Medicaid population, which was a financially untenable course of action.³ The discounts that these historically vulnerable populations had received prior to the 1990 legislation were, consequently, discontinued.

It was within this context that President George H.W. Bush and Congress implemented the 340B program. The purpose of Section 340B was to improve the availability of medicines to the vulnerable populations served by safety-net facilities who had lost access to their below market priced medicines following enactment of the 1990 legislation. The 340B program was designed to improve vulnerable populations' access to medicines by extending discounted drugs to safety-net providers.

The intentions of the 340B program are unassailable: ensure at-risk patients have access to the medicines they need. More precisely, the intention is to reduce the cost of outpatient drugs for true-safety net facilities serving large numbers of uninsured or vulnerable patients. Under the program, participating pharmaceutical manufacturers provide discounts between 20 percent and 50 percent of the costs for outpatient drugs that are sold to qualifying clinics and hospitals, also known as covered entities.

Manufacturers participate in the 340B program because Medicaid will not pay for drugs from any manufacturer that does not participate. Consequently, 340B is a mandate on pharmaceutical manufacturers in

all but name. Thus, thanks to 340B, health care organizations deemed as safety-net providers can purchase drugs at significantly lower prices.

Good policy is not judged solely on intentions however; it is the outcomes that matter. The outcomes of the 340B program are disappointing because the 340B program, like many government-mandated public policy *solutions*, suffers from a fundamental flaw in its design. Instead of directly addressing identified problems, typically the best way to reduce or eliminate any problem, government solutions will often create indirect and overly complex schemes to address a problem.

Due to the complexity of these schemes, each policy solution creates new problems that require fixing, typically implemented in a series of successive *solutions*. Ultimately, the government's approach is akin to the old lady in the children's rhyme who continually swallows progressively more absurd animals to prevent the fly she initially swallowed from killing her. Eventually, as in the children's rhyme, the problems created by each successive solution ends up creating complications that far exceed the original problem.

And, so it is with the 340B program. The 340B program, which was a response to the problems created by the passage of the 1990 Medicaid Drug Rebate Program, is now creating distortions that must be corrected. In the case of the 340B program, the government is attempting to ensure vulnerable patient populations have access to their medicines by forcing drug manufacturers to sell low-priced medicines to covered entities, in the anticipation that these lower prices will, ultimately, help vulnerable populations receive more affordable care. By attempting to help vulnerable patient populations in such an overly complicated manner, the 340B program creates inefficiencies throughout the program as well as throughout the broader healthcare market.

These inefficiencies and distortions include: the abuse of the 340B program by covered entities; the incentive of covered entities to prescribe more expensive medicines; a shifting of drug costs onto non-340B patients that raises the prices these patients pay for medicines; and, an unwarranted consolidation of medical practices. Due to these inefficiencies, the 340B program worsens the quality of the overall health care system.

Fixing these problems requires remedies to the 340B program. From a political feasibility perspective, the most effective reforms would return the 340B program to its original purpose of solely benefiting those vulnerable populations who require the assistance, and impose stringent oversight over the 340B program to reduce fraud and abuse.

Growing Abuse in the 340B Program

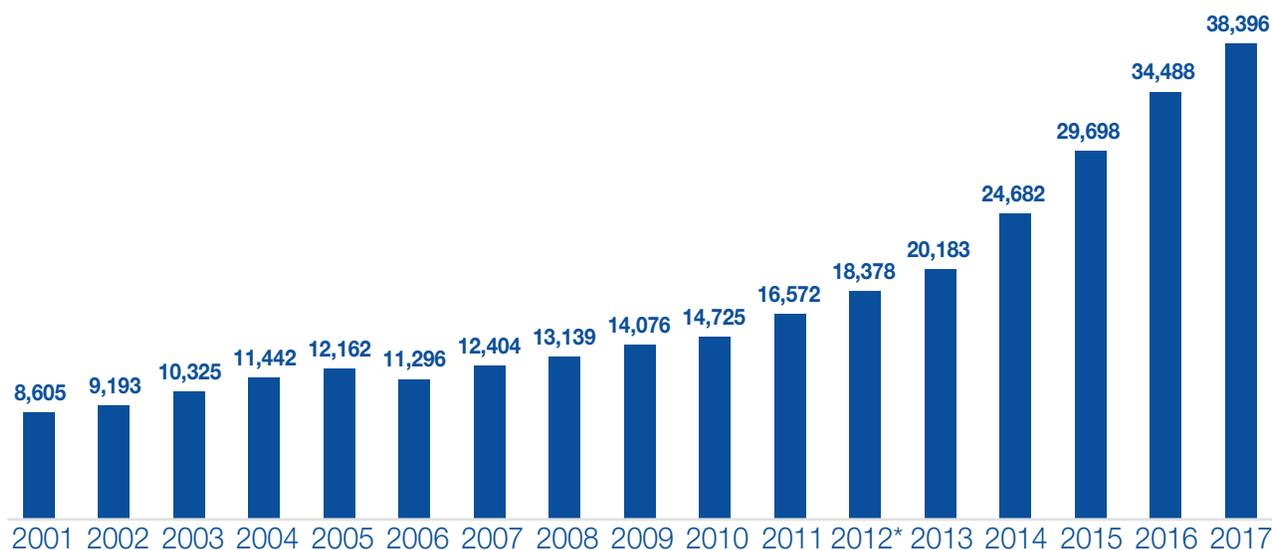
The 340B program has gotten off track in recent years because the federal statute governing the program provides limited guidance regarding how it is administered. Further, it does not require participating hospitals to provide the discounted drugs solely to people who are truly in need. And, because 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. The profit opportunity was accelerated by a combination of the Affordable Care Act (ACA), and recent guidance by the Health Resources and Services Administration (HRSA).

The ACA expanded the eligibility criteria enabling more hospital types to qualify for the 340B program. HRSA expanded its 1996 guidance in 2010, effectively creating the contract pharmacy program.⁴ Previously, HRSA only allowed safety-net clinics without an in-house pharmacy to contract out its pharmacy services to a retail pharmacy. The 2010 guidance allowed any covered entity, including large hospitals, to establish unlimited relationships with contract pharmacies.

This change was a clear example of administrative overreach given that contract pharmacies were never part of the 1992 law. Some hospitals have responded by building networks of hundreds of contract pharmacies that includes Walgreens, Rite Aid, CVS, and Wal-Mart⁵ – private, for-profit companies that clearly do not require government support. These eligibility expansions, coupled with the allure of government guaranteed profits, have encouraged adverse consequences, none of which are surprising.

First, both participation and total 340B sales have significantly expanded, raising the cost burden of the 340B program. The 340B program included 50 hospitals when it was created in 1992.⁶ Now, according to Barlas (2015) “about one-third of the hospitals in the country and a large number of federally-funded health clinics use the 340B program to generate revenue, in some cases millions of dollars, by selling discounted prescription drugs at outpatient clinics.”⁷

FIGURE 1: Number of 340B Covered Entity Sites 2001 - 2017



Source: Government Accountability Office

* The 2012 data point is extrapolated from the trend.

Evidencing this growth, the number of covered entity sites has grown to over 38,000 by 2017 – nearly three times the number of covered entity sites from just 10-years earlier, see Figure 1.⁸ Additionally, the estimated total drug sales in 2016 (valued at the 340B price) was \$16.2 billion, which was nearly 8 percent of the total branded, outpatient drug market, and has “grown by 125 percent in the last three years alone”.⁹

Further, contract pharmacies, such as Walgreens and CVS, represent an excessively large share of the growth in the 340B program, increasing from around 1,300 in 2010 to around 18,700 in 2017.¹⁰ As identified in a 2014 report from the Inspector General of the Department of Health and Human Services, contract pharmacies add “complications” to the 340B program.¹¹ These complications include diversion of 340B discounted medicines to non 340B-eligible patients, receiving duplicate discounts from both Medicaid and the 340B program when such duplication is prohibited, and not offering the 340B discounted price to uninsured patients, the *raison d’être* of the program. Summarizing these problems, the Alliance for Integrity and Reform of 340B (Summer 2014) (AIR 340B) noted that,

...there is little evidence to suggest that many vulnerable patients see any direct benefit from the expanding 340B contract pharmacy program, particularly because data indicates that neither the pharmacy nor the patient know that the transaction is “340B” at the point of sale. As a result, the patient often does not benefit from the covered entity receiving the 340B discounts. A lack of adequate program integrity standards and resources, coupled with seemingly unchecked growth in the number of contract pharmacy arrangements, has yielded a high-risk program with low rewards for patients that is ripe for reform. Additionally, the 340B contract pharmacy program may create disproportionate benefits and incentives for the largest retail pharmacies – often in wealthier areas – without demonstrating any tangible improvement in access to prescriptions for medically underserved Americans who should benefit from the program.¹²

Second, as exemplified by the problem of contract pharmacies not offering the discounted price to uninsured patients, the recent expansions of the 340B program are not reaching the targeted populations. While there are 340B hospitals, particularly the older 340B sites, that serve a disproportionate share of low-income patients, there has been a disconcerting trend of 340B hospitals serving higher-income and non-vulnerable patient populations to a greater extent. In a 2015 analysis of the 340B program, the Government Accountability Office (GAO) found that “12 percent of 340B DSH [disproportionate share] hospitals were among the hospitals that reported providing the *lowest* amounts of charity care across all hospitals in GAO’s analysis.”¹³

A study by Conti and Bach (2014) confirmed the GAO’s findings.¹⁴ Conti and Bach (2014) compared the communities served by covered entities before 2004, which was prior to a surge in enrollment, and after 2004 finding that

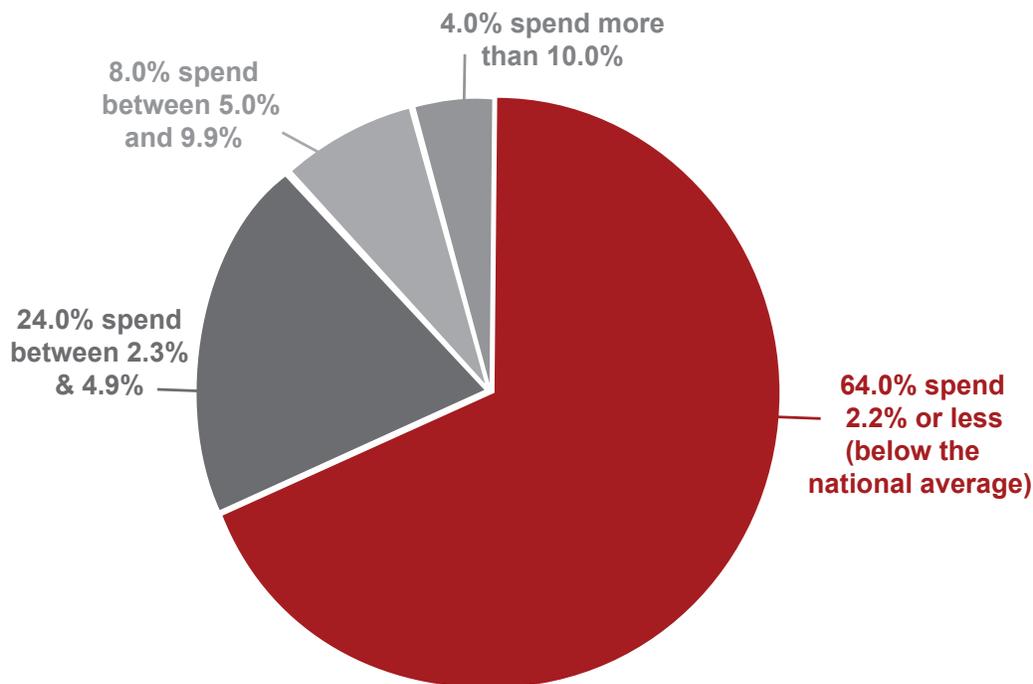
beginning around 2004, newly registered 340B DSH hospitals have tended to be in higher-income communities, compared to hospitals that joined the 340B program earlier.

We [Conti and Bach] also found that, compared to 340B DSH hospitals, their affiliated clinics tended to serve communities with socioeconomic characteristics that were more similar to the average U.S. community: The clinics served communities with lower poverty rates and higher mean and median income levels than their 340B DSH hospital parents did. These results suggest that the expansions among 340B DSH hospitals run counter to the program’s original intention.”¹⁵

Summarizing their results, Conti and Bach (2014) concluded that their “...findings support the criticism that the 340B program is being converted from one that serves vulnerable patient populations to one that enriches hospitals and their affiliated clinics.”¹⁶

Figure 2, reproduced from AIR 340B (Spring 2016), also supports the GAO’s finding that 340B hospitals are not necessarily serving the intended, at-risk populations.¹⁷ Figure 2 illustrates that, based on Avalere Health’s analysis of 2014 Medicare Cost data, the charity care spending as a percent of patient costs was below the national average (2.2 percent of patient costs for *all* hospitals) for nearly two-thirds of all 340B hospitals. Alternatively, as AIR 340B noted, “...more than one-third (37%) of 340B DSH hospitals provide charity care that represents less than 1% of their total patient costs.”¹⁸ Despite 340B’s unassailable intentions, the evidence clearly shows that the program is not serving its lofty goals in practice.

**FIGURE 2: Charity Care at 340B Hospitals as a Percent of Patient Costs
Based on 2014 Medicare Cost Report Data**



Source: Alliance for Integrity and Reform of 340B

Third, the growth and expansion of the 340B program is imposing additional distortions on the already heavily distorted U.S. health care market. These distortions include over-encouraging the use of higher-priced medicines, raising drug costs for non-340B consumers, and inciting unwarranted provider consolidation.

340B Encourages Covered Entities to Prescribe Higher Priced Medicines

The profit generating loophole in the 340B program exists because once a hospital is designated as a 340B covered entity, they can sell the medicine to all qualified patients of the covered entity, regardless of their income and insurance status. Since the 340B discounts are a percentage of a drug’s cost, providers earn more revenue when they prescribe the most expensive drug possible because more expensive medicines generate a larger dollar spread between the discounted 340B price and the reimbursed amount for the medicine. It logically follows that covered entities that prescribe more higher-priced medications, which were purchased at the discounted 340B price but reimbursed at commercially insured or Medicare rates, will earn more total revenues than if they sold fewer or less expensive medications.

Not only do these adverse incentives exist, they appear to be impacting prescribing behavior in practice. When evaluating the existence of these incentives, the GAO found (with respect to Medicare) that “there is a financial incentive at hospitals participating in the 340B program to prescribe more drugs or more expensive drugs to Medicare beneficiaries.”¹⁹ Since the GAO’s analysis controlled for patient health, the results were not driven by any differences in the proportion of sicker patients being seen at 340B hospitals compared to non-340B hospitals. Specifically, the GAO found 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.*²⁰

The GAO continued, stating that the

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.²¹

Similarly, the Pew Charitable Trusts, in an August 2017 letter to the Centers for Medicare & Medicaid Services (CMS) noted that while the disincentives exist throughout Medicare Part B, “...the current 340B payment methodology creates an incentive for hospitals to increase drug utilization.”²²

Conti and Bach (2013) concurred with these findings, noting, with respect to oncology, that “the availability of profits from administering expensive cancer drugs is known to alter physician prescribing behavior. This occurs because oncologists practicing in the out-patient setting generate profits from the difference between drug acquisition costs and insurer reimbursement and patient co-payments. For oncologists practicing in 340B-affiliated outpatient clinics, prescribing may shift toward more expensive drugs because profit margins will, in general, be larger.”²³

Drug Cost Shifting

Mandating that some hospitals and facilities receive a discount on medicines does not magically eliminate the economic costs of developing the medicines. As is always the case, when the government mandates that one group receives a benefit, those costs are paid by someone else. As the adage goes, there’s no such thing as a free lunch. As Conti and Rosenthal (2016) explain,

the scope of the 340B program is currently so vast for drugs that are commonly infused or injected into patients by physicians that their prices are probably driven up for all consumers. As pharmaceutical manufacturers face substantial and expanding demand for discounts on the acquisition prices of these drugs, they can and do pass the costs of these discounts on to other payers. Better targeting of the 340B program might improve affordability for patients in need while lowering prices for other payers.²⁴

These cost-shifting concerns are also shared by the GAO (2011), which argued 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.”²⁵

This cost shifting is initially borne by private insurance companies and pharmaceutical manufacturers, but the costs are not confined to just these entities. The costs created by the 340B program are ultimately integrated into the overall health care system and are manifested through:

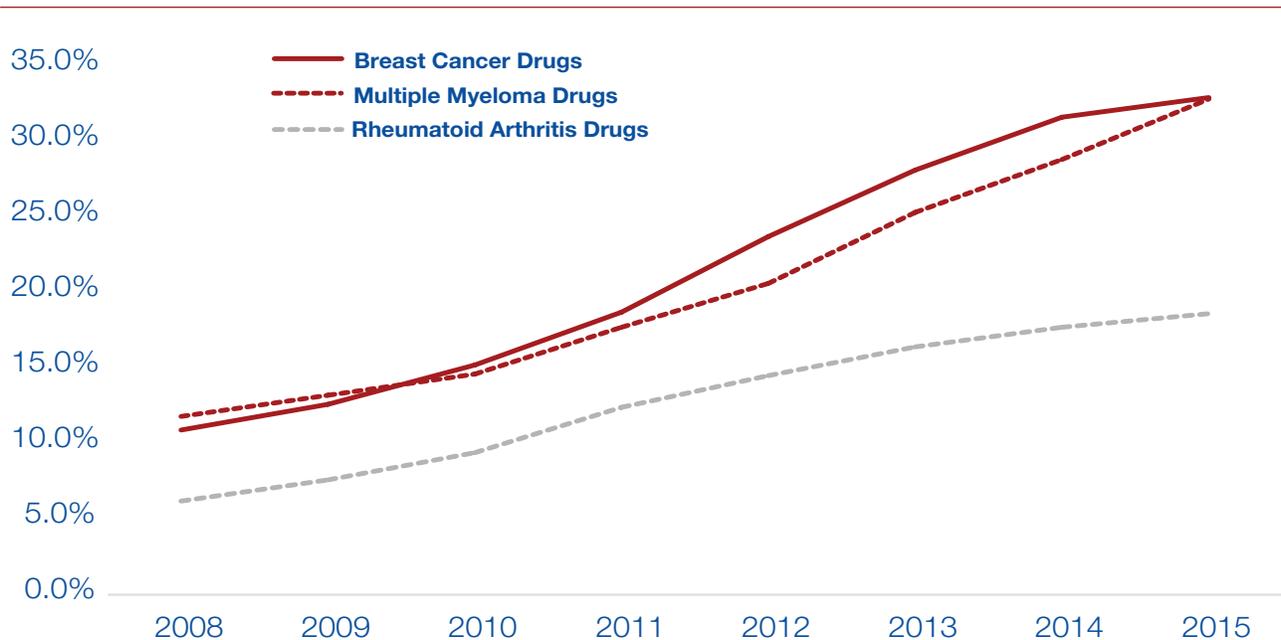
- Rising insurance premiums;
- Higher co-pays and deductibles; and,
- Rising medical costs in unrelated segments of the health care system.

Encourages Unwarranted Provider Consolidation that Creates Additional Cost Pressures

Under the rules of the 340B program, independent physician offices are not eligible for discounts on their purchases of medicines. However, hospital outpatient departments and their offsite outpatient facilities *are* eligible. This discrepancy in eligibility creates an incentive for hospitals to purchase independent practices and convert the previously independent practices into offsite hospital outpatient departments. This conversion transforms centers that were previously not eligible for the discounted medicines into centers that are now eligible for the discounts. The acquiring hospital can now reap the 340B enabled profit spread on a larger, and often times wealthier, patient population.²⁶

Vandervelde and Blalock (2017) document that as a result of this trend, there is a growing concentration of outpatient drug therapies at 340B hospitals, see Figure 3, while, at the same time, there has been a declining concentration of outpatient drug therapies at physician offices.²⁷

FIGURE 3: Growth in the Percentage of 340B Hospitals That Are Reimbursed in Medicare Part B for Administering Select Drugs 2008 - 2015



Source: Vandervelde and Blalock (2017)

Figure 3 illustrates that for the drug therapies investigated, the share of drugs dispensed at 340B hospitals have grown significantly for all three drug classes analyzed, and accounted for approximately one-third of all drugs reimbursed through Medicare Part B for breast cancer and multiple myeloma in 2015, compared to around 10 percent for both types of drugs in 2008. In contrast to the growth in 340B hospital settings, the share of drugs dispensed at physician offices declined between 2008 and 2015. These data indicate that while there are many reasons for M&A activity, gaining access to 340B drug discounts is an important consideration.

Conti and Bach (2013) also note the strong incentive to administer cancer drugs in 340B settings, directly linking the consolidation trends to rising health care costs. Specifically, they argue that

the 340B program creates a widening disparity between non-eligible and eligible hospitals and affiliated oncology practices in the profits they are able to obtain from the care of well-insured patients with cancer. This disparity is likely underlying trends toward consolidation and affiliations between community-based oncology practices and 340B eligible hospitals. This disparity may also lead to shifting of care out of community-based oncology practices and into hospital-based infusion suites. These trends will tend to increase total spending. Cancer care delivered in a hospital-based outpatient infusion suite is typically more expensive than that delivered in a physician's community-based office. Moreover, market consolidation may increase private insurance contracted rates and thus private insurance premiums and other patient costs.²⁸

Vandervelde and Blalock (2017), citing a 2017 report from Magellan, confirm the Conti and Bach (2013) findings that 340B drives care away from less expensive physician office settings into more expensive hospital settings, noting “that medical-benefit drug costs for these patients in the hospital outpatient setting cost more than twice as much as in the physician office setting. Due to these types of price differences, the hospital outpatient setting is typically the highest-cost setting for administration of medical benefit drugs.”²⁹

The current trend in hospital consolidation is well documented,³⁰ and 340B is by no means the only cause of the current consolidation trend. However, when the consolidation is driven by 340B considerations, it typically has adverse cost and quality implications. As a consequence, it is beneficial to eliminate the M&A incentives created by the 340B program in order to ensure that future hospital consolidations are based on fundamentals that can improve the costs and quality of the health care services delivered. These consolidations should not be based, even in part, on the potential profits that the 340B program can guarantee for covered entities.

Conclusion – Fundamental Reforms Are Necessary

Judging the 340B program on its outcomes, not intentions, reveals that the program is, at best, a very expensive and inefficient way to help vulnerable populations afford the medicines they need. It is, consequently, in desperate need of reform. The best politically feasible reform would return the scope of the 340B program to its original purpose of serving uninsured and low-income patients, and improve the oversight and administration of the program.

Specifically, Congress and the Administration should update the law governing the 340B program so that it clearly defines who qualifies for the discount; which should only include those patients who are truly in need. This would ensure that the subsidized drugs would only benefit the intended patients, and it would prevent covered entities from exploiting the program as a potential profit center. Non-340B patients would also benefit since drug prices would no longer reflect the cross subsidies necessary to offset the loss of revenue caused by the abuse of the 340B discount program.

Additionally, since the program is intended to help the vulnerable populations, measures should be adopted that ensure that the 340B savings are passed along to the uninsured patients when filling their prescriptions at the covered entities or their contract pharmacies. The possibility that these populations do not receive discounted prices when purchasing their medicines violates the entire spirit of the program. More stringent oversight practices should also be implemented to eliminate the proliferation of abuse in the program.

The market distortions created by the complex web of 340B regulations has led to negative consequences for health care consumers. Policymakers from both sides of the aisle should be able to agree that eliminating the abuses of the 340B program, and ensuring that the targeted populations actually benefit from the program, are reforms worth passing.

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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.

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