

340B Drug Discounts: An Increasingly Dysfunctional Federal Program

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Introduction

The 340B program requires drug companies to provide certain hospitals and clinics with drugs at significant discounts. The Health Resources and Services Administration (HRSA), a division of the U.S. Department of Health and Human Services, manages the program through its Office of Pharmacy Affairs. The program was established in 1992; hospitals and clinics were eligible to participate if they treated a certain percentage of Medicaid patients, which was thought to be a proxy for identifying entities that treated low-income uninsured patients. After its first decade, the program has undergone significant and likely unforeseen growth.

Significant Program Growth & Mission Drift

340B began as a worthy, targeted program that offered discounts to the low-income uninsured. Savings from these drug discounts also could be used, as HRSA describes it, to provide "comprehensive services" to vulnerable populations. At first, 340B largely fulfilled this mission. During its first 13 years, the program grew slowly, and by 2005 there were only 583 participating hospitals.²

Due to changes in the Affordable Care Act (ACA) that created incentives for hospitals to participate in the program, by 2019 the program had exploded in size and included more than 2500 hospitals with drug purchases totaling \$30 billion, accounting for 8 percent of all U.S. prescriptions.³ Since 340B participation is contingent upon the number of Medicaid patients that are treated, the vast expansion of Medicaid enrollment under the ACA allowed many more hospitals to become eligible for the program.

The 340B program would be difficult to criticize if the huge revenues from billions in drug sales were being used exclusively to assist low-income uninsured populations. But the data actually suggest that, as the program has grown exponentially, these populations are being helped less and less.

One estimate from the Berkeley Research Group projects that by 2026, 340B will be the largest federal drug program, eclipsing gross drug sales of both the Medicare and Medicaid drug programs. More specifically, as the number of 340B sites expanded to 30,000 between 2009 and 2015, there should have been significant improvement in low-income patients' ability to afford their prescription drugs. But the opposite seems to have happened: at a time of explosive growth in 340B, it became significantly more difficult for low-income populations to afford prescription drugs.

It is now difficult to characterize 340B as a program with the primary mission of providing low-income, uninsured patients with discounts on drugs, nor is it clear that the bulk of "savings" from the 340B program are channeled to "comprehensive services" for vulnerable populations. Many hospitals now use the program as for-profit retail arbitrager might, buying drugs at a low price through the 340B program and then reselling them to government and commercial payers at much higher prices. Many hospitals have discovered this profitable tactic, and their revenues from the program are soaring, not only at the expense of pharmaceutical companies, but with little benefit for those the program was designed to help. The irony is that a program that was intended to reduce drug costs for lower income populations now displays overwhelming incentives not only to prescribe more drugs, but also to prescribe more expensive drugs as hospitals generate more revenue from pocketing the spread on costlier drugs.

The hospitals have been creative in adopting arbitrage to drive their revenues, and there is significant evidence that the original mission of the 340B program — drug discounts and other services for the low-income uninsured — has taken a back seat to revenue generation. One recent study concluded that, with its significant recent expansion, the 340B program generated \$40 billion in profits during 2019 for hospitals, pharmacies, "and possibly patients (in the form of reduced-price medicines)." ⁵

The hospitals have expanded in significant ways to capitalize on this revenue opportunity. There is considerable evidence that the 340B program has caused hospitals to acquire community-based physician practices, such as oncology practices, in affluent areas.⁶ When hospitals are able to capture wealthy patients through these satellite offices, their arbitrage is more effective since

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the hospital can resell a 340B drug to a wealthy patient's commercial health plan or Medicare and then pocket the significant spread between the 340B price and the health plan reimbursement. According to the Government Accountability Office (GAO), "about three quarters of the approximately 37,500 covered entity sites participating in the program are affiliated with hospitals." It is unclear how the purchase of physician practices in affluent communities represents the expansion of "comprehensive services" to vulnerable populations.

The hospitals do not see it that way. They point to the many genuinely worthy programs they support and claim that these programs would not be possible without the 340B program. For example, 340B Health, the lobbying group for the hospitals, put out a press release late last year arguing that essential programs for low-income patients were being funded by the 340B program: "340B savings from drug company discounts go toward effective programs that are tailored to the needs of patients with low incomes and those who live in rural parts of our country. The fact that 340B accomplishes all this without relying on taxpayer dollars is a significant accomplishment."

Interestingly, the press release does not highlight the hospitals' success in passing along 340B drug discounts to uninsured patients, it simply highlights "programs" that do not have budget figures associated with them. Also, there is a mischaracterization of the revenues obtained through arbitraging the 340B discounts, which are described as "savings," not as revenue. The release goes on to describe some of those programs: "One hospital might provide home visits for heart failure patients, while another might integrate pharmacy support into hepatitis C care teams, while yet another might connect low-income HIV/AIDS patients with housing assistance."

When these programs are described in this anecdotal fashion, there is little accounting as to whether, as revenues from the 340B program exploded, the growth of those "comprehensive services" corresponded with that of 340B revenues. Anecdotes about admittedly worthy programs managed by these hospitals do not provide an accounting of how specific 340B revenues fund a variety of "comprehensive services" that cost the equivalent of those 340B revenues.

Without an accounting of how this growing 340B revenue is being spent, we cannot verify whether the "comprehensive services" offered to vulnerable populations have expanded at the same rate as the hospitals' 340B revenue. In fact, there is some evidence that, as 340B revenue has expanded exponentially, services provided to vulnerable populations have declined. One recent study concluded that "it is evident that the ability of people suffering severe economic hardship to afford needed medicines and medical care, relative to the general population, is negatively correlated with growth in the 340B program."

Another set of players that are now profiting from the 340B program are massive for-profit pharmacy chains. In 1996, HRSA provided guidance to hospitals that 340B drugs could only be dispensed through the hospital's in-house pharmacy or a single external contract pharmacy. In 2010, HRSA revised that guidance to allow hospitals to use an unlimited number of contract pharmacies.

Early in the program, the number of participating pharmacies could be counted in the hundreds, but 30,000 pharmacies now participate. Many of these are highly profitable chains such as CVS and Walgreens. Between June 2020 and June 2021, the number of participating pharmacies grew by an astonishing 2000. Of Given the desire of hospitals to arbitrage 340B drugs and resell as many as possible, the growth in pharmacy participation is understandable. And, in order to drive sales, 340B hospitals make it profitable for pharmacies to participate. As the well-respected drug policy blog *Drug Channels* describes pharmacy profits in 340B: "These profits are much higher than a pharmacy's typical gross profit from a third-party payer—especially when a 340B entity shares a portion of its 340B earnings with the pharmacy."

Unfortunately, the story of the 340B program is one that is all too common inside the Beltway: congressional policy makers develop a program to meet a genuine unmet need of low-income people, in this case making their drugs more affordable. However, the program is then designed in such a way that it is the vendors implementing it that benefit more than the low-income people the program was intended to help. Despite the program's obvious shortcomings, those vendors form a lobbying coalition that succeeds in expanding the program, making it even more profitable for the vendors, while the low-income uninsured fall even further behind. In the case of 340B, the

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program expanded to maximize the arbitrage of drug discounts to drive hospital revenues, not to expand services for the low-income or provide them with drug discounts.

Most unfortunately, the tens of thousands of hospitals and pharmacies that now benefit from the arbitrage of 340B discounts are a powerful lobby, so the prospects of reform are uncertain. As prominent local employers in many congressional districts, the 340B hospitals are certainly a more powerful lobby than low-income uninsured patients. In fact, 340B Health, an advocacy group for the program, sends out lists of 340B hospitals in each state and provides the corresponding member of Congress for each hospital.¹²

A Dubious Legislative Construction

The statute that created the 340B program is one of the most poorly constructed federal statutes of recent decades. Section 340B of 42 U.S. Code, is titled, "Limitation on prices of drugs purchased by covered entities." The lion's share of the statute is devoted to the level of drug discounts that must be provided by manufacturers to hospitals and clinics and how the government can check on the compliance of those participating in the program, especially the manufacturers. The statute does contain a lengthy definition of "covered entities" that can access these discounts, i.e., hospitals and clinics. But one must *infer* from this list of covered entities that the program is intended to help lower-income and uninsured populations because the entities listed in the statute serve a disproportionate share of this vulnerable population.

The infirmities in the statute are considerable. It does not define which patients should be eligible for drug discounts, making it possible for hospitals to prescribe 340B drugs to wealthy, commercially-insured patients. The statute does not require that savings and revenue from the program be devoted to programs that serve vulnerable populations. As we have seen from the legislative history, but not the statute, Congress did expect the program to fund "comprehensive services" for vulnerable populations, but there is no requirement that 340B revenues be devoted to such services. Moreover, those "services" are never defined. Again, one can infer from the statute that the common denominator of the "covered entities" that are permitted to participate in the program are that they serve lower-income uninsured populations, and therefore any "services" funded by the 340B program should be devoted to these populations—but this is only an inference, not a requirement. Finally, there is no requirement that the "covered entities" that participate in the program be located in areas that serve a high percentage of vulnerable patients. One would think that the statute would have been constructed to enroll 340B entities that would make it more likely that patients who sought emergency care at a 340B entity would be low-income and uninsured. As we have seen, as the program has grown, 340B entities are now less likely to be located in a medically underserved area.

In short, the only thing the 340B statute requires is this: drug manufacturers must provide substantial discounts to certain hospitals and clinics. It is no wonder that hospitals soon learned that they could arbitrage these discounts by treating wealthier and well-insured patients and that maximizing revenue, and not charity care, became the primary goal of many hospitals participating in the program.

340B Growth and Trends in Charity Care

A key question for the 340B program is whether the exponential growth in revenues for hospitals and clinics has led to a similar increase in the level of charity care provided to low-income uninsured patients. More specifically, can policymakers have a high degree of confidence that the vast majority of this new revenue has been devoted to drug discounts for vulnerable populations as well as improved programs and services for that population.

The enactment of the Affordable Care Act (ACA) made it likely that more patients would be entering hospitals with some form of health insurance. The combination of the ACA and the growth of the 340B programs should have increased healthcare access to low-income populations

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exponentially. The general consensus of the research is that, in the period after enactment of the ACA and the explosive growth in 340B, discounted drugs and community health services were *more* difficult to obtain. One study from the *New England Journal of Medicine* indicated that, in certain specialty areas the growth of the 340B program has not helped vulnerable populations: "Financial gains for hospitals have not been associated with clear evidence of expanded care or lower mortality among low-income patients.¹³ One Avalere study commissioned by the drug industry concluded that, "In total, 63% of 340B hospitals provide less charity care than the national average for all short-term acute care hospitals, including for-profit hospitals."¹⁴

The central problem in arriving at a definitive conclusion about this important question is related to the statutory language of 340B: there is no adequate definition of the services for low-income patients that the law seeks to improve. The 1992 House report issued along with the 340B legislation simply states that the program was created, "to enable [covered] entities to stretch Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." The Affordable Care Act added a new requirement that hospitals must conduct an assessment of the community's needs and promulgate policies related to charity care, but there is no requirement that these entities offer a certain level of charity care relative to 340B income or expenses. ¹⁶

While the congressional intent of the statute is that 340B revenues support safety-net care for vulnerable populations, there is **no** requirement in the law that 340B revenue be used in this way. A 2009 law required that hospitals report their "community spending" to the IRS, "broken out for charity care, the cost of unreimbursed Medicaid care and community improvement programs." ¹⁷

In fact, there is some evidence that, as 340B revenue increased, charity care provided by non-profit hospitals may have declined. The first indication that the program may not be serving the most vulnerable populations began to appear after 2004, when data became available suggesting that 340B hospitals were increasingly located in areas where fewer vulnerable patients could be found. As the program expanded after 2004, fewer large, public hospitals were enrolled in the program. One University of Southern California study concluded, "These results suggest that hospitals that began participating in the 340B program after 2004 are more likely to serve wealthier and more insured populations, which is counter to the original intent of 340B savings being used to support care for vulnerable populations. This USC study's conclusions seemed corroborated by another recent study that concluded, "a dismal 38% of 340B disproportionate share hospitals (DSH) are located in medically underserved areas (MUAs) as defined by the Health Resources and Services Administration, despite their mission of 'serving a significantly disproportionate number of low-income patients."

In addition, the data indicate that the rapid expansion of the 340B program brought in hospitals that provided less charity care. "These post-2010 participants tend to be smaller and provide little more uncompensated care than nonparticipants. Most importantly, they tend to take efforts to increase their DSH patient percentages to the minimum level to qualify for the program and no further." In other words, these hospitals draw in Medicaid patients to meet the 340B eligibility requirements and, once they are enrolled in the program, make little effort to expand services for low-income patients.

According to data from the American Hospital Association: "Total uncompensated care fell to a 25 year low in 2015 and held steady in 2016." Another study in the *Journal of the American Medical Association* found that the wealthiest nonprofit hospitals provided "disproportionately low levels of charity care." That same study indicated that the Affordable Care Act's expansion of Medicaid eligibility in many states caused nonprofit hospitals in those states to provide "less charity care than hospitals in other states."

The most troubling recent report about charity care and nonprofit hospitals was published in *Health Affairs* in April of 2021. This large study considered charity care data on 4,666 acute care hospitals (1024 government, 2709 nonprofit and 930 for-profit). That report concluded that nonprofit hospitals spend less on charity care than government or for-profit hospitals. Using 2018 data from Medicare Hospital Cost Reports, the study concluded that, "in aggregate, nonprofit

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hospitals spent \$2.3 of every \$100 in total expenses incurred on charity care, which was less than government hospitals, (\$4.1) or for-profit (\$3.8) hospitals."²³

Shockingly, the report seems to conclude that the government may wish to revisit the generous tax treatment of nonprofit hospitals, which is predicated upon obligations to provide more charity care than for-profit hospitals. "These results suggest that many government and nonprofit hospitals' charity care provision is not aligned with their charity care obligations arising from their favorable tax treatment."

This also raises the question of how many nonprofit hospitals that are failing to meet their charity care obligations continue to be "covered entities" under the 340B program.

340B and Medicaid

Data on charity care and community program spending are reported by hospitals on their IRS Form 990, Schedule H. Another study that examined IRS data confirmed the *JAMA* study's conclusion that Medicaid expansions were associated with lower charity care expenditures. That study concluded that "program (Medicaid) expansion was associated with lower uncompensated care costs and also higher Medicaid payment shortfalls for hospitals. Hospitals in non-expansion states saw only small post-ACA changes in their long-term trends for either uncompensated care or payment shortfalls."²⁴

The significant expansion of Medicaid should have caused policy makers to reconsider the 340B program, as many uninsured patients that 340B was intended to help were now insured through Medicaid. The Affordable Care Act significantly expanded Medicaid eligibility, causing enrollment to balloon by 14 million between the summer of 2013 and the beginning of the COVID pandemic in March of 2020.²⁵ The pandemic caused another spike in Medicaid enrollment, with the Kaiser Family Foundation reporting that between March 2020 and June 2021, Medicaid/CHIP enrollment increased by 12 million.²⁶ Medicaid enrollment is now 83 million, compared to about 71 million at the beginning of the pandemic. In 2012, prior to the pandemic and the ACA, Medicaid enrollment was 54 million.²⁷

Recent trends have indicated a substantial decline in the number of uninsured. As Medicaid expansions were implemented, the number of uninsured declined by 20 million from 2010 to 2016. Between 2017 and 2019, there was a slight uptick in the number of uninsured to 32.8 million non-elderly patients, but this is still below the 35.7 million uninsured in 2014.²⁸ The bottom line is that the number of uninsured fell from 48.2 million in 2010 to 30 million in 2020.

Given that 340B is intended to help the low-income uninsured population, one would have expected a decline in the size of the 340B program during these significant declines in the number of uninsured. Yet, the opposite happened, between 2010 and 2020, "the number of participating covered entities grew by 50%, from 3,600 unique covered entities to more than 5,000. However, the number of *sites*—provider locations affiliated with these entities—grew seven times over within the same period."²⁹ These data points are another indication that the 340B program is increasingly unmoored from the population it was intended to help.

Disrupting Community-Based Care

The 340B program has obvious incentives that cause hospitals to acquire physician practices in wealthy communities and designate these practices as "child sites," eligible for 340B discounts. This allows the hospitals to arbitrage those discounts with reimbursements from commercial health plans. Once again, studies have pointed to the expansion of 340B as corrupting the original mission of the program by incentivizing hospitals to expand their suburban presence in order to treat wealthier patients. One study concluded that, "DSH hospitals that registered for the 340B program in 2004 or later served communities with fewer low-income people compared to DSH hospitals that registered before 2004." This study made the obvious point that the acquisition of physician practices in wealthy areas allowed 340B hospitals to "generate profits by prescribing drugs to patients who have private insurance or Medicare."

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The acquisition of community-based physician practices has expanded significantly because of the arbitrage incentives in the 340B program. Certain specialties—oncology gastroenterology, and neurology—are particularly attractive acquisition targets because of the expensive drugs these practices tend to administer. One study found that "approximately 51% percent of oncology practices and 30% of rheumatology, gastroenterology and neurology practices that were independent in 2007 had vertically integrated by 2017." ³¹

The growth in the number of hospitals participating in the 340B program has, as one would expect, led to exponential growth in the number of "child sites," many in wealthier areas. "Between 2010 and 2017, the number of enrolled 'parent entities' has increased by over 30 percent. When including 'child sites,' the program grew over the same period by 60% to include 42,029 sites (12,722 parent sites and 29,307 associated sites.)" ³²

This acquisition and consolidation of community-based physician practices has, not surprisingly, led to increased costs. Hospital outpatient care is typically much more expensive than care delivered in a community-based physician-owned practice. As one study put it, "Care in hospital outpatient settings is notoriously more expensive overall. One study funded by the pharmaceutical industry indicated that hospitals markup medicine to five times their acquisition costs for outpatient medicines, and commercial payers reimburse these drugs at rates that are 252 percent of average hospital acquisition costs (without factoring in 340B discounts)."33

A GAO study found that 340B hospitals tended to prescribe more drugs, and more expensive drugs than other types of hospitals: "GAO found that 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." The irony is that a program intended to provide discounted drugs is actually incentivizing hospitals to prescribe more and more expensive drugs.

Consider the Medicare Part B program and how it may drive incentives for 340B hospitals to prescribe more expensive drugs. Medicare Part B reimburses physicians and hospitals for outpatient drugs at 106 percent of Average Sales Price (ASP), a figure determined by actual revenues that manufacturers secure from sales of the drug. Yet, 340B hospitals acquire these drugs at significant discounts but they are reimbursed at the same Medicare rate as non-340B hospitals and physician practices. Therefore, the more expensive the drug, the more potential revenue that is secured by the 340B hospital since the reimbursement by Part B will total 106 percent of ASP.

For example, if the ASP of a drug is \$50,000, Medicare will reimburse the hospital at \$53,000 for the drug (106 percent of ASP). If the hospital had acquired that drug at a 340B discount of 50 percent, or about \$25,000, then the profit for the hospital on that one drug would be approximately \$28,000. But consider how a more expensive drug will drive hospital revenue. For a \$100,000 drug, the Part B reimbursement will be \$106,000. If the hospital acquired the drug at the same 340B discount of 50 percent, then the profit would be \$56,000 on that one prescription.

The financial implications for the healthcare system involve more than drug costs. By driving more patients to hospital outpatient settings, the 340B program will drive up the cost of care overall. As one University of Minnesota study put it: "In the end, this policy will ultimately end up increasing health care costs for everyone, as patients are shifted from cheaper, community-based care to more expensive hospital settings and unnecessarily prescribed the most expensive drugs so 340B facilities capture the largest profits." ³⁵

The Troubling Growth of Contract Pharmacies

HRSA issued guidance in 1996 allowing hospitals and other "covered entities" to dispense 340B drugs through an in-house pharmacy or a *single* external pharmacy that would contract with the hospital. However, in 2010, HRSA allowed hospitals and other covered entities to contract with an unlimited number of outside pharmacies that could purchase and dispense 340B drugs.³⁶

This acquisition and consolidation of community-based physician practices has, not surprisingly, led to increased costs.

The result was an explosion in the number of pharmacies purchasing and dispensing 340B drugs. One study documented that HRSA's new guidance to allow unlimited contract pharmacies has "led to a 4228% increase in the number of participating pharmacies from 2010 to 2020." One recent study documented that: "In January 2010, fewer than 1,300 unique locations acted as 340B contract pharmacies. As of June 2021, DCI found 29,971 unique locations acting as 340B pharmacies." That same study indicated that for-profit pharmacy chains CVS and Walgreens now have a huge stake in 340B, with 80 percent of all Walgreens stores and two-thirds of CVS stores serving as 340B pharmacies.

This profitable arrangement for pharmacies was confirmed by a June 2018 GAO audit. "GAO's review of 30 contracts found that all but one contract included provisions for the covered entity to pay the contract pharmacy a flat fee for each eligible prescription. The flat fees generally ranged from \$6 to \$15 per prescription, but varied by several factors, including the type of drug or the patient's insurance status. Some covered entities agreed to pay pharmacies a percentage of the revenue generated from each prescription."³⁹ Of course, when pharmacies are paid as a percentage of the revenue from each prescription, they display the same arbitrage incentives of the covered entities, i.e., the more expensive the drug, the wider the spread between the 340B price and the reimbursement price, and the greater the revenue.

This explosive growth in the number of contract pharmacies ushered many for-profit entities into the 340B program. As a USC study documented, "large retail pharmacy chains—Walgreens, CVS, Walmart and Rite Aid—are disproportionately represented among contract pharmacies and together accounted for just over 60% of locations in 2020."⁴⁰

As one would expect, the rush into the 340B program by for-profit firms has likely been driven by one factor: profit-seeking. As one pharmacy expert described the retail pharmacy incentives in the 340B program, "Pharmacies profit from per-prescription fees paid by a 340B qualified entity. These profits are much higher than a pharmacy's typical gross profit from a third-party payer—especially when a 340B covered entity shares a portion of 340B earnings with the pharmacy." ⁴¹

At these contract pharmacies, patients and health plans (both commercial and Medicare) end up providing a significant amount of the profits earned by the pharmacies. As one pharmacy expert put it, "340B prescriptions at contract pharmacies cannot be identified at the time of adjudication." When a patient fills a prescription at one of these pharmacies, the prescription cannot be readily identified as a 340B drug that brings a significant discount. So, the health plan or Medicare Part D will reimburse the drug at the full price, not knowing that the pharmacy and hospitals purchased the drug at, for example, a discount of 75 percent or more. Moreover, the patient's copay or coinsurance will not be lowered because the drug was purchased at a 340B discount; the patient's out-of-pocket costs will be based upon the faulty assumption that the prescription is being filled at the standard, not the discounted, price.

Retail pharmacies are not the only for-profit entities benefitting from the 340B program. The \$472 billion for-profit pharmacy benefit management (PBM) industry, led by Cigna, CVS Health and UnitedHealthcare, is also reaping significant profits from the 340B program.⁴³ These profits derive from the fact that PBMs own a significant portion of the nation's "specialty pharmacies"—those that infuse or inject drugs that are many times more expensive than the pills a patient picks up in a yellow bottle at the pharmacy.

As with retail pharmacies, hospitals write contracts with specialty pharmacies that offer lucrative fees and allow the specialty pharmacy to share in a percentage of the revenue secured by the hospitals' arbitrage of the 340B discount. As one pharmacy expert notes, under these contracts, "the contract pharmacy earns profits that are three to four times larger than a specialty pharmacy's typical gross profit from a third-party payer."44

PBMs have also found that their large mail order business can benefit significantly from 340B discounts. Mail order purchases of non-340B drugs have shown healthy average growth rates of about 9 percent; mail order purchases of drugs eligible for 340B discounts grew at an annual rate of 56 percent between 2017 and 2020.⁴⁵

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While it is troubling that huge for-profit companies are securing billions in profits from a program intended to help low-income and uninsured patients, perhaps more troubling is that the 340B contract pharmacy world is rife with violations of federal law. This law-breaking comes in the form of "duplicate discounts."

The law creating the 340B program explicitly banned 340B entities from billing drug manufacturers for multiple discounts. For example, a Medicaid patient treated at a 340B hospital goes to the pharmacy to fill her prescription. The pharmacy is a 340B pharmacy and the drug has been bought by the hospital at a 50 percent discount under the 340B program. For simplicity's sake, let's say the hospital has paid \$50 for the drug that, to other customers, costs \$100. At the pharmacy counter, the patient presents the pharmacist with her Medicaid managed care drug card. The patient's prescription comes with a manufacturer's rebate of 60 percent, a percentage not uncommon for Medicaid drugs.

Under the duplicate discount problem, the hospital has paid the drug manufacturer \$50 for the drug, but the manufacturer receives an invoice to pay Medicaid a \$60 rebate under the federal rebate law. This hypothetical prescription has cost the drug manufacturer \$10, i.e., the manufacturer loses money every time its prescription for their drug is filled.

This type of arrangement is illegal under the 340B statute but, despite this fact, hospitals, contract pharmacies and others benefitting from this arrangement have not fixed the problem, even after multiple reports by federal watchdogs, including the GAO and the USHHS Inspector General. 46, 47, 48 While the OIG and GAO have highlighted the duplicate discount problem for more than a decade, their recommendations have gone unheeded. Here is the GAO recommendation from 2018 that has yet to be acted upon: "The Administrator of HRSA should issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care, working with CMS as HRSA deems necessary to coordinate with guidance provided to state Medicaid programs."

Federal Policy Recommendations

The 340B program is obviously in need of significant reform. A program intended to help low-income patients and the uninsured has become a cash cow for those administering the program, including multibillion dollar for-profit companies.

1. Require hospitals to report revenues from 340B programs

Along with more reliable reporting of charity care expenditures, hospitals and other covered entities should be required to report *all* revenues generated through the 340B program. Contract pharmacies participating in the program should have similar transparency obligations. Advocates for the 340B program issue many press releases and reports citing anecdotal examples of charity programs that assist vulnerable populations. These press releases and reports do not reliably report the *amount* of revenue secured each year from the 340B program and how much of that revenue finds its way to charity care discounts and programs. As this report has documented, 340B revenue has exploded in recent years and policy makers should have reliable assurances that this revenue is being deployed to assist vulnerable populations. In short, there should be full transparency regarding the amount of revenue flowing into covered entities from the 340B program and how, specifically, all that revenue is being spent.

2. Require covered entities to spend all revenues from 340B programs on charity care and community programs. In addition to simple transparency, covered entities should be required to spend all revenues generated through 340B programs on two things: drug discounts for vulnerable populations and charity care programs for those same populations. Congress should specifically define "vulnerable populations" in statute so 340B revenues cannot be used to replace uncollected debts from wealthy patients or to subsidize other non-charity care obligations.

Along with more reliable reporting of charity care expenditures, hospitals and other covered entities should be required to report all revenues generated through the 340B program.

3. Define patients eligible for drug discounts and charity care programs

There is considerable evidence that many hospitals have adopted conscious strategies to open "child sites" in upper income areas to arbitrage 340B discounts. This strategy runs counter to the original goals of the authors of the 340B statute. The program was not intended to help the wealthy access discounted drugs to drive hospital revenue. Congress should, by statute, precisely define the income categories of patients who are eligible for discounted 340B drugs and for charity care assistance. For example, patients enrolled in the Low-Income Subsidy (LIS) program in Medicare Part D should be automatically eligible for charity care programs and assistance as should patients enrolled in the Qualifying Individuals (QI) Program in Part B. Middle- and upper-income patients should not be eligible for discounted drugs or charity care programs and programs that serve middle- and upper-income populations should not be counted as charity care.

4. Disqualify child sites in wealthy areas from the 340B program

Given the obvious strategy of many hospitals to locate child sites in wealthy areas to bring 340B discounts to upper income patients, Congress should render child sites ineligible for 340B if the neighborhoods where they are located do not meet certain federal thresholds for impoverished areas. Congress should study the recent growth of child sites to determine if they are being located in areas with median incomes above 120 percent of the poverty level. If these sites are being located in higher income areas, Congress should consider legislative solutions to refocus the placement of child sites.

5. Standardize the definition of charity care and community programs

Congress should promulgate, by statute, a strict and reliable definition of "charity care." 340B entities are required to report their charity care amounts on various federal filings such as IRS 990 forms and Medicare (CMS) Cost reports. The problem is that the figures that land in those filings are quite opaque. For example, if a commercially insured patient fails to pay the coinsurance payment for an infused drug, can a hospital write off that debt as "charity care?" It appears that some hospitals may count this as charity care, while others do not. A standard definition and stricter reporting requirements are sorely needed so policy makers can have some assurance that the vast, and rising, revenues from the 340B program are benefitting needy populations.

6. Reform disproportionate share hospital eligibility requirements for 340B programs

When the Affordable Care Act (ACA) was passed, Medicaid eligibility underwent a significant expansion (as described above). Since institutions acquire 340B eligibility based upon their level of care for Medicaid patients, thousands of new covered entities were created by the ACA.⁵⁰ This Medicaid threshold seems an inexact method for establishing 340B eligibility. Medicaid patients are, after all, insured patients. We would recommend that Congress establish different eligibility requirements for 340B participation that are more closely related to the level of care provided to the uninsured and truly low-income populations.

7. Convert 340B discounts to rebates

As described above, duplicate discounts are not only a violation of federal law, but quite common in the 340B program. One pharmacy software provider found \$100 million in duplicate discounts in just a sample of claims that they analyzed. They believe the number of duplicate discounts runs much higher than \$100 million. They propose a simple solution to this problem: rather than offering 340B drugs through a discount program, provide rebates after adjudication to secure the 340B price. This software company points out that the AIDS Drug Assistance Program (ADAP) receives its 340B discounts in the form of a rebate and therefore they are able to ascertain when a duplicate discount may occur. Fraud is a significant problem in federal healthcare programs and when federal law is flouted—as it blatantly is with duplicate discounts—it sends the message that the federal government is not serious about enforcing laws it enacts.

Congress should promulgate, by statute, a strict and reliable definition of "charity care."

PART II: Trends in Charity Care in a Sample of Massachusetts' Hospitals

According to data from the program's administrator, the Health Resources and Services Administration (HRSA), purchases of discounted 340B drugs have more than quadrupled in value since 2014.⁵² The pharmacy blog *Drug Channels* submitted a FOIA request to HRSA indicating: "The compound average growth rate for the program was 27% from 2014 through 2020." Drug purchases under the program reached at least \$38 billion in 2020, and the program now exceeds the size of the Medicaid program's outpatient drug sales. According to the authoritative consulting firm IQVIA, the non-discounted value of the drugs running through the 340B program was \$80.1 billion in 2020, with for-profit contract pharmacies responsible for 30 percent of the program.

Given the explosive growth in 340B revenues flowing into "covered entities," such as hospitals, between 2014 and 2020, we wanted to examine the trends in charity care for a sample of Massachusetts hospitals. The sample was chosen based exclusively upon geography, not size or level of charity care. However, two hospital groups, Boston Medical Center, and the Cambridge Health Alliance (which consists of Cambridge Hospital and Everett Hospital) were included in the sample because they consistently provide the highest level of charity care in the state, and we wanted to examine their trends from 2013–2020.

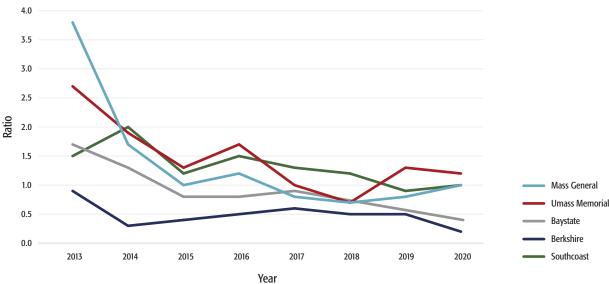
The level of charity care was taken from Medicare Hospital Cost Report Worksheet S-10, column 3, line 23 for each institution, which includes charity care for both the uninsured or patients with coverage from an entity that does not have a contract with the provider and insured patients on commercial insurance or a public program with a contract with the provider. As explained in other research, the charity care, "for uninsured patients is measured as the cost of the services (the charges for the services multiplied by the hospital's cost-to-charge ratio) offset by any partial payments. Charity care for insured patients consists of the amount owed for deductible and coinsurance payments written off by the hospital according to the hospital's charity care policy without expectation of payment, offset by any partial payments, after certain adjustments. This cost-based measurement of charity care mitigates the risk that hospitals with high charges report inflated charge-based charity care."⁵³

There are many methods that could be used to compare charity care levels between institutions of different sizes; this paper calculates charity care amounts relative to revenue in an effort to allow for a more apples-to-apples comparison. We acknowledge that there may be some limits to this method, but felt that looking at the same comparison over time provides an important picture of the changes happening with charity care levels.

In our sample of hospitals, there was an unmistakable trend: charity care has been declining significantly since 2013 in a number of important hospitals across the state. Massachusetts General Hospital, the largest hospital in Massachusetts with over 23,000 employees, saw a decline in spending on charity care from 3.8 percent of patient revenues in 2013 to just 1 percent of patient revenues in 2020. In every hospital in our survey, the high-water mark for the provision of charity care to the community peaked in either 2013 or 2014. Five regional hospitals saw declines of 50 percent or more.

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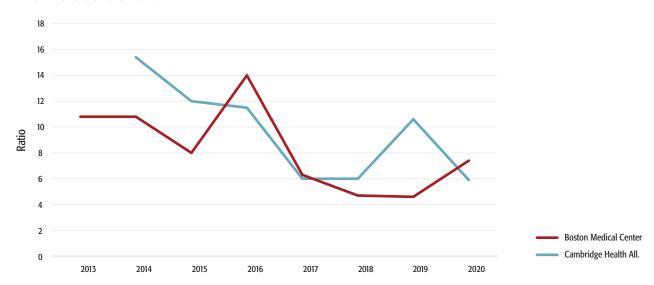


Some of these declines could be due to Medicaid expansions enacted as part of the Affordable Care Act. That law expanded Medicaid eligibility to new segments of the population and raised the income threshold for Medicaid eligibility. On the federal level, that expansion took effect on January 1, 2014. However, states could also "opt-in" to the more generous expansions of Medicaid eligibility, which Massachusetts chose to do when Governor Deval Patrick signed legislation in August of 2013. States choosing to expand their Medicaid programs received more generous federal matching funds.⁵⁴

These figures raise a significant policy issue for the 340B program. Purchases through 340B rose from \$9 billion in 2014 to \$38 billion in 2020. It seems beyond doubt that Massachusetts hospitals would have secured a significant increase in revenue during this expansion of the 340B program. Why, then, did we not see a significant rise in the provision of charity care during this period? One can point to the expansion of Medicaid as a factor, as more patients would have entered the hospital with insurance. Yet, if there was a declining need for charity care, why did the 340B program expand so exponentially? Shouldn't the program have witnessed a decline when the populations it was intended to serve gained insurance coverage?

For the two hospitals chosen in our survey based upon their generous rates of charity care, the declines were not as pronounced and seem not to have been directly related to Medicaid expansion. For example, the Cambridge Health Alliance's high-water mark for charity care was in 2014, when 15.4 percent of patient revenue was devoted to charity care. However, their charity care numbers declined to 6 percent of patient revenues in 2017–18 but spiked to 10.6 percent of patient revenues by 2019. Likewise for Boston Medical Center, the Medicaid expansion seems not to have had a direct impact upon their provision of charity care as their spending rose from 10.8 percent in 2013 to 14 percent in 2016 before declining to 7.4 percent in 2020.

Boston Medical Center and Cambridge Health Alliance Hospitals Total Charity Care/Net Patient Revenue 2013–2020



While hospitals are not required to report revenues deriving from the sale of 340B drugs, it seems very likely that 340B sales to the five Massachusetts hospitals were growing. We can make this supposition based upon the number of contract pharmacy relationships that developed in roughly the years when charity care was declining.

According to the Health Resources and Services Administration's Office of Pharmacy Affairs, here is the growth in contract pharmacy relationships in the last decade:

- UMass Memorial: 2012 3 contract pharmacies, 2022 196 contract pharmacies
- Baystate Medical Center: 2012 79 contract pharmacies, 2022 169 contract pharmacies
- Mass General Hospital: 2017 1 contract pharmacy, 2022 132 contract pharmacies
- Berkshire Medical Center: 2013 2 contract pharmacies, 2022 71 contract pharmacies
- Southcoast Hospitals: 2015 24 contract pharmacies, 2022 66 contract pharmacies

State Policy Recommendations

While states cannot change many elements of how 340B is administered, they can bring greater transparency to the program in their state and offset bad behavior when it is identified.

 Set a standard definition of charity care and 340B reporting, require annual reporting, and audit some reports submitted

Instead of waiting on the federal government to define "charity care," states can set an example that federal officials can follow by establishing strict and reliable definitions. Those definitions should focus on the cost of care provided for the uninsured or to services for individuals under a certain income level.⁵⁵ It should not allow for loopholes that exist now of writing off "under reimbursement" by public programs when compared to the chargemaster rate, which is meaningless. Prompt pay or community education or outreach, which often looks more like marketing, should not be allowed either. Once this standard is set, hospitals shall, or the state should, reserve the right to have any report audited to prevent gaming of the reporting. At minimum, states should require annual reporting on the amount of charity care being offered by a hospital broken down by the different categories of charity care as laid out in the hospital's charity care policy. This change in definition may require changing the definition of community benefit to charity care in state law, or if it is not defined in state law, attorneys general or state agencies

have regulatory authority as part of the licensing, consumer protection, and non-profit registration process to set such definitions.

 Require hospitals to report on their revenue from 340B each year to see trends emerge and better inform state and federal policy.

State agencies or legislative committees could then use these reports to better understand outlier institutions, and discuss possible future policy actions or recommendations to remedy potential abuse or misuse of the program.

Conclusion

There are innumerable federal programs that were conceived with the best of intentions. In urban and rural areas, and even in suburbs, there are many Americans in need of social welfare assistance: food, healthcare, clothing, housing, and drug treatment and mental health services. The list of needs is lengthy.

There is, unfortunately, an unflattering pattern for some federal programs that were designed to provide these social welfare needs. Programs that were begun to serve genuinely needy populations can become captives of the vendors who provide the services. As in the national security realm, there is a social welfare industrial complex of companies and organizations that benefit handily from these federal programs regardless of whether services are being delivered more efficiently or effectively to the needy.

This dubious pattern for federal programs is on full display with 340B. A program that was intended to serve the needs of the low-income uninsured is now a fountain of revenue for hospitals, clinics, for-profit pharmacies and pharmacy benefit managers while, the data strongly suggest, these same entities have pulled back from providing charity care, drug discounts, and community programs. Expanding the 340B program has certainly been a lucrative source of revenue for covered entities, but it has also served to enrich for-profit pharmacy chains and pharmacy benefit management firms, weakened community-based physician and oncology care, pushed patients into more expensive hospital-based care, created incentives for more expensive therapies—all while providing fewer and fewer services to the low-income uninsured. All these trends occurred while executives at nonprofit hospitals secured record compensation.⁵⁶

The 340B program cries out for reform. The road to reform will be challenging, as so many actors are now securing financial benefits from the program. Reform, nonetheless, is urgently needed.

Endnotes

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