GROWTH UNCHECKED:

A Call to Action for Policymakers to Reform 340B,

to Stop It from Driving Up Health Care Costs for Employers, Working Families and Taxpayers

February 2025

American Benefits Council

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Summary

This report examines the impact of the exponential growth of the 340B Drug Pricing Program on employers and their workers. With nearly 180 million Americans covered by employer-sponsored health plans,[1] a careful examination of the impact of the 340B program on employers and working families is essential in evaluating the true cost of the program and in considering legislation to reform it. Contrary to assertions that the 340B program does not impose any costs on taxpayers, it is the case that employers, employees and, therefore, taxpayers are shouldering a significant cost of the program's expansion. Meanwhile, 340B is failing to sufficiently benefit the vulnerable patients the program was intended to serve. A review of existing research demonstrates that the 340B program is raising health care costs for employer-sponsored health plans by $5.2 billion annually through the loss of rebates, and additionally by promoting the increased use of higher-cost therapies and fueling hospital and provider consolidation. Given these findings, the American Benefits Council urges Congress and the executive branch to prioritize 340B reforms that restore the program to its original intent without raising costs for America's employers, working families and taxpayers.

Introduction

The American Benefits Council ("the Council") is a national association dedicated to strengthening employer-sponsored benefit plans. The Council represents more major employers — over 220 of the world's largest corporations — than any other association that exclusively advocates on the full range of employee benefit issues. Council members also include organizations of all sizes that support employers. Collectively, Council members directly sponsor or support health and retirement plans covering virtually all Americans participating in employer-sponsored programs. This paper outlines the rapid growth of the 340B drug pricing program (the "340B program" or "the program") and its impact on employer and employee health care costs, as well as on taxpayers.

The 340B program was enacted in 1992 to help expand services and make health care more affordable for vulnerable patients treated at specific facilities.[2] Under Section 340B of the Public Health Service Act,[3] prescription drug manufacturers must provide discounts on outpatient prescription drugs for "eligible patients" to "covered entities" that meet statutory eligibility criteria and register for 340B. Covered entities include federally funded outpatient clinics ("grantees"), public hospitals, and private not-for-profit hospitals that either serve a disproportionate share of low income patients or meet criteria for a special hospital designation (cancer hospital, critical access hospital, rural referral center, etc.).[4]

The U.S. Department of Health and Human Services' (HHS) Health Resources and Services Administration (HRSA) administers the 340B program. Although the law does not provide broad rulemaking authority over 340B to HRSA in all areas,[5] the agency has shaped the program significantly over the years through guidance documents and other administrative and compliance actions (or inaction).[6] HRSA's policy choices over the years have contributed to the growth of the 340B program.

More than 30 years since its enactment, 340B has expanded far beyond the intended purpose. The volume of 340B discounted prescriptions has grown exponentially since 2010, and 340B now is the second largest federally authorized drug purchasing program behind Medicare Part D.[7] Employers are deeply concerned about the significant cost that explosive growth of 340B has imposed on employer-sponsored health plans. The Council expresses these strong concerns on behalf of employers.

The 340B program should not be seen as unrelated to employer-sponsored health coverage. The program does not operate in isolation, but instead impacts payers across the health care system including the commercial, Medicare, and Medicaid markets. Proponents of 340B claim it has no federal cost because it relies on discounts provided by one private entity (a prescription drug manufacturer) to another (a covered entity).[8] This claim that the 340B program has no cost beyond the discounts provided by manufacturers fails to consider the program's impact on employer-sponsored health plans, through which the majority of Americans receive their health coverage.

Participation in 340B allows a hospital to purchase prescription drugs at a discounted price and then request reimbursement on behalf of patients from payers at their regular reimbursement rate, with hospitals retaining the difference. For the reasons described in this paper, in the case of a patient enrolled in employer-sponsored health coverage, this practice increases the cost of employer-sponsored health insurance, which in turn has a federal budgetary impact of decreasing tax revenue — refuting the claim that the program has no cost to taxpayers.[9]

Research documents the myriad ways that 340B affects prescription drug costs for government and commercial health care purchasers, including employers. As explained below, the current 340B program increases employer health care costs, directly and indirectly, in several ways: (1) compromising the availability of prescription drug rebates and discounts otherwise available to employers, (2) promoting increased

use of higher cost medicines, and (3) fueling health care consolidation, which shifts care to more expensive settings and raises hospital prices.

As Members of Congress consider approaches for 340B reform, it is critical to shine a light on the program's hidden costs to employer-sponsored coverage and to address employers' concerns. Congress must prioritize restoring the program to its original intent — as a safety net program — rather than allow ongoing growth that increases costs for working families, employers, and the federal government.

How Did 340B Get So Big and Whom Does It Benefit?

For almost two decades the 340B program remained relatively small. However, the program has grown rapidly in recent years, particularly after 2010, and now accounts for nearly $1 of every $5 spent on brand outpatient medicines.[10] Total sales at the 340B discounted price reached $66 billion in 2023, which when measured at the undiscounted list price, is equal to an estimated $124 billion in drug spending.[11] In just ten years, annual 340B purchases grew more than 700%, from $7.5 billion in 2013 to $53.7 billion in 2022. Factors underlying this growth include the following:

- Exponential growth in participation by non-profit hospitals
- Hospital/provider consolidation and proliferation of offsite outpatient departments or "child sites"
- Increases in contract pharmacy arrangements
- A vague definition of "eligible patient"
- A lack of transparency and lax oversight of covered entities, especially hospitals, by HRSA

Shortly after Congress enacted 340B in 1992, just a handful of hospitals (roughly 50) participated in the program.[12] By 2023, more than 2,600 hospitals were enrolled in the 340B program.[13] Most 340B hospitals qualify for the program based on a disproportionate share hospital (DSH) percentage, which reflects the percentage of Medicaid and low-income Medicare inpatients the hospital serves.[14] As Medicaid enrollment has increased from approximately 35 million in 1992[15] to approximately 80 million in 2024,[16] more hospitals have qualified as covered entities. However, the threshold percentage of Medicaid and low-income Medicare patients served that is used for a hospital to qualify for 340B has not been updated since the program's inception. In 2023, nearly 80% of 340B purchases originated with DSHs, with just 13% of purchases made by grantees, i.e. federally funded clinics.[17]

The financial incentive for hospitals to participate in 340B is profound. Covered entities can purchase prescription medicines at a substantial discount — 57% off of list price, on average — but charge patients and their insurance (including employers) considerably more, allowing hospitals to retain the "spread."[18] Grantees generally are required to use revenue gained in this way for purposes aligned with their grant terms, but there is no similar restriction on hospitals' use of 340B revenue.[19] Participation in 340B thus generates significant revenue for hospitals without assurance or clear evidence of its use to support or improve services for vulnerable patients.[20] A recent synopsis of peer-reviewed literature discovered that covered entities qualifying for 340B based on DSH status appear to be using the 340B program in margin-motivated ways to increase profits rather than mission-motivated ways to expand safety-net engagement.[21] Another analysis found that 340B hospitals devote *fewer* resources to charity care than hospitals overall.[22]

In addition, the hospital market has become increasingly consolidated in the years since 340B was enacted, both horizontally, with hospitals purchasing other hospitals, and vertically, with hospitals purchasing physician practices. Consolidation has further allowed the reach of the 340B program to grow significantly. Recent trends in hospital-affiliated

340B growth show the program is expanding into comparatively wealthy and less diverse zip codes, often through “child sites” or contract pharmacies, as described below.

Because 340B covered entities can leverage 340B discounted pricing at their offsite outpatient facilities (“child sites”), the 340B program can be a lucrative incentive for 340B hospitals to purchase physician practices and turn them into outpatient child sites of the parent 340B hospital. Child sites eligible for 340B discounts should be serving the patient populations 340B was designed to serve. However, a 2022 analysis[23] showed that 61% of child sites are in a different ZIP code than the main 340B DSH hospital (“parent”) and of these, 60% are in areas with at least 10% higher median income than their parent hospital. Almost half (47%) are in ZIP codes with a median income at least 30% higher than their parent sites.

Covered entities also are increasingly contracting with outside pharmacies to dispense discounted 340B drugs. The use of contract pharmacies stems from HRSA guidance, which originally limited the use of contract pharmacies to covered entities that did not have in-house pharmacies and who were allowed to contract with only one outside pharmacy. However, 2010 HRSA guidance removed this limitation and allowed covered entities to have an unlimited number of contract pharmacies.[24] Some of the largest growth in 340B has come from contract pharmacy arrangements with hospitals, which increased dramatically from 2009 to 2022.[25] The number of contracts per pharmacy also increased over the period, and the average distance from covered entity to contract pharmacy increased. Even as pharmacy contracts with 340B providers multiplied, however, the proportion with “core safety net providers” decreased from 95% in 2009 to 54% in 2022.[26]

As with the proliferation of child sites, contract pharmacy growth has been concentrated in affluent and predominantly white neighborhoods, whereas the share of 340B pharmacies in socioeconomically disadvantaged and primarily non-Hispanic Black

and Hispanic/Latino neighborhoods has declined.[27] And, although the 340B statute reserves covered entity eligibility for non-profit and public entities, contract pharmacies tend to be owned by large, for-profit entities.[28] In 2022, for example, 71% of pharmacies in the four largest (vertically integrated) pharmacy/PBM/insurer chains participated in 340B as a contract pharmacy.[29] Growth of contracts with 340B hospitals has been less likely in areas with higher uninsured rates and in medically underserved areas.

The 340B statute includes modest provisions designed to reserve 340B discounts for the intended patient population. First, covered entities are prohibited from dispensing 340B discounted drugs to an individual who is not an "eligible patient" of the entity.[30] However, the lack of a clear and meaningful definition of an eligible patient has allowed covered entities to adopt their own expansive definition of the term, thereby substantially increasing the number of patients to whom the discounts apply. Second, duplicate discounting is prohibited, meaning a covered entity may not dispense a 340B discounted drug and then submit a claim for Medicaid reimbursement for the same drug.[31] Both provisions have proven difficult to enforce due to insufficient data, lax oversight, and an increasingly complex web of 340B providers and affiliates.[32] A 2021 paper from USC Schaeffer describes the challenge:

> "Vaguely worded legislation coupled with HRSA's limited regulatory authority have created a program that leaves implementation open for interpretation and provides limited meaningful oversight activities."[33]

Another report from the Community Access National Network explains:

> **"The lack of transparency and program standards for how DSH hospitals use 340B discounts, combined with the significant growth of the program driven by these hospitals, has greatly eroded the 340B program's initial vision."[34]**

A recent transparency report from the Minnesota Department of Health (MDH) provides a window into how much hospitals are profiting from the 340B program, how the commercial market is funding these profits and how large hospital systems are benefitting the most.[35] MDH determined that Minnesota providers participating in the federal 340B program earned a collective profit of at least $630 million for the 2023 calendar year from the program. MDH believes this figure may represent as little as half of the actual total 340B profit for Minnesota providers because office-administered drugs, which represent over 80% of spending in the 340B program and include many high-cost drugs, were not included in the reporting for all covered entities. MDH also collected data by payer type. This data confirmed that payments from commercial payers, including employers, generated more than half (54%) of the 340B profit for providers. The report also found that the 340B program in Minnesota is disproportionately benefiting large hospital systems. The state's largest 340B hospitals benefitted most from the 340B program, representing 80% — more than $500 million — of the total statewide net 340B revenue. Conversely, safety-net clinics receiving federal grants ("grantees") generated the least net 340B revenue. MDH also found that payments to contract pharmacies and third-party administrators were over $120 million. While the report shines a light on the profits generated from the 340B program, the report does not reveal how hospitals are actually using those profits. As the MDH acknowledges, "important questions remain."

Employers understand the importance of the safety net and support the mission of the 340B program as Congress originally intended it — to help underserved communities by increasing access to affordable drugs and health services for patients in those communities. With clear evidence of covered entities moving into more affluent areas, which expands the number of commercially insured patients potentially filling 340B prescriptions, employers are deeply concerned with the impact this has on their health care costs. It is critical to ensure that 340B is used to strengthen the safety net for vulnerable patients, as opposed to generating revenue for hospitals to use for other purposes at the expense of employers and working families.

340B Raises Costs for Employers, Workers and Taxpayers

Misaligned incentives, loose eligibility standards, and lack of adequate oversight have fueled the expansion of the 340B program in ways that do not serve the vulnerable populations that the statute intended to help while raising costs for the roughly 180 million people with employer-sponsored health coverage. Employers are the leading source of health insurance in the United States, and the impact of explosive growth of 340B on these businesses and individuals cannot be ignored.

Employers play a critical role in the health care system, leveraging purchasing power and plan design innovations to deliver substantial benefits to working families. Federal tax policy has long supported employer-sponsored health coverage by excluding employer and employee premium payments from payroll and income taxes, resulting in tremendous value for both working families and taxpayers alike.[36]

Employer-sponsored health insurance brings comprehensive health care within reach of working families in communities across America. However, employers are deeply concerned about rising health care costs that threaten this reach. Health insurance premiums have

increased steadily, putting a strain on employers and working families. The average premium for family coverage has increased by 24% over the past five years, outpacing the rate of inflation.[37] In 2022, according to the Centers for Medicare & Medicaid Services ("CMS"), hospital spending totaled $1.4 trillion, the largest health spending category in the United States.[38] Hospital spending accounts for 44% of total personal health care spending for the privately insured and hospital price increases are key drivers of per capita spending for these individuals.[39] Hospital spending has accounted for 42% of commercial health insurance spending growth since 2016, making it the largest contributor to such spending growth.[40] To lower the cost of employer-sponsored health coverage, it is therefore necessary to examine the factors contributing to rising hospital care prices.

As explained below, the 340B program is a key factor driving higher hospital prices and, in turn, higher prices for employer-sponsored health coverage. Working families and employers face higher health care costs because 340B compromises the prescription drug rebates and discounts that otherwise would go to employers.[41] The program also increases costs indirectly by encouraging use of higher-cost medicines and incentivizing hospital and physician practice consolidation.[42]

1 340B Increases Employer Costs Because Rebates Are Lost on Prescription Drug Claims

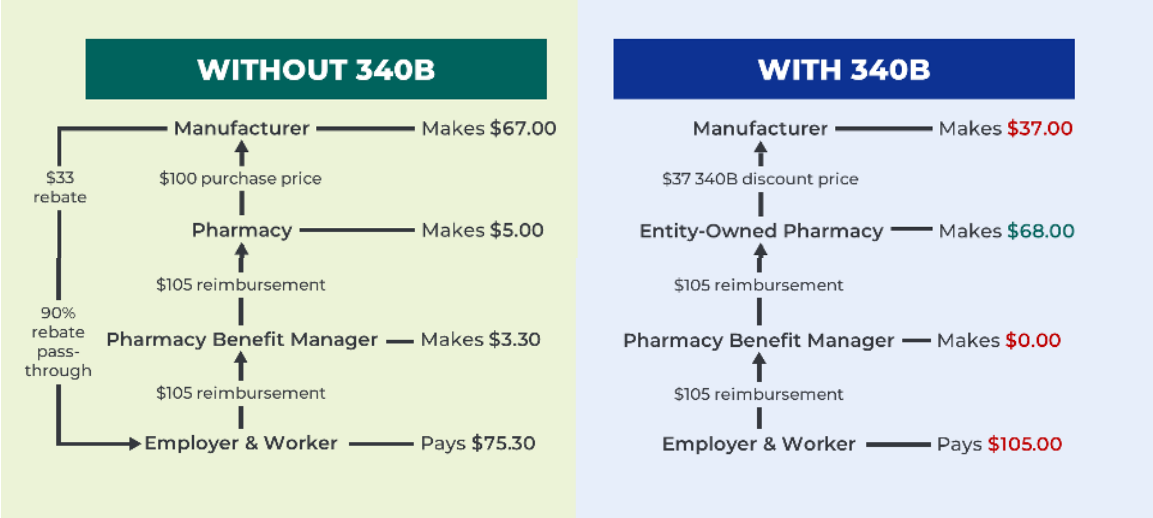
Most U.S. workers and families covered by employer-sponsored health insurance are in a self-funded plan. Employer sponsors of these plans bear the cost of workers' health care directly, often with assistance from administrative service providers. Prescription drug benefits are often administered by a pharmacy benefit manager ("PBM") that negotiates rebates and discounts with manufacturers on prescription medicines for the employer. In such arrangements, employers typically receive

rebates on prescription medicines after a prescription has been dispensed (not at the point-of-sale).[43] Employers in turn use these rebates to reduce premiums and health care service costs for themselves and their workers.[44]

The 340B program can disrupt the flow of rebates to employers, resulting in higher health care costs. As previously noted, the 340B statute prohibits rebate duplication for 340B and Medicaid. Similarly, rebate contracts between employers (or their PBM) and manufacturers typically prohibit duplication.[45] As depicted below, when a 340B discount is applied to a claim, that claim is no longer eligible for a commercial rebate. Even though the hospital retains the 340B discount, employers lose the rebate. This results in employers and workers paying more for prescriptions than they would in the absence of 340B.

Figure 1.

Simplified Flow of Rebates to Employers and Workers With and Without 340B



Source: IQVIA, Cost of 340B Part 1, 2024.[46]

In the simplified scenario above from a study by IQVIA, "costs have increased or revenue has decreased for all stakeholders other than the 340B provider."[46] The study calculated that prescription drug costs for self-insured employers and workers increase 4.2% due to the loss of rebates for drugs purchased through the 340B program that would otherwise be received. This equates to an annual increase of $5.2 billion in the cost of health care for self-insured employers and working families because of the 340B program.[47]

Because 340B savings are provided directly through pharmaceutical manufacturers, the 340B program has been characterized by some as operating at no cost to the taxpayer. However, because the program is costing employers and their workers billions of dollars from lost rebates alone, it is in fact also costing taxpayers. Though federal and state governments are not represented in Figure 1, they would see revenue fall in the 340B scenario as well. Employer-sponsored health insurance, federal and state tax revenues and corporate and employee income are interrelated. When employers and workers pay more for health insurance, tax revenue is estimated to decrease.[48]

In the words of one former Congressional Budget Office Director ...

> **"This reduction in negotiated rebates results in higher costs for employer health plans. Some employers pass the additional costs to employees in the form of reduced benefits, higher premiums, and more out-of-pocket costs. ... Due to these increased costs, employees and employers have less taxable income, resulting in lower federal and state tax revenue."[49]**
>
> – Dan Crippen, *former CBO Director*

2 340B Increases Employer Costs by Incentivizing Use of More Expensive Medicines

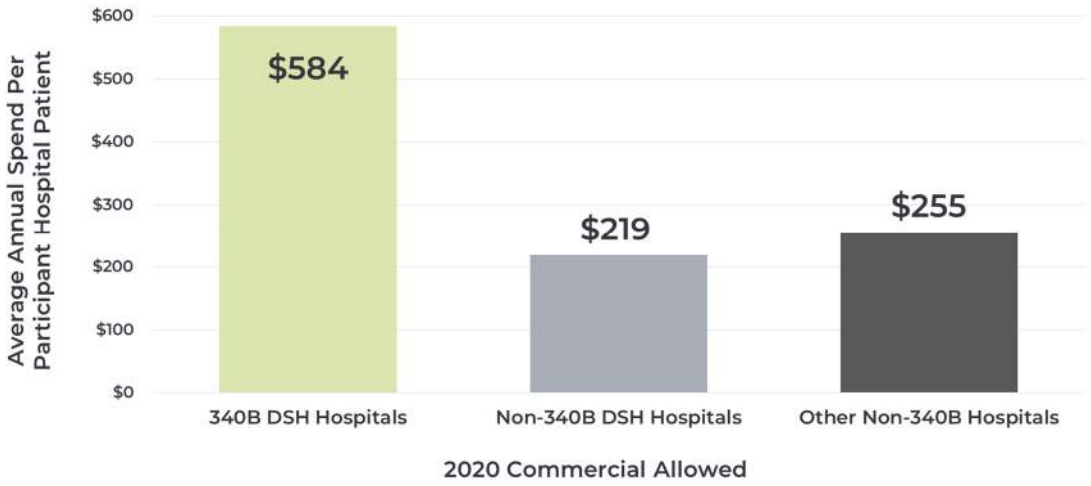
As a 2022 article published in the *New England Journal of Medicine* explains: "Insurers reimburse 340B clinics for [retail] medications at an amount close to their list price; the difference between the list price and the discounted 340B price results in revenue — known as the "340B spread" — that clinics can allocate toward other health services. The higher the drug's price, the bigger the spread."[50] Because covered entities may keep the spread between the 340B acquisition cost for a drug and amounts collected from patients and payers, including employers, "the most insidious effect of 340B … is the incentive it gives clinics to prescribe high-cost medications, even when effective and far cheaper options exist." [51]

Research into both private and public payer experiences underscores the strong financial incentive for 340B entities to favor expensive medicines over lower cost alternatives, particularly at hospitals.[52] For example, a government investigation of spending on Medicare Part B (outpatient) drugs found higher per capita spending at 340B DSH hospitals than at non-340B hospitals.[53] The study concluded that, "on average, beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other hospitals."[54]

An analysis of commercial payer claims yielded a similar result. This study found that average per patient spending on outpatient drugs was more than two times higher at 340B DSH entities than at non-340B hospitals.[55]

Figure 2:

Average Per Patient Spend on Outpatient Drugs, Commercial Market



Source: Milliman, "Commercial payers spend more on hospital outpatient drugs at 340B participating hospitals," March 2018.[52]

Higher costs for employers and working families are especially likely in the case of cancer medicines dispensed by 340B entities. A 2022 study revealed exponential mark-ups by cancer centers for 25 commonly infused medicines billed to commercial payers.[56] Most of the facilities included in the study were 340B covered entities, and median markups ranged from 118% to 634% of the estimated acquisition cost. A second study found that average prices billed by pediatric 340B hospitals to commercial insurers for newly approved oncology drugs exceeded the estimated acquisition cost by 102% to 630%.[57] Overall, the cost of oncology medicines for commercially insured patients at newly registered 340B hospitals were found to be over $4,000 more, on average, than at non-340B hospitals.[58]

The North Carolina state treasurer recently released a report finding that 340B hospitals billed state employees an average price markup of 5.4 times their discounted acquisition costs for oncology drugs, collecting an 84.8% higher average price markup than hospitals outside of the program.[59] The report also found that 340B hospitals generated average spread profits as high as $13,617 per claim on cancer drugs paid for by the North Carolina State Health Plan for Teachers and State Employees. Instead of using their discounts to benefit vulnerable communities, the same report found that 340B hospitals expanded into wealthier neighborhoods with a higher percentage of insured individuals who could pay more for the drugs.

Research also indicates that financial incentives from the 340B program may be inhibiting the adoption of lower-cost biosimilar drugs. An investigation into whether the program inhibits biosimilar uptake estimated that 340B eligibility was associated with an almost 30% reduction in biosimilar adoption.[60] Another study of biosimilar market share for commercially insured patients found that, on average, biosimilar utilization at 340B hospital outpatient departments (HOPDs) was lower than at non-340B HOPDs.[61] The study notes, "Since 340B providers' compensation is greater due to the larger margin between the acquisition cost and reimbursement for the drug, they may be incentivized to utilize medicines with a higher price." [62]

When profit incentives drive 340B hospitals to favor high-cost medicines over lower cost alternatives, employers and working families face higher premiums and out-of-pocket costs. Between 2015 and 2019, 340B covered entity profits more than doubled, reaching $40.5 billion in 2019.[63] Overall, 340B hospital profitability (measured as excess revenues after operating expenses for non-profit hospitals) was estimated to be 37% higher than the average across all hospitals.[64] An estimated 27% of the profits that 340B covered entities generated through the program in 2019, for example, were borne by consumers and payers.[65]

Profits earned for hospitals through the administration of the 340B program are purported to subsidize care for low-income patients. The evidence demonstrates that the program is, instead, providing an

incentive for hospitals to increase their market share of patients with private insurance, namely those with employer-sponsored coverage,[66] and to increase the use of higher-cost therapies for those patients.

3 340B Encourages Hospital Consolidation, Which Increases Employer Costs

Hospitals' success turning 340B discounted pricing into profits is a formidable factor in hospital consolidation and vertical integration of hospitals and physician practices. Hospital systems have strong incentives to expand their reach by acquiring additional hospitals, physician practices and off-campus clinics to achieve higher 340B volume.[67] Hospital consolidation has been shown to increase employers' health care costs.

> **"One of the greatest challenges to affordable health care is the high cost of American hospitals. The most important driver of higher prices for hospital care, in turn, is the rise of regional hospital monopolies. Hospitals are merging into large hospital systems and using their market power to demand higher and higher prices from the privately insured and the uninsured."[68]**
>
> *– Avik Roy, Senior Advisor to Bipartisan Policy Center; President, Foundation for Research on Equal Opportunity*

The Medicare Payment Advisory Commission (MedPAC) reviewed the published research on hospital consolidation and concluded that the "preponderance of evidence suggests that hospital consolidation leads to higher prices for commercially insured patients."[69] Hospital

consolidation and acquisition of physician practices raise affordability challenges in and of themselves for employers and their workers; when 340B dynamics are added to the mix, costs to employers and working families increase even further.

For more than a decade, vertical integration of health care providers has been shifting outpatient drug claims from physician offices and other non-340B provider settings to 340B hospital outpatient settings including child sites.[70] Today, more than half of physicians are employed by a hospital or outpatient facility.[71] These acquisitions of physician practices by hospital systems drive up health care costs for employers and redirect patients to higher-cost settings in rebranded hospital outpatient departments that now include an additional "facility fee" for the same medicine or service. After hospitals purchase physician practices, the prices for services provided by the acquired physicians increase an average of 14%.[72] Employer-sponsored health insurance payments for infused cancer medicines are nearly two times higher for the same drug when administered in a hospital outpatient department versus a physician office.[73]

When 340B hospitals purchase independent physician practices, employers and patients with private insurance end up paying more. A 2024 study published in the *New England Journal of Medicine* found that 340B hospitals mark up the cost of physician administered medicines 6.59 times more than independent physicians' offices.[74]

Another study isolated the effects of the 340B program on hospital-physician consolidation.[75] Hospital eligibility for 340B was associated with 2.3 more hematologist-oncologists per hospital practicing in facilities owned by the hospital, or 230% more hematologist-oncologists than expected in the absence of the program. In addition to finding that the 340B program was associated with hospital-physician consolidation in hematology-oncology, the study also found that the program was associated with more hospital-based administration of parenteral drugs in hematology-oncology and ophthalmology. However, the financial gains for hospitals from 340B discounts have not

been associated with clear evidence of expanded care or lower mortality among low-income patients.

As one economist cautions, the 340B program "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."[76] Cost increases are not limited to those directly associated with the 340B program, but are seen for diagnostics and primary care services as well.[77]

From a public policy perspective, one of the most troubling aspects of 340B-driven changes to the provider landscape is that these changes do not appear to be improving services or outcomes for the patients 340B was designed to serve. After large health care delivery systems acquire 340B hospitals, they can cut services to patients in lower-income communities and deploy 340B profits to expand access in wealthier communities with more insured patients.[78] This tactic allows the hospital system to expand its pool of commercially insured patients eligible for 340B drugs and increase its profits even further while leaving employers with a significant portion of the cost.

A recent investigation by the *New York Times* found that "starting in the mid-2000s, big hospital chains [would] build clinics in wealthier neighborhoods, where patients with generous private insurance could receive expensive drugs, but on paper make the clinics extensions of poor hospitals to take advantage of 340B."[79] In one case, a safety-net facility of a large hospital system in Virginia reported the highest profit margin in the state because the entire system was able to access 340B discounts and then mark up the medicines. However, the safety-net facility lacked basic medical equipment and access to specialists, as the system's 340B profits were used to enhance services for more affluent communities.[80]

A lack of transparency, accountably and oversight regarding how the profits generated by the 340B program are being used makes it difficult — if not impossible — to ensure that the program is in alignment with the congressional intent to support the safety-net. The opacity and lax

oversight do, however, allow the program to mask its hidden cost on employers, their employees and their families.

Congress Must Reform 340B to Ensure the Program Is Working as Intended Instead of Driving Up Costs for Employers and Working Families

Employers support a robust safety net and the related intent of 340B. However, the program has strayed far from its purpose, and is failing in its mission to assist low-income patients in vulnerable communities as it should.[81] When Congress enacted 340B, it indicated the purpose was to provide "protection from drug price increases to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans."[82] Given mounting evidence that 340B has deviated from its intent and grown in ways that are increasing costs for employers, working families, and taxpayers, comprehensive reform is urgently needed. In the words of economists at Harvard University and the University of Chicago:

> "[L]awmakers could lower the price of prescription drugs by reforming the federal 340B Drug Pricing Program... [which] 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."[83]

Unfortunately, proposals like the "340B Pharmaceutical Access To Invest in Essential, Needed Treatments & Support (PATIENTS) Act" and state legislation to protect unchecked growth in contract pharmacies

take the wrong approach. These proposals would accelerate growth in 340B by validating current uses of contract pharmacies and allowing exponentially more arrangements, without regard for the patient population being served. As of 2023, 340B had already eclipsed Medicaid prescription drug purchases by 40%.[84] Purchases at 340B discounted prices grew from $5 billion in 2010 to $66 billion in 2023 — more than a tenfold increase. Contract pharmacy arrangements have been a major vehicle for growth, with the number of unique covered entity / pharmacy contracts growing 7,300% over the same period.[85]

Employers and working families cannot sustain this level of growth in the 340B program given the impact on their health care costs. Taxpayers, too, have cause for concern. Reforms like those included in the *340B Affording Care for Communities and Ensuring a Strong Safety-net (ACCESS) Act* would take important steps to return the program to what Congress intended. Covered entities would be required to refocus on serving and lowering costs for vulnerable patients, thereby lowering costs for employers, workers and taxpayers as well. These reforms target the factors contributing to the program's explosive growth and include:

- **Increasing transparency, accountability and oversight:** Greater transparency, accountability and oversight are necessary to ensure that the 340B discounts are, in fact, being used to support access to affordable prescription drugs and health care services for vulnerable patients in underserved communities as originally intended. Much-needed transparency improvements include requiring hospitals to publicly report information on the margin generated from the 340B program. Congress should also strengthen accountability measures and oversight to ensure compliance with program requirements.

- **Codifying a clear 340B "patient" definition to ensure program integrity**: A clear and meaningful definition of a "patient" at a 340B entity is critical to supporting appropriate care of vulnerable patients and preventing diversion of 340B medicines beyond the program's intent. Congress should codify a clear 340B patient definition with strong safeguards.

- **Strengthening the eligibility criteria for 340B hospitals:** Congress should establish new standards for DSH hospitals participating in 340B to ensure that these hospitals are truly acting as safety-net providers.
- **Creating clear standards for "child sites":** Congress should create clear standards for 340B hospital off-campus clinics (child sites) to ensure they are focused on outpatient, safety net care in medically underserved communities.
- **Creating clear criteria for contract pharmacy arrangements:** Congress should establish clear standards for contract pharmacy arrangements that limit their use while still maintaining appropriate access and ensuring contract pharmacies comply with the same requirements to provide affordable access as covered entities.

Conclusion

More than 30 years after the 340B program was enacted, the time has come for Congress to act to restore its original intent of supporting the nation's safety net and to protect employers and working families from paying the price of the program's unfettered and unanticipated growth. By increasing prescription drug costs for employer-sponsored health insurance by billions of dollars and fueling the provider consolidation that increases the cost of health care services more broadly, the program is far from free for employers, working families, and taxpayers. As Congress considers legislation to reform the 340B program, we urge Congress to recognize the program's true cost and address the concerns raised by employers. The much-needed reforms described above would serve to both lower costs for vulnerable patients in underserved communities and to lower costs for the millions of Americans with employer-sponsored health insurance.

Notes

[1] US Census Bureau, Health Insurance Coverage in the United States: 2023, issued Sept 2024.

[2] Veterans Health Care Act of 1992. Pub. L. No. 102-585, § 602.

[3] 42 U.S.C § 256b.

[4] The initial list of covered entities included public hospitals, private non-profit disproportionate share hospitals, and several types of federal grantee clinics [federally qualified health centers ("FQHC"), FQHC look-alikes, tribal/urban Indian clinics, Native Hawaiian health centers, Ryan White HIV/AIDS program grantees, and five types of specialized clinics (e.g., hemophilia treatment centers)]. Congress added children's hospitals to the covered entity definition in 2006, and in 2010 added critical access hospitals, sole community hospitals, rural referral centers, and stand-alone cancer hospitals. 42 U.S.C. §256b(a)(4).

[5] K Mulligan, "The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments," (USC Schaeffer Center, 2021)

[6] Congressional Research Service ("CRS"), "Overview of the 340B Drug Discount Program" (2022).

[7] CRS, "Overview."

[8] The American Hospital Association has asserted, "340B doesn't cost the government one penny." See "340B Hospital Community Benefit Analysis" (2023).

[9] D Crippen, "340B Impact on the Federal Budget" (AIR340B, 2024).

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