AIR 340B
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340B Impact on the Federal Budget

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This memo summarizes the creation and subsequent explosive growth of the 340B Drug Pricing Program and explores the likely federal and state budgetary effects of legislation that requires pharmaceutical manufacturers to subsidize drug purchases by certain healthcare providers. Although the legislation implementing the 340B Program was enacted in 1992, administrative guidance and a change in law in 2010 fundamentally expanded the 340B Program by opening participation to significantly more providers and thousands of retail pharmacies.

The growth in the 340B Program has increased the federal deficit included in the Congressional Budget Office's (CBO) current-law baseline. This increase in the federal budget deficit is primarily attributable to the transfer of revenue from for-profit taxable entities, i.e., pharmaceutical manufacturers, to non-profit, tax-exempt entities, such as hospitals, which results in a concomitant decrease in taxable revenue. The significant growth in the program has also resulted in a large increase in federal taxpayer spending. Pending litigation and legislation could alter the impact of the Program on the deficit. In general, if the 340B Program is expanded, the effect will be to increase the federal deficit by increasing spending and reducing tax revenue, while narrowing the Program would lessen its impact on the deficit.

BACKGROUND

Two years after creating the Medicaid drug rebate program in 1990, Congress passed legislation establishing the 340B Program, which requires manufacturers to sell their drugs at substantial discounts to certain safety-net providers, "covered entities," to restore the unforeseen loss of voluntary manufacturer discounts caused by the 1990 law. The definition of covered entities was exclusively for safety net providers that served a substantial number of low-income and uninsured individuals. These discounts were to be given only on outpatient drugs prescribed to "eligible patients." *

These discounts are provided, not by the federal government or federal tax breaks, as are nearly all other programs for safety-net providers, but solely by pharmaceutical manufacturers. For drug manufacturers to have covered outpatient drugs eligible for reimbursement under Medicaid and Medicare Part B, the 340B Program requires them to provide discounts on outpatient drugs purchased by covered entities for eligible patients. These subsidies are required only of pharmaceutical manufacturers and no other vendors of health care products or services. The 340B discounts paid last year by manufacturers reduced the price of the drugs paid by covered entities by an average of over 50 percent.[1]

It is only after a prescription is filled that the eligibility for the 340B discount is ascertained. Based on their own determination of eligibility, covered entities submit a "claim" with manufacturers for reimbursement, which in turn is paid directly, or by a third-party administrator to the non-profit covered entity.

Initially, the 340B Program limited covered entities to 14 types of hospitals and clinics, generally including those hospitals that treated a minimum number of Medicaid and low-income Medicare inpatients. In 1996, The Health Resources and Services Administration (HRSA) issued sub-regulatory guidance stating that if hospitals or clinics did not have an in-house pharmacy to fill 340B eligible prescriptions, it was allowed to contract with one

* For simplicity here, the average price manufacturers charge for drugs is the list price. The net price charged the payer is the list price minus discounts and rebates.

external pharmacy to fill prescriptions. Covered entities are supposed to receive a discount only on outpatient drugs they provide to their eligible patients.

Unfortunately, however, the legislation did not specify that covered entities were required to pass the discounts on to indigent patients. Although the program is restricted to covered entities that serve a substantial number of patients with low-income, uninsured, or who are otherwise vulnerable, covered entities can charge eligible patients any price for the pharmaceuticals purchased through the 340B Program, regardless of the price the covered entity paid for the drug or the income or insurance status of the patient. Accordingly, dispensing drugs eligible for 340B discounts can generate larger profits for covered entities than dispensing non-340B drugs to higher-income and/or insured patients.[2]

Growth in Outpatient Prescription Drug Spending and the 340B Program

For nearly 20 years, the total amount of 340B discounts was relatively small. Two changes in 2010 altered the pattern. By 2022, sales at the 340B price, the total of subsidies from drug manufacturers to covered entities, totaled $55B.[3] The 340B Program is now the second largest federal drug pricing program, second only to Medicare Part D.[4] However, the 340B program, unlike Medicare, is funded by pharmaceutical manufacturers.

For a multitude of reasons, since 1992, and especially since 2010, the total value of 340B subsidies has grown dramatically. Some of the significant reasons for the growth are outlined below:

- **The number of covered entities has grown:** The Affordable Care Act (ACA), enacted in 2010, incorporated changes to the 340B Program and expanded the type of eligible entities to include Critical Access Hospitals, Rural Referral Centers, Sole Community Hospitals, and Freestanding Cancer Hospitals.[5] Furthermore, as Medicaid enrollment tripled from 30 million in 2010 to over 80 million in 2024 (including 20 million added by the ACA),[6] more hospitals have been able to qualify as covered entities. In addition, given the financial incentives for providers to participate in the 340B Program, potentially eligible providers are increasingly filing applications to qualify for subsidies. Accordingly, the number of covered entities has grown significantly. In 1992, there were only 50 hospitals participating in the 340B Program;[7] by 2020, there were 2,600 hospitals participating.[8] When the program was enacted, Congress expected a total of 90 hospitals to participate.[9]

- **The number of eligible patients has grown:** Total discounts have grown in part because of a large increase in the number of patients that covered entities claim to be "eligible." The ambiguous construction of the term "eligible," the definition of which is not fully and clearly articulated in the statute, has enabled covered entities to develop their own, expansive definitions of who they can designate as eligible patients, thereby enabling them to reap more benefits from the 340B Program. Covered entities have claimed "eligible" to include not just indigent patients, but all out-patients, including those with high incomes and private insurance.

- **The number of contract pharmacies has grown:** In 2010, the number of 340B contract pharmacies was fewer than 1,300.[10] However, in 2010, HRSA issued new sub-regulatory guidance that fundamentally changed the 340B Program, allowing covered entities to contract with an unlimited number of unrelated, for-profit, off-site retail pharmacies to

dispense 340B-eligible drugs. The number of contract pharmacies has increased by a factor of 25 and now approximates 33,000, which is more than half of the pharmacies in the country.[11] Covered entities typically pay contract pharmacies much more for 340B-eligible drugs than what they are reimbursed by commercial payers for filling non-340B drugs, resulting in a transfer of 340B subsidies to pharmacies.

All told, covered entities and contract pharmacies have more than 220,000 intertwined financial relationships,[12] which makes it even more difficult to know what these non-profit covered entities do with the subsidies they receive from pharmaceutical manufacturers. These financial relationships enable hospitals to broaden their distribution system and increase the number of eligible patients and their benefit from 340B subsidies. In 2022, hospitals and their contract pharmacies accounted for nearly 90 percent of total 340B purchases.[13]

- **Vertical integration is encouraged:** Discounts provided under 340B create a powerful incentive for providers to pursue vertical integration, most notably, hospital acquisition of physician practices, but the practices often remain intact as out-patient facilities, becoming eligible for 340B discounts as "child sites" of the hospital. Over half of all physicians now practice as employees of hospitals and out-patient facilities.[14] These physicians prescribe and administer medicines, from which the hospitals can benefit under 340B. Many of the practices specialize in oncology, which prescribe a disproportionate number of 340B prescriptions.[15] CBO recently reported that nearly half of all 340B sales were for cancer drugs.[16]

- **Incentive to use more expensive drugs:** GAO observed in its 2015 audit that 340B hospitals have a propensity to prescribe more expensive drugs (with a resulting larger 340B discount) than was necessary.[17] As a result, Part B spending on prescription drugs is higher than it would be in the absence of 340B, raising costs to patients and taxpayers.

- **Oversight is inadequate:** Beginning in 2011, GAO issued several reports recommending that HRSA develop better processes, definitions, and data to determine the outcomes of the 340B Program. In 2018, GAO audited a sample of hospitals participating in the 340B program and found HRSA had a lack of clear definitions, a lack of rigorous enforcement of 340B requirements, and a lack of guidance.[18] GAO continued that this unconstrained environment has likely contributed to 340B transactions that are inappropriate. GAO also found that HRSA had failed to effectively enforce the prohibition against covered entities receiving duplicate discounts from both Medicaid and 340B. Specifically, by 2018, HRSA's relatively few audits of covered entities only assessed the potential of duplicate discounts in Medicaid fee for service, and not Medicaid managed care plans.[19] As discussed below, HRSA has not implemented many of GAO's most important recommendations.

This potential abuse of the 340B Program has not gone unnoticed:

- Based on inquiries by Senator Chuck Grassley, *The Charlotte Observer* (April 28, 2015) reported Duke University Hospital made $69.7 million in profits through the 340B program:

> Duke University Hospital purchased $65.8 million in drugs through the 340B program, saving $48.3 million on the retail price of the $114.1 million in drugs. After selling the drugs to patients for $135.5 million, above retail price, Duke made $69.7 million in profits.

- A report by the *Wall Street Journal* (December 20, 2022) concluded that the drug discounts are not passed on to low-income patients:

  > A decades-old federal program that offered big drug discounts to a small number of hospitals to help low-income patients now benefits some of the most successful nonprofit health systems in the U.S. Under the program, hospitals buy drugs at reduced prices and sell them to patients and their insurers for much more, often at facilities in affluent communities.
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  > One participant is the Cleveland Clinic's flagship hospital, which reported $1.35 billion in net income last year, said the hospital doesn't admit enough Medicaid and low-income Medicare patients to qualify for low-cost drugs under the program's original requirements. But a quirk in federal law allowed the hospital to qualify as a "rural referral center," despite its location near the center of Cleveland (…A Journal analysis of HRSA data found that 88 out of the 111 rural referral centers in the 340B program weren't located in areas deemed rural by HRSA.)
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  > Despite the benefits, the program hasn't resulted in new drug discounts for low-income Cleveland Clinic patients, nor has it caused the hospital to increase the financial assistance it offers to those who can't afford care. The charity care the main hospital writes off represents less than 2% of its patient revenue, according to a Wall Street Journal analysis of hospital Medicare filings.

- A *New York Times* (September 24, 2022) article about Richmond Community Hospital in Virginia, owned by Bon Secours, concluded that the community hospital was using profits from the 340B program to improve facilities in wealthier areas:

  > …that instead of reinvesting profits from 340B drug sales into its DSH facility and improving patient care, the money was being used instead to invest in facilities in the city's wealthier neighborhoods. Dr. Lucas English, who worked in the hospital's emergency department until 2018, said, "Bon Secours was basically laundering money through this poor hospital to its wealthy outposts … It was all about profits." Dr. Peter B. Bach, who has written about the use of 340B profits to open more clinics in wealthier areas, said the hospitals are "nakedly capitalizing on programs that are intended to help poor people.

The cumulative effect of legislation, guidance, and hospital practices has resulted in an increase in the total gross amount of 340B drugs purchased by covered entities from $8B in 2010 to $125B in 2023.[20] Pharmaceutical manufacturers' subsidies to covered entities amounted to roughly half of the $125B. The result is that pharmaceutical manufacturers provided covered entities with an average discount on 340B drugs of more than 50 percent.[21] Because of the interplay of statutory requirements, pharmaceutical manufacturers were and are required to discount some drugs by 100 percent.[22] These subsidies thus enabled covered entities to increase their revenue, which is non-taxable, by upwards of $70B in 2023. Concomitantly, pharmaceutical manufacturers' taxable revenue decreased by up to $70B.

FEDERAL BUDGET CONSIDERATIONS

Data

One challenge Congress faces is that, even after 30 years, HRSA has reported very limited, relevant data on the 340B Program. This scant information makes it impossible to determine many important facts, including the actual value of 340B discounts received by each of the covered entities, the number of eligible patients covered entities treat and the type of insurance they have, the number of duplicate discounts paid by manufacturers to covered entities, or whether the covered entities use the $70B in discounts for the benefit of indigent patients.

Recently, CBO was able to analyze selected HRSA 340B data, including a breakdown by drug class and by contract pharmacy.[23] Unfortunately, this data was reported at the 340B discounted price, which masks trends for drug classes that are often subject to discounts of 90 percent or more.

CBO 1992 Cost Estimate

In 1992, there was little information available on many of the important assumptions of the net effects of the 340B Program on government budgets. CBO patched together data from multiple sources as well as interviews with "…health industry experts."

Ultimately, CBO concluded at the time that the reduction in Medicaid rebates from removing 340B net prices from the best price calculation were offset by the increase in the minimum rebates pharmaceutical manufacturers would be required to pay to Medicaid, and therefore the legislation had no net effect on direct spending for Medicaid. CBO further concluded that other provisions in the 1992 bill affected only appropriated accounts and likely had no effect on the federal budget. Essentially, CBO determined that the 340B Program operated outside the budget.

In providing support to safety-net hospitals that treat indigent patients, the 340B Program is like the Disproportionate Share Hospital (DSH) program, which also helps many of the same hospitals (but 340B assistance comes from manufacturer discounts as opposed to the government). DSH provided $16B in 2023 in federal support to hospitals. DSH payments are counted as spending in the federal budget.

Despite the 1992 determination that 340B would have no impact on the federal budget, the expansion of the program has significantly affected federal and state government budgets.

The size of the program now dwarfs anything anticipated in 1992. There have been major changes in the Medicare and Medicaid programs, including a large increase in enrollment. The ACA enrolled millions of people. The number and type of medications, many of which increase longevity, has grown dramatically. Many of the available medications are used to treat chronic disease, which consume 80 percent of all healthcare costs in the United States. Government spending on pharmaceuticals is five times greater than it was in 1992. All of this is to say that CBO could now adopt a very different perspective on assessing the impacts of 340B.

Decrease in Tax Revenue

Even without comprehensive HRSA data, it is possible to compute that the single largest impact of 340B on the federal budget is the transfer of funds from for-profit pharmaceutical manufacturers to tax-exempt non-profit entities. From a budgetary perspective, diminishing income for taxable entities by shifting the income to tax-exempt entities unambiguously increases annual budget deficits.

The value of the 340B discounts is estimated to be $70 billion last year alone. Since pharmaceutical manufacturers are taxed at an average federal rate of 15 to 20 percent, lost federal corporate tax revenue could be as much as $14B in 2023 and maybe $200B over the next 10 years. When state and local taxes are included in the calculation, the average combined tax rate for pharmaceutical manufacturers is roughly 25 percent. The addition to the tax rate results in a possible reduction of state and local tax revenue by $3.5B per year.

There are likely offsets to this tax loss. The five largest contract pharmacy chains earned approximately $3B in profit from 340B drug sales.[24] Therefore, taxable entities captured a portion of the subsidy from non-profit hospitals. As hospitals create more in-house pharmacies, this offset will diminish. The reduction in negotiated rebates to some payers and plans may also offset some of the 340B losses for manufacturers.

This budget effect through the tax code is very much like the use of special tax provisions, a.k.a. tax expenditures, which generally provide resources to individuals and companies for a specific activity. Tax expenditures diminish federal revenue by lessening taxable income, or by a direct reduction in taxes using tax credits. The effects are not recorded directly in the budget, even though, as the name implies, there could be a concomitant impact through a spending program to achieve the same objective. The loss of revenue through tax expenditures is reflected in the baseline budget deficit, i.e., tax expenditures increase the federal deficit.

In addition to the tax-to-non-tax transfer of revenue, there are other significant financial effects on healthcare beneficiaries, taxpayers, and manufacturers, that further reduce federal tax revenue. For example, the 340B Program reduces the rebates pharmaceutical manufacturers pay to employer-provided health plans, or pharmacy benefit managers acting on their behalf. The effect is that employers and employees lose some or all the value of the rebates manufacturers would have otherwise been providing to employer health plans if claims were not 340B eligible, while covered entities nonetheless receive the 340B discounts. Rebates are replaced by 340B discounts, transferring the value from other payers to covered entities.

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. These effects were recently estimated to raise costs for ERISA employer health plans by over $5B.[25] Due to these increased costs, employees and employers have less taxable income, resulting in lower federal and state tax revenue.

Increase in Government Spending

Medicare drug costs are covered by the government, i.e., taxpayers, and Medicare beneficiaries, who pay premiums and co-pays, are higher because of the 340B Program. Covered entities can receive higher reimbursement for drugs administered to Medicare patients than what they paid for the 340B-discounted drugs. These higher reimbursements translate into increased costs for Medicare Parts B and D, and the associated patients. Put another way, if 340B discounts were used to lower prices for Part B and D, taxpayers and patients would be better off financially.

Additionally, the propensity of covered entities to use more expensive drugs, as GAO's 2018 audit found,[26] will further increase Part B and Part D drug costs, thereby increasing federal spending, and increasing patients' out-of-pocket costs.

The 340B program also directly impacts the Medicare program in other ways. For example, the Office of the Inspector General for HHS (OIG) has found that, like the dynamics in employer plans discussed above, the Part D program is also losing some of the value of rebates manufacturers would otherwise be providing to Part D plan sponsors if prescriptions were not 340B eligible.[27] These lost rebates increase taxpayer costs for the Part D program. In addition, the size of the 340B Program has a direct impact on rebates collected from medical manufacturers under the IRA's Part B and Part D inflation rebates. Because medications on which a 340B discount have been paid are excluded from Part B inflation rebate calculations (and will be excluded from Part D inflation rebate calculations beginning in 2026), as the 340B Program grows larger, inflation rebate collections will fall.

CONCLUSION

Obviously, a decrease in tax revenue and an increase in spending results in an increase in the federal deficit. The 340B Program, like most other "off-budget" provisions, directly reduces federal and state revenue and, in this case increases spending for the Medicare program and its beneficiaries.

Even at current levels, the 340B Program results in a large transfer of taxable income to non-profit entities. As a result, last year alone, federal and state tax revenues were reduced by as much as $17B. Other spillover effects of the discounts reduce revenue even more. The subsidies to covered entities also contribute to an increase in government spending on other health programs, including Medicare Part D.

The 340B Program has grown by double digits every year over the last five years. The Program will continue to grow as more potentially eligible covered entities will apply for 340B designation; more consolidation will occur in the health care sector; the number of people enrolled in Medicare and Medicaid will increase; and the number of eligible patients will continue to expand (especially considering the recent Genesis ruling).

Unlike many other off-budget programs, the indirect impacts of the 340B Program on the federal budget and the deficit have not been documented. The effects of the 340B Program, however, are nonetheless contributing to the federal deficit. Any legislation that has an impact on the budget, now or in the future, is implicitly included in current budget baselines, including CBO's baseline. Accordingly, any legislated reduction in 340B subsidies would

result in a decrease in the federal deficit. Any increase in the subsidies would increase the federal deficit.

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