The 340B Drug Discount Program

Overview

The 340B drug discount program helps covered entities, such as AIDS Healthcare Foundation (AHF), deliver high quality care to under and uninsured patients. AHF provides life-saving specialty prescription drugs at no cost to people living with HIV. The 340B program design provides all parties – drug companies, the federal government, and covered entities – their desired outcomes. Drug companies reap substantial profits. The federal government reduces expenditures. Covered entities receive resources to care for the medically underserved. Now drug companies want to neuter the program. The about-face by the pharmaceutical industry is surprising. Drug makers lobbied aggressively for the 2010 Affordable Care Act (ACA), knowing it would expand the 340B program. For-profit opponents attack the program on multiple fronts. Detractors level dishonest attacks to chip away at the program's bipartisan support. 340B providers can handle unfounded charges. Yet, drug companies go beyond propaganda. Major drug companies ignore lawful federal guidelines and abrogate contractual agreements made with 340B nonprofit providers.

In 1992, federal lawmakers designed section 340B of the Public Health Service Act to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." 340B enables qualified entities to purchase drugs at a significant discount from drug companies. Nonprofit providers use savings from the discounted price to provide comprehensive healthcare services to patients. The drug industry voluntarily participates in the program to access the much more profitable Medicaid and Medicare drug markets. Ever since President George H.W. Bush signed the bill into law, the program has worked as intended. 340B providers strengthen the healthcare safety net by delivering high-quality medical care to low-income Americans at no cost to taxpayers.

What is a 340B Drug?

Covered entities access 340B prices for certain drugs delivered in specific healthcare settings. The statutory formula that determines 340B ceiling prices depends on two pricing benchmarks in the Medicaid Drug Rebate Program: the Basic Medicaid Rebate and the Consumer Price Index (CPI) penalty.[1] The rebate is equal or greater to 23.1% of the average manufacturer's price (AMP) benchmark. The CPI penalty exists to deter drug companies from raising prices higher than the rate of inflation. The 340B ceiling price equals the AMP from the preceding quarter less the unit rebate amount and CPI penalty.[2] The Health Resources & Services Administration (HRSA), an agency within the U.S. Department of Health and Human Services, promulgates guidelines to ensure only eligible patients[3] benefit from 340B discounts. Of note, not all drugs can be purchased at 340B prices. The program mandates discounts *only* for outpatient drugs prescribed by covered entity physicians. 340B prices do not extend to vaccines and drugs provided at 340B providers during inpatient care.[4] Drug makers also do not have to extend discounts for orphan drugs. The Orphan Drug List limits the scope of 340B eligible drugs. HRSA develops the list, which it updates quarterly, as a reference for covered entities.[5] Contrary to drug industry claims, 340B functions as a narrow network of healthcare providers for limited prescription medication categories.

340B Expansion

Multiple legislative changes have focused on

congressional intent for 340B savings to expand healthcare access. Congress did not design 340B as an entitlement program. 340B does not provide prescription drug subsidies to individual consumers. Program structure focuses on covered entities rather than uninsured patients.[6] Legislators planned for 340B price savings to resource comprehensive healthcare for the medically underserved. The plan worked. At the law's inception, covered entities included Medicare/Medicaid disproportionate share hospitals (DSH), federally qualified health centers, Ryan White program grantees, tribal/urban Indian clinics, native Hawaiian health centers, and five types of specialty clinics.[7] The following changes to law expanded the healthcare safety net:

- In 1998, family planning centers became eligible for 340B covered entity status.

- The 2003 Medicare Modernization Act adjusted DSH qualification percentages to make more rural hospitals eligible.
    - The cap on DSH rates changed from 5.25% to 11.75%.[8]

- In 2005, the Deficit Reduction Act extended 340B status to children's hospitals.[9]

- The 2010 Affordable Care Act (ACA) broadened the "covered entity" definition. Under which, critical access hospitals, sole community hospitals, rural referral centers, and cancer centers became 340B eligible.[10]

How to Determine the Size of the 340B Program

340B opponents suggest increases in the number of drug dispensing sites prove the program is out of control. Drug companies reference site growth to obfuscate their attempts to shirk the law. The more accurate measure remains the number of providers deemed covered entities. Sites do not determine 340B discounts. Sites cannot access drugs at 340B prices. Covered entity status alone determines program eligibility. Covered entities purchase prescription drugs at 340B discounted prices for their patients. Sites merely dispense drugs. Drug makers do not lose money when an uninsured, 340B patient procures a brand name medicine. Without the 340B program, drug makers would not have the customer.

Drug Industry Supports and Benefits from Obamacare

Drug companies and health insurers supported the ACA. Overall, the healthcare industry spent over $270 million lobbying for the legislation.[11] In 2009, the Pharmaceutical Researchers and Manufacturers of America (PhRMA) spent nearly $150 million on advertising to support healthcare reform.[12] The drug industry's most powerful trade association recognized the law would be a financial boon for its members. Medicaid expansion and the individual mandate guaranteed millions of new customers backed by a federal payer. Now, drug companies want to renege on their 340B obligations. The drug industry presumes that if not for 340B ceiling prices, each sale would occur at manufacturer list prices. Companies presuppose demand inelasticity for brand name prescription drugs. Yet, the federal payer guarantee creates an advanced market commitment replete with customers that otherwise would not exist. The pharmaceutical industry still makes a healthy profit from 340B sales, just not for retail prices that exceed inflation rates. Drug maker complaints ignore that 340B discount prices build-in demand by the federal government.

Federal Prescription Drug Spending Since the ACA

Prospective Medicaid and Medicare prescription drug spending enticed drug companies to support healthcare expansion embedded in the ACA. The Medicaid Basic Rebate Program requires drug companies to pay the largest rebate amount as a percentage of the AMP for brand name pharmaceuticals. The basic rebate rate started at 12.5%; in 1993, the rate rose to 15.7%; the rate fell to 15.1% in 1996.[13] The ACA set the rebate percentage at its current level, 23.1%. For generic drugs, the rebate rate is 13% of AMP, with no best price provision.[14] Although the ACA passed in 2010, Medicaid expansion did not start until 2014. In 2014 with millions of new enrollees, Medicaid spent $43.2 billion on drugs; with rebates, net spending dropped to $23.2 billion.[15] By 2021, gross spending ballooned to $80.6 billion; rebates lowered net spending to $38.1 billion.[16] Despite the ACA increasing the AMP rate by 53% (from 15.1 to 23.1), drug companies still lobbied for the bill to become law. Medicaid drug spending growth suggests drug makers made an adept decision. Medicare Part D offers an even larger market. Part D began in 2006. First year federal outlays were $33.9 billion; by 2014, costs more than doubled to $72.6 billion; in 2021, expenditures reached $110.1 billion.[17] 2031 outlay estimates come in at $198.5 billion.[18]

Federal Regulators and 340B

Regulatory guidelines have helped expand healthcare access and ensure the proper functioning of the 340B program. HRSA administers the program. Before 1996, covered entities could only distribute drugs through in-house pharmacies.[19] The restriction limited the scope of 340B. At the time, fewer than 5% of covered entities had in-house pharmacies.[20] In response, HRSA allowed covered entities to contract with one outside pharmacy to dispense drugs. Significant program growth traces back to 2010. HRSA allowed covered entities to use multiple contract pharmacies. The change, in line with Congressional intent, extended the reach of an already successful healthcare delivery program.

Covered Entity Audits

Despite HRSA guidelines, drug makers claim 340B lacks sufficient oversight. The pharmaceutical industry insists the program suffers from large-scale ineffective monitoring and compliance challenges. The data tell a different story. HRSA provides sufficient guidelines to ensure program integrity. Covered entities face potential audits from drug companies and the federal government. Compliance failures can result in fines or loss of 340B status. Covered entities must apply for recertification each year and attest that they are in full compliance.[21] The number of covered entities has grown from 9,700 in 2010 to over 12,700 in 2020.[22] HRSA conducted 1,242 audits on covered entities from fiscal years 2012-2019. The audits focused on three areas: covered entity eligibility, drug diversion, and duplicate discounts. Across seven years, HRSA only found 561 instances of covered entity eligibility issues; the overwhelming majority (457) consisted of incorrect record reporting to the Office of Pharmacy Affairs Information System; more importantly, only 40 instances concerned contract pharmacy oversight lapses; 546 instances of 340B drugs dispensed to ineligible patients; 429 instances of drugs receiving both a 340B discount and a Medicaid rebate; of which, only 23 occurred at contract pharmacies.[23] 1,536 total noncompliance occurrences over seven years represent a miniscule number of infractions compared to the number of covered entities (between 9,700 – 12,700), patient interactions, and prescriptions distributed. Drug companies assert the absence of evidence for

systemic nonfeasance requires robust HRSA monitoring to uncover program noncompliance. Rather, absence of such evidence indicates HRSA program integrity efficacy. HRSA program integrity checks from a random sample of 340B covered entities provided the following results:

- HRSA relies on Medicare cost report checks to confirm hospitals only provide 340B prices for outpatient drugs. From 2017 to 2019, only three of the 75 hospitals subject to review had their registration denied due to information in their Medicare cost reports indicating they were ineligible to participate in 340B.[24]

- HRSA reviews covered entity contract pharmacy arrangements to ensure contracts comply with 340B program guidelines. From 2017 to 2019, less than 2% of the 589 contract pharmacy arrangements reviewed were terminated for not meeting HRSA guidelines.[25]

- HRSA requires annual recertification to assess covered entity eligibility to participate in 340B. From 2012 through 2019, almost 2,000 healthcare providers were terminated from the program and thus could no longer access 340B drug discount discount prices.[26]

Based on the evidence, HRSA has a robust accountability system in place.

Drug Companies and 340B Compliance

Drug makers decry HRSA audit capacity, yet drug companies avoided federal oversight for years. HRSA calculates 340B ceiling prices as reference points for audits of both drug makers and covered entities. Covered entities, however, had no access to the information since it is based on proprietary drug maker data.[27] 340B providers could not know if companies overcharged statutorily mandated prices. HRSA waited until 2019, nearly a decade after passage of the ACA (initial guidance on ceiling price "reconciliation" was issued in 1995),[28] to set up the ceiling price database. Without the mechanism in place, drug company good will could masquerade as program compliance.

By law, 340B price hikes which exceed inflation rates will be subject to "penny pricing." Drug companies bemoan "penny pricing" that supposedly crushes their balance sheets. The penalty requires companies to sell the 340B-price overcharged drug to covered entities in the next quarter for one cent. Due to five delays over ten years, the civil monetary penalty existed in theory, not practice.[29] Furthermore, the final rule issued on Jan 1, 2019 stated that the penalty would not be applied retroactively.[30] Federal neglect prevented covered entities from uncovering drug company overcharges. As a result, the for-profit pharmaceutical industry enjoys a 340B pre-2019 price gouging reprieve at the expense of nonprofit healthcare providers.

Database Revelations

Data transparency helps covered entities combat unfounded drug company attacks on 340B. A strong correlation exists between the advent of the ceiling price database and a substantial increase in overcharge findings. Besides self-policing in which companies report overcharges unprompted, HRSA conducts five drug company audits per year. Pre-ceiling price database results from fiscal years 2015 through 2018 only found overcharging in 6% of audits.[31] Since 2019, audits have uncovered overcharging in 67% of cases; in 2021, four-of-five audits showed drug company overcharging.[32] Turns out, the pharmaceutical industry did not reciprocate the good faith efforts by covered entities to

comply with 340B regulatory guidelines. Drug makers alone set list prices for their products. Covered entities play no role in the formulas for statutory pricing benchmarks. The law entitles covered entities to 340B prices. Pre-2019, drug companies knew the requisite 340B prices program compliance demanded and disregarded that legal obligation. 340B price reconciliations accelerated post-2019:

- In December 2022, Eli Lilly announced for the fifth time in one year that it overcharged covered entities for drugs. The most recent instance dates back to the first quarter of 2020.[33]

- In October 2022, Amgen notified HRSA of a second round of refunds for overcharges for 6 brand name drugs dating back to the third and fourth quarters of 2019; the drugs included the market leading treatments such as Enbrel for rheumatoid arthritis ($4.4 billion in sales) and the neutropenia drug, Neulasta ($1.5 billion in sales).[34]

- In August 2022, GlaxoSmithKline announced its third round of refunds for overcharges on 16 unique drugs in the third quarter of 2020; the drugs included several inhaled medicines and a type-2 diabetes treatment.[35]

How Much Does 340B Cost?

The 340B program represents a fraction of overall prescription drug spending in the United States. In 2021, the healthcare system spent $603 billion on prescription medicines; retail drugs accounted for $421 billion of the total.[36] 340B covered entity purchases amounted to $43.9 billion; Ryan White providers, such as AHF, accounted for approximately $1.9 billion.[37] Overall, 340B purchases make up just 7.28% of prescription drug spending. Per prescription spending explains growth more than an increase in utilization.[38] Thus, price increases explain explain growth much better than an increase in the number of drugs prescribed. Many drug price increases exceed inflation. The 340B remedy, penny pricing, likely accounts for substantial growth in 340B reimbursement totals. As drug companies can avoid inflationary penalties, they should not be counted when calculating 340B expenditures.[39] Drug makers count the CPI penalty as revenue loss and part of total 340B purchases. As a sliver of American prescription drug spending, 340B cannot be responsible for rising total drug expenditures. In fact, the 340B CPI penalty puts downward pressure on prescription drug prices.

Drug Companies Ignore Contract Pharmacy Provisions

Drug companies disguise contract pharmacy restrictions in program integrity language to facilitate their desired financial outcomes. HRSA guidelines allowed 340B providers to use multiple contract pharmacies in 2010; yet, en masse restrictions did not start until 2020, just one year after the ceiling price database came online. With restrictions, drug makers dodge lawful HRSA contract pharmacy guidelines to sidestep mandated penny pricing. The most significant 340B discounts result from the civil monetary penalties.[40] Drug makers have an easy remedy; raise list prices in line with inflation rates, not more. To parry revenue losses, pharmaceutical companies justify restrictions as best practices to avoid duplicate discounts. Drug companies argue out of control growth in contract pharmacy agreements preclude proper oversight. Simply stated, drug companies want to be able to raise list prices year-over-year without inflation penalties. The problem involves how the pharmaceutical industry now views a program it once championed.

Program obligations threaten the balance sheet. In legal terms, 340B prices have become akin to financial exposure. Drug companies limit those risks by ignoring their contractual obligations. Restrictions limit patient access to medications. Drug company maneuvers violate federal law. The law is clear. Drug companies must provide 340B prices to covered entities irrespective of the drug dispensing locations.

- As higher list prices generate significant revenue, drug companies have a financial incentive to maximize profit – inflation penalties encourage lower list prices. A study of 606 brand name drugs from 2013-2017 shows that lower prices to avoid inflation penalties in Medicare Part D saved the program $7 billion over the period.[41]

- Contract pharmacy restrictions couched as best practices to prevent duplicate discounts represent a cynical ploy to solve a nonexistent problem. HRSA conducted 638 hospital audits since 2018 to ensure Medicaid fee-for-service compliance rules; not one 340B contract pharmacy duplicate discount occurred.[42]

- In 2021, HRSA told six drug companies they were violating federal law by using contract pharmacy restrictions to deny covered entities 340B prices.[43]

Conclusion

For decades, the 340B program has worked as intended. If protected, the program will continue to deliver high-quality care to underserved patients. 340B program design creates incentives for private and public sector participation. Legislative and regulatory changes expanded healthcare access. At each step, drug companies supported expansion. 340B expansion created a larger market for pharmaceutical industry products. Drug companies received what they signed up for, increased revenues with healthy profits. With their expectations met, drug companies decided to renege on the deal. Significant revenue growth from all federal healthcare programs will not satisfy drug industry profit-motives. Drug companies resent that they cannot maximize profits at the expense of 340B patients. 340B savings help nonprofits, such as AHF, reach patients the for-profit healthcare system shuns. Federal lawmakers and HRSA must enforce the contractual 340B program obligations drug companies ignore.

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[1] Aaron Vandervelde, Kevin Erb, and Lauren Hurley," For-Profit Participation in the 340B Program," Berkeley Research Group, 2020: 6. https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf

[2] Health Resources and Services Administration, 340B Drug Pricing Program, FAQs, https://www.hrsa.gov/opa/faqs?categories=All&keywords=

[3] According to the Federal Register, Vol. 61, No. 207, Thursday, October 24, 1996 / Notices, pg 55157: To be eligible, a patient must: 1) have a prior relationship with the covered entity, 2) receive healthcare services from the covered entity, and 3) the healthcare services remain consistent with federal grant.

[4] C. Frederick Geilfuss and Maureen Kwiecinski, "Patient Protection and Affordable Care Act Expands Preferential 340B Drug Pricing to New Entities," Bloomberg Law Reports, Vol. 3, No. 8, 2010.
[5] Health Resources and Services Administration, 340B Drug Pricing Program, Orphan Drugs, https://www.hrsa.gov/opa/program-requirements/orphan-drug-exclusion
[6] Andrew W. Mulcahy, Courtney Armstrong, Jeffrey Lewis, and Soeren Mattke, "The 340B Prescription Drug Discount Program," RAND, 2013: 5.
[7] Karen Mulligan, "The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments," USC Schaeffer, 2021: 1.
[8] "340B Discount Program," 6.
[9] *Deficit Reduction Act of 2005*, 109th Congress, 2005-06, https://www.govinfo.gov/content/pkg/PLAW-109publ171/pdf/PLAW-109publ171.pdf
[10] "340B Discount Program," 5.
[11] Alyce McFadden, "The Long, Costly Battle Over Obamacare Might Be Over," *Open Secrets*, June 23, 2021, https://www.opensecrets.org/news/2021/06/costly-battle-obamacare-over/
[12] Brett Norman and Sara Karlin-Smith, "The One that Got Away: Obamacare and the Drug Industry," *Politico*, June 13, 2016, https://www.politico.com/story/2016/07/obamacare-prescription-drugs-pharma-225444
[13] Congressional Budget Office, "How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry," January 1996: 12, https://www.cbo.gov/sites/default/files/104th-congress-1995-1996/reports/1996doc20.pdf
[14] Rachel Dolan, "Understanding the Medicaid Prescription Drug Rebate Program," Kaiser Family Foundation, November 12, 2019, https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/
[15] Ibid.
[16] Medicaid and CHIP Payment and Access Commission, "Trends in Medicaid Drug Spending and Rebates," October 2022, https://www.macpac.gov/publication/trends-in-medicaid-drug-spending-and-rebates/
[17] Centers for Medicare & Medicaid Services, "2022 Medicare Trustees Report," August 15, 2022, pg 228, https://www.cms.gov/files/document/2022-medicare-trustees-report.pdf
[18] Ibid.
[19] Ted Slafsky, "The 20 Key Moments in the 340B Program's 30-Year History," *The Omnicell Blog*, November 2, 2022, https://www.omnicell.com/blog/the-20-key-moments-in-the-340b-programs-30-year-history
[20] "340B Challenges and Developments," 1.
[21] Health Resources & Services Administration, 340B Drug Pricing Program, Program Integrity, https://www.hrsa.gov/opa/program-integrity
[22] Government Accountability Office, "Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements," December 2020: 1. https://www.gao.gov/assets/gao-21-107.pdf
[23] Ibid, 17.
[24] Ibid, 17.
[25] "HHS Mechanisms," 18.
[26] Ibid, 19.
[27] "340B Challenges and Developments," 7.
[28] Department of Health and Human Services, Public Health Service, *Notice Regarding Section 602 of the Veterans Health Care Act of 1992; New Drug Pricing*, Federal Register, Final Notice, Vol. 60, No. 190, October 2, 1995, https://www.govinfo.gov/content/pkg/FR-1995-10-02/pdf/95-24349.pdf
[29] Lisa Scholz, "340B Program Transparency: Is It 'Transfairency'"? *The Pharmacy Times*, March 8, 2020, https://www.pharmacytimes.com/view/340b-program-transparency-is-it-transfairency
[30] Department of Health and Human Services, Center for Medicare & Medicaid Services, *Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses*, Federal Register, Final Rule, Vol. 84, No. 100, May 23, 2019, https://www.govinfo.gov/content/pkg/FR-2019-05-23/pdf/2019-10521.pdf
[31] "340B Transparency Efforts Uncovering More Drug Company Overcharges," *340B Informed*, December 8, 2021, https://340binformed.org/2021/12/340b-transparency-efforts-uncovering-more-drug-company-overcharges/
[32] "340B Transparency Efforts."

[33] Tom Mirga, "Lilly for the Fifth Time This Year Announces Refunds for 340B Overcharges," *340B Report*, Dec 8. 2022, https://340breport.com/lilly-for-the-fifth-time-this-year-announces-refunds-for-340b-overcharges/
[34] Laura Gilcrest, "Amgen Announces Second Round of Refunds this Year for 340B Overcharges," *340B Report*, October 12, 2022, https://340breport.com/amgen-announces-second-round-of-refunds-this-year-for-340b-overcharges/
[35] Tom Mirga, "GSK Announces Third Round of Refunds This Year for 340B Overcharges," 340B Report, August 23, 2022, https://340breport.com/gsk-announces-third-round-of-refunds-this-year-for-340b-overcharges/
[36] Department of Health and Human Services, Office of Science & Data Policy, "Issue Brief: Trends in Prescription Drug Spending, 2016-2021," September 2022, https://aspe.hhs.gov/sites/default/files/documents/88c547c976e915fc31fe2c6903ac0bc9/sdp-trends-prescription-drug-spending.pdf
[37] Health Resources & Services Administration, "2021 340B Covered Entity Purchases," accessed December 12, 2022, https://www.hrsa.gov/opa/updates/2021-340b-covered-entity-purchases
[38] Trends in Drug Spending."
[39] Allen Dobson, Kennan Murray, and Joan E. DaVanzo, "Assessing the Financial Impact of the 340B Drug Pricing
[40] Maureen Testoni, "Pursuit of Profits is Driving Drug Companies to Break the 340B Law," *STAT News*, June, 10, 2022, https://www.statnews.com/2022/06/10/pursuit-of-profits-is-driving-drug-companies-to-break-the-340b-law/
[41] Sean Dickson, "Association Between the Percentage of US Drug Sales Subject to Inflation Penalties and the Extent of Drug Price Increases," *JAMA Network Open*, September 11, 2020, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2770540
[42] "Contract Pharmacy Restrictions Represent Growing Threat to 340B Hospitals and Patients," *340B Health*, March 2022, https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_FINAL_05-05-2022.pdf
[43] Robert King, "HRSA demands 6 Drug Makers Stop Cutting Off Sales of 340B Drugs to Contract Pharmacies," *Fierce Pharma*, May 7, 2021, https://www.fiercehealthcare.com/hospitals/hrsa-demands-6-drug-makers-stop-cutting-off-sales-340b-drugs-to-contract-pharmacies