



How DSH Hospitals Abuse the 340B Drug Pricing Program

Many hospitals in the 340B Program are exploiting lax eligibility criteria and program guardrails to profit from the substantial 340B discounts that were intended to ensure low-income access to discounted prescription drugs and services. Despite the intent of the program, the 340B statute does not restrict how DSH hospitals and other covered entities can use revenue from the 340B Program.¹ **Many studies have shown how the actions of hospitals have hurt, rather than helped patients by limiting their access to treatment and affordable therapy options.**^{2,3}

Growth of 340B Program in recent years:

In 2021, 340B discounted purchases totaled \$44 billion, representing \$93.6 billion in sales at list prices.⁴ By the end of 2021, 340B Program sales made up 14% of total U.S. brand-name pharmaceutical sales and grew four times faster than the overall pharmaceutical market. In 2022, the program reached \$106 Billion in sales at list prices.⁵

If the program continues growing at this rate it will soon surpass even Medicare Part D, which is projected to be \$119 billion in 2023.⁶

The trends driving this growth are:

- Exploitation of 340B eligibility criteria and lax oversight;
- Perverse financial incentives embedded in the program;
- Inappropriate growth of “off-site clinics” that have resulted in consolidated outpatient clinics, specifically in wealthier areas, running counter to the original intent of the program; and,
- Substantial use of contract pharmacies by 340B DSH Hospitals.

This growth in the program has been associated with tremendous acquisition and consolidation of outpatient clinics, especially in hematology and oncology space,⁷ leading to increased costs to patients and fewer community clinics to access care. These explosive trends have largely been caused by the dramatic growth and abuse of the 340B Program by disproportionate-share (DSH) hospitals. According to the Medicare Payment Advisory Commission (MedPAC), DSH hospitals now account for more than 80% of 340B sales.⁸

Hospital Eligibility

- Government-owned and private non-profit hospitals must meet certain requirements before being deemed eligible to participate in the 340B Program. The first is that the hospital must have a formalized relationship with state or local government to provide services for the 340B low-income population.

¹ MedPAC, “Overview of the 340B Drug Pricing Program,” May 2015. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf (Accessed: April 25, 2023)

² Desai, Sunita, Ph.D., and McWilliams, J. Michael, M.D., Ph.D., “Consequences of the 340B Drug Pricing Program,” New England Journal of Medicine, February 8, 2018. <https://www.nejm.org/doi/full/10.1056/nejmsa1706475> (Accessed: April 25, 2023)

³ “How Abuse of the 340B Program is Hurting Patients,” Community Oncology Alliance, August 31, 2017. <https://mycoa.communityoncology.org/education-publications/studies/how-abuse-of-the-340b-program-is-hurting-patients> (Accessed: May 11, 2023)

⁴ Fein, Adam, “The 340B Program Climbed to \$44 Billion in 2021—With Hospitals Grabbing Most of the Money,” Drug Channels, August 15, 2022. <https://www.drugchannels.net/2022/08/the-340b-program-climbed-to-44-billion.html#:~:text=For%202021%2C%20discounted%20purchases%20under,of%20these%20skyrocketing%20340B%20purchases.> (Accessed: April 20, 2023)

⁵ Martin, Rory, Ph.D., “The 340B Drug Discount Program Exceeds \$100B in 2022,” IQVIA, April 2023. <https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2023/340b-drug-discount-program-exceeds-usd-100b-in-2022.pdf> (Accessed: April 20, 2023)

⁶ “An Overview of the Medicare Part D Prescription Drug Benefit,” Fact Sheet, Kaiser Family Foundation, October 19, 2022. <https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/> (Accessed: May 11, 2023)

⁷ Consequences of 340B, February 8, 2018.

⁸ MedPAC, Overview, May 2015.

Hospital Eligibility (Continued)

- The second eligibility requirement is that all hospitals, except for critical access hospitals, rural referral centers, and sole community hospitals,⁹ **must have a disproportionate share adjustment percentage (DSH percentage) of 11.75% or above**, as reported on a hospital's Medicare cost report.
 - Using this metric equates apples to oranges in that it measures the extent that a hospital treats a disproportionate share of low-income Medicaid and Medicare beneficiaries in the inpatient setting, while the 340B Program is limited to outpatient drugs.
 - In addition, the DSH percentage does not reflect care provided by a hospital to other uninsured or charity-care patients, whom the 340B Program is intended to benefit.
- As the US Government Accountability Office (GAO) indicates, **financial incentives provide great motivation for hospitals to meet 340B eligibility criteria**.¹⁰ Research has shown that hospitals appear to be strategically adjusting their DSH percentage to become eligible for the 340B Program. The number of hospitals slightly above the 11.75% threshold increases by 41% than those just below the threshold.¹¹ "The increase at the cutoff is significantly larger than what would be expected by chance alone . . ."¹²
- The GAO found that the processes at the Health Resource and Services Administration (HRSA) **do not provide assurances that private non-profit hospitals meet eligibility criteria**.¹³ HRSA relies mainly on self-reporting to verify state and local contracts for eligibility, and "weaknesses in the reviews of contracts it does conduct hamper the identification of potential eligibility issues."¹⁴
- Many state and local contracts that were used to qualify for 340B eligibility are questionable. According to the GAO, one contract it reviewed was for the treatment of tuberculosis that clearly stated that only 1 patient had been treated in the previous 7 years for the purpose of the contract, yet it qualified for the lucrative discounts under 340B.¹⁵

Financial Incentives

Non-profit 340B hospitals' profitability is 37% more than all average hospitals.¹⁹

- As the GAO notes, there are vast financial incentives embedded in the 340B Program. Hospitals can produce great profit from participating in the 340B Program by purchasing covered outpatient drugs at discounts ranging from 20% to well more than 50%, often even up to near 100%.^{16, 17, 18} Then they receive reimbursement from insured patients typically at full list price.
- One example of the significant profits that can be made was highlighted in an anti-kickback lawsuit (unrelated to the 340B profits) brought by US Attorney's District Attorney's Office in the Middle District of Tennessee against Methodist Le Bonheur and Methodist Healthcare-Memphis Hospitals (Methodist) and West Clinic, P.C. After purchasing West's outpatient oncology locations, Methodist was able to take in \$50 million in profits in one year alone off of the 340B Program.²⁰
- Financial incentives have caused trends in which newly registered 340B DSH hospitals and clinics, beginning in 2004, have tended to be in higher-income communities compared to hospitals that joined the 340B Program earlier.²¹
- These trends appear to be leading hospitals to **steer patients toward more expensive drugs**. The GAO found, "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."
- Further, according to a study by the Community Oncology Alliance, "340B hospitals' own self-reported pricing data reveals that **they price the top oncology drugs at 4.9 times their 340B acquisition costs, assuming a 34.7 percent discount**, which is a conservative estimate based on 340B hospital survey data collected by the Centers for Medicare & Medicaid Services (CMS)."²³

In 2012, average per beneficiary spending at 340B DSH hospitals was \$144, compared to approximately \$60 at non-340B hospitals. The differences did not appear to be explained by the hospital characteristics GAO examined or patients' health status."²²

⁹ Eligibility for critical access hospitals, rural referral centers, and sole community hospitals were allowed in 2010 in the *Affordable Care Act* and they have contributed to the number of hospitals participating in the 340B Program. Rural referral centers and sole community hospitals must meet a DSH Percentage threshold of 8%, while critical access hospitals do not need to meet any threshold.

¹⁰ "340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements," US Government Accountability Office, December 2019. <https://www.gao.gov/assets/gao-20-108.pdf> (Accessed: April 24, 2023)

¹¹ Mulligan, Karen, Romley, John A., and Myerson, Rebecca, "Access to the 340B Drug Pricing Program: Is there evidence of strategic hospital behavior?", *BMC Research Notes*: Open Access, 2021. <https://bmcrsnotes.biomedcentral.com/articles/10.1186/s13104-021-05642-4#:~:text=We%20found%20no%20comparable%20change,oversight%20of%20the%20340B%20program.> (Accessed: April 24, 2023)

¹² *Ibid.*

¹³ *Increased Oversight Needed*, GAO, December 2019.

¹⁴ *Ibid.*

¹⁵ *Ibid.*

¹⁶ *Increased Oversight Needed*, GAO, December 2019.

¹⁷ 42 CFR Part 10, 1210, Federal Register, January 5, 2017. <https://www.hrsa.gov/sites/default/files/hrsa/opa/federal-register-1-5-2017.pdf> (Accessed: April 25, 2023)

¹⁸ Health Resources and Services Administration.

¹⁹ Winegarden, Wayne, "Profiting from 340B: A Review of Charity Care and Financial Performance at 340B Hospitals," Pacific Research Institute Center for Medical Economics and Innovation, November 2021. https://www.pacificresearch.org/wp-content/uploads/2021/11/340B-Study_FinalWeb.pdf (Accessed: April 25, 2023)

²⁰ United States Files Suit Against Methodist Le Bonheur Healthcare and Methodist Healthcare-Memphis Hospitals," Press Release, US Attorney's Office, Middle District of Tennessee. April 11, 2022. <https://www.justice.gov/usao-mdtn/pr/united-states-files-suit-against-methodist-le-bonheur-healthcare-and-methodist> (Accessed: April 20, 2023)

²¹ Conti RM, Bach PB. The 340B drug discount program: hospitals generate profits by expanding to reach more affluent communities. *Health Affairs*, 2014. <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.0540> (Accessed: April 25, 2023)

²² "Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals" U.S. Government Accountability Office, June 2015. <https://www.gao.gov/assets/gao-15-442.pdf> (Accessed: April 25, 2023)

²³ "Examining Hospital Price Transparency, Drug Profits, and the 340B Program 2022," Community Oncology Alliance, September 12, 2022. <https://mycoa.communityoncology.org/education-publications/studies/examining-hospital-price-transparency-drug-profits-and-the-340b-program-2022> (Accessed: May 3, 2023)

²⁴ Nikpay, Sayeh, et al., "The Incidence of Hospital Drug Price Subsidies: 340B, Drug Utilization, and Subsidized Medical Care," Conference Study Paper, American Society of Health Economists Conference, American Society of Health Economists, June 26, 2019. <https://ashecon.confex.com/ashecon/2019/webprogram/Paper8192.html> (Accessed: May 3, 2023)

²⁵ Desai, Sunita, Ph.D., and McWilliams, J. Michael, M.D., Ph.D., "Consequences of the 340B Drug Pricing Program," *New England Journal of Medicine*, February 8, 2018. <https://www.nejm.org/doi/full/10.1056/nejmsa1706475> (Accessed: April 25, 2023)

Financial Incentives (Continued)

- It follows that there is an increase in out-of-pocket costs because patient cost-sharing is based on the amount the off-site clinic and hospital are reimbursed for the drug, not the amount they paid. This is supported by additional study results that indicate that hospital 340B participation increases cost-sharing amounts billed to Medicare beneficiaries by 16.79%.²⁴

Off-Site Clinics

One area in which the 340B Program is experiencing substantial growth and abuse relates to the increased participation of hospital off-site clinics (often called “child sites”).

As of August 12, 2021, there were 1,129 340B-enrolled DSH hospitals, which had 21,841 registered off-site clinics, only 29% of which were in medically underserved areas.²⁶

- There is evidence that **hospitals are increasingly acquiring community-based physician practices, especially in oncology**—often in wealthier or distant locations—motivated, in part, by enabling these acquired facilities to participate in the 340B Program, through converting them to hospital outpatient departments with substantial financial benefits for the parent hospital.²⁵
 - In one example, as highlighted in the New York Times, Ben Secours Mercy Health (Mercy) in Richmond, Virginia opened new clinics in suburban more affluent areas with the 340B profits from Richmond Community Hospital, which serves a predominantly Black neighborhood. Mercy had slashed services at Richmond Community Hospital, leaving it with a radiology unit in disrepair and closing its intensive care unit. The hospital exists today with a mere emergency room and a psychiatric ward. Yet, Richmond Community Hospital has the highest profit margins of any hospital in Virginia generating as much \$100 million per year because of its 340B purchases. Unfortunately, while services have been cutback in a community that sorely needs it, Mercy has used that money to open nine off-site clinics in wealthier parts of Richmond since 2013.²⁷
 - In another example, the Cleveland Clinic, in Cleveland, Ohio, adopted the 340B Program in April 2020. While the hospital’s main campus is in a medically underserved area, it has hundreds of off-site clinics in wealthier areas with more private health insurance. The hospital’s 340B profits for the 3 quarters it participated in 2020 were a staggering \$136 million.²⁸
- According to a study funded by the U.S. Agency for Healthcare Research and Quality (and others), “the 340B Program has been associated with hospital–physician consolidation in hematology–oncology and with more hospital-based administration of parenteral drugs in hematology–oncology and ophthalmology. **Financial gains for hospitals have not been associated with clear evidence of expanded care or lower mortality among low-income patients.**”²⁹

Contract Pharmacy

By using external “Contract” pharmacies, a 340B DSH hospital can profit from the program when patients fill their prescriptions at a pharmacy that is not located within or owned by the hospital. DSH hospitals have played a significant role in contract pharmacy growth.

- An October 2020 study found that from April 2010 to April 2020 contract pharmacy arrangements in the program grew by 4,228% from 2,321 in 2010 to 101,469 in 2020,³⁰ in 2022, this number increased to 168,000.³¹ Unique pharmacy locations have grown from approximately 1,300 in 2010 to roughly 32,000 in 2022.³²
 - According to one analysis, “the average profit margin on 340B medicines commonly dispensed through contract pharmacies is an estimated 72% compared with just 22% for non-340B medicines dispensed through independent pharmacies.”³³
- Studies show, DSH hospitals use for-profit pharmacies to expand their reach into more affluent areas, while their use of contract pharmacies in low-income medically underserved areas declined.³⁴
- DSH hospitals have played a significant role in contract pharmacy growth. According to the GAO, “Among covered entities that had at least 1 contract pharmacy, **the number of contract pharmacies ranged from 1 to 439, with an average of 12 contract pharmacies per entity.** However, the number of contract pharmacies varied by covered entity type, with disproportionate share hospitals having the most on average (25 contract pharmacies), and critical access hospitals having the least (4 contract pharmacies).”³⁵

²⁶ 340B and Health Equity: a missed opportunity in medically underserved areas,” Xcenda, 2021. https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_issue_brief_340b_muas_nov2021.pdf (Accessed: April 25, 2023)

²⁷ Thomas, Katie, and Silver-Greenberg, Jessica, “Profits Over Patients: How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits,” *New York Times*, September 27, 2022. <https://www.nytimes.com/2022/09/24/health/bon-secours-mercy-health-profit-poor-neighborhood.html?smid=tw-share> (Accessed: April 25, 2023)

²⁸ Mathews, Anna Wilde, et al., “Many Hospitals Get Big Drug Discounts. That Doesn’t Mean Markdowns for Patients,” *Wall Street Journal*, December 20, 2022. <https://www.wsj.com/articles/340b-drug-discounts-hospitals-low-income-federal-program-11671553899> (Accessed: April 26, 2023)

²⁹ Consequences of 340B, NEJM, February 8, 2018.

³⁰ Vandervelde, Aaron, et al., “For-Profit Pharmacy Participation in the 340B Program,” BRG Group, October 2020. <https://www.thinkbrg.com/insights/publications/for-profit-pharmacy-participation-340b/> (Accessed: April 25, 2023)

³¹ Nikpay, Sayeh, Ph.D., MPH, and Gracia, Gabriela Ph.D., “Association of 340B Contract Pharmacy Growth with County-Level Characteristics, American Journal of Managed Care, March 2022. <https://www.ajmc.com/view/association-of-340b-contract-pharmacy-growth-with-county-level-characteristics> (Accessed: May 9, 2023)

³² Fein, Adam, “Exclusive: Five Pharmacy Chains and PBMs Dominate 2022’s Still Booming 340B Contract Pharmacy Market,” July 12, 2022. Accessed: January 4, 2023. <https://www.drugchannels.net/2022/07/exclusive-five-pharmacies-and-pbms.html>

³³ Ibid.

³⁴ Vandervelde, October 2020.

³⁵ Nikpay, Sayeh, Ph.D., MPH, and Gracia, Gabriela Ph.D., “Association of 340B Contract Pharmacy Growth with County-Level Characteristics, American Journal of Managed Care, March 2022. <https://www.ajmc.com/view/association-of-340b-contract-pharmacy-growth-with-county-level-characteristics> (Accessed: May 9, 2023)

³⁶ “Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement,” US GAO, June 2018. <https://www.gao.gov/assets/gao-18-480.pdf> (Accessed: May 9, 2023)

Contract Pharmacy (Continued)

- According to research, the average distance between a contract pharmacy and the 340B Hospital is 334 miles.³⁶ **There is no requirement limiting the geographic distance between a covered entity and any of its contract pharmacies;** at least 45% of DSH hospitals have at least one contract pharmacy that is more than 1,000 miles away, with some being more than 5,000 miles away.³⁷
- **Pharmaceutical benefit managers (PBMs) have now expanded into the contract pharmacy business. Today, five pharmacy chains and PBMs control 73% of the 340B contract pharmacy business,** four of which are PBMs:
 - Walgreens (Boots Alliance)
 - CVS Health (including Caremark and Aetna)
 - Express Scripts (owned by Cigna)
 - OptumRx (owned by United Health).³⁸
- Approximately, 70% of contract pharmacy relationships are with DSH or children's hospitals.³⁹

"The three largest PBMs—CVS Health, Express Scripts, and OptumRx—collectively have about 500 mail, specialty, and infusion pharmacy locations acting as 340B contract pharmacies. Combined, these locations have nearly 35,000 relationships with covered entities. Consequently, the big three PBMs' non-retail pharmacies account for only 1.5% of 340B contract pharmacies—but 21% of 340B contract pharmacy relationships."⁴⁰

Charity Care at Non-Profit Hospitals is Decreasing

- Despite the dramatic uptick in sales and the fact DSH hospitals now account for more than 80% of 340B sales,⁴¹ 340B DSH hospitals have been providing less charity care. **Studies show the majority of 340B DSH hospitals (63%) provide charity care at a level less than the national average of all hospitals.**⁴² Further "nearly one-third (29%) of 340B DSH hospitals provide charity care that represents less than 1% of their total patient costs."⁴³ This is also underscored by the fact that for-profit hospitals have been found to provide more charity care than their non-profit counterparts.⁴⁴
- In addition to the significant profits these non-profit hospitals receive from the 340B Program, **these hospitals also receive significant tax breaks from the government, with tax exempt status for providing charity care.** Unfortunately, according to the Lown Institute Hospitals Index, 77% of non-profit hospitals it evaluated had a fair share deficit, meaning they spent less on charity care and community investment—a requirement in order to receive the tax breaks—than they received in tax breaks.⁴⁵
- **These same hospitals have been known to conduct rapacious debt collection against many people who would normally qualify for charity care services.** According to a study by Johns Hopkins University of America's top 100 hospitals, between January 2018, and July 2020, tens of thousands of lawsuits were brought against patients. These suits were most prevalent amongst government and non-profit hospitals,⁴⁶ many of which are 340B hospitals.

Conclusion

There are numerous examples and studies demonstrating how 340B DSH hospitals abuse the 340B Program. This abuse has played a significant role in the dramatic growth in the 340B Program over the last 13 years. **Unfortunately, rather than helping patients, these activities have directly harmed them by steering them toward more expensive medicines, increasing their out-of-pocket costs and limiting their treatment options.**

³⁶ Vandervelde, October 2020.

³⁷ Oversight of Compliance, GAO Report, June 2018.

³⁸ "Five Pharmacy Chains and PBMs Dominate 2022's Still Booming 340B Contract Pharmacy Market," Drug Channels Blog, July 12, 2022. <https://www.drugchannels.net/2022/07/exclusive-five-pharmacies-and-pbms.html> (Accessed: April 25, 2023)

³⁹ Fein, Adam, "340B Continues Its Unbridled Takeover of Pharmacies and PBMs," Drug Channels, June 15, 2021. <https://www.drugchannels.net/2021/06/exclusive-340b-continues-its-unbridled.html> (Accessed: April 26, 2023)

⁴⁰ Pitts, Peter J., and Popovian, Robert, "340B and the Warped Rhetoric of Healthcare Compassion," Food Drug Law Institute, Fall 2022. <https://www.fdli.org/2022/09/340b-and-the-warped-rhetoric-of-healthcare-compassion/> (Accessed: April 25, 2023)

⁴¹ MedPAC, Overview of the 340B Drug Pricing Program, May 2015. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf (Accessed: April 25, 2023)

⁴² "Left Behind: An Analysis of Charity Care Provided by hospitals enrolled in the 340B Discount Program," Air340B, November 2019. https://340breform.org/wp-content/uploads/2021/04/AIR340_LeftBehind-v6.pdf (Accessed: April 25, 2023)

⁴³ Ibid.

⁴⁴ Bai, Ge, et al. "Analysis Suggests Government And Nonprofit Hospitals' Charity Care Is Not Aligned With Their Favorable Tax Treatment," Health Affairs, April 2021. <https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01627>

⁴⁵ "Fair Share Spending: How much are hospitals giving back to their communities?," Lown Institute Hospitals Index, April 2023. <https://lownhospitalsindex.org/2023-fair-share-spending/> (Accessed: April 24, 2023)

⁴⁶ McGhee, Michelle, and Chase, Will, "How America's Top Hospitals Hound Patients with Predatory Billing," Johns Hopkins University Study in partnership with Axios, June 14, 2021. <https://www.axios.com/hospital-billing> (Accessed: April 24, 2023)