HOW DSH HOSPITALS ABUSE THE 340B DRUG PRICING PROGRAM

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 restricted their affordable therapy options.**

Growth of the 340B Program

In 2022, the 340B Program reached **$106 Billion in sales** at list prices[2] and is now the second largest pharmaceutical program in the nation behind Medicare Part D, fueled largely by the dramatic growth and abuse of the 340B Program by disproportionate-share (DSH) hospitals. If the program continues growing at the rate it will soon surpass even Part D that is projected to amount to $119 billion in 2023. This explosive trend has been largely caused by the dramatic growth and abuse of the 340B program by disproportionate-share (DSH) hospitals, which now account for more than 80% of 340B sales. This growth in the program has been associated with tremendous acquisition and consolidation of outpatient clinics, especially in hematology and oncology space, leading to increased costs to patients and fewer community clinics to access care.

The key trends driving this growth are:

- Exploitation of 340B eligibility criteria and lax oversight;
- Perverse financial incentives embedded in the program;
- Inappropriate growth of "child sites," specifically in wealthier areas, running counter to the original intent of the program; and,
- Substantial use of contract pharmacies by 340B DSH hospitals.

Hospital Eligibility

Government-owned and private non-profit hospitals must meet certain requirements before being deemed eligible to participate in the 340B Program:

- The hospital must have a formalized relationship with state or local government to provide services for the 340B low-income population. The US Government Accountability Office (GAO) found that Health Resource and Services Administration (HRSA) does not assure that private non-profit hospitals meet eligibility criteria.[3]
- All hospitals, except for critical access hospitals, rural referral centers, and sole community hospitals,[4] 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. It also does not reflect care provided by a hospital to other uninsured, or charity-care, patients, whom the 340B Program is intended to benefit.

Financial Incentives

- As GAO indicates, hospitals can produce great profit from participating in the 340B Program by purchasing covered outpatient drugs at discounts ranging from 20% **to sometimes near 100%**.[5,6,7] They then receive reimbursement from insured patients typically at full list price.
- 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."[10]

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 from the 340B Program.[11]

Non-profit 340B hospitals' profitability is 37% more than all average hospitals.[8]

"On average, beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs [to widen the price spread] than beneficiaries at the other hospitals in [GAO's] analysis."[9] —GAO

[1] MedPAC, Overview, May 2015.
[2] 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)
[3] "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)
[4] 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.
[5] Increased Oversight Needed, GAO, 2019.
[6] 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)
[7] Health Resources and Services Administration
[8] 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)
[9] "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)
[10] "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)
[11] 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)

Biotechnology Innovation Organization

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.[13]

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").

- Hospitals are increasingly acquiring community-based physician practices,—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.[12] This exacerbates existing health inequities, as demonstrated by the examples below.

Ben Secours Mercy Health (Mercy) in Richmond, Virginia opened new 9 new off-site clinics since 2013 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 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.[14]

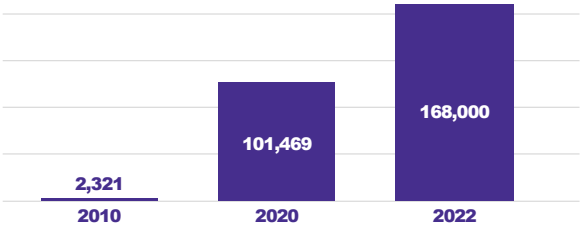
The Cleveland Clinic, in Cleveland, Ohio, adopted the 340B Program in April 2020. While the hospital's main campus is in a medically underserved area, it has hundreds of off-site clinics in wealthier areas with large numbers of private health insurance. The hospital's 340B profits for the 3 quarters it participated in 2020 were a staggering $136 million.[15]

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.

- The expansion of contract pharmacy after 2010 has contributed greatly to the explosion of growth in the 340B Program. 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,[16] in 2022, this number increased to 168,000.[17]

The expansion of contract pharmacy since 2010



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,[18] 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.[19]
- 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.[20]

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.

[12] 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)
[13] 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)
[14] 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.
[15] 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)
[16] Vandervelde, Aaron, et al., For-Profit Pharmacy Participation in the 340B Program, BRG Group, October 2020.)
[17] 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)
[18] 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)
[19] "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)
[20] "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)