BIO ISSUE BRIEF

340B Issue Brief: Patient Benefits from 340B Have Eroded

Congress created the 340B Drug Discount Program to help uninsured and vulnerable patients gain access to affordable prescription drugs and services. Over the years this program has expanded well past the original intent of Congress and now patients are not seeing the benefits they deserve.

The 340B Program has grown exponentially in recent years because of the significant financial incentives embedded within the program. Unfortunately, many of the trends that have contributed to the explosive growth in the program are "caus[ing] a decline in affordability of needed prescription drugs, needed medical care . . . for the most medically underserved areas,"[1] exacerbating health inequities.

Most Patients are Not Receiving the Discounts

A 2022 study by IQVIA suggests only 1.4% of patients are receiving discounts on 340B drugs at contract pharmacies.[2] This is because while 340B-eligible providers may pass along the discounts to patients, most are not required to do so. Indeed, a majority of disproportionate share (DSH) hospitals do not, and the 340B statute does not require them to, pass along drug discounts to patients. DSH hospitals now account for more than 80% of 340B sales,[3] while children's and DSH hospitals account for more than 70% of contract pharmacy arrangements.

According to a report by the U.S. Government Accountability Office (GAO), only 12 hospitals that responded to a GAO survey indicated that they provide some or all of the discounts to patients at contract pharmacies.[4]

Health Inequity

Physicians are leaving private practice for hospital employment, and hospitals are acquiring community-based physician practices, especially in oncology—often in wealthier locations. Hospitals convert these facilities to outpatient departments so they can participate in the 340B Program. This provides lucrative financial benefits for the hospital.[5,6] 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.[7] This results in patients having reduced access to private physician offices and fewer community clinics, particularly in areas where they lack public transportation to travel to wealthier areas, which is often the case in poorer, medically underserved areas. This can exacerbate health inequities.

[1] Levinson, Bruce, "Measuring the Effectiveness of the 340B Program," Center for Regulatory Effectiveness, November 1, 2018. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3284078 (Accessed May 18, 2023).
[2] Martin, Rory, Ph.D., and Illich, Kepler, MA, "Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?", White Paper, IQVIA, September 2022.
https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/are-discounts-in-the-340b-drug-discount-program-being-shared-with-patients-at-contract-pharmacies.pdf (Accessed April 23, 2023)
[3] 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)
[4] "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)
[5] 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)
[6] Conti, Rena M., and Bach, Peter B., "The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities," *Health Affairs*, October 2014.
https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.0540 (Accessed: May 23, 2023)
[7] 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)

Health Inequity (Continued)

These arrangements do not produce better outcomes for patients. According to a study funded by the U.S. Agency for Healthcare Research and Quality (AHRQ), financial gains for hospitals have not been associated with clear evidence of expanded care or lower mortality among low-income patients.[8]

- In one example, as highlighted in the *New York Times*, Ben Secours Mercy Health (Mercy) in Richmond, Virginia opened new clinics in 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, and no maternity ward. Services have been cutback in an underserved community that sorely needs it, while Mercy has opened nine off-site clinics in wealthier parts of Richmond since 2013. Richmond Community Hospital now has the highest profit margins of any hospital in Virginia generating as much $100 million per year because of its 340B purchases.[9]

- In another example, the Cleveland Clinic, 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, instead of expanding services in its own backyard. The hospital's 340B profits for the 3-quarters it participated in 2020 were a staggering $136 million.[10]

Finally, 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.[11,12] Between 2011 and 2019, the share of 340B retail pharmacies in socioeconomically disadvantaged and primarily non-Hispanic Black and Hispanic/Latino neighborhoods declined by 3.6% and 1.9%, respectively. The percentage of 340B pharmacies in the lowest income neighborhoods declined by 5.6%. However, the number of 340B pharmacies in the highest income neighborhoods increased by 5%.[13]

Increasing Spending and Out-of-Pocket Costs for Patients

The expansion of off-site clinics and provider consolidation, especially in oncology, is making care more expensive for the most vulnerable patients. This is because there are fewer community clinics, so patients must seek care at more expensive hospital outpatient departments.[14]

According to a study in the *Journal of Health Services Research*, "[t]he probability of a patient receiving cancer drug administration in hospital outpatient departments (HOPDs) versus physician offices increased 7.8 percentage points more in new 340B markets than in markets with no 340B hospital. Per-patient spending on other cancer care increased $1,162 in new 340B markets than in markets with no 340B hospital."[15]

Moreover, another study published by the Journal of the American Medical Association examined outpatient biologic oncology drug episodes in 478 hospitals. "[T]otal episode spending increased $4,074.69 in the first year of 340B participation relative to nonparticipating hospitals, with continued higher spending in the first 3 years of participation."[16]

[8] *Consequences of 340B*, NEJM, February 8, 2018.
[9] 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)
[10] 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)
[11] 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)
[12] Lin, John, MD, MSHP, et al., "Assessment of US Pharmacies Contracted with Health Care institutions Under the 340B Drug Pricing Program by Neighborhood Socioeconomic Characteristics," *JAMA Health Forum*, June 17, 2022. file:///C:/Users/jgeisser/Downloads/lin_2022_ld_220014_1655237074.69207.pdf (Accessed: May 23, 2023)
[13] Ibid.
[14] Jung, Jeah, Ph.D., Xu, Wendy Y., Ph.D., and Kalidindi, Yamini, M.H.A., "Impact of the 340B drug Pricing Program on Cancer Care Site and Spending in Medicare," *Journal of Health Services Research*, January 22, 2018. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6153182/
[15] Ibid.
[16] "Association Between New 340B Program Participation and Commercial Insurance Spending on Outpatient Biologic Oncology Drugs," JAMA Network, Chang, Jessica, MA, Karaca-Mendic, Pinar, PhD, Nikpay, Sayeh, PhD. June 23, 2023. Accessed: June 28, 2023. https://jamanetwork.com/journals/jama-health-forum/fullarticle/2806517

Increasing Spending and Out-of-Pocket Costs for Patients (Continued)

Further, according to a study by the Community Oncology Alliance (COA), "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)."[17]

In addition, 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. For example, 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."[18]

In one real example, a retiree with neuroendocrine cancer, after receiving treatment from a community oncology clinic for years, was told by her Medicare insurance that she now had to receive her treatment at the local hospital. She was told it was meant to reduce expenses. At her previous clinic, the charge was $4,000 per month, $3,000 per month was paid by Medicare. Yet, for the same medication, she was charged $9,500, of which Medicare only pays $3,800.[19] In this case and many like it, the increase in out-of-pocket costs results 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%.[20]

Non-Profit Hospitals Continue Cutting Charitable Care, Making It Harder for Vulnerable Patients to Receive Affordable Healthcare

Hospitals operating as non-profits are providing less charity care, despite the dramatic uptick in 340B sales.[21] Studies show the majority of 340B DSH hospitals **(63%)** provide charity care at a level less than the national average of all hospitals.[22] Further "nearly one-third (29%) of 340B DSH hospitals provide charity care that represents less than 1% of their total patient costs."[23] This reduces access to free and discounted drugs and services that safety net providers were meant to help.

Conclusion

The 340B Drug Pricing Program is failing the most vulnerable patients. Uncontrolled growth and lax oversight has bred a platform for abuse that harms the very people it was created to assist.

[17] "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)
[18] "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)
[19] "The 340B Drug Discount Program in Review: How Abuse of the 340B Program is Hurting Patients," Community Oncology Alliance, September 2017.
[20] 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)
[21] 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)
[22] "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)
[23] Ibid.