



Biotechnology Innovation Organization
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July 28, 2023

Re: Statement on Senate Request for Information on Safeguarding and Strengthening 340B

Dear members of the Senate 340B Bipartisan Working Group:

The Biotechnology Innovation Organization (BIO) appreciates this opportunity to comment on the 340B Information Collection Request. BIO believes that this is a unique time to achieve substantive, bipartisan reform that can preserve the program amidst a lot of turmoil and uncertainty for all parties. We thank the Senate 340B Bipartisan Working Group for beginning this process.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than thirty other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics yield not only improved health outcomes, but also reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

Safety-net providers provide important services to the communities they serve. Many of the 340B Program's covered entities use the program for which it was intended, using their increased resources to provide discounted medicines and other services to indigent patients in their community. However, there are many covered entities that have abused the program and caused it to extend well beyond its intended purposes.

The 340B Program has grown exponentially in recent years. In 2021, 340B discounted purchases totaled \$44 billion, representing \$93.6 billion in sales at list prices.¹ 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.² The 340B Program is now the second largest pharmaceutical program in the nation behind Medicare Part D. If the program continues growing at this rate it will soon surpass even Medicare Part D, which is projected to be \$119

¹ 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)

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)



billion in 2023.³ This growth in the program has been associated with tremendous acquisition and consolidation of outpatient clinics, especially in hematology and oncology space,⁴ 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.

General Comments

Contract Pharmacy Arrangements

Since the inception of the 340B Drug Pricing Program in 1992, the 340B statute never authorized—nor referred to the concept of—contract pharmacies. Nevertheless, in 1996, the Health Resources and Services Administration (HRSA) issued sub-regulatory guidance, which does not carry the force of law, purportedly allowing covered entities without an on-site pharmacy to contract with a *single* off-site pharmacy.⁵ Then, in 2010, HRSA issued an “updated” sub-regulatory guidance that eliminated the one pharmacy limitation purportedly permitting all covered entities, regardless of whether they lacked an on-site pharmacy, to enter into unlimited contract pharmacy arrangements.⁶ In addition, there was no requirement limiting the geographic distance between the covered entity and any of its contract pharmacies; at least 45% of disproportionate share hospitals have at least one contract pharmacy that is more than 1,000 miles away, with some being more than 5,000 miles away.⁷ These contract pharmacies are a primary driver of the explosive growth in the 340B Drug Pricing Program since 2010 and a significant source of prohibited diversion and duplicate discounts.

According to an October 2020 study, the number of contract pharmacy arrangements in the program grew by 4,228% from 2,321 in 2010 to 101,469 in 2020,⁸ and as of today this number has increased to 194,016.⁹ Additionally, the number of unique pharmacy locations have grown from approximately 1,300 in 2010 to roughly 33,000 in 2023.¹⁰ 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.”¹¹

³ “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)

⁴ Consequences of 340B, February 8, 2018.

⁵ See 61 Fed. Reg. 43,549 (Aug. 23, 1996).

⁶ 75 Fed. Reg. at 10,275.

⁷ *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO Report, June 2018.

⁸ 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)

⁹ Fein, Adam, “Exclusive: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market,” July 11, 2023. Accessed July 13, 2023. <https://www.drugchannels.net/2023/07/exclusive-for-2023-five-for-profit.html>

¹⁰ Ibid.

¹¹ Vandervelde, October 2020.



Studies indicate that disproportionate share hospitals (DSH) have utilized for-profit pharmacies to expand their reach into more affluent areas, while decreasing their use of contract pharmacies in low-income medically underserved areas.¹² DSH hospitals have played a significant role in the growth of contract pharmacy. According to the Government Accountability Office (GAO), covered entities that had at least one contract pharmacy had a varying number of contract pharmacies, ranging from 1 to 439, with an average of 12 contract pharmacies per entity. Disproportionate share hospitals had the highest average number of contract pharmacies (25), while critical access hospitals had the lowest (4).¹³

Research has shown that the average distance between a contract pharmacy and the 340B Hospital is 334 miles.¹⁴ 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.¹⁵

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), and OptumRx (owned by United Health).¹⁶ Approximately, 70% of contract pharmacy relationships are with DSH or children's hospitals.¹⁷ Part of this dynamic is because of the dramatic growth in outpatient clinics that DSH hospitals rely on to deliver physician-administered drugs. While approximately 20% of DSH hospitals own specialty pharmacies, most do not. However, "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."¹⁸

The GAO and the Office of Inspector General (OIG) have both acknowledged before Congress and in reports that the complexity of contract pharmacy arrangements makes

¹² 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)

¹³ "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)

¹⁴ Vandervelde, October 2020.

¹⁵ *Oversight of Compliance*, GAO Report, June 2018.

¹⁶ "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)

¹⁷ 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)

¹⁸ 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)



oversight difficult, in part, because the definition of “patient” is ambiguous^{19,20,21} and even less clear is how HRSA’s patient definition should be applied in contract pharmacy arrangements, leading to statutorily prohibited duplicate discounts and diversion. Both agencies also noted that HRSA does not adequately scrutinize contract pharmacy arrangements. Establishing an effective process to prevent duplicate discounts is even more important now that 340B discounts are also prohibited for drugs subject to inflation rebates and drug price negotiation in Medicare under the *Inflation Reduction Act*.

- **340B Discounts should directly benefit low-income and vulnerable patients**

BIO believes that 340B discounts should be passed along to low-income and vulnerable patients. Congress created the 340B Drug Discount Program to help uninsured and vulnerable patients gain access to affordable prescription drugs and/or other healthcare services. Over the years this program has expanded well past the original intent of Congress, resulting in lack of benefits and an exacerbation of health inequities for patients in need.

The financial incentives within the program have led to the emergence of troubling trends. Since 2004, newly registered 340B DSH hospitals and clinics have tended to be in higher-income communities compared to earlier program participants.²² These wealthier areas have a larger population of fully insured patients, exacerbating health inequities and contradicting the program's original purpose of assisting safety-net providers and medically underserved patients. These trends also appear to influence hospitals to prescribe more expensive drugs to patients. On average, beneficiaries at 340B DSH hospitals receive either more drugs or costlier drugs compared to beneficiaries at other hospitals. For instance, in 2012, the average per beneficiary spending at 340B DSH hospitals was \$144, whereas it was approximately \$60 at non-340B hospitals. These differences could not be explained by the examined hospital characteristics or patients' health status.²³ Furthermore, a study by

¹⁹ *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO Report, June 2018.

²⁰ “Contract Pharmacy Arrangements in the 340B Program,” *Memorandum to HRSA Administrator Mary Wakefield*, Office of Inspector General, February 4, 2014.

²¹ “Examining HRSA’s Oversight of the 340B Drug Pricing Program,” Testimony before the US House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, Erin Bliss, Assistant Inspector General for the Evaluation and Inspections, Office of Inspector General, HHS, July 18, 2017.

²² 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)

²³ “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)



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the Community Oncology Alliance revealed that 340B hospitals priced top oncology drugs at 4.9 times their 340B acquisition costs, assuming a conservative 34.7% discount.²⁴

As a result, patients experience increased out-of-pocket costs because their cost-sharing is based on reimbursement amount the off-site clinic and hospital are reimbursed for the drug, rather than the amount they paid. Additional studies indicate that hospital participation in the 340B Program leads to a 16.79% increase in cost-sharing amounts billed to Medicare beneficiaries.²⁵

Non-profit hospitals, despite experiencing a significant increase in sales accounting for over than 80% of 340B sales,²⁶ have been reducing their provision of charitable care. Studies reveal that the majority of 340B DSH hospitals (**63%**) offer charity care at a level less than the national average of all hospitals.²⁷ Further “nearly one-third (29%) of 340B DSH hospitals provide charity care that represents less than 1% of their total patient costs.”²⁸ This discrepancy is further highlighted by the fact that for-profit hospitals tend to offer more charity care than their non-profit counterparts.²⁹

Moreover, in addition to benefiting from substantial profits generated through the 340B Program, non-profit hospitals receive significant tax advantages from the government due to their tax-exempt status providing charity care. Unfortunately, according to the Lown Institute Hospitals Index, 77% of non-profit hospitals it evaluated had a deficit in fulfilling their obligations of investing in charity care and community support – a prerequisite for obtaining tax breaks – compared to the value of the tax breaks they received.³⁰

Furthermore, these same hospitals have been criticized for engaging in aggressive debt collection practices against individuals who would typically qualify for charity care services. According to a study by Johns Hopkins University on America’s top 100 hospitals discovered that between January 2018, and July 2020, tens of thousands of lawsuits were brought

²⁴ “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)

²⁵ 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)

²⁶ 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)

²⁷ “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)

²⁸ Ibid.

²⁹ Bai, Ge, et al. “[Analysis Suggests Government And Nonprofit Hospitals’ Charity Care Is Not Aligned With Their Favorable Tax Treatment](https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01627),” Health Affairs, April 2021. <https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01627>

³⁰ “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)



against patients. These lawsuits were most prevalent among government and non-profit hospitals,³¹ many of which are 340B hospitals.

A 2022 study by IQVIA revealed that only 1.4% of patients are receiving discounts on 340B drugs at contract pharmacies.³² While eligible providers have the option to pass these discounts to patients, they are not required to do so. In fact, a majority of DSH hospitals, which now account for over 80% of 340B sales,³³ do not pass along drug discounts to patients. The limited number of hospitals that do provide discounts to patients at contract pharmacies is evident from a report by the U.S. Government Accountability Office (GAO), which found that only 12 hospitals out of those surveyed offered some or all the discounts.³⁴

The growth and abuse of the 340B Program are particularly notable in the context of off-site clinics operated by hospitals, often referred to as "Child Sites." Evidence indicates that hospitals are increasingly acquiring community-based physician practices, especially in oncology, and converting them to hospital outpatient departments to participate in the 340B Program, resulting in substantial financial benefits for the parent hospital.³⁵ 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.³⁶ Consequently, patients in these areas face reduced access to private physician offices and community clinics, exacerbating health inequities.

The expansion of off-site clinics and provider consolidation, particularly in oncology, results in increased costs for the most vulnerable patients. Community clinics are decreasing in number, forcing patients to seek care at more expensive hospital outpatient departments.³⁷ 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

³¹ 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)

³² 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)

³³ 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)

³⁴ "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)

³⁵ 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)

³⁶ 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)

³⁷ 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.



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in new 340B markets than in markets with no 340B hospital.”³⁸ The Community Oncology Alliance (COA) conducted a study revealing that 340B hospitals price top oncology drugs at 4.9 times their 340B acquisition costs, assuming a conservative estimate of a 34.7 percent discount.³⁹

Real-life examples further illustrate the negative impact of the program. For instance, as highlighted in the *New York Times*, Bon Secours Mercy Health (Mercy) in Richmond, Virginia utilized the profits from 340B purchases made by Richmond Community Hospital, which serves a predominantly Black neighborhood, to open new clinics in wealthier areas. This led to service reductions at Richmond Community Hospital, leaving it with only an emergency room and a psychiatric ward. In contrast, the hospital experienced substantial profit margins, generating up to \$100 million per year.⁴⁰ Similarly, the Cleveland Clinic, despite being located in a medically underserved area, established numerous off-site clinics in wealthier areas following the adoption of the 340B program in 2020. The hospital’s profits from the program amounted to a staggering \$136 million in just three quarters.⁴¹

Finally, studies show DSH hospitals utilize for-profit pharmacies to expand their reach into more affluent areas, while their use of contract pharmacies in low-income medically underserved areas declined.^{42,43} 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%.⁴⁴

These arrangements, primarily driven by hospitals financial gain, do not produce better outcomes for patients. Despite hospitals’ financial gains, there is no clear evidence of expanded care or lower mortality rates among low-income patients, as revealed by a study funded by the U.S. Agency for Healthcare Research and Quality (AHRQ).

³⁸ Ibid.

³⁹ “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)

⁴⁰ 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)

⁴¹ 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)

⁴² 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)

⁴³ 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_id_220014_1655237074.69207.pdf (Accessed: May 23, 2023)

⁴⁴ Ibid.



- **Claims-level data should be made available to manufacturers to safeguard program integrity**

Statutorily prohibited diversion and duplicate discounts continue to plague the program. A conservative estimate puts duplicate discounts between 3% and 5%.⁴⁵ As of September 2020, the HRSA had finalized 1,242 audits and had issued 1,536 findings of non-compliance, 546 of which were issued for diversion and 429 were for duplicate discounts.⁴⁶ The importance of program integrity, including a 340B claims modifier or non-modifier, is more important than ever. In addition to the diversion and duplicate discount prohibitions within the 340B statute, there are non-duplication provisions included in the *Inflation Reduction Act* under implementation of the Medicare maximum fair price, and also with regard to Medicare inflation rebates. In 2020, CMS issued a “Best Practices for Avoiding 340B Duplicate Discounts in Medicaid,” which outlined their recommendations for developing a strategy to avoid billing manufacturers for Medicaid rebates, commonly known as duplicate discounts. In the report, CMS notes “manufacturers likely need claims level data for true invoice validation purposes.”⁴⁷ The Guidance continues, “340B duplicate discounts can often best be identified from a review of claims level data by the manufacturers. Some states have chosen to provide claims level data via a secured web portal managed by the state’s invoicing vendor and/or an independent third-party data company. If claims level data is provided, this may reduce the state’s administrative burden and expense of researching manufacturer dispute issues.”⁴⁸ BIO agrees with this approach. However, states providing claims-level data does not provide enough transparency to ensure duplicate discounts are not occurring, covered entities should be required to provide the same data so it can be compared with the state’s data to easily confirm any duplicate discounts. In addition, the use of an independent, third-party administrator or clearinghouse would be able to validate the propriety of invoice data.

- **Hospital eligibility should be changed to capture true safety-net providers**

To participate in the 340B Program, government-owned and private non-profit hospitals must meet specific requirements. Firstly, the hospital must have an established relationship with a state or local government to offer services to the 340B low-income population. Secondly, all hospitals, except for critical access hospitals, rural referral centers, and sole community hospitals, must have a disproportionate share adjustment percentage (DSH percentage) of 11.75% or above, as reported on their Medicare cost report.⁴⁹ However,

⁴⁵ <https://www.drugchannels.net/2022/03/the-340b-noncompliance-data-gap-leaves.html>

⁴⁶ “Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements,” U.S. GAO, December 2020. Accessed: July 16, 2023. <https://www.gao.gov/assets/gao-21-107.pdf>

⁴⁷ U.S. Dept. of Health & Human Services. “Best Practices for Avoiding 340B duplicate Discounts in Medicaid.” Jan. 8, 2020. https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/cib010820_142.pdf

⁴⁸ Ibid.

⁴⁹ 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.



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using the DSH percentage as a metric for eligibility can be misleading because it measures the extent to which a hospital treats low-income Medicaid and Medicare beneficiaries in the inpatient setting, whereas the 340B Program is limited to outpatient drugs. Additionally, the DSH percentage fails to reflect the care provided by hospitals to uninsured or charity-care patients, whom the 340B Program is specifically designed to benefit.

According to the US Government Accountability Office (GAO), financial incentives provide great motivation for hospitals to meet 340B eligibility criteria.⁵⁰ 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.⁵¹ "The increase at the cutoff is significantly larger than what would be expected by chance alone . . ."⁵²The GAO also identified weakness in the Health Resource and Services Administration (HRSA) review process, stating that the reliance on self-reporting and inadequate contract reviews hinder the identification of potential eligibility issues.^{53, 54} Moreover, numerous contracts that qualify for 340B eligibility raise questions. For instance, the GAO found a contract for the treatment of tuberculosis that explicitly stated that only one patient had been treated under the contract in the previous seven years, yet it still qualified for the lucrative discounts offered by the 340B Program.⁵⁵

As we've noted the 340B Program provides substantial financial incentives for hospitals. Non-profit 340B hospitals have been found to be 37% more profitable than the average hospital, clearly indicating their efforts to maximize these discounts.⁵⁶ Notably, a lawsuit unrelated to the 340B profits revealed that Methodist Le Bonheur and Methodist Healthcare-Memphis Hospitals, along with West Clinic, P.C., made \$50 million in profits in a single year from the 340B Program after acquiring West's outpatient oncology locations.⁵⁷

⁵⁰ "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)

⁵¹ 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://bmcreresnotes.biomedcentral.com/articles/10.1186/s13104-021-05642-4#:~:text=We%20found%20no%20comparable%20change,oversight%20of%20the%20340B%20program.> (Accessed: April 24, 2023)

⁵² Ibid.

⁵³ Ibid.

⁵⁴ *Increased Oversight Needed*, GAO, December 2019.

⁵⁵ Ibid.

⁵⁶ 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)

⁵⁷ "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)



- **Audit capabilities should be strengthened to ensure program integrity**

Manufacturer Audits of Covered Entities. Under current HRSA policy and practice, manufacturer audits of covered entities are a wasted opportunity to help ensure the integrity of the 340B program. Manufacturers are subjected to expensive and cumbersome procedures, and, critically, there is no commitment on the part of HRSA to take action against covered entities that are shown to be out of compliance with program requirements. Thus, there is little incentive for manufacturers to conduct these audits, no matter how much evidence they may have that a covered entity is violating the duplicate discount or diversion prohibition. To redress these concerns, HRSA should:

- Permit manufacturers to perform a limited number of audits each year without prior approval from HRSA so long as manufacturers have a reasonable basis for doing so.
- Permit manufacturers to conduct audits using their own internal certified public accountants (CPAs), instead of independent CPAs, a requirement that is overly burdensome.
- Commit to taking timely action against covered entities based on audit results showing program non-compliance.
- Clarify that audits extend not only to covered entities but also to their child sites, contract pharmacies, and any other entities with a formal relationship with the covered entity related to the 340B program, including software vendors and third-party administrators.
- Clarify that a failure by a covered entity to provide access to all 340B program-related records as part of an audit can result in HRSA concluding that the covered entity is out of compliance with program requirements, obligating the covered entity to refund all affected manufacturers with respect to all affected drug purchases.

HRSA Audits of Covered Entities. HRSA did not conduct its first audits of covered entities until 2012. Widespread covered entity program non-compliance is apparent. Fully 136 of 197 of the audits of covered entities conducted by HRSA in 2016 yielded adverse findings. These results confirm the importance of such audits in safeguarding the integrity of the 340B program. To enhance the effectiveness of this important program integrity tool, HRSA should:

- Provide written notice of adverse audit findings to both covered entities and all affected manufacturers, and ensure that all affected parties have an opportunity to participate in any related hearing.
- Clarify that the failure of a covered entity to follow a corrective action plan can result in the covered entity's termination from the program, and ensure that such plans are provided to all affected manufacturers.



- Publish on HRSA’s website more details regarding covered entity audit results so that manufacturers can better understand the nature of any violation and how it may affect them.
- Where HRSA uncovers a compliance concern in a covered entity audit that may be common to other covered entities (for example, where a 340B tracking software vendor may be providing non-compliant software programs to multiple covered entities), publish on HRSA’s website the adverse finding so that other covered entities can take any appropriate remedial action.

HRSA Audits of Manufacturers. HRSA has issued little guidance on its procedures for auditing manufacturers and wholesalers. HRSA should establish procedures that are fair to manufacturers and clear as to the details of the audit process.

- **Transparency should be required for covered entities**

Many hospitals in the 340B Program have been taking advantage of the lenient eligibility criteria and program guardrails to exploit the significant discounts intended to benefit low-income individuals in need of discounted prescription drugs and services. Despite the intent of the program, the 340B statute lacks restrictions on how DSH and other covered entities can utilize the revenue from the 340B program.⁵⁸ Extensive research has demonstrated that the actions of hospitals have harmed patients by limiting their access to treatment and affordable therapy options.^{59,60}

As such, BIO believes, at a minimum, covered entities should be required to disclose and report:

- Their patient mix, broken down by payer status, for both the parent covered entity hospital and each child site;
- The charity care provided at each 340B hospital and each child site;
- The hospital’s (including each child site’s) aggregate amount of gross reimbursement of 340B drugs and the entity’s aggregate acquisition cost for such drugs;
- A copy of the contract with a state or local government if such a contract was used to qualify for the 340B Program.

However, it should be noted grantees are required to make similar transparency reporting as a condition of the grants they receive. Hospitals should be required report at least the

⁵⁸ 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)

⁵⁹ 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)

⁶⁰ “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)



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same information as grantees. Moreover, it is also important to require this information be made public on the HRSA website.

We thank you for the opportunity to register our thoughts and concerns on this topic and look forward to future discussions. Please do not hesitate to contact Kate Callanan at kcallanan@bio.org or Amber Manko at amanko@bio.org should you have additional questions.