



Biotechnology Innovation Organization
1201 New York Ave., NW
Suite 1300
Washington, DC, 20005
202-962-9200

April 1, 2024

**Senate 340B Bipartisan Working Group
United States Senate
Washington, DC 20510**

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 latest 340B Request for Information (RFI) issued by the Senate 340B Bipartisan Working Group (Working Group). We thank the Working Group for its ongoing work in this area.

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 this 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.

The 340B Program, originally created in 1992 to support vulnerable patient populations, has since grown well beyond its intended scope. Meanwhile the financial incentives inherent in the program's discounts, combined with broad and over-expansive interpretations of clear statutory language and lax oversight, create significant program integrity risks.

We believe the draft circulated by the Working Group takes some positive steps towards 340B Program reform, particularly the provisions regarding patient affordability, transparency, claims clearinghouse, and user fees designed to provide the Health Resources and Services Administration (HRSA) with the necessary resources. However, it is imperative that any 340B Program reform efforts do not inadvertently undermine the programs' original intent - to benefit vulnerable and underserved patients. Considering this, BIO recommends the working group adopt the following reforms to protect the integrity of the program and to ensure that any ultimate updates to current law are designed to meaningfully strengthen the program's benefits for underserved patients in a sustainable way. In the next draft of the SUSTAIN Act, we urge the Working Group to:

- Adopt a strong patient definition, consistent with existing statute and the definition HRSA proposed in 2015, to prevent diversion and curb unsustainable program growth.



- Impose meaningful restrictions on contract pharmacy arrangements to promote program integrity.
- Ensure the financial benefits of the 340B Program accrue to vulnerable patients through enhanced patient affordability requirements.
- Establish clear “child site” eligibility criteria to verify 340B Program eligibility and to ensure vulnerable patients benefit from “child site” participation in the program.
- Strengthen audit capabilities to ensure program integrity.
- Review and reform hospital eligibility criteria, including requiring a minimum level of charity care.
- Ensure access to data, including via the proposed clearinghouse, to implement 340B and Inflation Reduction Act (IRA) duplicate discount prohibitions.
- Establish clear federal preemption requirements to ensure consistent 340B Program implementation and oversight.

We look forward to working with the Working Group to reorient the 340B Program for those that truly need it. It is in this spirit that we offer the following general comments.

General Comments

A Strong Patient Definition is Essential to Preventing Diversion and Curbing Unsustainable Program Growth.

Under the 340B statute’s “diversion” prohibition, a covered entity may dispense covered outpatient drugs purchased through the 340B Program only to the entity’s own “patients.”¹ The term “patient” is therefore central to establishing the scope of the 340B Program. However, the existing “patient” definition, adopted by HRSA back in 1996,² has not been effective in preventing the diversion of 340B drugs to individuals who have no legitimate patient relationship with the covered entity. Indeed, the Government Accountability Office (GAO) and Department of Health and Human Services (HHS) Office of Inspector General (OIG) have each repeatedly found that HRSA’s guidance has increased the risk that some covered entities will continue to divert 340B covered outpatient drugs to non-patients. This has the effect of unlawfully expanding the program’s scope.

The GAO and the OIG have further found this risk is enhanced in the context of contract pharmacy arrangements, which further complicate HRSA’s already lackluster oversight of the agency’s vague “patient” standard.^{3,4,5} Specifically, contract pharmacies are a significant

¹ 42 U.S.C. § 256b(a)(5)(B).

² See 61 Fed. Reg. 55,156 (Oct. 24, 1996).

³ Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, GAO Report, 2018.

⁴ “Contract Pharmacy Arrangements in the 340B Program,” *Memorandum to HRSA Administrator Mary Wakefield*, Office of Inspector General, February 4, 2014. <https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf> Accessed: March 1, 2024.

⁵ “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. <https://oig.hhs.gov/documents/testimony/50/20170718 - Bliss Testimony.pdf> Accessed: March 1, 2024.



source of diversion in part because they often do not identify patients as 340B-eligible until after the prescription has been dispensed.⁶ The GAO report found that: “66 percent of the 380 diversion findings in HRSA audits involved drugs distributed at contract pharmacies.”⁷ The potential for drug diversion has accelerated since the decision in *Genesis Healthcare, Inc. v. Becerra*, demonstrating the need for a clear patient definition.⁸

To address these concerns, BIO urges the Working Group to adopt a patient definition consistent with existing statute⁹ and similar to HRSA’s proposed definition in 2015.¹⁰ Under this definition, an individual would be considered a “patient” of a 340B covered entity only if all six of the following criteria are met “on a prescription-by-prescription or order-by-order basis:”

1. ***The individual received a healthcare service at a covered entity site registered for the 340B Program and listed on the 340B covered entity database (OPAIS), which may include a “child site” of a covered entity.***
 - This requirement has two parts, both of which are important to promote program integrity: (1) the receipt of a healthcare service is critical to forming a patient relationship; (2) the requirement to be listed on OPAIS is essential to ensure there is an objective mechanism for ensuring the entity’s eligibility for 340B discounts.
2. ***The healthcare service described in (1) was performed by a provider employed by or acting as an independent contractor for the covered entity, such that the covered entity billed for the service on behalf of the provider.***
 - This requirement ensures the individual has received the requisite healthcare service from a provider with a formal relationship with the covered entity. This relationship is essential to ensuring that the covered entity is responsible for the care provided. This formal relationship is demonstrated when the covered entity bills on the provider’s behalf for the service, which is an objective standard that can be audited by both manufacturers and HRSA, as needed.
3. ***The drug, including a prescription renewal, was ordered or prescribed by the covered entity provider described in (2) as a result of the healthcare service described in (1).***
 - This requirement ensures there is a close relationship between the service the covered entity provided and the drug ordered or prescribed. This requirement

⁶ GAO Report, June 2018.

⁷ Ibid.

⁸ Court Guts 340B Program “Patient” Definition, Opening Door to More 340B Use. November 6, 2023. Bass Berry Sims.

⁹ Veterans Health Care Act of 1992, P.L. 102-585 § 602; PHS Act § 340B; 42 U.S.C. § 256b.

¹⁰ 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52300 (Aug. 28, 2015).



- is essential because providers may practice at various locations, not all of which are 340B covered entities. An individual should be qualified as a patient of a covered entity only for those prescriptions written by a physician as a part of an outpatient visit at the covered entity, even if the individual receives one or more other prescriptions written by the same physician unrelated to that visit. An individual should not be qualified as a patient of a covered entity if the only health care received by the individual from the covered entity is the dispensing of a drug. Further, the healthcare service described in (1) should not be merely an administrative or non-clinical service such as care coordination or care management.
4. ***For private non-profit disproportionate share (DSH) hospitals operating under a contract with a state, the service described in (1), including the ordering or prescribing of the drug described in (3), was consistent with the hospital's contract with the state.***
 - HRSA has historically required that the service an individual receives at a covered entity acting as a grantee be consistent with the scope of the covered entity's grant. A similar requirement should apply to covered entity hospitals that are eligible for the 340B Program by virtue of a state contract, such that the service the individual receives at the hospital, including the drug ordered or prescribed as a part of the service, must be consistent with the contract.
 5. ***The service described in (1) was classified as an outpatient service when the drug is ordered or prescribed, as determined by the applicable payer.***
 - This is one place where we recommend diverging from HRSA's 2015 patient definition, which would have assessed inpatient status based on how the service was *billed by the covered entity*. Such a standard could be prone to gaming given the significant financial incentive associated with 340B discounts. To prevent such gaming, the inpatient determination should be based on how the service was *actually reimbursed by the payer*. Further, consistent with HRSA's 2015 guidance, an individual who is self-pay, uninsured, or whose cost of care is covered by the covered entity will be considered a patient if the covered entity has clearly defined policies and procedures that it follows to classify such individuals consistently.
 6. ***The covered entity had a demonstrable ongoing relationship with the individual such that the covered entity maintains auditable records of the individual's care that demonstrate a provider-to-patient relationship between the individual and the covered entity, that the covered entity maintains responsibility for the service leading to the ordering or prescribing of the drug, and that all other requirements of this patient definition are met.***



- To demonstrate a relationship with the individual, the covered entity should be in control of and maintain the medical records supporting the provision of the drug, not merely have access to them. In addition, given the statutory language referring to an individual who “is” (not “was”) a patient of the covered entity, the provider-to-patient relationship should be ongoing and current, and the healthcare service described in (1) must have occurred during the last 12 months.

For the reasons noted above, the elements of this proposed patient definition would provide increased clarity and auditability over the existing patient definition in place since 1996. In particular, BIO strongly believes the definition should ensure that a covered entity can document that the covered entity is truly responsible for the care provided to a given patient related to the prescription for the covered outpatient drug.

Meaningful Limitations on Contract Pharmacy Arrangements Are Necessary to Promote Program Integrity

BIO strongly opposes the codification of contract pharmacy arrangements within the draft SUSTAIN Act. The proposal to codify contract pharmacy arrangements for the first time would create significant program integrity risks when oversight of these arrangements is already significantly lacking.

Contract pharmacies originated as a creation by HRSA via sub-regulatory guidance rather than by statute and has grown far beyond Congress’ vision for when the program was created. While HRSA issued additional guidance in 2010 which covered entities have used to authorize covered entity arrangements with unlimited numbers of contract pharmacies, the U.S. Court of Appeals for the Third Circuit has ruled there is nothing in the statute that requires manufacturers to distribute 340B drugs to an unlimited number of contract pharmacies. Meanwhile, in recent years, the growth of contract pharmacies has led to significant diversion of medications to non-eligible recipients; more than half of the entities audited by HRSA showed adverse findings.¹¹

Beyond this legal issue, authorizing unlimited contract pharmacy arrangements creates perverse incentives in an already opaque program, ultimately making it harder to hold covered entities accountable and ensure that the benefits they are trusted to deliver to patients aren’t being diverted to intermediaries’ profit margins. Many contract pharmacies are for-profit corporations whose shareholders benefit from unfettered program expansion. For instance, 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

¹¹ Health Resources and Services Administration Audits of 340B Covered Entities:
<http://www.hrsa.gov/opa/programintegrity/auditresults/fy1>



Biotechnology Innovation Organization
1201 New York Ave., NW
Suite 1300
Washington, DC, 20005
202-962-9200

1.5% of 340B contract pharmacies—but 21% of 340B contract pharmacy relationships.¹² 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.”¹³ The 340B Program was meant to help medically underserved patients of covered entities, and was not intended to be a source of revenue for for-profit contract pharmacies and other profiteering third parties.

Further, contract pharmacies are not appropriate for the administration of certain medications such as gene therapies. Due to the specialization required for the administration of cell and gene therapies, manufacturers generally contract with a limited number of hospitals that have the appropriate experience and facilities necessary for the administration of these therapies. Some gene therapies are administered in outpatient hospital setting, which may also be a 340B hospital. Administering gene therapies requires high-touch and seamless coordination across multiple hospital departments and stakeholders. These factors include patient safety considerations, clinicians trained in dosing gene therapy and complexities related to storage, handling, and preparation. In most cases, manufacturers require hospital sites to go through a ‘certification-like’ process to ensure they are equipped to administer gene therapies. Additionally, dosing gene therapy often requires pre- and post-patient monitoring. For these reasons, it is important that gene therapies only be administered at sites that are trained to dose. Contract pharmacies are therefore not appropriate sites for administering gene therapies.

Congress should not codify HRSA’s deeply misguided 2010 contract pharmacy sub-regulatory guidance, which ventured far beyond the 340B statute and has led to severe program abuse, with little oversight. Unlimited contract pharmacy arrangements pose significant risk of program abuse. As noted previously, contract pharmacy arrangements increase the risk of diversion. Further, the GAO and the OIG have both found that the complexity of contract pharmacy arrangements lead to statutorily prohibited duplicate discounts.^{14,15} Instead, the Working Group should impose meaningful restrictions on contract pharmacy arrangements, including to:

1. Restrict contract pharmacy arrangements to pharmacies serving medically underserved populations.

- Studies indicate that DSH hospitals have utilized for-profit pharmacies to expand their reach into more affluent areas, while decreasing their use of contract

¹² 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)

¹³ Vandervelde, October 2020.

¹⁴ *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO Report, June 2018.

¹⁵ OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 (Feb. 4, 2014)



- pharmacies in low-income medically underserved areas.^{16,17} 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%.¹⁸ A similar effect occurs with other types of covered entities, so that income is higher in areas served by contract pharmacies for both hospitals (28%) and grantees (25%).¹⁹ These arrangements, primarily driven by covered entities' 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).²⁰
- Contract pharmacies should be located only in areas that serve medically underserved populations, which can be established through HRSA's use of the Health Professionals Shortage Area (HPSA) or Medically Underserved Area/Population (MUA/MUP) scoring criteria or the Census Bureau's ZIP code data to identify areas where people with lower incomes predominately reside.

2. Update the eligibility standards for Rural Referral Centers (RRCs) to ensure that RRCs are located in rural areas and meaningfully treat rural patients.

- The current RRC designation allows for a looser financial assistance threshold than DSH hospitals, requiring a disproportionate share adjustment percentage of 8% rather than the usual DSH threshold of 11.75%. Hospitals have exploited these looser criteria to serve lower rates of low-income and vulnerable patients; a study conducted by the Alliance for Integrity & Reform of 340B (AIR 340B) found that RRCs served a lower share of Medicaid patients and reported a lower share of charity care compared to 340B DSHs. Meanwhile, as the number of RRCs have increased, RRCs have opted to locate farther away from rural areas instead of serving rural patients as the designation originally intended. AIR 340B found that 48% of all RRCs were located in metro areas more than 20 miles away from the nearest rural area.²¹ Updating the eligibility standards for RRCs

¹⁶ Nikpay, Sayeh, et al. "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>

¹⁷ 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. <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2793530>

¹⁸ Ibid.

¹⁹ Masia, Neal, Ph.D., and Kuwonza, Farai, MS. "Income Differences Between Locations of 340B Entities and Contract Pharmacies." *Am J Manag Care*. 2023;29(6):e184-e188. doi:10.37765/ajmc.2023.89377

²⁰ Smith K, et al. "The Impacts of the 340B Program on Health Care Quality for Low-Income Patients. *Health Serv Res*. October 2023. <https://pubmed.ncbi.nlm.nih.gov/37475113/>

²¹ "What's in a Name? Rural Referral Centers Capture 340B Discounts Without Serving Rural, Vulnerable Patients." Alliance for Integrity & Reform of 340B.



would ensure that underserved, rural patients actually receive the treatment they need.

3. Limit access to 340B discounts via mail order pharmacies.

- The expansive reach of today's contract pharmacies is compounded by contract pharmacies operating via mail order.²² Mail order pharmacies should be permitted under the 340B Program only if the covered entity attests that the use of mail-order pharmacy is the only available mechanism to secure prescription drug access for eligible patients, for instance for a patient who needs one or more specialty drugs that are dispensed only through a specialty pharmacy via mail-order due to the specialized nature of the drug(s) distributed. The attestation should also state that the covered entity has implemented controls to prevent program violations through such contract pharmacy arrangements, including the capability to identify a patient as 340B at the time the drug is dispensed/mailed.

4. Cap contract pharmacy fees.

- In many cases, contract pharmacies are much larger and more sophisticated than covered entities, meaning that contract pharmacies can exert their superior negotiating power to extract elevated fees from contract pharmacies.
- To prevent this transfer of 340B discounts from covered entities to for-profit contract pharmacies, contract pharmacy fees should be limited to usual customary dispensing fees, such as bona fide service fees or usual and customary dispensing fees paid by state Medicaid programs.

5. Permit manufacturer audits of contract pharmacies.

- The 340B statute currently authorizes manufacturers to audit covered entity compliance with the prohibitions on diversion and duplicate discounts.
- Given the program integrity risk posed by contract pharmacies, many of which service a large number of covered entities, manufacturers should be allowed to audit contract pharmacies independently of the covered entity.
- Further, to prevent ongoing abuse, contract pharmacies found to be in violation of the duplicate discount and diversion prohibitions should be expelled from the program and required to repay any amounts earned from unlawful discounts.

6. The role and financial impact of pharmaceutical benefit managers (PBMs) and plans in the 340B program should be limited.

- PBMs now control much of 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).²³
- To mitigate the financial incentives for PBMs to further expand the reach of the 340B Program beyond its intended purpose, the Working Group should consider:

²² *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO Report, June 2018. [emphasis added]

²³ "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)



limiting PBM fees to bona fide service fees, prohibiting PBMs from requiring expanded pharmacy networks, and prohibiting PBMs from requiring patients to fill prescriptions that are vertically integrated with the PBM/plan.

340B discounts should directly benefit low-income and vulnerable patients.

As we pointed out in our 2023 RFI response, low-income and vulnerable patients should be the primary beneficiaries of the 340B program. Congress created the 340B 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 in the exact opposite direction Congress originally intended, resulting in lack of direct patient benefits, increased out-of-pocket costs, and an exacerbation of health inequities for patients in need. The financial incentives within the program have led to the emergence of troubling trends, including:

1. Expansion of 340B to Wealthier Areas, Exacerbating Inequities.

Since 2004, newly registered 340B DSH hospitals and clinics have tended to be in higher-income communities compared to earlier program participants.²⁴ These wealthier areas have a larger population of fully insured patients, exacerbating health inequities, increasing duplicate discounts, and contradicting the program's original purpose of assisting 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.²⁵ Furthermore, a study by 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.²⁶

2. Increased Patient Cost-Sharing

Patients experience increased out-of-pocket costs because their cost-sharing is based on the reimbursement amount the "child site" and hospital are reimbursed for the drug, rather than the amount they paid. Additional studies indicate that hospital participation in the 340B

²⁴ 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)

²⁵ "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)

²⁶ "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)



Program leads to a 16.79% increase in cost-sharing amounts billed to Medicare beneficiaries.²⁷

These issues are exacerbated in the contract pharmacy context. A 2022 study of contract pharmacy claims by IQVIA found evidence that just 1.4% of patients were directly receiving discounts on 340B drugs at contract pharmacies.²⁸ While covered entities have the option to pass these discounts to patients, they are not required to do so. In fact, a majority of DSH hospitals²⁹ do not pass along drug discounts to low-income patients. In addition, one third of grantees did not provide discounts to low-income patients at contract pharmacies.³⁰ As previously mentioned, this stems in part because contract pharmacies do not identify patients as 340B-eligible until after the prescription has been dispensed.

Given these factors, we strongly support the patient affordability provisions in the draft SUSTAIN Act, which require pull-through of patient assistance policies. However, we urge the Working Group to build on these patient protections by adding the following additional provisions:

- **Identify eligible low-income patients at point-of-sale.**
- **Outline the parameters of the sliding fee scale that would grant discounts to patients of the covered entity in the form of lower patient cost-sharing.**
- **Prohibit 340B hospitals from conducting medical debt collection.**

DSH 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, between January 2018 and July 2020, these hospitals brought tens of thousands of lawsuits against patients for unpaid bills. These lawsuits were most prevalent among government and non-profit hospitals,³¹ many of which are 340B hospitals. Given the significant financial benefits 340B hospitals receive from the program, they should be prohibited from engaging in medical debt collection as a condition of program participation.

- **Require 340B hospitals to provide a minimum level of charity care as a condition of eligibility for the 340B Program.**

²⁷ 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)

²⁸ 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)

²⁹ 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)

³⁰ Ibid.

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)



340B hospitals, despite their non-profit status³² and ability to generate profit from 340B scripts,³³ 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.³⁴ Further “nearly one-third (29%) of 340B DSH hospitals provide charity care that represents less than 1% of their total patient costs.”³⁵ This discrepancy is further highlighted by the fact that for-profit hospitals tend to offer more charity care than their non-profit counterparts.³⁶ Requiring 340B hospitals to provide charity care at a certain threshold of total patient costs as a condition of program eligibility would better ensure that the value of 340B discounts accrues to the patients the program was intended to benefit.

- **Establish standardized reporting requirements based on uniform definitions of charity care.**

Enacting a standardized reporting obligation will allow policymakers to hold 340B hospitals accountable to ensure that 340B profits meaningfully go toward reducing the costs of outpatient drugs for patients.

- **Include comparable patient affordability language in the “child site” and contract pharmacy sections.**

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.³⁷ As of August 12, 2021, there were 1,129 340B-enrolled DSH hospitals, which had 21,841 registered

³² “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). 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.

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 “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)

³⁵ Ibid.

³⁶ 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>

³⁷ 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)



Biotechnology Innovation Organization
1201 New York Ave., NW
Suite 1300
Washington, DC, 20005
202-962-9200

"child site" clinics, only 29% of which were in medically underserved areas.³⁸ Consequently, patients in these areas face reduced access to private physician offices and community clinics, exacerbating health inequities.

The expansion of "child sites" 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.³⁹ 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."⁴⁰

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.⁴¹ Similarly, the *Wall Street Journal* reported that the Cleveland Clinic, despite being located in a medically underserved area, established numerous "child sites" 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.⁴²

For these reasons, both "child sites" and contract pharmacies should be held to the same patient affordability measures as covered entities.

Clear Eligibility Criteria on Off-Site Clinics or "Child Sites" Are Needed to Verify "Child Site" Eligibility and to Ensure Vulnerable Patient Benefit from "Child Site" Participation.

As we noted in our 2023 RFI comments, the growth and abuse of the 340B Program are particularly notable in the context of off-site clinics operated by hospitals, often referred to

³⁸ 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)

³⁹ 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.

⁴⁰ Ibid.

⁴¹ 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)

⁴² 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)



Biotechnology Innovation Organization
1201 New York Ave., NW
Suite 1300
Washington, DC, 20005
202-962-9200

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.⁴³ While there may be other factors driving these acquisitions, the availability of deeply discounted 340B pricing allows 340B hospitals to generate higher net revenues than independent physician offices for administering the same medicine. This opportunity—never intended or foreseen by Congress—creates financial incentives for 340B hospitals to purchase independent physician practices and bring them under the 340B umbrella, and studies suggest that these incentives are, in fact, driving 340B hospital acquisitions of formerly independent physician practices.⁴⁴ Meanwhile, nothing in the current 340B statute provides for any offsite hospital outpatient facility to participate in the 340B Program; rather, like contract pharmacies, 340B eligibility for hospital “child sites” is a doctrine developed by HRSA alone. This doctrine should not legitimately be used to extend 340B eligibility to offsite facilities—including formerly independent physician practices—that are distinct from the covered entity hospital and serve distinct patient populations that the 340B Program was not created to assist.

As previously noted, only 29% of “child sites” were in medically underserved areas (MUAs).⁴⁵ Consequently, patients in these areas face reduced access to private physician offices and community clinics, exacerbating health inequities. Further, the expansion of “child sites” 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.⁴⁶

To ensure “child sites” are truly serving needy patients, and to verify “child site” eligibility as part of the covered entity, we urge the Working Group to require all outpatient facilities—even those located on the same site as the hospital—to meet the following criteria:

1. MUA Location: Be located in an area that serves medically underserved populations.

⁴³ 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)

⁴⁴ Data from Avalere Health finds that 340B hospitals are more likely than other hospitals to purchase independent physician offices that administer medicines. Avalere Health. Hospital acquisitions of physician practices and the 340B program (June 8, 2015). The study authors found that 61 percent of hospitals identified in the study as potentially acquiring physician practices participated in the 340B Program, as compared to a 45 percent 340B participation rate among all hospitals in the data set. Also, a 2014 *Health Affairs* study concluded that 340B is a “powerful contributor” to driving these hospital acquisitions of physician practices. Bradford Hirsch, Suresh Balu & Kevin Shulman, *The Impact of Specialty Pharmaceuticals as Drivers of Health Care Costs*. 33 *Health Affairs* 1714-20 (Oct. 2014).

⁴⁵ 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)

⁴⁶ 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.



- Fewer than 30% of “child sites” are located in MUAs, the very communities the 340B Program was designed to assist. It defies logic that the very abuses outlined above be allowed to continue unchecked while there would be no assurance that MUAs benefit from the 340B Program itself.
- A hospital “child site” should be required to be located in medically underserved areas. This can be established through HRSA’s use of the Health Professionals Shortage Area (HPSA) or Medically Underserved Area/Population (MUA/MUP) scoring criteria or the Census Bureau’s zip code data to identify areas where people with lower incomes predominately reside. Some exceptions could be made for covered entities in rural or frontier area because of their unique geographic challenges.

2. Provider-Based Status: Obtain provider-based status under the applicable Medicare regulations with respect to the parent hospital.

- Provider-based status is the standard used by Medicare for assessing that a facility in fact is an integral part of a parent hospital, such that the parent hospital may permissibly bill Medicare for services provided by that facility.
- The use of this standard to determine “child site” eligibility aligns with longstanding HRSA policy and helps to ensure that a legitimate relationship exists between the covered entity and “child site.” HRSA adopted this standard for purposes of assessing “child site” eligibility because, as the Agency explained in its 1994 guidance, it establishes “criteria that are not ambiguous” and that form “an independent and objective basis on which to determine eligibility.”⁴⁷
- To illustrate, this standard assesses, among other things, that the child is operated under the ownership of the parent; that there is full integration of clinical services, medical records, and financial operations between the parent and the child; and that the parent maintains the same monitoring and oversight over the child as it does over other provider departments.⁴⁸
- As CMS has explained, the provider-based regulation is designed to “provide a high level of assurance that a facility complying with [the regulation] is, in fact, an integral and subordinate part of the facility with which it is based, and do[es] not accord provider-based status to facilities that . . . have only a nominal relationship with [the main] provider.”⁴⁹ If a facility does not demonstrate its integration with the parent hospital under these criteria, there is no basis for justifying the “child site’s” participation in the 340B Program, unless that site is independently eligible for the program.

⁴⁷ 59 Fed. Reg. at 47,885. HRSA similarly explained in 2007 that the decision to rely on provider-based status was made “because HRSA believes that the requisite integration of facilities necessary to demonstrate that the secondary facility is functioning as part of the DSH under 42 C.F.R. § 413.65, the regulation on when a facility is ‘provider-based,’ is appropriate for facilities eligible under the 340B program. Compliance with the rule for provider-based facilities would . . . [e]nsure that the individuals [served by a DSH hospital’s outpatient facilities] are truly patients of the DSH.” 72 Fed. Reg. 1543, 1545 (Jan. 12, 2007).

⁴⁸ See 42 C.F.R. § 413.65(d)-(e).

⁴⁹ 67 Fed. Reg. 49,981, 50,088 (Aug. 1, 2002).



- Provider-based status similarly should form the basis for independent auditors to assess whether a “child site” of a children’s hospital that does not file a Medicare cost report is an integral part of the parent hospital and would be included on the parent’s Medicare cost report if one were filed.
 - Establishing standards to this effect are necessary not only to protect the integrity of the 340B Program, but to ensure that the Program’s scope is sustainable so it can continue to benefit those who truly need it.
- 3. Medicare Cost Report: Be listed on the parent hospital’s most recently filed Medicare cost report on a line that is reimbursable under Medicare, and demonstrates that the services provided at the facility or clinic have associated outpatient Medicare costs and charges.**
- We are pleased that the Working Group has proposed using Medicare’s provider-based status requirements (outlined at 42 C.F.R. § 413.65). However, we also believe it is important that a “child site” be listed on the hospital’s most recent Medicare cost report as is the case today.
 - A hospital “child site” must have *outpatient* Medicare costs and charges in order to be 340B eligible. Given that the 340B Program is limited to “covered *outpatient* drugs,” it is important that *only* outpatient facilities be included in the program as “child sites”, as is the case today.
- 4. Enrollment and 340B Database: Be enrolled in the 340B Program and listed on the public 340B database.**
- We also strongly believe a covered entity and its “child site” must be both enrolled in the 340B Program and listed on the 340B database.⁵⁰
 - These requirements align with HRSA’s requirements that a covered entity be registered and appear on the public 340B database and help ensure that manufacturers have a means to confirm that “child sites” that are 340B-eligible.

In terms of the specific documentation that HRSA should be required to review to confirm compliance with these requirements, **we urge the Working Group to require HRSA to direct hospitals, as part of the “child site” registration process, to:**

- **Provide proof of ownership (i.e., non-profit, wholly owned by parent hospital) and operations status; and,**
- **Provide proof of compliance with Medicare’s provider-based status requirements.**

Audit Capabilities Should be Strengthened to Ensure Program Integrity.

While we appreciate the fact that the Working Group addressed the concern for the process used by HRSA to conduct audits, we reiterate the need for change in the process for

⁵⁰ Ibid.



manufacturer audits of covered entities. We restate our 2023 RFI response regarding improvements in this area. 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, program integrity modifications to the program should also:

- Permit manufacturers to perform a number of random and for-cause audits of covered entities and associated third-party vendors each year without prior approval from HRSA.
- 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 and removal from the 340B Program.
- Allow manufacturers to coordinate in auditing a single covered entity where there is reason to believe that the covered entity is violating the 340B statute for multiple manufacturers’ drugs.
- HRSA should provide more information about audits that it conducts, so that manufacturers understand any audit findings and can seek payments for any duplicate discounts or diversion identified by HRSA.

Additional Data are via the Proposed Clearinghouse, to Implement 340B and IRA Duplicate Discount Prohibitions.

BIO greatly appreciates the inclusion of language in the discussion draft that provides for sharing of all-payer claims-level data with manufacturers through a clearinghouse and efforts to improve duplicate discount prevention. However, claims-level data should be



available to manufacturers without restriction, rather than in a limited capacity. We believe providers should be required to furnish claims level data to manufacturers as required to process an individual claim, including the 340B or non-340B claims modifier, and for any sales to contract pharmacies. As CMS notes in its communication to states entitled, "Best Practices for Avoiding 340B Duplicate Discounts in Medicaid," manufacturer access to claims level data is likely needed for invoice validation.⁵¹ CMS further notes "340B duplicate discounts can often best be identified from a review of claims level data by the manufacturers."⁵² In addition, we are concerned that the discussion draft allows certain types of covered entities to provide aggregate claims data or 340B claims modifier. Aggregate data about 340B utilization is not useable by manufacturers, who must prove at a bottle or unit level that a drug was subject to a 340B discount, and we urge the working group to strike paragraph (b)(7) of proposed Sec. 1150D entirely.

Moreover, we believe it is important to note that manufacturers also need shared claims-level data for Medicaid managed care claims. According to the Kaiser Family Foundation, 72% of all Medicaid beneficiaries are enrolled in a Medicaid managed care plan. Currently, a serious deficiency in enforcement exists; namely, HRSA has been using one primary means of ensuring duplicate discounts do not occur for "covered outpatient drugs" provided to Medicaid fee- for-services (FFS) patients, which is the "Medicaid Exclusion File" (MEF).⁵³ In 2010, the ACA included a provision that extended Medicaid rebates to outpatient drug utilization in managed care organizations (MCOs). The extension of these rebates created a new liability for manufacturers, as duplicate discounts are now occurring for Medicaid patients in MCOs. Difficulty stems from the fact that HRSA does not have a MEF, or any other similar mechanism, to identify and segregate claims processed under Medicaid MCOs. As the House Energy and Commerce Committee reports, "this is a very significant and growing problem because an increasing number of Medicaid programs rely on MCOs to deliver Medicaid benefits."⁵⁴

Further, duplicate discounts in Medicare are also now a major concern as 340B duplicate discounts in inflation rebate penalties and Maximum Fair Price negotiated drugs are prohibited. Therefore, with respect to the IRA maximum fair price/340B effectuation and inflation rebate penalties we strongly believe this claims data should also be required to be shared.

Federal Preemption is Needed to Ensure Consistent Program Oversight.

BIO would also point out that there are many states that have passed a variety of laws surrounding the 340B Program. Some state laws include placing covered entity transparency requirements, contract pharmacy requirements, and some around PBM activities. We believe it is essential for any reform of the 340B Program to include a federal

⁵¹ Best Practices for Avoiding 340B Duplicate Discounts in Medicaid, CMS, January 8, 2020. https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/cib010820_221.pdf.

⁵² Ibid.

⁵³ "Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Duplicate Discounts and Rebates on Drug Purchases", 58 *Federal Register*, 34058 (June 23, 1993).

⁵⁴ Review of the 340B Drug Pricing Program, House Energy and Commerce Committee Report, 2017.



Biotechnology Innovation Organization
1201 New York Ave., NW
Suite 1300
Washington, DC, 20005
202-962-9200

preemption clause. The integrity of the 340B Program relies on credible enforcement actions that are based on a consistent standard. HRSA should not be undercut by state laws that likely cater to specific interests of certain participants in the program. Also, this program is extremely complex, and every participant in the program should be held to the same standard and should not have to abide by federal legislative and regulatory oversight rules, and then 50-different state laws, particularly when there are significant penalties for violating the statute.

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 us with any questions.