Biotechnology Innovation Organization
1201 New York Avenue NW
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October 10, 2024

Carole Johnson
Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

RE: 340B Rebate Model

Dear Administrator Johnson:

I am writing on behalf of the Biotechnology Innovation Organization (BIO) in strong support of a 340B rebate as an option for manufacturers to make 340B pricing available to covered entities. The 340B statute provides flexibility for a participating manufacturer to give access to the 340B ceiling price in more than one way, including through a rebate. We think the Health Resources and Services Administration (HRSA) has a unique opportunity to leverage that flexibility to protect 340B program integrity, preserve administrative resources, and help validate that the 340B benefit is accessed appropriately while enhancing the integrity of the program.

BIO is the world's largest trade association representing biotechnology companies and related organizations, with members 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, delay the onset of such diseases, or prevent them in the first place. Our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but have reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

Our comments can be summarized as follows:

- Manufacturers should have the choice to effectuate the 340B Ceiling Price in a manner they deem appropriate, i.e., the current model or use of a 340B rebate, to ensure efficiency and program integrity;
- Use of 340B Rebates would significantly help to mitigate the duplication and diversion risk inherent in the current model;
- Given current approaches under the Medicare Drug Price Negotiation Program, use of 340B rebates would help effectuate the interrelated statutory provisions of the Drug Price Negotiation Program and the Medicare inflation rebate programs.

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I. BACKGROUND

As you know, under the 340B program, participating manufacturers must offer 340B pricing on their covered outpatient drugs by covered entities, as a condition of having those drugs federally payable under Medicare Part B and Medicaid.[1] Critically, Congress established that several conditions of compliance must be satisfied for a provider to access 340B pricing. Among other things, if a participating provider is out of compliance with either the statutory prohibition on Medicaid rebate-340B discounting duplication (hereinafter, "Medicaid-340B duplication") or the statutory prohibition on diversion, it is no longer a "covered entity" eligible for 340B pricing.[2] There is also no obligation to offer 340B pricing multiple times on the same unit.[3]

Such fundamental guardrails on the 340B pricing obligation reflect Congress' considered judgment of the limitations necessary to help ensure the appropriate use and sustainability of the 340B program to support vulnerable patient populations. Of particular relevance here, they necessitate a meaningful mechanism to validate the eligibility of each unit for 340B pricing in a way that helps to ensure the integrity of the program, consistent with Congress' intent.

As HRSA's audits and other federal agency reports confirm, the 340B program has long operated in transgression of its statutory bounds, with regular findings of systemic covered entity noncompliance with the Medicaid-340B duplication and diversion prohibitions.[4] And such program integrity concerns are only compounded by the explosive growth of the 340B program over the past fifteen years: In 2022, 340B purchases ballooned to $53.7 billion, equaling $106 billion in sales at list prices. In 2023, sales at list prices grew to more than $124 billion,[5] making the 340B program the second largest governmental pharmaceutical program in the nation behind only Medicare Part D.[6]

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[1] *See* 42 U.S.C. § 256b(a)(1).
[2] *See 42 U.S.C.*§ 256b(a)(1) (requiring a manufacturer to offer 340B pricing only to a "covered entity"), (4) (defining a "covered entity" as an entity in compliance with the Medicaid-340B duplication and diversion prohibitions), (5) (prohibiting Medicaid-340B duplication and diversion).
[3] *See id.* § 256b(a)(1) (requiring a manufacturer to offer no more than the 340B ceiling price on a unit).
[4] *See, e.g.*, HRSA, Program Integrity FY 23 Audit Results (last reviewed September 2024), https://www.hrsa.gov/opa/program-integrity/fy-23-audit-results; U.S. Gov't Accountability Off., *HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, GAO-21-107 at 1 (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf (finding that, from 2012 to 2019, HRSA audits of covered entities uncovered 1,536 instances of noncompliance, 429 of which concerned Medicaid-340B duplication, 546 of which concerned diversion, and 561 concerned other covered entity eligibility requirements); *see also* Ashwin Mundra, *The 340B Noncompliance Data Gap Leaves Drug Manufacturers in the Dark, Drug Channels*, Mar. 18, 2022, https://www.drugchannels.net/2022/03/the-340b-noncompliance-data-gap-leaves.html (a conservative estimate is that three to five percent of Medicaid rebates duplicate 340B pricing, amounting to billions of dollars in abuse).
[5] Martin, Rory, Ph.D., and Karne, Harish, "The 340B Drug Discount Program Grew to $124B in 2023," IQVIA, April 2023. https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2024/iqvia-update-on-size-of-340b-program-report-2024.pdf (Accessed: October 10, 2024)
[6] Adam Fein, *The 340B Program Reached $54 Billion in 2022—Up 22% vs. 2021, Drug Channels*, Sept. 24, 2023, https://www.drugchannels.net/2023/09/exclusive-340b-program-reached-54.html.

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Indeed, this growth appears to be a direct byproduct of such programmatic abuse, reflecting the financial motivation of some covered entities and their for-profit contracted middlemen to grow the program, by any means, to expand their profiteering off of it. The US Government Accountability Office (GAO) found that over half of 340B profits retained by contract pharmacies are concentrated in just three pharmacy chains (Walgreens, Walmart, CVS Health) plus a payer-owned specialty pharmacy (Cigna's Accredo specialty pharmacy).[7] Another recent analysis found that those 4 entities and UnitedHealth Group (via its pharmaceutical benefit manager, OptumRx) account for *three-quarters of all* 340B contract pharmacy relationships with covered entities.[8]

The historical record could not be clearer: To date, the program has lacked a meaningful mechanism to adequately police eligibility for 340B pricing beyond HRSA's own attempts to keep up with the increasing size of the program and the number of new interrelated programs. To help ensure the integrity of the program, we believe alternative approaches are needed.[9]

Compounding such need, newly enacted statutory provisions that have altered the overall 340B scheme further necessitate the accurate and timely identification of 340B units to avoid duplication of discounted pricing. The Inflation Reduction Act of 2022 (IRA) established both the Drug Price Negotiation Program and the Medicare inflation rebate programs. Under both programs, the statute guarantees nonduplication with respect to the 340B price. Under the Drug Price Negotiation Program, the statute requires a manufacturer to offer only the lower of the maximum fair price (MFP) under such program or the 340B price—not both.[10] And, under the Medicare inflation rebate programs, the statute precludes an inflation rebate on a 340B unit.[11] As discussed below, such evolution of the 340B landscape only reinforces the need for alternative approaches.

[7] "Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement," GAO Report, June 2018.
[8] Fein, Adam, "Exclusive: Five Pharmacy Chains and PBMs Dominate 2022's Still-Booming 340B Contract Pharmacy Market," July 12, 2022. Accessed: October 10, 2024. https://www.drugchannels.net/2022/07/exclusive-five-pharmacies-and-pbms.html
[9] The post-transaction 340B administrative dispute resolution process and its associated audit requirement offer no meaningful solution. To fully assure itself of the propriety of each 340B transaction, a manufacturer (even assuming it could satisfy the requirement to show reasonable cause) would have to undertake the expense and hassle of an audit of each transaction with each covered entity for each of its covered outpatient drugs, in perpetuity—a patently unrealistic proposition.
[10] 42 U.S.C. § 1320f–2(d).
[11] 42 U.S.C. §§ 1395w–3a(i)(3)(B)(ii)(I), 1395w–114b(b)(1)(B).

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II. 340B THROUGH A REBATE

We strongly support the manufacturer's ability to use a 340B rebate as an appropriate option to make 340B pricing available to covered entities.[12] By surfacing the data necessary to validate the eligibility of a unit for 340B pricing, the use of 340B rebates could help provide more of the transparency needed to protect the integrity of the program. Further, data visibility can lower government costs through lower auditing costs, fewer costs for administrative dispute resolution, and fewer Medicaid disputes. Such mechanisms would also help enable accurate and timely identification of 340B units to effectuate the nonduplication of discounted pricing under interrelated statutory provisions. We elaborate on these key considerations below.

First, a manufacturer's use of a 340B rebate could materially enhance the integrity of the 340B program. Under the current model — and considering the historical shift by covered entities away from the physical inventory model that prevailed at the outset of the program where covered entities determined 340B eligibility before dispensing a 340B-purchased product — there can be no assurance, at the time of sale, whether a unit will later be subject to Medicaid-340B duplication or diversion. The current model thereby heightens the risk of programmatic abuse. Use of 340B Options to use a rebate would significantly help to mitigate this risk inherent in the current model.[13]

HRSA has created guidance related to fee-for-Service Medicaid by creating a "Medicaid Exclusion File," but to date – and despite having 14 years to establish policy – neither HRSA nor the Centers for Medicare & Medicaid Services (CMS) has taken any effective steps to curtail duplicate discounts generated by Medicaid Managed Care. Given the difficulty in ensuring compliance with the Medicaid duplicate discount prohibition, BIO advocates strongly for HRSA and CMS to work together with manufacturers to develop flexible alternatives that ensure non-duplication under the Drug Price Negotiation Program, inflation rebate programs, and Medicaid.

Second, given current approaches under the Medicare Drug Price Negotiation Program, options to use 340B rebates are needed to help effectuate the interrelated statutory provisions of the Drug Price Negotiation Program and the Medicare inflation rebate programs. Accurate and timely identification of 340B units is essential to effectuating MFP-340B nonduplication under the Drug Price Negotiation Program.

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[12] HRSA has already approved of a rebate model with respect to the AIDS Drug Assistance Programs (ADAPs), whereby ADAPs reimburse a third-party pharmacy for covered outpatient drugs dispensed to ADAP enrollees by the third-party pharmacy.

[13] Notably, the 340B replenishment model countenanced by the agency is itself a retrospective 340B pricing effectuation model, not a true discount model. Such model is deeply flawed in many respects—most fundamentally, because it necessarily engenders diversion, in contravention of the 340B statute. Regardless, the 340B rebate model would bring to all program stakeholders' efficiencies that the 340B replenishment model lacks.

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Yet, the Drug Price Negotiation Program provides no meaningful mechanism to identify such units. CMS has stated that it "is not charged with verifying or otherwise reviewing whether a particular drug claim is a 340B-eligible claim and will not, at this time, assume responsibility for deduplicating discounts between the 340B ceiling price and MFP."[14] CMS instead has charged manufacturers with the responsibility for ensuring that they properly pay the lower of the MFP or the 340B price.[15] Indeed, use of 340B rebates not only would enable manufacturers to fulfill CMS's charge, but is one of few, if not the only, mechanisms through which the agency has indicated they can do so.[16]

Finally, 340B rebates are necessary to effectuate inflation rebate-340B nonduplication, as the inflation rebate programs do not provide for a meaningful alternative. As to Part D inflation rebates in particular, CMS seeks to rely on a deeply flawed methodology for identifying the 340B units to be excluded from the rebate calculation.[17] By the agency's own admission, the proposal would rely on incomplete data to only loosely estimate such units.[18] With respect to all Medicare inflation rebates, use of 340B rebates would help ensure that 340B units are appropriately identified and properly excluded from rebate invoicing.

The inherent advantages of using the 340B rebate are reflected in the adoption of such a model across federal programs:

- The Medicaid Drug Rebate Program;[19]
- The Medicare Part D Coverage Gap Discount Program;[20]
- The Manufacturer Discount Program;[21]
- Voluntary manufacturer rebates in Medicare Part D;[22]
- The Drug Price Negotiation Program;[23]
- The Medicare inflation rebate programs;[24]

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[14] CMS, Drug Price Negotiation Program IPAY 2027 Revised Guidance 55 (Oct. 2, 2024), https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.
[15] *Id.*
[16] Compounding the need for the 340B rebate model to accurately and timely identify 340B units, manufacturers must pay MFP rebates where they are due by the end of a fourteen-day prompt payment window or be subjected to significant civil monetary penalties. *Id.* at 196, 294.
[17] 89 Fed. Reg. 61,596, 61,969-70 (July 31, 2024).
[18] *See id.*
[19] 42 U.S.C. § 1396r-8(b)(1)(A).
[20] 42 U.S.C. § 1395w-114a; 42 C.F.R. § 423.2315 (provides for manufacturer payment of Medicare CGDP obligations within 38 calendar days of receipt of invoices).
[21] 42 U.S.C. § 1395w-114c; CMS, Medicare Part D Manufacturer Discount Program Final Guidance (Nov. 17, 2023), § 80.2.
[22] 42 U.S.C. § 1395w-102(d)(1)(B)
[23] *See* Drug Price Negotiation Program IPAY 2027 Revised Guidance at 57.
[24] 42 U.S.C. § 1395w-3a(i)(1)(B); *Id.* § 1395w-114b(a)(2).

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- Medicare Part B discarded drug refunds;[25]
- TRICARE Retail Refund Program;[26] and, indeed,
- The 340B program itself, as to AIDS Drug Assistance Programs[27] (and the current replenishment model to the extent it is a retrospective 340B pricing effectuation model).

Here, use of 340B rebates would, among other things, enhance the transparency and integrity of the 340B program and facilitate the effectuation of the interrelated nonduplication provisions of the IRA. For these reasons, BIO strongly supports the use of 340B rebates as an option for manufacturers to effectuate 340B pricing.

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Thank you for consideration. We strongly support the use of 340B rebates as an option for manufacturers to make 340B pricing available to covered entities. If you have questions, please contact us at 202-962-9200 or at parthur@bio.org or jgeisser@bio.org.

Sincerely,

/s/

Phyllis A. Arthur
Executive Vice President
Health and Policy Programs

/s/

Jack Geisser
Vice President
Health Policy

cc: Chantelle Britton, Director, HRSA Office of Pharmacy Affairs

[25] *Id.* § 1395w-3a(h)(2).
[26] 10 U.S.C. § 1074g(f); 32 C.F.R. § 199.21(q).
[27] *See* 63 Fed. Reg. 35,239 (June 29, 1998).