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October 11, 2024

Via Email

Carole Johnson
Administrator
Health Resources and Services Administration (HRSA)
U.S. Department of Health and Human Services (HHS)
Parklawn Building
Room 13N188
Rockville, MD 20857

Dear Administrator Johnson,

The Pharmaceutical Research and Manufacturers of America (PhRMA) is writing to express serious concerns regarding HRSA's recent public statements about use of a rebate option to offer statutory 340B ceiling prices to covered entities.

PhRMA represents the country's leading innovative biopharmaceutical research companies, developing innovative medicines that transform lives and create a healthier world. Over the last decade, PhRMA member companies have invested more than $800 billion in the search for new treatments and cures, and they support nearly five million jobs in the United States.

HRSA's decision responding to a recent manufacturer announcement proposing to use a rebate model overlooks well-documented and pervasive 340B/Medicaid duplicate discount violations that HHS has not addressed. The agency's decision also ignores the 340B statute itself and improperly interferes with manufacturers' rights under the statute to implement reasonable business practices to improve transparency and compliance, as articulated by two federal appellate courts.[1] PhRMA urges HRSA to support, or not impede, manufacturer implementation of alternative approaches to address duplicate discounting and other program abuse, such as employing a rebate to ensure covered entities receive 340B ceiling prices. The agency's decision to instead threaten termination of a manufacturer's Pharmaceutical Pricing Agreement—and the ability of Medicare and Medicaid beneficiaries to access the company's medicines—simply because a manufacturer proposed a rebate mechanism raises questions about HRSA's impartial administration of the 340B program.

The remainder of this letter outlines PhRMA's specific concerns with HRSA's decision and addresses the following key points:

- Unrestrained 340B growth— due in part to a lack of program integrity measures—is raising costs for patients, the government, and payers.
- HHS has ignored recommendations from government watchdogs and has not taken necessary steps to prevent statutorily prohibited 340B/Medicaid duplicate discounts.

[1] *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452 (D.C. Cir. 2024); *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696 (3rd Cir. 2023).

- The current 340B audit and administrative dispute resolution (ADR) processes do not provide meaningful mechanisms to detect and address illegal behavior.
- Manufacturers face additional duplicate discount risks due to new obligations under the Inflation Reduction Act (IRA), and HRSA is standing in the way of reasonable practices to address those risks.
- Current levels of opacity and covered entity non-compliance in the 340B program are unsustainable, and alternative methods are needed to improve transparency and covered entity compliance.
- Rebates are commonly used in other federal health care programs, and their broader use in 340B would be a commonsense approach to achieving needed program integrity improvements.
- The statute contemplates manufacturers using discounts or rebates to offer 340B prices on covered outpatient drugs.

* * *

The 340B Program's Unrestrained Growth Jeopardizes Its Integrity and Long-Term Sustainability

Congress created the 340B drug pricing program in 1992 as a result of the Medicaid drug rebate statute's unanticipated impact on voluntary manufacturer discounts. These voluntary discounts previously offered to safety-net clinics and hospitals caring for large shares of vulnerable patients could have triggered a new best price under the Medicaid drug rebate statute.[2]

The significant price reductions biopharmaceutical manufacturers provide to covered entities under the 340B program should be used to help low-income, uninsured, and other vulnerable patients obtain outpatient medicines from true safety-net providers participating in the program. However, the unrestrained and unaccountable expansion of 340B is not benefiting patients. Instead, the program is being abused for the financial benefit of large, financially successful not-for-profit health systems and their contracted for-profit consultants, chain pharmacies, and pharmacy benefit managers, while jeopardizing the fundamental, core purpose of the program: to provide affordable access to medicines for vulnerable patients.

340B is now the nation's second largest federal prescription drug program with more than $54 billion in annual sales at discounted prices.[3] Nearly 60 percent of all hospitals participate in the program.[4] The 340B program grew at a compound annual growth rate of 24 percent from 2015 to 2022.[5] Over the same period, net drug sales (excluding COVID-19 vaccines) grew at an average annual growth rate of only 4 percent.[6] Manufacturers currently do not have access to the information they need to safeguard the integrity of this outsized program and ensure that statutory requirements are met.

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[2] H.R. Rep. No. 102-384(II), at 12 (1992) (stating that the 340B statute is intended to apply "to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans").
[3] HRSA, 2022 Covered Entity Purchases (Sept. 2023), https://www.hrsa.gov/opa/updates/2022-340b-covered-entity-purchases; Berkeley Research Group, Measuring the Relative Size of the 340B Program: 2020 Update (Jun. 2022), https://www.thinkbrg.com/insights/publications/measuring-relative-size-340b-program-2020-update/.
[4] MedPAC, Report to Congress: Medicare and the Health Care Delivery System (Jun. 2022), https://www.medpac.gov/document/june-2022-report-to-the-congress-medicare-and-the-health-care-delivery-system/.
[5] Drug Channels, The 340B Program Reached $54 Billion in 2022 – Up 22% vs. 2021 (Sept. 24, 2023), https://www.drugchannels.net/2023/09/exclusive-340b-program-reached-54.html.
[6] *Id.*

As described in greater detail below, growth in the 340B program and broader changes in the health care system have contributed to—and indeed worsened—program integrity challenges, and HRSA's oversight has not kept pace. For example, HRSA has, to date, failed to ensure that manufacturers have access to basic claims-level data for medicines on which 340B pricing is requested. This complete lack of transparency has undermined the program's integrity and makes it difficult for manufacturers to verify even basic information about program sales. Without access to claims-level data, manufacturers are not able to verify that medicines on which 340B pricing is requested were actually dispensed by a 340B entity. The fact that covered entities are aggressively resisting even this basic measure of transparency and accountability is striking.

The unrestrained and unaccountable growth in 340B threatens program integrity and raises costs for the health care system. The 340B program causes hospital price markups and consolidation that increase costs to patients, the government, and payers, and could ultimately reduce pharmaceutical innovation.[7] In some cases, for-profit chain pharmacies and PBMs are profiting from 340B at the expense of states and the federal government in foregone Medicaid rebate dollars.[8]

HHS Has Not Taken Necessary Actions to Prevent Statutory 340B/Medicaid Duplicate Discount Violations

The statutory prohibition on duplicate discounts bars covered entities from purchasing a covered outpatient drug at the 340B price if that drug also generates a Medicaid rebate.[9] This is an absolute prohibition under the law and is intended to result in zero instances of duplicate discounts—across both Medicaid fee-for-service and Medicaid managed care utilization.[10] Since the inception of the 340B program, avoiding duplicate discounts has been an ongoing challenge—but duplicate discount risks have increased sharply with the expansion of Medicaid rebates to Medicaid managed care and the proliferation of 340B contract pharmacy arrangements.[11] Growing enrollment in Medicaid managed care organizations (MCOs) has further heightened the risk of statutorily prohibited duplicate discounts. Today, about half of Medicaid beneficiaries receive their pharmacy benefit managed through an MCO.[12]

HRSA has ignored government watchdog recommendations to address duplicate discounts

The Government Accountability Office (GAO) and the HHS Office of Inspector General (OIG) have both found that neither HRSA nor the Centers for Medicare & Medicaid Services (CMS) has taken effective steps to prevent these statutory violations, particularly with respect to Medicaid MCOs. HRSA has been aware of many of these problems since 2011. The attached appendix provides a snapshot of the many

[7] Robinson, J.C. et al., Hospital Prices for Physician-Administered Drugs for Patients with Private Insurance, N. Engl. J. Med. (Jan. 25, 2024), https://pubmed.ncbi.nlm.nih.gov/38265645/; Robinson, J.C., Hospitals' Drug Price Markups Incentivize Consolidation and Reduce Funding for Pharmaceutical Innovation, Health Affairs Forefront (Mar. 6, 2024), https://www.healthaffairs.org/content/forefront/hospitals-drug-price-markups-incentivize-consolidation-and-reduce-funding; Nikpay S. et al., Association of 340B Contract Pharmacy Growth with County-Level Characteristics, Am. J. Manag. Care (Mar. 2022), https://pubmed.ncbi.nlm.nih.gov/35404549/.
[8] N. Masia and F. M Kuwonza, "Measuring the 340B Drug Purchasing Program's Impact on Charitable Care and Operating Profits for Covered Entities," Health Capital Group, Available at: https://nclnet.org/340b_briefing/.
[9] 42 U.S.C. § 256b(a)(5)(A).
[10] *See also id.* §§ 1396r-8(j)(1), 1396b(m)(2)(A)(xiii)(III).
[11] *See, e.g.*, OIG, State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates (Jun 2016), https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf; GAO, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement (Jul. 2018), https://www.gao.gov/products/gao-18-480.
[12] Analysis of Gifford K, et al, State Approaches to Managing the Medicaid Pharmacy Benefit, HMA (Aug. 2024); Kaiser Family Foundation analysis of the Centers for Medicare and Medicaid Services' Medicaid Managed Care Enrollment Reports, 2023.

watchdog agency reports highlighting the longstanding, pervasive, and unaddressed issue of statutory duplicate discount violations, among numerous other program integrity deficiencies.

In 2019, GAO sent a letter to HHS containing "Priority Open Recommendations" that warranted the Secretary's "continued personal attention" given the potential to "significantly improve government operation…by realizing large dollar savings; eliminating mismanagement, fraud, and abuse; or making progress toward addressing a High Risk or duplication issue."[13] In this letter, GAO recommended HRSA "issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care" and assess "covered entities' compliance with the prohibition on duplicate discounts" as part of its audit process.[14] GAO previously made these recommendations to HRSA in June 2018.

GAO further stated that, "[w]ithout addressing [these] recommendations…, HHS does not have assurance that covered entities are complying with program requirements, which puts manufacturers at risk of being required to erroneously provide duplicate discounts for Medicaid prescriptions."[15] These recommendations—and the stated risk of erroneous duplicate discount payments by manufacturers—have been included in GAO's Priority Open Recommendations to the HHS Secretary in 2020,[16] 2021,[17] 2022,[18] 2023,[19] and 2024.[20] HHS has yet to implement these recommendations.

HRSA's covered entity audits are not a meaningful mechanism to ensure program compliance

HRSA's own audits also suggest a concerning trend of non-compliance. In an analysis of HRSA's FY 2021 covered entity final audit results, 62 percent of audited covered entities had at least one adverse finding, and nearly 30 percent had two or more adverse findings.[21] HRSA's audits are intended to assess a covered entities' compliance with requirements related to 340B/Medicaid duplicate discounts,[22] diversion,[23] and data submission and reporting errors and inaccuracies. However, it is unclear what audit standards HRSA and its contractors are currently using. Following a legal challenge in 2019, HRSA "concluded that in the absence of binding and enforceable regulations, the agency would no longer issue findings based solely on noncompliance with guidance."[24] Additionally, only a very small share of covered entities is audited each year. As of July 2024, there were 199 completed covered entity audits for

[13] GAO, Priority Open Recommendations: Department of Health and Human Services, GAO-19-364SP (Mar. 28, 2019), https://www.gao.gov/products/gao-19-364sp.
[14] *Id.*
[15] *Id.*
[16] GAO, Priority Open Recommendations: Department of Health and Human Services, GAO-20-552PR (Apr. 23, 2020), https://www.gao.gov/products/gao-20-552pr.
[17] GAO, Priority Open Recommendations: Department of Health and Human Services, GAO-21-527PR (May 19, 2021), https://www.gao.gov/products/gao-21-527pr.
[18] GAO, Priority Open Recommendations: Department of Health and Human Services, GAO-22-105646 (May 26, 2022), https://www.gao.gov/products/gao-22-105646.
[19] GAO, Priority Open Recommendations: Department of Health and Human Services, GAO-23-106467 (May 10, 2023), https://www.gao.gov/products/gao-23-106467.
[20] GAO, Priority Open Recommendations: Department of Health and Human Services, GAO-24-107257 (May 28, 2024), https://www.gao.gov/products/gao-24-107257.
[21] ADVI, Analysis of FY 2021 HRSA 340B Covered Entity Audits (Feb. 2023), https://www.advi.com/insight/analysis-of-fy-2021-hrsa-340b-covered-entity-audits/#HRSA-footer-ten.
[22] 42 U.S.C. § 256b(a)(5)(A).
[23] *Id.* § 256b(a)(5)(B).
[24] GAO, Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf.

the 2022 fiscal year and 159 completed for the 2023 fiscal year.[25] These figures represent less than one percent of covered entities being audited each year.

When audits do find program violations, they typically do not result in sanctions that meaningfully deter and penalize covered entities. For example, one relatively common audit finding is that covered entities have not met requirements designed to prevent fee-for-service Medicaid duplicate discounts. When this is discovered in an audit, typically the covered entity must only make a repayment to manufacturers.[26] They do not face a monetary penalty, and manufacturers report that HRSA often does not enforce repayment of price concessions covered entities should never have received, even when there is no dispute that the covered entity owes a repayment.[27] While covered entities may also have to implement a corrective action plan, this only requires they make changes that should always have been in place. Thus, the corrective actions do not create a meaningful incentive for covered entities to meet current program requirements. In the meantime, according to GAO, manufacturers continue to receive requests "to erroneously provide duplicate discounts for Medicaid prescriptions"[28] contrary to clear prohibitions in the 340B and Medicaid statutes.[29] This is to say nothing of covered entities' non-compliance with other 340B statutory requirements, including the diversion prohibition, which bars the transfer of a 340B drug to any person who is not a 340B patient of a covered entity.[30]

The manufacturer audit guidelines and the ADR process drastically limit manufacturers' ability to seek resolution of statutory violations, in particular duplicate discounts

While manufacturer audits of covered entities theoretically could help manufacturers detect violations of the 340B statute's diversion and duplicate discount prohibitions, HRSA's manufacturer audit guidelines,[31] issued in 1996, impose onerous and unnecessary barriers on manufacturer audits that extend beyond the statute and often effectively foreclose manufacturer audits.[32] These barriers include a requirement to use a third-party auditor and to seek prior approval from HRSA.

Because the 340B statute requires manufacturers to conduct an audit of a covered entity prior to initiating the ADR process, HRSA's onerous manufacturer audit requirements make it difficult or nearly impossible for the audit and ADR process to work as Congress intended.[33] These outdated audit guidelines also overlook the significant changes to the 340B program and were developed long before Congress enacted the ADR process with an audit prerequisite. Today, manufacturers are effectively foreclosed from relief under ADR because they cannot bring a claim without first conducting an audit of a covered entity. It also bears emphasizing that, when a manufacturer has managed to obtain HRSA's approval to audit a covered

[25] HRSA, Program Integrity: FY22 Audit Results (updated Jul. 24, 2024), https://www.hrsa.gov/opa/program-integrity/fy-22-audit-results; HRSA, Program Integrity: FY23 Audit Results (updated Sept. 20, 2024), https://www.hrsa.gov/opa/program-integrity/fy-23-audit-results.
[26] *See id.*
[27] *See also* GAO, 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement, GAO-20-212 (Jan. 21, 2020), https://www.gao.gov/products/gao-20-212 ("HRSA officials told us they would not require a covered entity to develop a corrective action plan or make offers of repayment to a manufacturer if a drug manufacturer's audit of that covered entity identified a duplicate discount in managed care.").
[28] GAO, Priority Open Recommendations: Department of Health and Human Services, GAO-24-107257 (May 28, 2024), https://www.gao.gov/products/gao-24-107257.
[29] 42 U.S.C. §§ 256b(a)(5)(A), 1396r-8(j)(1), 1396b(m)(2)(A)(xiii)(III).
[30] *Id.* § 256b(a)(5)(B). *See* Appendix.
[31] 61 Fed. Reg. 65406 (Dec. 12, 1996).
[32] HRSA has acknowledged the infrequency of manufacturer audits, stating "over the history of the 340B program, manufacturers have rarely utilized the process in the [HRSA] guidelines to conduct an audit." 75 Fed Reg. 57233, 57235 (Sept. 20, 2010). In April 2024, HRSA disclosed that "[i]n the last 5 years, six [manufacturers] have followed the guidelines to request audits of covered entities." 89 Fed. Reg. 28643, 28646 (Apr. 19, 2024).
[33] 42 U.S.C. § 256b(d)(3)(A), (d)(3)(B)(iv).

entity, it has become increasingly common for covered entities to try to thwart the audit by refusing to cooperate with manufacturers and even suing HRSA to challenge its audit approval decision.[34] Covered entities' resistance to audits to remedy instances of statutory non-compliance on the back end while simultaneously resisting claims data conditions designed to promote transparency and accountability on the front end reflects a view of 340B program compliance that simply cannot continue.

Manufacturers Face Extra Duplicate Discount Risks Due to New Obligations Under the IRA

The IRA enacted new requirements for manufacturers to provide entities access to the MFP of a drug, as well as new manufacturer inflation rebate obligations for both Part D and B drugs. Congress recognized that manufacturers must not be required to pay discounts twice on the same unit of drug. Specifically, the IRA's 340B/MFP "nonduplication" provision provides that a manufacturer of a selected drug is not required to provide access to the MFP for a selected drug that is subject to 340B pricing where the 340B ceiling price is lower than the MFP for the drug (or the differential between the 340B price and MFP if MFP is lower).[35] The IRA also prohibits CMS from including 340B units in the calculations of manufacturers' Medicare Part B and Part D inflation rebate amounts.[36] As PhRMA has repeatedly raised with HHS, we have significant concerns that HHS has not pursued a holistic and integrated approach across CMS and HRSA to ensure statutorily prohibited duplicate discounts do not further proliferate under the IRA. As a result, manufacturers face substantial new risks of additional types of 340B duplicate discounts. In fact, HRSA's recent decision fails to appreciate that a 340B rebate could be the only way to implement the "maximum fair price" (MFP) nonduplication requirement, a critical aspect of the IRA.

With respect to 340B/MFP deduplication, CMS has maintained that it "will not, at this time, assume responsibility for nonduplication of discounts between the 340B ceiling price and MFP," nor will it require pharmacies to indicate to manufacturers which selected drug claims are for 340B-eligible units.[37] With respect to excluding 340B units from the Part D inflation rebate calculation, instead of requiring covered entities and their contract pharmacies to identify these 340B units so CMS can simply exclude them from the rebate calculation, as the statute requires, CMS instead proposes to adopt an estimation methodology[38] that, if finalized, is so significantly flawed that it would fail to meet the Secretary's obligation under the statute.

Rebates are Commonly Used in Other Federal Health Care Programs

Far from being a "dramatically transforming" approach[39] to drug pricing as alleged by the American Hospital Association, rebates are a common form of discount used in many federal health care programs to provide access to statutory and negotiated prices. Rebates help improve integrity and transparency because they typically require documentation of a purchaser's compliance with applicable conditions or programmatic requirements before a manufacturer pays an amount that reduces the purchase price of a drug. Manufacturers make (or will make) retrospective payments using rebates and refunds across numerous other federal health care programs, such as those listed below:

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[34] *See, e.g.*, *Children's Nat'l Med. Ctr. v. Johnson*, No. 1:24-cv-02563 (D.D.C. Sept. 6, 2024); *Univ. of Rochester v. Johnson*, No. 1:24-cv-02268 (D.D.C. Aug. 1, 2024); *MaineGeneral Med. Ctr. v. Johnson*, No. 1:24-cv-02187 (D.D.C. Jul. 24, 2024); *Oregon Health & Sci. Univ. v. Johnson*, No. 1:24-cv-02184 (D.D.C. Jul. 24, 2024).
[35] 42 U.S.C. § 1320f-2(d).
[36] *Id.* §§ 1395w-3a(i)(3)(B)(ii)(I), 1395w-114b(b)(1)(B).
[37] CMS, Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 (Oct. 2, 2024).
[38] 89 Fed. Reg. 61596, 61969 (Jul. 31, 2024).
[39] AHA Letter to HRSA (Aug. 28, 2024).

- Coverage Gap Discount Program (Medicare Part D)[40]
- Manufacturer Discount Program (Medicare Part D)[41]
- Voluntary manufacturer rebates in Medicare Part D[42]
- Medicare Drug Price Negotiation Program[43]
- Medicare Part B and Part D inflation rebates[44]
- Medicare Part B discarded drug refunds[45]
- Medicaid Drug Rebate Program[46]
- TRICARE Retail Refund Program[47]

Retrospective rebates or refunds are used to effectuate a drug's price in all of these federal programs, yet HRSA's recent decision appears to ignore their widespread and effective use. In fact, in final guidance for manufacturer effectuation of the MFP in 2026 and 2027, issued just last week, CMS said a manufacturer "may provide access to the MFP prospectively *or retrospectively*," which—under the latter approach—the manufacturer "retrospectively provid[es] reimbursement for the difference between the dispensing entity's acquisition cost and the MFP."[48] Similarly, rebates can be an effective mechanism to offer the 340B ceiling price. HRSA's decision is even more puzzling, given that it has countenanced widespread use of the replenishment model, which—like a rebate—retrospectively provides covered entities access to 340B pricing, but replenishment does so in the least transparent way possible.

A rebate approach would help alleviate some of the challenges presented by 340B audits by providing manufacturers with claims level data to *prevent* statutory violations instead of having to resort to audits and potentially ADR to attempt to remedy violations that have already occurred. The 340B statute grants audit rights to manufacturers; however, in practice, HRSA has significantly curtailed those rights, as described in part above. Moreover, audits are not a complete solution to addressing covered entity non-compliance, in part because they are limited in scope, require significant resources, and depend on cooperation from covered entities. And, as stated above, there have been notable recent examples of covered entities refusing to cooperate with HRSA-approved manufacturer audits. Thus, the 340B program lacks basic transparency and program integrity safeguards that exist in other federal programs.

When the 340B program was first created in 1992, the health care system looked very different than it does today. The 340B program itself looks very different as well. As one recent *JAMA Health Forum*

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[40] 42 U.S.C. § 1395w-114a; 42 C.F.R. § 423.2315 (generally providing for manufacturer payment of Medicare Coverage Gap Discount Program obligations within 38 calendar days of receipt of invoices).
[41] 42 U.S.C. § 1395w-114c; CMS, Medicare Part D Manufacturer Discount Program Final Guidance (Nov. 17, 2023), § 80.2 (describing manufacturer invoicing and reimbursement process under the Part D Manufacturer Discount Program as "similar to the process used for the Coverage Gap Discount Program").
[42] 42 U.S.C. § 1395w-102(d)(1)(B) (voluntary manufacturer rebates on covered Part D drugs may help reduce negotiated prices).
[43] *Id.* § 1320f-2(a)(3); CMS, Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 (Oct. 2, 2024).
[44] 42 U.S.C. §§ 1395w-3a(i)(1)(B), 1395w-114b(a)(2).
[45] *Id.* § 1395w-3a(h)(2).
[46] *Id.* § 1396r-8. A 340B rebate mechanism is consistent with congressional intent to provide covered entities with the same or lower net price as Medicaid, which also is a rebate program. *See* 138 Cong. Rec. 34293 (1992) (summarizing the conference agreement and stating that the statute "require[s] a manufacturer to enter into an agreement with the Secretary of HHS under which the manufacturer must agree to extend to a covered entity a discount for a covered outpatient drug or biological *equal to or greater than the discount provided for that drug or biological under the Medicaid outpatient drug rebate program*" (emphasis added)).
[47] 10 U.S.C. § 1074g(f); 32 C.F.R. § 199.21(q).
[48] CMS, Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 (Oct. 2, 2024) (emphasis added).

article noted, there were approximately 1,000 covered entities in 1992 (including child sites); by 2021, there were more than 50,000.[49] In addition to growth in 340B sales and the number of 340B entities, covered entities have also been developing new means of expanding their use of the program. This includes alternative distribution models that "involve the 340B replenishment drug being initially delivered directly to a covered entity pharmacy, then subsequently transferred to the contract pharmacy for dispensing."[50]

HRSA's oversight simply has not kept pace with the changing health care landscape and growth in the 340B program. Changes to other parts of health care have made the 340B program more complicated to administer over time, and evidence suggests the 340B program is out of step with the realities of the current health care system. The 340B program needs to modernize in a way that reflects how the program has evolved and accounts for expanded manufacturer obligations under the IRA. To do so, it is essential that HRSA not interfere with manufacturers' rights to impose reasonable conditions on the sale of their drugs at 340B prices to ensure that, while covered entities are able to access covered outpatient drugs at the 340B price, duplicate discounting and other abuses are not allowed to persist. Alternative approaches—a rebate as one possible method—are needed to enable the program to operate efficiently and effectively in today's marketplace.

The 340B Statute Contemplates Manufacturers Using Discounts or Rebates to Offer 340B Ceiling Prices on Covered Outpatient Drugs

Among the different mechanisms manufacturers could use to offer the 340B ceiling price, rebates are explicitly enumerated in the 340B statute. The 340B statute directs the Secretary of Health and Human Services to "enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account *any rebate or discount*, as provided by the Secretary) to the manufacturer for covered outpatient drugs…does not exceed" the ceiling price.[51]

Additionally, the section of the 340B statute prohibiting 340B pricing on drugs that generate Medicaid rebates is titled "[p]rohibiting duplicate discounts *or rebates*."[52]

Thus, it is clear from the 340B statute's text that a rebate option is permissible and that Congress contemplated both rebates and discounts as options for manufacturers to offer 340B ceiling prices. In addition, the legislative history makes clear that the 340B statute "*does not specify* whether 'covered entities' would receive these favorable prices through a point-of-purchase discount, *through a manufacturer rebate*, or through some other mechanism."[53] HRSA has agreed in guidance that "Section 340B has no explicit language as to whether the required reduction in price should be obtained by an initial reduction in the purchase price (i.e., a discount mechanism) or received as a required reduction in cost rebated after purchase, dispensing, and payment are completed (i.e., a rebate option)."[54]

[49] R.P. Knox, "Outcomes of the 340B Drug Pricing Program," *JAMA Health Forum*. 2023 Nov; 4(11): e233716.
[50] Quarles, Amidst Ongoing Manufacturer Restrictions, 340B Covered Entities and Contract Pharmacies Get Creative, (Sept. 2023), https://www.quarles.com/newsroom/publications/amidst-ongoing-manufacturer-restrictions-340b-covered-entities-and-contract-pharmacies-get-creative.
[51] 42 U.S.C. § 256b(a)(1) (emphasis added).
[52] *Id.* § 256b(a)(5)(A) (emphasis added).
[53] H.R. Rep. No. 102-384(II), at 16 (1992) (emphasis added).
[54] 62 Fed. Reg. 45823, 45824 (Aug. 29, 1997).

HRSA asserts that a rebate does not comply with the requirement to offer covered entities the 340B ceiling price.[55] **But the 340B statute clearly contemplates use of a "rebate" as an option to offer 340B ceiling prices**. Moreover, rebates are already a permitted mechanism through which manufacturers can offer the 340B ceiling price to AIDS Drug Assistance Programs.[56] As noted above, rebates are a common approach to offering price reductions in numerous other federal health care programs, and they can be an effective mechanism to provide the 340B ceiling price to other covered entity types while reducing the risk of legal violations and improving transparency and accountability. Given the pervasive and well-documented statutory violations and risks catalogued in our letter and Appendix, it would be wrong of HRSA to reject a rebate mechanism out of hand for other covered entity types without considering the program integrity improvements such a mechanism could offer.

Lessons from appellate courts also bear emphasis here. Just this year, the D.C. Circuit Court of Appeals held that the 340B statute preserved manufacturers' ability to place reasonable conditions on their 340B offers, including requiring submission of standard information, such as claims data regarding prescriptions on which 340B pricing is sought.[57] The D.C. Circuit examined the text and structure of the 340B statute and concluded that Congress "preserve[d]…the ability of [manufacturers] to impose at least some" reasonable conditions on their statutorily required offer.[58] An appropriately-designed rebate mechanism fits squarely within the holdings of the court's decision; such an approach is eminently reasonable, as rebates are explicitly mentioned in the statute, and a rebate option would uphold the legal rights and responsibilities of both manufacturers and covered entities, enabling manufacturers to verify claims prior to payment so as to promote compliance with statutory prohibitions and enabling covered entities to receive a net price at or below the 340B ceiling price.

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We are concerned HRSA's decision in response to recent rebate announcements fails to consider manufacturers' need to mitigate the well-documented and pervasive statutory 340B/Medicaid duplicate discount violations that HHS has not adequately addressed and the increased risk that other statutorily prohibited duplicate discounts will proliferate under the IRA. HRSA's statements also have failed to take into account appellate court decisions recognizing manufacturers' rights under the 340B statute to adopt conditions reasonably designed to improve transparency and compliance. PhRMA urges HRSA to support, or not impede, alternative approaches for manufacturers to address program integrity violations such as by offering 340B ceiling prices as a rebate and seeking reasonable claims level data from covered entities.

/s/
Elizabeth Carpenter
Executive Vice President, Policy & Research

/s/
James C. Stansel
Executive Vice President and General Counsel

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

[55] HRSA Letter to J&J (Sept. 17, 2024).
[56] 63 Fed. Reg. 35239 (Jun. 29, 1998).
[57] *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460, 463-64 (D.C. Cir. 2024).
[58] *Id.* at 460.

Appendix: Selected Government Reports Addressing the 340B Program

- **GAO, 340B Drug Discount Program: Information about Hospitals that Received an Eligibility Exception as a Result of COVID-19**, GAO-23-106095 (May 11, 2023), https://www.gao.gov/products/gao-23-106095.
  - "According to HRSA, as of July 2022, the agency had audited 25 of the 53 excepted hospitals. Our review of HRSA documentation found that the agency issued a total of 19 findings related to noncompliance for 14 of these hospitals as a result of these audits. Five of the hospitals had more than one finding of noncompliance. The most common finding among the excepted hospitals that were audited related to the potential for duplicate discounts…."
- **GAO, Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements**, GAO-21-107 (Dec. 14, 2020), https://www.gao.gov/products/gao-21-107.
  - "HRSA reported that the agency issued a total of 1,536 findings to address covered entity noncompliance found in the 1,242 finalized audits conducted from fiscal years 2012 through 2019 as of September 2020. These findings, which address violations of statutory requirements and a failure to follow guidance that HRSA developed to clarify these requirements, were in the areas of eligibility (561), diversion (546), and duplicate discounts (429)…."
  - "HRSA officials also said that there were instances among fiscal year 2019 audits in which the agency also did not issue duplicate discount findings for a failure to follow a state's Medicaid requirements, including billing the state Medicaid office for a 340B drug without using a claim identifier to indicate a drug purchased at the 340B discounted price."
- **GAO, 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement**, GAO-20-212 (Jan. 21, 2020), https://www.gao.gov/products/gao-20-212.
  - "GAO found that limitations in the Department of Health and Human Services'[] (HHS) oversight of the 340B and Medicaid Drug Rebate Programs may increase the risk that duplicate discounts occur."
  - "HHS's Centers for Medicare & Medicaid Services (CMS) conducts limited oversight of state Medicaid programs' efforts to prevent duplicate discounts. CMS does not track or review states' policies or procedures for preventing duplicate discounts, and GAO found that the procedures states used to exclude 340B drugs are not always documented or effective at identifying these drugs. As a result, CMS does not have the information needed to effectively ensure that states exclude 340B drugs from Medicaid rebate requests. CMS also does not have a reasonable assurance that states are seeking rebates for all eligible drugs, potentially increasing costs to state and federal governments due to forgone rebates."
  - "HHS's Health Resources and Services Administration's (HRSA) audits of covered entities do not include reviews of states' policies and procedures for the use and identification of 340B drugs. As a result, the audits are unable to determine whether covered entities are following state requirements, and taking the necessary steps to comply with the prohibition on subjecting manufacturers to duplicate discounts."
  - "GAO reported in 2018 that HRSA had not issued guidance on, and did not audit for, duplicate discounts in Medicaid managed care and recommended the agency do so as the majority of Medicaid enrollees, prescriptions, and spending for drugs are in managed care…. In this report, GAO found that, unlike Medicaid fee-for-service, when duplicate discounts in Medicaid

managed care claims are identified, HRSA does not require covered entities to address them or work with manufacturers to repay them. As a result, manufacturers may be subject to duplicate discounts for drugs provided under managed care."

- "Given these limitations in federal oversight, HHS does not have reasonable assurance that states and covered entities are complying with the prohibition on duplicate discounts."

- **GAO, 340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements**, GAO-20-108 (Dec. 11, 2019), https://www.gao.gov/products/gao-20-108.
  - After analyzing contract documentation for more than 250 private, nonprofit hospitals participating in the 340B program, GAO concluded that "[g]iven the weaknesses in HRSA's oversight, some hospitals that do not appear to meet the statutory requirements for program eligibility are participating in the 340B Program and receiving discounted prices for drugs for which they may not be eligible." For example, GAO observed that 13 of the hospitals reviewed that currently participate in the 340B program had contracts with no requirement to provide care to low-income, vulnerable patients.
  - "HRSA's current processes and procedures do not provide reasonable assurance that nongovernmental hospitals seeking to participate and benefit from the 340B Program meet the program's eligibility requirements…continued growth in the number of participating hospitals and 340B purchased drugs highlights the need for HRSA to improve its oversight processes. This is critical to safeguarding the integrity of the 340B Program."

- **GAO, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement**, GAO-18-480 (Jun. 21, 2018), https://www.gao.gov/products/gao-18-480.
  - "GAO found weaknesses in HRSA's oversight that impede its ability to ensure compliance with 340B Program requirements at contract pharmacies, such as: HRSA audits do not fully assess compliance with the 340B Program prohibition on duplicate discounts for drugs prescribed to Medicaid beneficiaries. Specifically, manufacturers cannot be required to provide both the 340B discount and a rebate through the Medicaid Drug Rebate Program. However, HRSA only assesses the potential for duplicate discounts in Medicaid fee-for-service and not Medicaid managed care. As a result, it cannot ensure compliance with this requirement for the majority of Medicaid prescriptions, which occur under managed care."

- **OIG, State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates,** OEI-05-14-00430 (Jun. 6, 2016), https://oig.hhs.gov/reports/all/2016/state-efforts-to-exclude-340b-drugs-from-medicaid-managed-care-rebates/.
  - "We found that, to identify 340B drug claims and correctly collect rebates for MCO drugs, most States use methods that identify providers using 340B purchased drugs. However, we found that these provider-level methods may not accurately identify all individual 340B drug claims, creating a risk of duplicate discounts and forgone rebates. By contrast, we found that methods that operate at the claim level can improve accuracy in identifying 340B drug claims, and thereby, help States correctly collect rebates."
  - "We recommend that the Centers for Medicare & Medicaid Services (CMS) require States to use claim level method to identify 340B claims. CMS did not concur with our recommendation, noting that while it agrees with the importance of claim level methods, the statute does not contemplate such a requirement for States. We continue to recommend that CMS require the use

of claim level methods to improve accuracy in identifying 340B claims and thereby reduce the risk of duplicate discounts and forgone rebates."

- "We also recommend that the Health Resources and Services Administration (HRSA) clarify its guidance on preventing duplicate discounts for MCO drugs to align with this new requirement. HRSA concurred with our recommendation."

- **OIG**, **Contract Pharmacy Arrangements in the 340B Program**, OEI-05-13-00431 (Feb. 4, 2014), https://oig.hhs.gov/reports/all/2014/contract-pharmacy-arrangements-in-the-340b-program/.
  - "We found that contract pharmacy arrangements create complications in preventing diversion, and that covered entities are addressing these complications in different ways. The covered entities that we reviewed in our study reported different methods of identifying 340B eligible prescriptions to prevent diversion in their contract pharmacy arrangements. In some cases, these different methods lead to differing determinations of 340B eligibility from one covered entity to another for similar types of prescriptions. As a result, there is inconsistency within the 340B Program as to which prescriptions filled at contract pharmacies are treated as 340B eligible."
  - "We also found that contract pharmacy arrangements create complications in preventing duplicate discounts. Most covered entities in our study prevent duplicate discounts by not dispensing 340B purchased drugs to Medicaid beneficiaries through their contract pharmacies. However, some covered entities that do dispense 340B purchased drugs to Medicaid beneficiaries through their contract pharmacies did not report a method to avoid duplicate discounts."
  - "Additionally, we found that some covered entities in our study do not offer the discounted 340B price to uninsured patients in their contract pharmacy arrangements."
  - "Finally, we found that most covered entities in our study do not conduct all of the oversight activities recommended by HRSA. Although almost all covered entities reported monitoring their contract pharmacy arrangements, the extent of such monitoring varies. Few covered entities reported retaining independent auditors for their contract pharmacy arrangements as recommended in HRSA guidance."

- **GAO, Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement**, GAO-11-836 (Sept. 23, 2011), https://www.gao.gov/products/gao-11-836.
  - "Increased use of the 340B program by contract pharmacies and hospitals may result in a greater risk of drug diversion, further heightening concerns about HRSA's reliance on participants' self-policing to oversee the program. Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies."
  - "We found that HRSA has not always provided covered entities and drug manufacturers with guidance that includes the necessary specificity on how to comply with program requirements. There also is evidence to suggest that participants may be interpreting guidance in ways that are inconsistent with the agency's intent. Finally, participants have little incentive to comply with program requirements, because few have faced sanctions for non-compliance."