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VIA ELECTRONIC FILING – http://www.regulations.gov

Thomas J. Engels
Administrator
Health Resources and Services Administration
5600 Fishers Lane, Mail Stop 14W52
Rockville, MD 20857

Re: Request for Information: 340B Rebate Model Pilot Program and Request for Public Comment; HHS Docket No. HRSA-2026-03042

Dear Administrator Engels:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is writing in response to the Health Resources and Services Administration's (HRSA) "Request for Information: 340B Rebate Model Pilot Program" (RFI).[1]

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are focused on developing innovative medicines that transform lives and create a healthier world. PhRMA member companies have invested more than $850 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States.

PhRMA supports reforms to the 340B program that would conform the program to the purpose of the 340B law: to help low-income and uninsured patients afford their medications.[2] PhRMA's members have long sought, and urgently need, a rebate model in the 340B program to ensure that key program stakeholders—taxpayers, employers, federal health care programs, and innovative pharmaceutical manufacturers—are no longer obligated to shoulder the ever increasing costs of rampant 340B program violations.

As the 340B program has become the second largest federal prescription medicine program, surpassing Medicare Part B and Medicaid drug benefits,[3] and is becoming increasingly interconnected with other health care programs, reforms are desperately needed to modernize the 340B program and place the program on a sustainable path.[4] Today, the financial benefits of the 340B program flow to the bottom

[1] 91 Fed. Reg. 7287 (Feb. 17, 2026).
[2] *See* H.R. Rep. 102-384(II), at 12 (1992) (noting that the 340B program is meant to "provide[] protection from drug price increases to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans"); *see also* H.R. Rep. 102-384(II)at 10 (stating that a hospital official's testimony "describe[d] the adverse impact of drug price increases on public hospitals which serve large numbers of low-income and uninsured patients").
[3] Blalock E. (May 2025). Measuring the Relative Size of the 340B Program: 2022 Update. *Berkeley Research Group*. Available at: https://www.thinkbrg.com/insights/publications/measuring-relative-size-of-340b-program-2022-update/.
[4] In 2023, the most recent year data is available, covered entities and their for-profit partners collected nearly $65 billion in 340B profit. Blalock E., Ferritto M., Taylor, J. (January 2025). The Pharmaceutical Supply Chain, 2013–2023. *Berkeley Research*

lines of participating hospitals,[5] clinics, and for-profit companies, rather than to the patients Congress sought to help.[6] The large profits that covered entities and their partners obtain from 340B drugs create a strong financial incentive for them to go beyond what the statute permits.

Despite longstanding statutory prohibitions on duplicate Medicaid and 340B discounts[7] and on diversion of 340B drugs to persons who are not patients of a covered entity,[8] independent government watchdogs continue to find current safeguards highly inadequate.[9] Covered entities are able to take advantage of lax oversight to collect discounts on prescriptions for which they may not be eligible. The Inflation Reduction Act (IRA) has introduced the risk of a new set of 340B duplicate discounts[10] that adds further complexity and increases the urgency for solutions to prevent program integrity violations.

After years without any mechanisms within the program to reliably avoid impermissible claims, manufacturers identified a rebate model that would serve as a rapid verification of 340B claims and would be a commonsense solution to inject transparency and accountability into the program. For several years, manufacturers have advocated for the use of a rebate model in the 340B program. Following the IRA's passage, with the impending risk of paying unauthorized dual Maximum Fair Price (MFP) and 340B discounts, manufacturers' interest in a rebate model grew more pressing. PhRMA was accordingly supportive of HRSA's 2025 plan to launch the Rebate Pilot[11] starting January 1, 2026—and consequently alarmed and disappointed that the Pilot could not launch following last-minute litigation brought by hospitals adverse to transparency.[12] The termination of the 2025 Rebate Pilot left manufacturers of IRA-selected drugs with no reliable way—using the very limited and flawed data available to them—to consistently deduplicate 340B and MFP discounts in accordance with the statute.

PhRMA strongly supports HRSA's RFI as a positive step toward developing and carrying out an urgently needed 340B rebate model. The 340B statute clearly authorizes a rebate model,[13] which can introduce

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Group. Available at: https://cdn.aglty.io/phrma/global/blog/import/pdfs/PhRMA_Supply-Chain-2013-2023_White-Paper_V484.pdf.

[5] Magnolia Market Access. (2025). The 340B Prescription Drug Coverage Program: How Covered Entities Are Failing to Reinvest in Patient Care. *Magnolia Market Access Insight*. Available at: https://www.magnoliamarketaccess.com/insight/the-340b-prescription-drug-coverage-program-how-covered-entities-are-failing-to-reinvest-in-patient-care/.

[6] *See* GAO. (June 2018). Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, GAO-18-480. Available at: https://www.gao.gov/assets/gao-18-480.pdf ("Thirty of the 55 covered entities GAO reviewed reported providing low-income, uninsured patients discounts on 340B drugs at some or all of their contract pharmacies. Of the 30 covered entities that provided discounts, 23 indicated that they pass on the full 340B discount to patients, resulting in patients paying the 340B price or less for drugs. Additionally, 14 of the 30 covered entities said they determined patients' eligibility for discounts based on whether their income was below a specified level, 11 reported providing discounts to all patients, and 5 determined eligibility for discounts on a case-by-case basis."); *see also* HELP Committee. (April 2025). Congress Must Act to Bring Needed Reforms to the 340B Drug Pricing Program. Available at: https://www.help.senate.gov/imo/media/doc/final_340b_majority_staff_reportpdf1.pdf (finding that Bon Secours Mercy Health and Cleveland Clinic do not directly pass 340B discounts to patients).

[7] 42 U.S.C. § 256b(a)(5)(A)(i).

[8] 42 U.S.C. § 256b(a)(5)(B).

[9] GAO. (January 2020). 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement, GAO-20-212. Available at: https://www.gao.gov/assets/gao-20-212.pdf; OIG. (June 2016). State Efforts to Exclude 340B Drugs from Managed Care Rebates. Available at: https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf.

[10] Social Security Act (SSA) §§ 1193(d), 1847A(i)(3)(B)(ii)(I), 1860D-14B(b)(1)(B).

[11] 90 Fed. Reg. 36163 (Aug. 1, 2025) (corrected 90 Fed. Reg. 38165 (Aug. 7, 2025)).

[12] Am. Hosp. Ass'n v. Kennedy, No. 2:25-cv-600 (D. Me. Feb. 10, 2026) (Order Granting Motion to Vacate and Remand). Hospitals frequently fight efforts at transparency, see for example, American Hospital Association v. Azar, 967 F.3d 818 (D.C. Cir. 2020).

[13] As stated in prior correspondence with the agency, PhRMA maintains that as a matter of law, HRSA preapproval of manufacturers' 340B rebate models is not required. 42 U.S.C. § 256b(a)(1) ("The Secretary shall enter into an agreement with

safeguards that prevent certain violations of the 340B law. To that end, PhRMA urges HRSA to act promptly in order for a rebate model to begin as soon as possible, and by no later than January 1, 2027, when the next set of manufacturers also must begin to deduplicate 340B and MFP discounts.

Given the strong promise of a 340B rebate model, which could rapidly verify 340B claims eligibility, to address some of the current program integrity challenges, a rebate model should be an option for all 340B drug purchases immediately, without first limiting implementation to a pilot. However, if HRSA elects to begin with a pilot, it should, at minimum, include all units of all selected drugs under the IRA. Once launched, we would also urge HRSA to begin to review data from the pilot and draw conclusions regarding the pilot's efficacy at the earliest possible juncture, and to consider a prompt expansion of the rebate model. Looking ahead, HRSA should work toward a broader rebate model that goes beyond IRA-selected drugs, as operational and program integrity benefits of such a rebate approach apply broadly across the 340B program.

We also emphasize that—despite unfounded comments from covered entities—there is no reason to expect the rebate model will affect patients in any way. The steep 340B discounts covered entities receive generally are not passed on to patients. As the U.S. Court of Appeals for the Fourth Circuit recently noted, "covered entities need not pass these savings on to patients or their insurers. As a result, covered entities can pocket significant sums when they buy drugs at the discounted 340B price but get paid by patients or insurers at much higher prices."[14] The industry strongly supports any efforts to require covered entities to pass through discounts on 340B medicines to uninsured and low-income patients, along with other patient-centered program reforms. A rebate model could directly benefit patients by encouraging 340B patient identification at the pharmacy or point of administration, which is necessary to operationalize passing through discounts to eligible patients.

Below, we detail the basis for our strong endorsement of a rebate model as a promising commonsense approach to addressing certain program integrity challenges in the 340B program and respond to relevant questions set forth in HRSA's RFI.

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 . . .") (emphasis added).

[14] *Pharm. & Res. Mfrs. of Am. v. McCuskey*, No. 25-1054, 2026 U.S. App. LEXIS 9272, at *29-31 (4th Cir. Mar. 31, 2026).

Executive Summary

A rebate model is a commonsense, workable solution to longstanding program integrity failures that have worsened as the 340B program has grown and become increasingly interconnected with other health care programs, including, most recently, the Inflation Reduction Act (IRA).

Flaws with Current System: The 340B program has evolved into an opaque system that lacks basic safeguards to ensure statutory compliance. Federal watchdogs have repeatedly documented violations of the prohibitions on duplicate discounts and diversion, while also concluding that existing oversight mechanisms are inadequate. The IRA has introduced new and significant risks of unauthorized duplicate discounts, increasing the urgency for reform.

Rebate Model Benefits: A rebate model could address core structural weaknesses in the program by serving as a rapid verification system to confirm eligibility using claims-level data. In addition to facilitating the deduplication of MFP/340B discounts, a rebate model could help address other program integrity issues, including facilitating the exclusion of 340B units from Medicare inflation rebates, providing a reliable way to deduplicate 340B and Medicaid claims, preventing multiple covered entities from requesting 340B pricing on the same unit, and providing HRSA with information to reform audits and administrative dispute resolution (ADR).

Inadequate Alternatives: A rebate model is a more effective and efficient solution than proposed alternatives such as audits, claims modifiers, or clearinghouses. Those approaches are inherently retrospective and depend on compliance by covered entities that have repeatedly resisted transparency. Ensuring their compliance would increase government enforcement burdens. By contrast, a well-designed rebate model creates incentives for compliance as a prerequisite to receiving the 340B discount.

No Cash Flow Impact: A rebate model with similar requirements as the 2025 Rebate Pilot would not create new cash flow challenges for covered entities. They would typically receive rebates well before wholesaler invoices are due. Independent analyses show that a rebate model performs as well as, or better than, existing inventory models with respect to cash flow, and could even improve it for some covered entities.

Applicability and Data Requirements: For a rebate model to achieve its intended benefits, it must apply broadly across all covered entities and payers and utilize a targeted, standardized set of data elements that covered entities already collect and maintain. Narrow carveouts or incomplete data would undermine the model's effectiveness and perpetuate current integrity risks. If HRSA elects to begin with a pilot, it should, at minimum, include all units of all IRA-selected drugs and be evaluated in a timely manner to allow for prompt expansion.

PhRMA appreciates HRSA's quick efforts to implement a rebate model and stands ready to work collaboratively with the agency and other stakeholders to support timely implementation. A rebate model is a necessary and overdue step to modernize the 340B program, protect taxpayers and federal health care programs, and ensure that the program's benefits are more closely aligned with the patients Congress intended to help.

I. A Rebate Model Would Use a Common Mechanism for Providing Price Concessions to Improve Transparency and Program Integrity while Minimizing Burden

Manufacturers in many markets, including the pharmaceutical product market, routinely use rebates to provide discounts and other price concessions. Extending their use in the 340B program would be a commonsense way to bring transparency to the program, promote compliance with the 340B law and align the 340B program with many other health care programs, without imposing undue burden or costs on covered entities.

Pharmacies and providers typically serve a mix of patients with different insurance coverage and varying eligibility for certain discount programs. Thus, when a hospital, clinic or pharmacy acquires a drug, it is unknown which specific patient will receive it and what the applicable drug price will be. Rebates allow for the applicable price concession to be provided after the patient's insurance coverage and discount eligibility are known. By applying price concessions only after patient-specific information is provided, rebate-based programs avoid a "pay-and-chase" dynamic that can occur when discounts are provided before eligibility and coverage are confirmed and subsequently need to be clawed back if determined to be paid incorrectly.

Rebates are already used to provide access to discounted pricing in Medicaid, the TRICARE retail pharmacy program, Medicare Part D, the IRA's Drug Price Negotiation Program, and the commercial insurance market. Rebates have also been used in the 340B program for decades: AIDS Drug Assistance Programs (ADAPs) currently employ a rebate model to purchase 340B drugs. Otherwise, the 340B program is an outlier in this regard, as the use of a "replenishment model" allows covered entities to receive price concessions without verification of eligibility. Under the replenishment model, after an initial purchase of a medicine at the list price, all subsequent purchases of the medicine are made with an upfront discount at the 340B price. In this way, covered entities receive 340B pricing on the replacement inventory after a full package's worth of product has been dispensed or administered to patients the covered entity deems eligible for 340B. The use of the replenishment model has contributed to an opaque system in which manufacturers have little to no visibility into dispensing, patient eligibility or whether statutory requirements for the 340B discount have been met.

A rebate model is a much-needed step to align 340B with the way the rest of the health care reimbursement system functions and to help ensure claims for 340B pricing are legally authorized. The U.S. District Court for the District of Maine recently confirmed that the 340B price can be implemented through a rebate model.[15] A rebate model, together with the related claims data requirements to establish qualification for rebates, will strengthen the 340B program and help prevent statutorily unauthorized duplicate discounts with other programs.

II. Current Oversight is Inadequate, Based on Ineffective Guidance, and Hampered by Covered Entity Resistance (Question 7)

Given the size and complexity of the 340B program, current oversight tools and efforts have proven insufficient to prevent unauthorized duplicate discounts, diversion and other violations of program

[15] Am. Hosp. Ass'n v. Kennedy, No. 2:25-cv-600 (D. Me. Dec. 29, 2025) (Order on Motion for Preliminary Injunction), at 21.

requirements, leaving a landscape that invites aggressive efforts to maximize use of 340B pricing in ways that often exceed the bounds of federal law. For example, in 2019, when the 340B program was less than half its current size, it was estimated that Medicaid/340B duplicate discounts amounted to as much as $1.5 billion annually.[16] The Government Accountability Office (GAO) and the Department of Health and Human Services (HHS) Office of Inspector General (OIG) have long urged action to prevent duplicate discounts,[17] recommendations that remain largely unaddressed. This evidence points to a serious, longstanding program integrity problem.

The 340B program currently includes 27,138 covered entities and 36,340 child sites and reached $81.4 billion in purchases at discounted 340B pricing in 2024.[18] The opportunity to collect enormous profits has supercharged covered entities' interest in the program. Between 2010 and 2021, purchases in the 340B program grew by an average of 19 percent per year, according to the Congressional Budget Office (CBO), much faster than the prescription medicine market overall.[19] Currently, 340B pricing is available up-front without verification of eligibility, and manufacturers have faced challenges obtaining the data on 340B claims necessary to confirm compliance.[20] Manufacturers' lack of access to data makes detection of violations challenging and, in many cases, impossible. When manufacturers do have the information needed to suspect or detect violations of the 340B statute, resolution can be sought only after the fact through audit and dispute resolution processes. To date, these processes have proved to be extraordinarily resource intensive and ineffective in reaching appropriate resolution and implementation of corrective actions to prevent future violations. This pay-and-chase model is wholly ineffective at preventing program violations, avoiding and correcting unauthorized duplicate discounts and reversing other 340B discounts that should not have been provided in the first place, such as multiple covered entities claiming a 340B discount on the same unit of a medicine.

HRSA's 1996 manufacturer audit guidelines are outdated and impose onerous and unnecessary barriers to manufacturer audits. These barriers, which are not authorized by statute, combined with covered entities' determination to challenge and delay audits at every turn, has made the audit process largely unworkable for manufacturers and resulted in the completion of few manufacturer audits.[21] Today, manufacturers must audit in accordance with HRSA's 1996 audit guidelines, which include prohibiting manufacturers from using their own audit staff and requiring that manufacturers have reasonable cause for audits and obtain

[16] Kalderos. (2021). Making health policy work for patients. Available at: https://f.hubspotusercontent40.net/hubfs/7227094/2021%20Annual%20Report/Annual_report_2021.pdf.
[17] OIG. (June 2016). State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates. Available at: https://oig.hhs.gov/reports/all/2016/state-efforts-to-exclude-340b-drugs-from-medicaid-managed-care-rebates/; GAO. (January 2020). 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement. Available at: https://www.gao.gov/products/gao-20-212.
[18] HRSA Office of Pharmacy Affairs Information System (OPAIS). (2025). 340B covered entity database. Available at: https://340bopais.hrsa.gov; HRSA. (December 2025). 2024 340B Covered Entity Purchases. Available at: https://www.hrsa.gov/opa/updates/2024-340b-covered-entity-purchases.
[19] CBO. (September 2025). Growth in the 340B Drug Pricing Program. Available at: https://www.cbo.gov/system/files/2025-09/60661-340B-program.pdf.
[20] A number of states have enacted laws designed to hinder manufacturers' access to claims data or prevent the use of rebates in the 340B program. *See, e.g.*, W. Va. Code § 60A-8-6a; Vt. Stat. tit. 18, § 4682; N.D. Cent. Code. § 43-15.3-08; 5 R.I. Gen. Laws § 5-19-3.3. As the United States recently explained, laws of this type "interfere[] with and obstruct[]" the federal government's "strong interest in the proper functioning of the [340B] program." Br. of United States, *AbbVie v. Murrill*, No. 24-30645 (5th Cir. Apr. 1, 2026); *see also, e.g.*, Br. of United States, *Pharm. Res. & Mfrs. of Am. v. Neronha*, No. 26-1039 at 1 (1st Cir. Feb. 25, 2026); Br. of United States, *AstraZeneca Pharms. v. Drummond*, No. 25-6183 at 1 (10th Cir. Mar. 30, 2026); *accord Pharm. & Res. Mfrs. of Am. v. McCuskey*, No. 25-1054, 2026 U.S. App. LEXIS 9272, at *29-31 (4th Cir. Mar. 31, 2026).
[21] 61 Fed. Reg. 65407 (Dec. 12, 1996).

HRSA's approval before they begin auditing. Additionally, only one manufacturer is permitted to audit a covered entity at a time. This leaves all other manufacturers vulnerable to the conduct of bad actors during that period without recourse, while each must wait their turn to attempt the costly and burdensome audit process to recoup discounts that were illegally collected.

HRSA oversees the program through its own audits of 340B covered entities as well, yet it audits fewer than one percent of covered entities annually. Roughly 70 percent of HRSA covered entity audits return adverse findings.[22] That figure, though troubling on its own terms, almost certainly underrepresents the true magnitude of statutory violations within the 340B program.

In addition to only auditing a small share of covered entities each year, in 2019, HRSA stopped issuing audit findings based solely on noncompliance with guidance. This effectively means that most noncompliance is no longer identified, since 340B policies are largely implemented through guidance.[23] GAO reported that during fiscal year 2019, this change in HRSA's methodology for reporting adverse audit findings resulted in a 16 percent reduction in adverse findings being reported.[24] The 340B program has grown substantially since 2019, and covered entities have no doubt become more aware of this decreased enforcement of HRSA guidance. It is very likely that compliance rates have fallen even further as a result, while HRSA oversight has failed to keep pace. As discussed in more detail below, HRSA audits are inadequate and, as a fundamentally retrospective exercise, not an effective way to prevent future violations.

Covered entity recalcitrance in the face of manufacturer proposed audits imposes additional burdens on both manufacturers and HRSA. Our members report that it has become increasingly common for covered entities to try to thwart a manufacturer's audit by refusing to cooperate altogether, for example, by blocking access to necessary data HRSA has explicitly informed covered entities they need to provide, refusing to respond to good faith inquiries and claiming policies related to their engagement in the 340B program are "proprietary." In some cases, covered entities have even sued HRSA over its authorization of a manufacturer audit.[25]

III. A Rebate Model is an Efficient and Effective Way to Address Numerous Program Integrity Issues and Promote Compliance (Question 7)

A rebate model is a commonsense means to detect and prevent violations and promote compliance with many legal requirements pertaining to the 340B program. Only covered entities and their 340B program administrators have complete insight into which drug dispenses or administrations are 340B-eligible. Today, manufacturers receive little, if any, claims-level data to understand which claims a covered entity has determined are eligible for 340B. A rebate model would address current program oversight shortcomings while offering an effective and efficient way to provide 340B covered entities with the 340B price on eligible patient prescriptions in a timely manner.

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[22] ADVI. (March 2025). Analysis of HRSA 340B Covered Entity Audits. Available at: https://advi.com/insight/advi-analysis-hrsa-340b-covered-entity-audits/.
[23] GAO. (December 2020) Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements. Available at: https://www.gao.gov/assets/gao-21-107.pdf.
[24] *Ibid.*
[25] *See MaineGeneral Med. Ctr. v. Engels*, No. 25-5297, 2025 WL 2982893 (D.C. Cir. Oct. 21, 2025).

a. A Rebate Model Would Allow for More Efficient and Accurate 340B/MFP Deduplication

The IRA changed the contours of the already complex 340B program by including new 340B non-duplication provisions related to MFPs.[26] A rebate model is the best and most efficient way to ensure manufacturers receive the data they need to prevent unauthorized 340B/MFP duplicate discounts. Thus far, the Centers for Medicare & Medicaid Services (CMS) has repeatedly stated it will not take responsibility for deduplication.[27] Without a reliable way to identify whether both MFP and 340B pricing are requested for the same unit of a drug, which the 2025 Rebate Pilot would have facilitated, manufacturers of IPAY 2026 and 2027 selected drugs collectively face a risk of paying $5.23 billion in duplicate discounts in 2027 alone.[28]

The IPAY 2026 and 2027 selected drugs are among the most highly utilized in Medicare Part D. In 2024, the most recent full year of data publicly available, there were nearly 87 million total claims for these selected drugs, and a weighted average of over 25,500 claims per day.[29] The lack of transparency into the 340B status of a claim leaves manufacturers exposed to a high volume of potential duplicate 340B/MFP discounts.

As discussed in more detail below, when the 2025 Rebate Pilot was halted, manufacturers were forced to quickly adapt in an effort to try to avoid unauthorized duplicate MFP/340B price concessions. These alternative processes are slower and involve more administrative steps for everyone involved, including covered entities and pharmacies, and are highly unlikely to identify all potential duplicate discounts.

b. A Rebate Model Could Be Used to Facilitate Exclusion of 340B Units from Medicare Inflation Rebates

A rebate model could also play a similarly important role in assisting CMS in carrying out the IRA's requirement to exclude 340B units from the calculation of manufacturers' Medicare Part B and Part D inflation rebate obligations.[30] Using data from a 340B rebate model, especially a model that includes all covered outpatient drugs, could be a simpler method than the current approaches utilized by CMS.

- Part B Inflation Rebate: To exclude 340B units from manufacturers' inflation rebate obligations, CMS is relying on covered entities to use a claims modifier to identify prescriptions purchased at the 340B price. However, there does not appear to be a penalty for covered entities that fail to comply with the existing required modifier, and manufacturers are limited in their ability to verify whether modifiers are applied accurately or consistently. A 2023 report by IQVIA found that for Part B separately payable drugs, only 61 percent of treatments originating at rural referral centers

[26] SSA § 1193(d).
[27] CMS. (September 2025). Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028. Page 255. Available at: https://edit.cms.gov/files/document/ipay-2028-final-guidance.pdf.
[28] Blalock E. (April 2026). Update on Effectuation of the Maximum Fair Price in 2026 and Outlook for 2027. *Berkeley Research Group*. Available at: https://media.thinkbrg.com/wp-content/uploads/2026/04/03101442/Effectuation-of-the-Maximum-Fair-Price-in-2026-and-Outlook-to-2027.pdf
[29] PhRMA analysis of the CMS Medicare Quarterly Part D Spending by Drug files. Data accessed on March 5, 2026. File available at: https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-quarterly-part-d-spending-by-drug
[30] SSA §§ 1847A(i)(3)(B)(ii)(I), 1860D-14B(b)(1)(B).

(RRCs) or sole community hospitals (SCHs) used a relevant 340B modifier.[31] While there are situations where covered entities are not eligible for 340B pricing for certain drugs,[32] this finding seems outside the lower bound of expected utilization. Only the 340B covered entity and its third-party administrator know the 340B status of every claim. As such, it is impossible for other stakeholders to fully assess whether there is underutilization of the 340B claims modifier in Part B. A 340B rebate model could allow manufacturers and CMS to identify 340B units based on affirmative, unit-level data, reducing reliance on potentially incomplete modifier reporting and improving the accuracy of inflation rebate calculations.

- Part D Inflation Rebate: CMS has not yet developed an accurate method to identify and exclude 340B units from Part D inflation rebate calculations. Instead, in the 2026 Medicare Physician Fee Schedule final rule, CMS adopted a claims-based estimation approach,[33] which CMS itself acknowledges is inexact.[34] CMS also committed to establishing a 340B data repository (akin to a claims clearinghouse), however the Agency declined to mandate covered entity reporting at this time or include any enforcement mechanism.[35] In the absence of mandated reporting and enforcement, the 340B data repository will be of very limited use, because as the current experience with voluntary 340B claims modifiers shows, participation is likely to be minimal. By contrast, a 340B rebate model could provide a precise way for CMS to exclude these units, obviating the need to rely on an imprecise estimation approach as well as eliminating a need for CMS to develop and maintain a separate 340B data repository and enforce complete data submission of required data.

c. A Rebate Model Could Provide a Reliable Method for Deduplicating 340B and Medicaid Claims, including in Medicaid Managed Care

A rebate model that would serve as a rapid verification of 340B claims could enable manufacturers to more effectively tackle 340B/Medicaid deduplication.[36] Currently, manufacturers often lack the necessary information to ascertain and correct these violations, which as previously mentioned, totaled an estimated $1.5 billion in 2019, when the program was half of its current size.[37] A rebate model could equip manufacturers with the relevant information to identify these duplicate discounts in an efficient and targeted manner and resolve them consistent with applicable law.

The use of a rebate model could be particularly important in addressing 340B/Medicaid managed care (MCO) duplicate discounts. HRSA and CMS have not developed a mechanism for preventing these discounts despite the 2010 change in statute requiring manufacturers to pay Medicaid rebates on drugs used by MCO beneficiaries. In fact, rather than providing manufacturers with a means for deduplication,

[31] Martin R, Harish K, Duffy J. (February 2023). Can 340B Modifiers Avoid Duplicate Discounts in the IRA? *IQVIA.* Available at: https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2023/can-340b-modifiers-avoid-duplicate-discounts-in-the-ira.pdf.
[32] For example, RRCs and SCHs (and certain other hospital covered entities) are subject to the orphan drug exclusion and in some cases the state is claiming a Medicaid rebate on the drug; therefore, in some cases the covered entity would not claim the 340B discount and accordingly would not utilize the relevant modifier on the Part B claim.
[33] 90 Fed. Reg. 49266, 49741-48 (Nov. 5, 2025).
[34] 90 Fed. Reg. at 49746 (stating that the Agency "acknowledged in the CY 2026 PFS Proposed Rule that the proposed Prescriber-Pharmacy Methodology is likely to overestimate the number of 340B-eligible claims").
[35] 90 Fed. Reg. at 49749–50.
[36] 42 U.S.C. §§ 256b(a)(5)(A)(i),(a)(5)(B), 1386r-8(j)(1), 1396b(m)(2)(A)(xiii)(III).
[37] Kalderos. (2021). Making health policy work for patients. Available at: https://f.hubspotusercontent40.net/hubfs/7227094/2021%20Annual%20Report/Annual_report_2021.pdf.

HRSA issued guidance stating that the mechanism used to prevent 340B/Medicaid Fee For Service duplicate discounts (the Medicaid Exclusion File) does not apply to MCOs.[38]

A rebate model also could buttress other efforts to prevent 340B/Medicaid duplicate discounts. In the 2024 MDRP final rule, CMS finalized a requirement for Medicaid managed care plans to use unique Medicaid-specific BIN/PCN and group number combinations on enrollee ID cards for pharmacy benefits. Although CMS stated this "may help States and their managed care plans avoid invoicing for rebates on 340B drugs by identifying which plans are covered under Medicaid," the Agency acknowledged that it was not a complete solution.[39]

For many years, the GAO has sounded the alarm on the lack of any mechanism to prevent or detect illegal 340B/MCO duplicate discounts. GAO noted in 2020 that this deficiency "is particularly problematic as the majority of Medicaid enrollees, prescriptions and spending for drugs are in managed care."[40]

In the same 2020 report, GAO also stated that:

> HRSA's audits are not assessing compliance with the prohibition against duplicate discounts in managed care because the agency has yet to put forth guidance on this issue. . . . In the meantime, however, HRSA still must ensure that covered entities are complying with 340B Program requirements, including the prohibition on duplicate discounts in managed care. Failure to do so not only puts drug manufacturers at risk of providing duplicate discounts, but also compromises the integrity of the 340B Program.[41]

Last year, GAO noted that this recommendation "remains unaddressed" and urged further action to address 340B program integrity weaknesses.[42] Additionally, GAO has raised concerns that HRSA often does not require repayment of 340B/Medicaid managed care duplicate discounts that covered entities should not have received, even when there is no dispute that repayment is owed.[43] Similarly, the HHS OIG also found that methods to identify and prevent duplicate discounts are inadequate, "creating a risk of duplicate discounts and forgone rebates."[44] A rebate model that applies in Medicaid could improve compliance with some states' Medicaid carve-out rules, potentially increasing rebates to states, while also reducing administrative burden to Medicaid programs by providing greater transparency and minimizing the iterative, manual reconciliation currently required between states and manufacturers.

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[38] HRSA. (December 2024). Clarification on Use of the Medicaid Exclusion File. Available at: https://www.hrsa.gov/sites/default/files/hrsa/opa/clarification-medicaid-exclusion.pdf.
[39] 89 Fed. Reg. 79020, 79024 (Sep. 26, 2024).
[40] GAO. (January 2020). 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement. Available at: https://www.gao.gov/products/gao-20-212.
[41] GAO. (January 2020). 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement. Available at: https://www.gao.gov/assets/gao-20-212.pdf.
[42] GAO. (October 2025). Agency Oversight Has Improved, but Actions Needed to Address Weaknesses. Available at: https://www.gao.gov/assets/gao-26-108784.pdf.
[43] GAO. (January 2020). 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement. Available at: https://www.gao.gov/products/gao-20-212.
[44] OIG. (June 2016). State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates. Available at: https://oig.hhs.gov/documents/evaluation/2918/OEI-05-14-00430-Complete%20Report.pdf.

d. A Rebate Model Could Prevent Diversion, including when Multiple Covered Entities Request 340B Pricing on the Same Unit

A rebate model could prevent diversion, which is when a covered entity resells or otherwise transfers a drug purchased at the 340B discounted price to an individual or entity that is not the covered entity's own "patient," as defined by the 340B statute and HRSA guidance.[45] While diversion is expressly prohibited by statute, lax oversight, vague guidance and a lack of transparency combine to increase the risk and likelihood of these violations.[46]

For example, as the 340B program and the associated opportunity for profit grow, hospitals, clinics and their for-profit partners have powerful incentives to track individuals' prescription activity long after a single covered entity visit or a visit at an unaffiliated provider. While 340B pricing is supposed to be available only for drugs provided to a covered entity's patients, some hospitals and clinics have taken creative approaches to exploit this rule by claiming 340B pricing on any medicines prescribed to an individual who received any type of care from the entity at any point in time, regardless of who wrote the prescription, and even years after the individual actually visited the covered entity for care. Covered entities and Apexus have presented on methods to maximize 340B volume, such as a practice called "reverse referrals" where "a patient who already has a relationship with a specialist who prescribed them a drug(s) is referred to a CHC/RWC."[47] Without a meaningful patient definition, these practices will continue to grow, contributing to growing oversight challenges for HRSA.

These practices also risk increasing the share of prescriptions that could be claimed by more than one covered entity, which has been described as a form of diversion,[48] and which HRSA has stated is not permitted.[49] To date, however, HRSA has not developed a method to prevent this practice from occurring, an issue the 340B Prime Vendor has also warned against.[50] Researchers estimate as much as 22 percent of 340B prescriptions could be claimed by more than one covered entity.[51] A rebate model would not only provide manufacturers with the transparency needed to identify these double discount scenarios, but could also provide the tools needed to prevent them from occurring in the first place.

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[45] 42 U.S.C. §§ 256b(a)(5)(B).
[46] GAO. (September 2011). Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement. Available at: https://www.gao.gov/products/gao-11-836.; Bliss E. (July 2017). Examining HRSA's Oversight of the 340B Drug Pricing Program. Testimony Before the United States House of Representatives Committee on Energy and Commerce: Subcommittee on Oversight and Investigations. Available at: https://oig.hhs.gov/documents/testimony/50/20170718_-_Bliss_Testimony.pdf
[47] Pihl D, Smith D, Marr M, Fox M, Veer S, Meiman C. (2022). Compliant Strategies to Maximize Your 340B Program. *340B Grantees Conference*. Available at: https://rwc340b.org/wp-content/uploads/2022/10/WP1-Strategies-to-Maximize-340B-Value.pdf
[48] 340B Prime Vendor Program. (September 2020). FAQ ID: 1599. 340B Patient Definition. Available at: https://www.340bpvp.com/search#tab=faq&cf-p_faq_category_hierarchy=Policy/Implementation,Patient%20Definition.
[49] *See* 90 Fed. Reg. at 38166.
[50] 340B Prime Vendor Program. (November 2014). FAQ ID: 1249. 340B Purchasing/Inventory/Reimbursement. Available at: https://www.340bpvp.com/search#tab=faq&cf-p_faq_category_hierarchy=Policy/Implementation,Patient%20Definition.
[51] Blalock E. (April 2026). 340B Patient Definition and Implications for Duplicate Replenishment. *Berkeley Research Group.* Available at: https://media.thinkbrg.com/wp-content/uploads/2026/04/10141302/340B-Patient-Definition-and-Implications-for-Duplicate-Replenishment.pdf

e. A Rebate Model Could Provide HRSA with Information to Inform Changes to Improve Audit and Administrative Dispute Resolution (ADR) Processes

Appropriate audits of covered entities could help detect violations of 340B's diversion and duplicate discount prohibitions. However, only a small share of covered entities is audited each year. A rebate model could ensure that covered entities provide basic claims data, which could be used to help HRSA more accurately identify covered entities most likely engaging in statutory violations and provide HRSA with clearer evidence of the need for an audit. This will better target audits toward covered entities most likely to be violating the statute while simultaneously reducing the audit risk for compliant covered entities. The increased transparency afforded by the rebate model could improve HRSA's oversight efficiency, reducing agency burden while more effectively identifying and rooting out fraud, waste and abuse in the program. And, because a manufacturer must audit a covered entity before it can bring a claim to ADR, improvements to the audit process arising from a rebate model could facilitate more efficient audits and resolution of ADR claims of covered entity noncompliance.

IV. Absent a Rebate Model, Manufacturers are Left with Inefficient and Unreliable Options to Avoid Duplicate Discounts (Question 5)

Covered entities and their 340B administrators are the only parties with full visibility into which drug claims are designated as 340B-eligible. All other stakeholders, including manufacturers, the government, and payers, generally lack access to timely, claims-level information that would allow them to independently verify how individual claims are classified. As discussed above, this information asymmetry has created persistent challenges in the Medicaid program with respect to preventing duplicate discounts—and those same challenges have become even more pronounced under the IRA, where accurate, claim-level identification is essential to administering MFP refunds and avoiding overlapping price concessions. For IRA selected drugs eligible for 340B pricing, manufacturers are not required to provide access to the MFP if the 340B price is lower than the MFP.[52] If a pharmacy or dispensing entity believes the MFP refund was due, CMS guidance allows the dispenser to file a complaint or dispute.[53]

After the 2025 Rebate Pilot was blocked by litigation in late December, manufacturers were forced to quickly adapt in an effort to try to avoid unauthorized duplicate MFP/340B price concessions. Under existing CMS guidance, manufacturers of selected drugs may develop an approach to identifying which MFP refund claims the manufacturer reasonably believes involve a 340B drug.[54] With limited options, manufacturers were, and still are, left to piece together incomplete and flawed information from a variety of sources.[55] These imperfect alternatives can result in inefficiencies in covered entity receipt of MFP refund payments on claims for IRA selected drugs when a manufacturer's reasonable belief of 340B eligibility is at odds with the covered entity's determination. Overall, these alternative approaches are less accurate, less efficient and involve more steps for everyone involved—including covered entities and

[52] SSA § 1193(d).
[53] CMS. (September 2025). Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028. Available at: https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf.
[54] *Ibid.*
[55] Such as Part D claims data received from the Medicare Transaction Facilitator Data Module and wholesaler purchase and chargeback data for 340B drugs purchased by the covered entity.

pharmacies—and will likely lead to more disputes that ultimately require additional CMS oversight and resources. These alternative approaches are also unlikely to identify all potential duplicate discounts, leaving manufacturers at risk of paying the vast majority of the $5.23 billion in potential unauthorized MFP/340B duplicate discounts in 2027.[56]

If the covered entity instead confirmed 340B eligibility for each unit at the time a claim is submitted for payer reimbursement, as would be expected to occur under a 340B rebate model, the covered entity would receive MFP refund payments more quickly on non-340B claims while still receiving access to the lesser of the 340B price or MFP on 340B claims as required by law. That improved efficiency would result because manufacturers would receive timely and accurate data they need to avoid unauthorized duplicate discounts.

V. A Rebate Model Would Offer a More Efficient and Effective Solution to Program Integrity Challenges Compared to Proposed Alternatives

We are aware that some stakeholders have contended that existing or alternative mechanisms could obviate the need for a rebate model, including a clearinghouse, claims modifiers, or audits. This is not correct. While PhRMA would support improvements in these areas to provide additional transparency and oversight, none of these alternatives would be as efficient or effective as a rebate model in addressing program integrity challenges.

As previously discussed, existing mechanisms for oversight are insufficient. HRSA and manufacturer audits inadequately ensure compliance in the 340B program due to structural flaws, overly burdensome requirements, lax oversight of many types of violations (including MCO/340B duplicate discounts) and covered entity recalcitrance. Additionally, retrospective audits cannot effectively prevent *future* violations of 340B program requirements. In fact, between 2015 and 2024, just 68 covered entities (0.1 percent) were reaudited by HRSA due to previous adverse findings. Of these reaudits, over two-thirds returned continued or additional evidence of noncompliance.[57]

Further eroding the incentives for covered entities to prospectively comply with program rules, covered entities rarely face meaningful repercussions when audits identify adverse findings. A "covered entity" under the 340B statute is defined as an entity within a category listed in section 340B(a)(4) that meets certain requirements under section 340B(a)(5) (i.e., abiding by the prohibitions against duplicate discounts and diversion, as well permitting audits by manufacturers and HRSA).[58] Thus, under the statute, an entity that engages in these unlawful behaviors does not qualify as a covered entity at all.[59] Yet, program terminations or suspensions are rare, even after adverse findings of diversion or duplicate discounts. Most commonly, covered entities have been required only to repay manufacturers for discounts

[56] Blalock E. (April 2026). Update on Effectuation of the Maximum Fair Price in 2026 and Outlook for 2027. *Berkeley Research Group*. Available at: https://media.thinkbrg.com/wp-content/uploads/2026/04/03101442/Effectuation-of-the-Maximum-Fair-Price-in-2026-and-Outlook-to-2027.pdf.
[57] ADVI. (March 2025). Analysis of HRSA 340B Covered Entity Audits. Available at: https://advi.com/insight/advi-analysis-hrsa-340b-covered-entity-audits/.
[58] 42 U.S.C. § 256b(a)(4).
[59] *Ibid*.

they should not have received in the first place.[60] HRSA has not required covered entities to pay any additional penalties or interest payments as a result of noncompliance identified through these audits.

A clearinghouse model similarly relies on retrospective identification of violations after covered entities receive discounted prices, which significantly undercuts incentives for compliance with data reporting requirements. Any form of a clearinghouse would need to be accompanied by aggressive enforcement and robust data submission standards. Additionally, a clearinghouse would require complex data verification methods. For example, a clearinghouse would need to be able to compare the volume of 340B purchases to the volume of claims data provided to the clearinghouse: a complex and time-consuming process that requires matching data from multiple sources, some of which may not be directly accessible to the clearinghouse. Unlike a clearinghouse, a rebate model, by its very nature, incentivizes covered entity compliance as a precursor to receiving the 340B discount.

Alternative oversight mechanisms similarly rely on data collection that occurs after covered entities have received the discounted 340B prices and would therefore require aggressive oversight and enforcement to ensure compliance from covered entities. Covered entities have consistently demonstrated that they will not voluntarily take steps to increase transparency in the 340B program. For example, 0.5 and 0.4 percent of 2026 and 2027 MFP selected drug claims, respectively, were identified as 340B by the dispensing entity.[61] Given that 10 to 12 percent of Part D claims are eligible for 340B pricing, this suggests fewer than 5 percent of 340B claims are being voluntarily identified.[62]

Even strong enforcement and penalties have failed to ensure hospital compliance. Covered entities routinely evade federal requirements through noncompliance, obfuscation, or procedural and legal barriers. Evidence suggests some hospitals prefer paying fines over complying with price transparency laws. In 2024, HHS OIG found that 37 percent of a sample of 100 hospitals failed to meet all federal price transparency requirements.[63] Compliance with publishing machine-readable pricing data reached 88 percent only after penalties were increased based on hospital size, indicating that large hospitals often opted to pay penalties rather than disclose prices.[64] And, even when hospitals technically comply, transparency remains limited: a recent analysis found that only 62 percent of hospital pricing files contained usable pricing for the most commonly used inpatient drugs.[65]

More recently, the American Hospital Association (AHA) has stated it does not believe hospitals need to comply with the Administration's Outpatient Prospective Payment System (OPPS) Drug Acquisition Cost

[60] *See, e.g.*, HRSA. (January 2026). Program Integrity: FY25 Audit Results. Available at: https://www.hrsa.gov/opa/program-integrity/fy-25-audit-results.
[61] ADVI. (April 2026). Analysis of 340B modifier usage in Medicare Part D claims for IPAY 2026 and IPAY 2027 selected drugs. Available at: https://www.advi.com/wp-content/uploads/2026/04/ADVI-White-Paper-340B-Modifier-Usage-in-Medicare-Claims_Final_2026.04.14.pdf.
[62] Blalock E. (April 2026). Update on Effectuation of the Maximum Fair Price in 2026 and Outlook for 2027. *Berkeley Research Group*. Available at: https://media.thinkbrg.com/wp-content/uploads/2026/04/03101442/Effectuation-of-the-Maximum-Fair-Price-in-2026-and-Outlook-to-2027.pdf.
[63] HHS OIG. (November 2024). Not All Selected Hospitals Complied With the Hospital Price Transparency Rule. Available at: https://oig.hhs.gov/documents/audit/10042/A-07-22-06108.pdf.
[64] Kong E, Ji Y. (2023). Provision of Hospital Price Information After Increases in Financial Penalties for Failure to Comply With a US Federal Hospital Price Transparency Rule. JAMA Network Open. 6(6):e2320694. Available at: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2806485.
[65] 3 AXIS Advisors. (March 2026). Analysis of Prescription Drug Prices in Hospitals. Available at: https://www.3axisadvisors.com/projects/2026/3/5/analysis-of-prescription-drug-prices-in-hospitals.

Survey (ODACS).[66] Opposition to this survey comes after the AHA sued the Trump Administration to oppose Part B payment cuts for 340B hospitals, arguing the cuts were illegal because CMS failed to complete an acquisition cost survey. The AHA took this case to the Supreme Court, which agreed that the payment cuts were not authorized absent a survey of hospitals' acquisition costs, which a number of hospital trade associations then stated they did not need to participate in.[67]

Based on previous behavior by covered entities, it is reasonable to assume that even with strict enforcement mechanisms, compliance and participation would remain low for any efforts to increase 340B transparency. In contrast, a well-designed rebate model inherently incentivizes transparency as a precursor for receiving the 340B discount, significantly reducing system complexity, violations, and federal burden.

a. For a Rebate Model to Be Effective, it Must Apply to All Covered Entities and All Payers

The success of a rebate pilot that would serve as a rapid verification of 340B claims is highly dependent on manufacturers' access to comprehensive and complete claims level data on every 340B prescription for a specific medicine. Consistent with the 2025 Rebate Pilot, any future rebate model must include claims data for 340B prescriptions dispensed or administered to patients across all payers and covered entity types. This scope is critical to ensure all potential MFP/340B duplicate discounts are accounted for, address situations where multiple covered entities claim a 340B rebate on the same unit of a drug, and prevent unintended consequences.

Any carveouts would require the cumbersome and complex alternatives to deduplicate MFP/340B to stay in place, producing higher costs and burden for covered entities, and undermining the purpose of the pilot. For example, limiting the pilot to only Medicare claims would greatly increase the complexity of a pilot while also limiting its effectiveness. Without a complete view of all claims, manufacturers will have no way to know if they have captured all Medicare claims accurately for MFP/340B deduplication. Additionally, utilizing a mix of approaches to providing access to 340B pricing (as would be the result from receiving rebate claims for a subset of a specific medicine's utilization while the remainder continued receiving an upfront discount) would necessarily result in additional complications, delays, diversion, and continued duplicate discounts.

Without a complete picture of 340B claims from all covered entity types, manufacturers will not have the information they need to prevent multiple covered entities from collecting rebates on the same unit of a medicine. Carve-outs of specific covered entity types would significantly undermine the benefits of a rebate model because, with the vague patient definition in the 340B program, one analysis shows 340B hospitals could be claiming up to 36 percent of prescriptions prescribed by Community Health Centers (CHCs).[68]

Moreover, program violations are not concentrated exclusively among large hospitals, but in fact commonly occur among smaller covered entities as well. According to an analysis of HRSA audit

[66] AHA, et al. Letter to Katie Wilder. Available at: https://www.aha.org/lettercomment/2026-01-12-aha-other-groups-its-wrong-tell-hospitals-they-are-complete-drug-acquisition-cost-survey.
[67] Am. Hosp. Ass'n v. Becerra, 596 U.S. 724, 738 (2022).
[68] Blalock E. (April 2026). 340B Patient Definition and Implications for Duplicate Replenishment. *Berkeley Research Group.* Available at: https://media.thinkbrg.com/wp-content/uploads/2026/04/10141302/340B-Patient-Definition-and-Implications-for-Duplicate-Replenishment.pdf.

findings, grantees were nearly twice as likely as hospitals to have duplicate discount findings between 2020 and 2024.[69] Exempting a subset of covered entities, like grantees, would create a loophole that would prevent the system from realizing the full benefit of a rebate model. Additionally, such a carve-out would be challenging to implement because there is no clear line between grantees and hospitals: In 2022, approximately 21 percent of 340B hospitals had at least one grantee clinic registration, and 7 percent of grantees were located within a 340B hospital.[70] Exempting grantees could even have the unintended effect of driving more consolidation in the health care system if hospitals look to acquire or affiliate with grantees in an effort to take advantage of a carve-out to avoid the transparency afforded by the rebate model.

b. A Targeted, Standardized Set of Data Elements will Further Simplify the Rebate Pilot

Similarly important to the scope of claims collected is the list of data elements reported by the covered entities. PhRMA has included a proposed list of data elements supported by our membership in Appendix A, which we believe are the minimum elements necessary to enable manufacturers to accurately determine a claim's 340B rebate eligibility. As discussed below, covered entities already maintain most of these data elements in a readily shareable format.

The data elements suggested in Appendix A are comprised of (1) pharmacy claims data elements and (2) medical (physician-administered) claims data elements, both of which align with the list included by HRSA in the 2025 Rebate Pilot, as well as (3) covered entity purchase data.

While the purchase data were not listed by HRSA in the 2025 Rebate Pilot, we strongly believe these data are critical to help a rebate model run efficiently and effectively, ultimately benefiting both manufacturers and other stakeholders. These data will allow manufacturers to verify that the covered entity seeking the rebate actually purchased the supply of the drug dispensed or administered—the most basic statutory requirement for a covered entity to obtain 340B pricing. Requiring covered entities to report purchase data is no different from the common practice of requiring consumers to show proof of purchase, such as a receipt, to earn cash back. Purchase data is also needed to validate the covered entity's purchase price.[71]

If HRSA does not allow for collection of that data in connection with the Rebate Pilot, we ask that HRSA clearly state that covered entities subject to a rebate model are required to make all purchases of selected drugs dispensed, administered, or furnished (or to be dispensed, administered, or furnished) to patients under the 340B program through their wholesaler 340B account that manufacturers participating in the pilot load with WAC pricing. Covered entities should be required to certify to HRSA that they are complying with this requirement. Without this express requirement, manufacturers will not be able to adequately monitor and validate, using the limited data they receive from their wholesalers, that purchases are being made on the appropriate wholesaler account.

PhRMA supports consistency in data collection across all 340B claims under a rebate model, which would streamline data collection processes for covered entities. If HRSA requires covered entities to

[69] HRSA. (January 2026). Program Integrity. Available at: https://www.hrsa.gov/opa/program-integrity.
[70] Blalock E. (May 2023). Federal Grantee Clinics and the 340B Drug Discount Program. *Berkeley Research Group*. Available at: https://www.thinkbrg.com/insights/publications/federal-grantee-clinics-340b-drug-discount-program/.
[71] In some cases, covered entities purchase at a manufacturer-offered price other than WAC, and even if the covered entity purchases at the then-current WAC, WAC changes periodically.

submit the data elements suggested in Appendix A, it would not be necessary, for purposes of a rebate pilot, for HRSA to allow manufacturers to require covered entities to submit any additional data elements.

VI. An Efficiently Structured Rebate Model Can Achieve Program Integrity Benefits Without Imposing Undue Burden or Costs on Covered Entities (Question 1)

HRSA requests information about covered entities' "current administrative costs, including costs to third parties (*e.g.,* contract pharmacies) related to 340B program operations and compliance." We urge HRSA to scrutinize the reported figures carefully, only to consider costs that are actually "related to 340B Program operations and compliance," and to disregard costs that covered entities elect to incur to maximize the discounts they receive under the 340B program or for other purposes. For example, according to the Minnesota Health Department's 340B Transparency Report, the majority of covered entities' costs related to 340B derive from fees paid to for-profit contract pharmacies, which expand the locations from which 340B prescriptions can be dispensed, and third-party administrators (TPAs), who often mine data to maximize the number of scripts on which covered entities can claim 340B pricing.[72] Neither of these activities is required to participate in the 340B program, however, covered entities engage in these activities because it is in their best interest, financially, to do so.

To the extent that some of these administrative costs relate to ensuring compliance with program requirements and maintaining auditable records, such costs are entirely appropriate given that covered entity participation in the 340B program is optional and covered entities and their for-profit partners earn nearly $65 billion in profit from the program.[73] Indeed, all payers implement requirements that create compliance costs for providers. For example, hospitals' costs to participate in Medicaid and Medicare likely dwarf what they spend on 340B compliance.[74]

More importantly, HRSA also requests information about "incremental administrative and operational costs" to covered entities under a potential rebate model. These costs, if reliably established, are the costs that the Agency should assess when considering a potential rebate model. Further the Agency must balance such costs against the program integrity benefits that, as discussed below, would flow from an efficiently structured rebate model (such as that HRSA planned for the 2025 Rebate Pilot), without imposing undue burden or costs on covered entities.

In comments on the 2025 Rebate Pilot and the 2025 Rebate Pilot Information Collection Request (ICR), various covered entities and organizations representing them claimed that a rebate model would have imposed substantial costs and administrative burden on covered entities for two reasons: (1) because obtaining and submitting the claims data required under the 2025 Rebate Pilot would be a burdensome new task, and (2) because the 2025 Rebate Pilot would uniquely impose costs of "floating" drug purchases on covered entities. For the reasons explained below, both of these claims are incorrect and

[72] Minnesota Department of Health (2025). 340B Covered Entity Report: Report to the Minnesota Legislature, 2025. Available at: https://www.health.state.mn.us/data/340b/docs/2025report.pdf.
[73] Blalock E., Ferritto M., Taylor, J. (January 2025). The Pharmaceutical Supply Chain, 2013–2023. *Berkeley Research Group*. Available at: https://cdn.aglty.io/phrma/global/blog/import/pdfs/PhRMA_Supply-Chain-2013-2023_White-Paper_V484.pdf.
[74]AHA. (September 2024). Skyrocketing Hospital Administrative Costs, Burdensome Commercial Insurer Policies are Impacting Patient Care. Available at: https://www.aha.org/guidesreports/2024-09-10-skyrocketing-hospital-administrative-costs-burdensome-commercial-insurer-policies-are-impacting?utm.

unsupported by reliable evidence; such evidence shows instead that a 340B rebate model should be no more costly or burdensome to covered entities than the replenishment models they typically use today.

A rebate model would not increase recurring 340B administrative costs. Rather, as detailed below and as HRSA should take into account, a rebate model would readily leverage existing data collection and retention requirements, which would minimize incremental costs and burdens associated with covered entity participation in the pilot. We therefore urge HRSA to look with skepticism on unsupported or conclusory claims by covered entities that the requirements of a rebate model would cause them to incur substantial new costs or burdens. For example, in its comments on the 2025 Rebate Pilot ICR, the AHA argued – without reliable justification – that hospitals would require "up to two full-time equivalents to manage the entire rebate model process," resulting in approximately 4,160 hours per hospital annually, or 11.2 million burden hours across all 340B hospitals.[75] This assertion disregards several important and relevant facts.

First and most importantly, the data elements and reporting requirements included in the 2025 Rebate Pilot align with information already captured and retained by covered entities for 340B compliance and other purposes, and therefore would not lead to significantly new administrative burdens. Specifically, most of these data elements[76] are (1) already captured in electronic health records,[77] (2) necessary to comply with 340B audit requirements,[78] (3) submitted to manufacturers in connection with certain contract pharmacy policies,[79] or (4) necessary for billing both private and government insurance payers[80] and inventory management.

As HRSA recognizes in the recent rebate model ICR, the burden associated with a rebate model "may not be significant" if covered entities are required to submit data that is "comparable to data already being collected and maintained by covered entities through existing third-party vendor relationships or data that is already being provided to manufacturers with respect to certain contract pharmacy policies, in-house pharmacy claims requests, and data elements provided for claims with drugs dispensed under the Medicare Drug Price Negotiation Program."[81] We support this approach of minimizing burden on covered entities by relying largely on data elements they already collect and maintain, and as noted above, we believe the data elements we recommend in Appendix A to this letter are consistent with this approach and objective.

Given that covered entities already routinely compile and transmit claims data to third parties that is similar to what we propose HRSA adopt for a future rebate model, transmitting the data to a 340B rebate

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[75] Golder C. (September 2025). AHA Comments to HRSA Re: The 340B Rebate Model Pilot Program. *AHA*. Available at: https://www.aha.org/system/files/media/file/2025/09/aha-letter-to-hrsa-on-the-340b-rebate-model-pilot-program-9-30-2025.pdf.

[76] The data elements we propose here are the same elements that HRSA included in the Rebate Pilot, plus a limited number of data elements to verify that the covered entity actually purchased the drug and the price at which it made the purchase.

[77] *See e.g.,* the United States Core Data for Interoperability (USCDI) data elements maintained by the Office of the National Coordinator for Health Information Technology (available here). The USCDI defines the standardized classes and individual data elements that certified EHR systems must be able to capture and exchange.

[78] *See for example* Section 3(C), Sample HRSA 340B Audit Data Request List (DRL) for Covered Entities. Available at: https://www.340bpvp.com/Documents/Public/340B%20Tools/sample-hrsa-340b-audit-data-request-for-covered-entities.pdf

[79] *See* 340B ESP, Data Submissions FAQ 9. Available at: https://help.340besp.com/en/articles/8808065-frequently-asked-questions-faqs#h_a1adc6cecc.

[80] For example, covered entities are required to provide many of the data fields HRSA contemplated in the 2025 Rebate Pilot as part of the 837P form required for providers to bill Medicare for separately payable drugs covered under Part B and as part of the D.0 electronic telecommunication standard utilized for pharmacy billing.

[81] 91 Fed. Reg. at 9633.

vendor should not require significant additional labor. In the lead up to the 2025 Rebate Pilot, some TPAs confirmed they were able to provide the support necessary to implement the rebate model without changes to covered entity software.[82] In light of the existing data submission and transmission requirements that already apply to covered entities, which presumably are performed by current covered entity employees, it is extraordinarily unlikely that each covered entity will need two additional full-time employees working year-round to compile and submit fundamentally the same data. A rebate model would not be a novel data collection burden for covered entities already in compliance with applicable requirements. Given the crowded field of for-profit companies offering services in the 340B space,[83] we are confident that market competition will drive down additional TPA costs associated with the Rebate Model.

In the recent rebate model ICR, HRSA estimated that each covered entity would prepare and submit 52 annual responses (weekly submissions) at an average of 5 hours per response.[84] This estimate also is inflated. An assumption that five hours of labor per weekly submission is needed even after initial setup and testing has been completed ignores that:

- Data elements likely to be necessary and appropriate are elements that covered entities already collect and maintain for other purposes;
- Modern pharmacy systems can automate data extraction and formatting;
- Electronic submissions to standardized platforms require minimal manual intervention once initially configured;
- Batch processing capabilities allow submission of multiple claims simultaneously; and
- Most "submission time" consists of automated system-to-system data transfer.

Accordingly, HRSA should update, correct, and significantly reduce its burden estimate for covered entities. In doing so, HRSA should evaluate the actual burden for *recurring* weekly submissions—*after* initial system configuration. Its assessment should be that these recurring submissions will require just minutes, not hours, of human labor per week. Even 2 hours per week—HRSA's estimate in the 2025 Rebate Pilot ICR—is unrealistic under the circumstances proposed. While 2 hours per week may be a reasonable estimate for initial setup and testing, it is not a credible estimate for routine ongoing submissions.

[82] *See, e.g.,* The Craneware Group press release, "95% of 340B processes remain unchanged…TCG confirmed that its customers can participate in the 340B Rebate Pilot without procuring additional software or new vendor contracts. The rebate workflow is demo-ready today." The Craneware Group. (October 2025). The Craneware Group Hosts 340B Rebate Forum, Confirms No New Vendor Needed for Pilot. Available at: https://www.kxan.com/business/press-releases/cision/20251031FL12663/the-craneware-group-hosts-340b-rebate-forum-confirms-no-new-vendor-needed-for-pilot/.

[83] Nikpay S, Halvorson L. (2023). Growing administrative complexity in the 340B program and the rise of third-party administrators. *Health affairs scholar*, *1*(5), qxad052. Available at: https://doi.org/10.1093/haschl/qxad052.

[84] 91 Fed. Reg. at 9633.

a. A Rebate Model Would Not Introduce New Cash Flow Challenges for Covered Entities (Question 2)

We anticipate that HRSA will receive numerous responses to this RFI from covered entities containing exaggerated claims that the "float" associated with a rebate model (meaning, the time lag between the purchase of a medicine and the receipt of the rebate) will have devastating financial consequences. We urge the agency to weigh these assertions in light of the demonstrable facts:

1) covered entities already routinely carry a "float" for their initial purchase under the replenishment model and must wait until a full package of medicines is used before replenishing at the discounted price;

2) under a rebate model similar to the 2025 Rebate Pilot, the vast majority of covered entities would receive rebate payments *before* invoices are due to their wholesaler, eliminating any cash flow concerns; and

3) the "float" under a rebate model, to the extent there is one, would likely be of the covered entity's own creation and temporary in nature.

Under the 2025 Rebate Pilot, manufacturers would have been required to pay the rebate within 10 calendar days of the covered entity submitting an eligible rebate claim. If a new rebate model has a 10-calendar-day deadline for the manufacturer to pay the rebate on eligible claims, covered entities would likely be able to obtain 340B pricing more quickly than under the current replenishment model they claim to favor, since the rebate payment could occur on a unit-by-unit basis rather than requiring the covered entity to wait until it has dispensed an entire package before replenishing the package with a 340B discounted order.[85] In this regard, a rebate model could smooth or otherwise improve cash flow for smaller covered entities or for less commonly dispensed drugs. For those less commonly used drugs, the receipt of 340B pricing is often delayed under the replenishment model because it can take weeks or months before a full package is dispensed and thus for a 340B discounted package to be ordered. In other words, a rebate model could provide a 340B covered entity with the 340B price faster than the current replenishment model.

In terms of any perceived "float" due to wholesalers invoicing at WAC rather than the 340B discounted price, a recent IQVIA report found that in most cases, covered entities would receive the rebate well before they would be required to pay their wholesaler invoice, eliminating any potential cash flow issues.[86] IQVIA modeled covered entities' cash flow for eight different 340B payment models, including a rebate model paid within 10 days (in line with the 2025 Rebate Pilot). Assuming a wholesaler credit term for hospitals and clinics of 30 days—the standard payment term found in its interviews—IQVIA found that with respect to cash flow, the rebate model performed better than or equal to other common inventory models used today.[87] Therefore, a 10-calendar-day rebate payment deadline would be sufficient to ensure

[85] HRSA. 340B Rebate Model Pilot Program. Available at: http://web.archive.org/web/20260102161509/https://www.hrsa.gov/opa/340b-model-pilot-program (noting that "All approved manufacturer plans will issue rebates based at the unit level").
[86] Sun C, et al. (December 2025). How Will a Rebate Model Impact Cash Flow in the 340B Drug Pricing Program?, *IQVIA*. Available at: https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2025/iqvia-cash-flow-impact-in-340b-white-paper-2025.pdf.
[87] *Ibid.*

that covered entities do not face negative cash flow issues under a rebate model and could potentially even improve cash flow for covered entities compared to several of the 340B payment models used today.

The IQVIA study assumed a hypothetical covered entity that would purchase all inventory at WAC on day one of the pilot and face wholesaler invoices on day 30, and still found little to no effect on covered entities' cash flow. Notably, this is the most dramatic version of how a covered entity would experience a rebate model. In reality, covered entities already have inventory in stock that would be dispensed after a rebate model has taken effect. Existing inventory would be replaced over time with new inventory purchased at WAC as drugs are dispensed and rebates are paid shortly thereafter—resulting in a gradual transition to WAC purchasing, not the abrupt "shock" at the outset of the rebate model that covered entities claim. This gradual replacement of existing inventory further reduces any cash flow concerns.

Even in the hypothetical case where a covered entity would need to pay wholesalers prior to the receipt of 340B rebates, any cashflow issues that may result would be temporary. CMS has noted that pharmacy cashflow concerns created by retrospective MFP refund payments under the IRA, which involve a somewhat longer timeframe for manufacturer payment, is likely most acute at the start of each initial price applicability year.[88] CMS did not anticipate cashflow challenges persisting once MFP refund payments were routinely flowing,[89] and since MFPs have gone into effect, there has not been evidence of meaningful disruptions. While pharmacy cashflow concerns over MFP refund payments are in some ways different from covered entity concerns over timing of 340B rebates, the principle remains the same—once rebate payments are continually flowing, any cashflow concerns would resolve.

Finally, we note that the increasingly common "credit-based replenishment" includes delays in obtaining the 340B price and in that sense is like a rebate model. However, unlike the 2025 Rebate Pilot, these credit-based replenishment models do not necessarily have a 10-day requirement for payment. Additionally, these models rely on a complex set of opaque financial transactions that are independent of the shipment of 340B units.[90] The growing popularity of these credit-based models in the face of this payment delay illustrates the willingness of covered entities to agree to changes to obtaining the 340B price when those changes serve the interests of covered entities and their contract pharmacies, and result in decreased program transparency. Accordingly, HRSA should look skeptically upon assertions that any delay in the realization of the 340B price due to a rebate model is inherently problematic from a cash-flow perspective or otherwise.

b. The Covered Entity Survey Stating Harm from the Rebate Model is Flawed and Should be Disregarded

A survey by 340B Health claiming covered entities would be unable to operate under a rebate model is methodologically flawed, systematically biased, and based on an outdated and exaggerated set of assumptions. For these reasons, the findings of the survey should be viewed with skepticism and

[88] CMS. (October 2024). 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. Available at: https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.
[89] *Ibid.*
[90] AmeriSourceBergen, Inventory Synchronization Program Guide. Available at: https://web.archive.org/web/20240426164057/https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/pdf/hgs-230633-isp-guide-12dec23-v2.pdf.

ultimately dismissed given empirical evidence elsewhere that a rebate model would not create cash flow concerns for covered entities.

340B Health surveyed a self-selected set of just 347 respondents—a small fraction of the 50,000 covered entities in the United States—a non-random sample carrying a meaningful risk of response bias. Additionally, the survey questions on the financial impact were based on the incorrect assumption that a rebate model would require covered entities to wait 30 days or more to receive rebates. By contrast, pharmaceutical companies committed to paying rebates within 10 days under the 2025 Rebate Pilot. The survey also fails to account for payment terms to wholesalers, which would further insulate covered entities from experiencing any cash flow impact. In most cases, covered entities will receive 340B rebates before they are required to pay wholesalers for the medicines. Finally, the calculations on estimated "float" included in the survey report rely on meaningless assumptions based on overall annual 340B purchases and not an actual rebate model where covered entities would receive the rebate within 10 days, often well before their wholesaler invoice is due.

VII. Rebate Denials (Question 3)

HRSA should evaluate rebate denials as part of any rebate model it implements and, based on its evaluation, should consider whether a standardized template for adjudications of improper denials is needed in the future. We also urge HRSA to commit to working collaboratively with key stakeholders to develop standard processes and timelines, if needed. We note also that existing 340B processes may be used to address disputed denials of rebates.

VIII. Required Reporting (Question 6)

We recommend that HRSA require manufacturers to report the data elements listed in Appendix B, which largely align with the elements HRSA listed in the 2025 Rebate Pilot ICR. These data elements would provide HRSA with empirical information on the use of rebates to effectuate the 340B ceiling price, which the agency could use both to assess manufacturer and covered entity compliance with a rebate model and to evaluate its effectiveness. We recommend that manufacturers report these elements to HRSA on a monthly basis to allow for rapid assessment of the pilot.

HRSA should publicly share the following data in aggregate form across all drugs (or as an average, as indicated below for certain of the data elements): 1) total purchases by covered entity type (in dollars at the 340B ceiling price and at WAC); 2) average days from clean claim submission to rebate payment; 3) number of rebates paid within 10 days of clean claims submission (out of specified number of total rebate claims, so that an average can be calculated); 4) number of rebates denied, with reasons (out of specified number of total rebate claims, so that an average can be calculated); and 5) number of claims where an MFP refund was denied due to a 340B rebate being paid.

We believe that transparency of non-proprietary data will assist all 340B stakeholders in understanding how well a rebate model is performing and help in identifying ways to improve and expand the model over time. Publicly reported data could also be useful to policymakers, taxpayers, employers and other stakeholders to make informed decisions about program-related activities.

340B ceiling prices and data that could be used to calculate the 340B ceiling price are confidential and proprietary and therefore should not be publicly released.[91] We recommend that HRSA confirm that not only will this information be secure, but that it will also be kept confidential, by HRSA as well as any agency or entity working with HRSA or on its behalf.

Furthermore, only HRSA and other government partners should evaluate the model. We urge HRSA to work with the HHS OIG and with groups across CMS to establish transparent and measurable criteria that will be used when evaluating a rebate model and in considering any potential changes to such a model. OIG will provide valuable insight based on their past recommendations for program improvements.[92] Within CMS, the Center for Program Integrity should be involved in any assessment of a rebate model given their expertise in preventing and reducing waste, fraud, and abuse. CMS' Medicare Drug Rebate and Negotiations Group and the Center for Medicaid and CHIP Services should also be part of any evaluation to determine how well a rebate model helped ensure compliance with the IRA and Medicaid nonduplication requirements, respectively.

To the extent that HRSA uses contractors for non-evaluative functions related to the rebate pilot, HRSA should be careful to select contractors without actual or perceived conflicts of interest. Under the 2025 Rebate Pilot, HRSA would have required manufacturers to submit data to the 340B Prime Vendor, Apexus. This was problematic given this organization's well-known conflicts of interest. As highlighted in a *New York Times* investigation published in early 2025, the current Prime Vendor compensation model creates an incentive for Apexus to "supercharge" the 340B program.[93] Apexus also is currently the subject of an investigation by the Chairman of the Senate Health, Education, Labor, and Pensions (HELP) Committee scrutinizing (among other things) how "Apexus has expanded its business beyond its core role as the 340B prime vendor... to increase its profits."[94] In addition, we are concerned that Apexus' ownership is another source of potential conflicts because Apexus is a subsidiary of Vizient, a private company owned by hospitals.[95] For these reasons, we have serious concerns that the Prime Vendor cannot commit to impartial involvement in a rebate model pilot and, therefore, should not play any role in evaluating a rebate model nor should it have access to any confidential or sensitive data related to the pilot.

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[91] This information may be protected from disclosure under Exemption 4 of the Freedom of Information Act (FOIA) and, the Trade Secrets Act (18 U.S.C. § 1905), and the PPA (which states that "[i]nformation disclosed by the Manufacturer in connection with the [PPA], except as otherwise required by law, will not be disclosed by the Secretary or his designee in a form which reveals the Manufacturer," except as necessary to carry out section 340B or permit review by the Comptroller General). Pharmaceutical Pricing Agreement. Available at https://www.hrsa.gov/sites/default/files/hrsa/opa/manufacturer-ppa.pdf.
[92] OIG. (June 2016). State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates. Available at: https://oig.hhs.gov/reports/all/2016/state-efforts-to-exclude-340b-drugs-from-medicaid-managed-care-rebates/.
[93] Gabler E. (January 2025). How a Company Makes Millions Off a Hospital Program Meant to Help the Poor. *NY Times.* Available at: https://www.nytimes.com/2025/01/15/us/340b-apexus-drugs-middleman.html.
[94] HELP Committee. (February 2026). Chair Cassidy Continues Investigation into 340B Drug Program, Seeks Information from 340B Prime Vendor. Available at: https://www.help.senate.gov/rep/newsroom/press/chair-cassidy-continues-investigation-into-340b-drug-program-seeks-information-from-340b-prime-vendor-1. *See also* Gabler E. (February 2025). Senate Questions Health Care Firm for Profiting Off Program Meant for Poor. *NY Times*. Available at: https://www.nytimes.com/2026/02/12/us/health-care-apexus-340b.html.
[95] Gabler E. (January 2025). How a Company Makes Millions Off a Hospital Program Meant to Help the Poor. *NY Times.* Available at: https://www.nytimes.com/2025/01/15/us/340b-apexus-drugs-middleman.html.

PhRMA appreciates the opportunity to comment on this important initiative and looks forward to continued dialogue with the Agency to ensure the prompt launch, success, and then expeditious expansion of a rebate model. As HRSA evaluates next steps following what we anticipate will be a successful pilot, it should work toward a broader rebate model that goes beyond IRA selected drugs as operational and program integrity benefits of such a rebate approach apply broadly across the 340B Program.

Please do not hesitate to reach out to Sylvia Yu (syu@phrma.org) and Karyn Schwartz (kschwartz@phrma.org) with any additional questions.

/s/

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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

Appendix A:
Data elements needed to accurately implement a rebate model

<table>
<tr><th>Pharmacy Claims Data</th><th>Medical Claims Data</th></tr>
<tr><td>Date of service
Date prescribed
Rx number
Fill number
11 digit National Drug Code (NDC)
Quantity Dispensed
Prescriber ID
Service provider ID
340B ID
Rx Bank Identification Number (BIN)
Rx Processor Control Number (PCN)</td><td>11 digit NDC
Quantity
Date of service
340B ID
Service provider ID
Claim number (analogous to Rx number)
Health plan ID & health plan name (analogous to Rx BIN & Rx PCN)
Rendering physician ID (analogous to Prescriber ID)
Claim line number
Unit of measure</td></tr>
<tr><td colspan="2">Purchase data elements
(for pharmacy and medical claims)</td></tr>
<tr><td colspan="2">Wholesaler Name
Wholesaler Account Number
Invoice Date
Invoice number
Ship-to pharmacy NPI
11-digit NDC
Package units
340B ID</td></tr>
</table>

Appendix B:

HRSA should require manufacturers to report the following data elements

- Claim submission date
- 340B ID
- NDC-11 and quantity purchased
- Unit WAC, 340B Ceiling, and MFP
- Rebate amount and date paid
- Rejection reason (if applicable)
- Aggregated sales by covered entity type
- Average days from claim submission to rebate payment
- Number of rebates paid within 10 days of clean claims submission
- Number of rebates denied, with reasons
- Number of claims where an MFP refund was denied due to a 340B discount being paid

Appendix C:

Selected Government Reports Addressing the 340B Program

- **CBO, Growth in the 340B Drug Pricing Program,** CBO-60661, (September 2025), http://www.cbo.gov/publication/60661.
    - "Because 340B facilities generate net revenue when they dispense drugs purchased through the program, those facilities have an incentive to prescribe more drugs and to shift prescriptions to drugs for which the difference between the insurance rate and the 340B discounted price is large. Increasing prescription volume results in higher spending on drugs by federal insurers and in larger federal subsidies for insurance premiums."
- **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."