

September 8, 2025

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

Mr. Thomas J. Engels
Administrator
Health Resources and Services Administration
Department of Health and Human Services
Attention: HRSA-2025-14619
5600 Fishers Lane, Mail Stop 08W05A
Rockville, MD 20857

Re: 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program

Dear Administrator Engels:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is writing to express support for, and provide feedback on, the Health Resources and Services Administration's (HRSA) notice regarding an application process for the "340B Rebate Model Pilot Program."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.

HRSA's announcement of a 340B Rebate Pilot Program ("Rebate Pilot") is a positive first step towards leveraging commonsense solutions to improve the 340B program.² We anticipate that the Rebate Pilot will spur a larger private sector role in addressing 340B compliance challenges, which have been exacerbated by the Inflation Reduction Act ("IRA"), thereby lessening federal burden and saving taxpayers money. PhRMA and our members stand ready to work to ensure the successful implementation of the Rebate Pilot as described in the HRSA notice. Our members are committed to engaging in good faith with HRSA and covered entities to ensure a successful pilot and expect that all stakeholders will do the same.

As discussed in more detail below, HRSA should quickly expand this Rebate Pilot to all 340B covered outpatient drugs and allow for the broad use of rebates in the 340B program. This would be an important step towards safeguarding the program, without sacrificing support for true safety net providers and the patients they serve.

¹ 90 Fed. Reg. 36163 (August 1, 2025) (corrected 90 Fed. Reg. 38165 (August 7, 2025)).

² 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).

Rebates are a commonly used mechanism for manufacturers to provide discounts and other price concessions, and their use in 340B would leverage data to bring transparency to, improve the accuracy of, and ensure timely payments in the 340B program.

Rebates are already used to provide access to discounted pricing in Medicaid, TRICARE retail and Medicare Part D. Pharmacies and providers typically serve a mix of patients with different insurance coverage and program eligibility statuses. Thus, when a hospital 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 retroactively after the patient's insurance coverage and program eligibility status are known. 340B is an outlier in this regard, and this has contributed to an opaque system where basic claims data are not available to ensure statutory requirements are met. HRSA's pilot is a welcome (if limited) step in aligning 340B with the way other federal programs function. The broad use of rebates in 340B, which is permitted by statute,³ will strengthen the 340B program and help ensure statutory requirements related to interactions with other programs are met. For drugs covered under the Rebate Pilot, covered entities (CEs) will be required to provide basic, readily accessible claims-level data for units subject to 340B pricing, a requirement that aligns with past recommendations from the HHS Office of the Inspector General (OIG)⁴ and is consistent with HRSA's responsibility for promoting adherence to the 340B program rules. We note as well that PhRMA's member companies interested in using a rebate model have stated, in communications with HRSA and otherwise, that manufacturers' rebate models will comply with their obligations under the 340B statute.

For CEs, a rebate model may have benefits beyond program integrity improvements. In many instances, 340B medicines today are purchased at list price and replenished at the 340B price under a "replenishment model" only once the entire package of the medicine has been dispensed or administered to 340B patients of a covered entity. Under the guaranteed timelines in the Rebate Pilot, CEs may be able to obtain 340B pricing more quickly than under the replenishment model, since the rebate payment will not hinge on use of the remaining units of medicine in the package. Additionally, it is our understanding from conversations with industry experts that payments under most wholesaler invoices are due 14 to 30 calendar days after receipt of the medicine. Assuming CEs submit data to support the 340B rebate in a timely manner, they would receive 340B rebates before payments under those invoices are due.

The 340B program is large and complex and the current reliance on audits to ensure program integrity is insufficient.

A rebate model provides an efficient, private market solution to the numerous flaws present in the current "pay and chase" 340B system. In the years since the 340B program began in 1992, program growth combined with broader changes in the healthcare system have contributed to—and indeed worsened—340B program integrity challenges. Manufacturers previously made 340B pricing available without the benefit of claims-level data and then were forced to resolve any detected violations of the 340B statute after the fact.

³ 42 U.S.C. § 256b(a)(1) ("The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs . . .") (emphasis added).

⁴ 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-medicare-managed-care-rebates/>.

In 2019, when the program was less than half its current size, it was estimated that as much as \$1.5 billion in duplicate discounts were claimed by CEs.⁵ This, alongside the Government Accountability Office (GAO) and the OIG urging for action to prevent duplicate discounts in Medicaid managed care,^{6,7} paints the picture of a serious integrity problem. With the program having more than doubled in size, today featuring 26,506 CEs and 35,750 child sites and over \$66 billion in purchases,^{8,9} this “pay and chase” model is not up to the task of ensuring compliance in the 340B program.

Today HRSA oversees the program through its own 340B audits, but that tool is not adequate for a program as large and complex as 340B. Currently, HRSA audits less than one percent of CEs, and roughly 70 percent of those HRSA audits return adverse findings.¹⁰ While already egregious, this likely underrepresents the true magnitude of statutory violations within the 340B program. After a lawsuit called into question HRSA’s enforcement capabilities regarding who is a 340B patient, the agency announced it would stop issuing findings based solely on noncompliance with guidance. According to GAO, this resulted in 36 instances during FY 2019 where an audit did not result in an adverse finding that previously would have resulted in an adverse finding according to HRSA.¹¹ As the program has grown and CEs have become more aware of this lack of enforcement, this problem has likely gotten worse.

Additionally, these audits are only retrospective in nature and are not an effective way to prevent future violations of 340B program requirements. Between 2015 and 2024 there have been only 68 CEs that have been reaudited by HRSA due to previous adverse findings, with 68 percent of these reaudits returning continued or additional evidence of non-compliance.¹² When HRSA audits during this period resulted in sanctions against CEs, they were most commonly required only to repay manufacturers for discounts they should not have received. HRSA did not require that CEs pay any additional penalties or interest payments, nor did HRSA terminate any CEs from the 340B program as a result of noncompliance identified through these audits.

While manufacturer audits of CEs could be another tool to address 340B violations, HRSA’s 1996 manufacturer audit guidelines are outdated and impose onerous and unnecessary barriers that are not authorized by the statute and make these audits costly and rare.¹³ This guidance—combined with CEs’ determination to challenge and delay audits—has made the audit process largely unworkable for manufacturers and resulted in few audits actually being completed. CE recalcitrance in the face of manufacturer audits imposes burdens on HRSA, too. For example, our members report that it has become increasingly common for CEs to try to thwart a manufacturer’s audit by refusing to cooperate. In some

⁵ Kalderos. (2021). Making health policy work for patients. Available at:

https://f.hubspotusercontent40.net/hubfs/7227094/2021%20Annual%20Report/Annual_report_2021.pdf.

⁶ 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/>.

⁷ 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>.

⁸ Health Resources and Services Administration Office of Pharmacy Affairs Information System (OPAIS) (2025). 340B covered entity database. Available at: <https://340bopais.hrsa.gov>.

⁹ Health Resources and Services Administration. (October 2024). 2023 340B Covered Entity Purchases. Available at:

<https://www.hrsa.gov/opa/updates/2023-340b-covered-entity-purchases>.

¹⁰ ADVI. (March 2025). Analysis of HRSA 340B Covered Entity Audits. Available at: <https://advi.com/insight/advi-analysis-hrsa-340b-covered-entity-audits/>.

¹¹ 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>.

¹² ADVI. (March 2025). Analysis of HRSA 340B Covered Entity Audits. Available at: <https://advi.com/insight/advi-analysis-hrsa-340b-covered-entity-audits/>.

¹³ 61 Fed. Reg. 65407 (Dec. 12, 1996).

cases, CEs even sue HRSA over its authorization of a manufacturer audit.¹⁴ Government watchdogs have raised concerns that, when manufacturers are able to audit and do uncover statutory violations, HRSA often does not require repayment of price concessions that CEs should never have received, even when there is no dispute that the repayment is owed.¹⁵

A rebate is the best and most efficient way to ensure new statutory IRA requirements related to 340B nonduplication are met. Because nonduplication requirements apply beyond the drugs selected for initial price applicability year (IPAY) 2026, the Rebate Pilot should be expanded as quickly as possible.

The IRA adds new challenges to an already complex 340B program by including new 340B nonduplication requirements related to both “maximum fair prices” (MFPs) and inflation rebate obligations. Without a rebate model, the systems and policies developed by CMS do not ensure compliance with the full breadth of IRA requirements.

The Rebate Pilot ensures manufacturers have the data they need to avoid paying duplicate MFP and 340B rebates for drugs selected for MFPs in 2026. This is crucial given the importance of the MFP non-duplication provision and the fact that CMS has stated thus far it will not take responsibility for this deduplication.¹⁶

However, the need for a rebate model goes beyond the IPAY 2026 drugs. Most urgently, manufacturers with IPAY 2027 drugs need assurance that the Rebate Pilot will be available for these medicines to prevent statutorily prohibited MFP/340B duplicate discounts. We urge HRSA to clarify as soon as possible that it will extend the pilot to those medicines with ample time for manufacturers of IPAY 2027 medicines to incorporate a 340B rebate into their MFP effectuation plans.

A rebate is also the best and most efficient way to carry out the IRA’s requirement that CMS exclude 340B units from the calculations of manufacturers’ Medicare Part B and Part D inflation rebate obligations.^{17, 18} In the case of each of these calculations, a 340B rebate is simpler than the current approach.

- **Part B inflation penalty:** To exclude 340B units from this calculation, CMS is relying on CEs to use a claims modifier, but there is no clear mechanism to enforce that requirement, and manufacturers are limited in their ability to police this type of non-compliance. A 2023 report by IQVIA found that for Part B separately payable drugs only 61 percent of treatments originating at rural referral centers and sole community hospitals used a relevant 340B modifier.¹⁹ While there are situations where it is appropriate for CEs not to use the relevant 340B claims

¹⁴ See, e.g., *Children’s Nat’l Med. Ctr. v. Johnson*, No. 1:24-cv-02563 (D.D.C. Sept. 6, 2024); *Univ. of Rochester v. Johnson*, No. 1:24-cv-02268 (D.D.C. Aug. 1, 2024); *MaineGeneral Med. Ctr. v. Johnson*, No. 1:24-cv-02187 (D.D.C. Jul. 24, 2024); *Oregon Health & Sci. Univ. v. Johnson*, No. 1:24-cv-02184 (D.D.C. Jul. 24, 2024).

¹⁵ 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/products/gao-20-212>.

¹⁶ 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. Page 231. Available at: <https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf>.

¹⁷ 42 U.S.C. §§ 1395w-3a(i)(3)(B)(ii)(I), 1395w-114b(b)(1)(B).

¹⁸ 42 U.S.C. § 1320f-2(d).

¹⁹ IQVIA. (February 2023). Can 340B Modifiers Avoid Duplicate Discounts in the IRA? Available at: <https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2023/can-340b-modifiers-avoid-duplicate-discounts-in-the-ira.pdf>.

modifiers,²⁰ this finding suggests that a 340B rebate could identify 340B units (and thus exclude them from inflation rebate calculations) more effectively than a modifier requirement.

- **Part D inflation penalty:** CMS has not yet implemented an accurate method to identify and exclude 340B units from Part D inflation rebate calculations. Instead, in the 2026 Medicare Physician Fee Schedule proposed rule, CMS proposed relying on a claims-based estimation approach.²¹ CMS itself acknowledges that this method is inexact. A 340B rebate would provide a precise way for CMS to exclude these units and obviate the need to rely on an imprecise estimation approach.

In addition to a rebate, PhRMA continues to advocate for a 340B claims clearinghouse that would collect data on all 340B claims and share that data with manufacturers. Data collected through the 340B rebate pilot could feed into such a clearinghouse, which should also collect data on other 340B claims and relevant Medicare and Medicaid data to ensure all statutory non-duplication provisions are met and manufacturers receive a complete set of claims-level data. A claims clearinghouse would not eliminate the need for a rebate model, in part because a clearinghouse will likely face delayed data submissions.

A fair evaluation of the Rebate Pilot must include appropriate metrics and allow for a timely assessment. HRSA should prepare to quickly expand the pilot, assuming it proves successful.

HRSA should consult with the OIG and partner with groups across CMS to establish transparent and measurable criteria that will be used when evaluating the Rebate Pilot and considering expansion. OIG will provide valuable insight based on their past recommendations.²² Within CMS, the Center for Program Integrity should be involved in any assessment of the Rebate Pilot given their expertise in preventing and reducing waste, fraud and abuse. The Center for Medicare's Medicare Drug Rebate and Negotiations Group should also be part of any evaluation to help determine how well the rebate model helped ensure compliance with the IRA's nonduplication requirements. This collaborative effort between HRSA, OIG, and CMS should begin by developing quantitative and objective metrics. These metrics could include:

- CE engagement with IT platforms (e.g., number of registrations, data submissions, support inquiries)
- Accuracy of rebate payments such that CEs pay a net of rebate price no more than the 340B ceiling price
- The average number of days it takes for CEs to receive rebate payments after full data submission for eligible claims
- An assessment from CMS of how well the rebate model has worked to enable timely and accurate MFP deduplication
- How frequently disputed claims are ultimately overturned in cases where their initial determination was made based on a full data submission by the CE

²⁰ For example, RRCs and SCHs 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 CE would not claim the 340B discount and not utilize the relevant modifier on the Part B claim.

²¹ 42 U.S.C. § 1395w-114b(b)(1)(B).

²² 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-medicare-managed-care-rebates/>.

- Number and percent of claims denied, categorized by reason for denial

The evaluation of the Rebate Pilot must be completed in a timeframe that balances the need for a prompt evaluation and decision regarding expansion of the Rebate Pilot to more medicines and the recognition that the Rebate Pilot starts on the same day that IPAY 2026 MFPs take effect. We suggest the best way to approach this is to begin analysis of the pilot after the first quarter of 2026. Waiting one quarter will provide data on the long-term viability of this model and help to limit confounding factors that could obscure the actual performance of the Rebate Pilot.

The pilot should be designed to make an efficient and clear-eyed assessment of the rebate model, focusing on data elements such as those described above. Once HRSA confirms the pilot is successful, HRSA should rapidly expand use of a rebate to all 340B drugs. In the meantime, HRSA should clarify as soon as possible that the pilot will be available for IPAY 2027 drugs. Manufacturers need this information very soon to make decisions related to their MFP effectuation plans given that the first submission is due June 1, 2026.²³

While we support the Rebate Pilot, we recommend some slight adjustments to help ensure successful rollout.

- 1. The pilot should add a few additional data elements to its standard list of data elements for the rebate model. With those elements added, it would not be necessary to allow manufacturers to individually request more data elements.**

While we appreciate HRSA's stated flexibility for manufacturers to request additional data elements,²⁴ we believe that the data list could be standardized if just a few additional data elements were added. We understand that some CEs have raised concerns about the burden of having to comply with ten different data lists, and so we worked with our members to develop one comprehensive set of suggested data elements.²⁵ PhRMA has included in the appendix a proposed list supported by our membership that would enable manufacturers to accurately determine a 340B claim's eligibility. We also note that CEs should have all the data elements listed in the appendix for the purpose of maintaining 340B auditable records, and therefore this list should not lead to additional costs for CEs, which already have an obligation to have these records in a shareable format.²⁶

The data elements suggested in the appendix fall into two categories:

- Purchase data to confirm that a physical purchase by the CE requesting the rebate occurred and the price at which the drug was purchased: Limited purchase data are necessary to validate CE purchases because WAC does change periodically and in some cases CEs purchase at a price other than WAC. These purchase data may end up being reported

²³ CMS. (May 2025). Medicare Drug Price Negotiation Program: Draft 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-draft-guidance.pdf>.

²⁴ HRSA. (August 2025). 340B Rebate Model Pilot Program FAQs. Available at: <https://www.hrsa.gov/opa/340b-model-pilot-program>.

²⁵ Golder C. (August 2025). AHA Comments to HRSA on Proposed 340B Rebate Model Pilot Program. AHA. Available at: <https://www.aha.org/2025-08-27-aha-comments-hrsa-proposed-340b-rebate-model-pilot-program>.

²⁶ *Univ. of Wash. Med. Ctr. v. Kennedy, et al.*, No. 1:24-cv-02998 (D.D.C. filed Oct. 22, 2024) (declaration of Chantelle Britton); Apexus. (August 2024). 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>.

separately from other data and in that case certain data elements should also be included with the purchase data to link the acquisition of medicines to the eligible 340B claim.

- Physician administered data elements that are analogous to the data elements listed by HRSA that are only relevant for retail drugs: HRSA noted in its FAQs that the rebate model applies to “all selected drugs under IPAY 2026 to the extent they are covered outpatient drugs, including physician- or clinic-administered drugs.”²⁷ HRSA should clarify the technical data elements needed for physician-administered medicines as outlined below.

2. When the rebate is expanded more broadly, we expect there will be opportunities to update the list of required data elements based on stakeholder feedback and real-world experience.

A fallback is needed if manufacturers are not permitted to collect the purchase data elements listed in the appendix.

As discussed above, the recommended purchase data elements are needed to validate (1) that the CE requesting the rebate purchased the drug, and (2) the purchase price of the drug. If HRSA does not allow for collection of that data in connection with the Rebate Pilot, we ask that HRSA clearly state that CEs subject to a rebate model are required to make all purchases of selected drugs furnished (or to be furnished) to patients under the 340B program through their wholesaler 340B account that manufacturers participating in the pilot load with WAC pricing. CEs 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 CE purchases are being made on a CE’s appropriate wholesaler account.

Finally, clarification in select areas would provide additional alignment across stakeholders, minimize unintended consequences, and best set the pilot up for success.

- Administrative Costs: We believe that the Rebate Notice is clear that the requirement that “all costs for data submission through an Information Technology (IT) platform be borne by the manufacturer and no additional administrative costs of running the rebate model shall be passed onto the CEs” does not extend to any CE costs associated with data collection (e.g., data preparation, submission and quality control). These activities should already be occurring, and it is our understanding that most CEs already use vendors to collect these data for compliance and auditing purposes.²⁸ As outlined in the Rebate Notice, manufacturers will cover all costs required for their chosen 340B rebate IT platforms to operate. However, given comments raised by other stakeholders,²⁹ HRSA may wish to reconfirm its position to provide certainty to all stakeholders and make clear it is not changing this policy.
- Manufacturer Engagement: In the notice, HRSA stated that the Office of Pharmacy Affairs (OPA) “reserves the right to revoke approval of a manufacturer plan at any time if a manufacturer is not in compliance” with the Rebate Pilot. PhRMA appreciates the importance of compliance, and our members are committed to doing everything they can to make the pilot a success. As part of working collaboratively with all stakeholders to ensure the success

²⁷ HRSA. (August 2025). 340B Rebate Model Pilot Program FAQs. Available at: <https://www.hrsa.gov/opa/340b-model-pilot-program>.

²⁸ Nikpay S., Halvorson L. (October 2023). Growing administrative complexity in the 340B program and the rise of third-party administrators. Health Aff Sch. Available at: <https://pubmed.ncbi.nlm.nih.gov/38756978/>.

²⁹ Golder C. (August 2025). AHA Comments to HRSA on Proposed 340B Rebate Model Pilot Program. AHA. Available at: <https://www.aha.org/2025-08-27-aha-comments-hrsa-proposed-340b-rebate-model-pilot-program>.

of the pilot, we anticipate that OPA will attempt to engage with manufacturers if there are any instances of noncompliance before revoking approval of the manufacturer rebate plan. Giving manufacturers the chance to address any potential inadvertent problems will prevent avoidable mid-year changes that could create confusion for everyone.

- **340B Rebate Amount:** HRSA should clarify that while a 340B rebate amount defined as WAC minus the 340B ceiling price is generally appropriate, there will likely be scenarios where this is not the case and in such cases the acquisition price should be used. Additionally, HRSA should clarify that the WAC used for 340B rebate calculations (when relevant) is the WAC on the date the drug was purchased and not the date the drug was dispensed.

PhRMA also notes that at least one other stakeholder has requested that HRSA either manage a centralized platform for rebate data submissions or contract with a neutral, third-party entity to do so.³⁰ We strongly recommend that HRSA maintain its approach to allow manufacturers to select their own vendor. Private sector vendors have been working with manufacturers to stand up rebate platforms for more than a year and are well-positioned to successfully execute the Rebate Pilot. Relying on HRSA or a government contractor would disrupt the timelines in HRSA's notice, cost the government money, and be a less efficient approach that is not consistent with the Trump administration's streamlining efforts.

PhRMA appreciates the opportunity to weigh in on this important issue and looks forward to continued dialogue with the Administration to ensure the success and rapid expansion of this Rebate Pilot. Please do not hesitate to reach out to Sylvia Yu (syu@phrma.org) and Karyn Schwartz (kschwartz@phrma.org) with any additional questions.

/s/

Elizabeth Carpenter

Executive Vice President, Policy & Research

/s/

James C. Stansel

Executive Vice President and General Counsel

³⁰ Golder C. (August 2025). AHA Comments to HRSA on Proposed 340B Rebate Model Pilot Program. AHA. Available at: <https://www.aha.org/2025-08-27-aha-comments-hrsa-proposed-340b-rebate-model-pilot-program>.

Appendix:
Data elements needed to accurately implement the rebate model

Retail medicine	Physician-administered medicines
<p><u>Already included in rebate notice:</u></p> <ul style="list-style-type: none"> • 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) 	<p><u>Already included in rebate notice:</u></p> <ul style="list-style-type: none"> • 11 digit NDC • Quantity • Date of service • 340B ID • Service provider ID <p><u>New data elements specifically for physician-administered medicines:</u></p> <ul style="list-style-type: none"> • Claim number (analogous to Rx number) • Health plan ID & health plan name (analogous to Rx BIN & Rx PCN) • Rendering physician NPI (analogous to Prescriber ID) • Claim line number • Unit of measure
<p style="text-align: center;">New Purchase data elements (for retail and physician-administered)</p>	
<ul style="list-style-type: none"> • Wholesaler Name • Wholesaler Account Number • Invoice Date • Invoice number • Ship-to pharmacy NPI ▪ 11-digit NDC ▪ Package units ▪ 340B ID 	