This file contains 53 Part D comments received on the Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of the Social Security Act, and Solicitation of Comments. As noted in the Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Revised Guidance, Implementation of Section 1860-D-14B of the Social Security Act (the "revised guidance"), for comment letters from individuals not representing organizations, CMS has removed the name, address, and contact information of the individual for privacy purposes. Any organization or academic institution have not been deidentified.

Due to technical constraints, we have separated some comments into separate files.

340B HEALTH

Submitted via email to IRARebateandNegotiation@cms.hhs.gov

March 11, 2023

Dr. Meena Seshamani, M.D., Ph.D.
Department of Health & Human Services
Centers for Medicare & Medicaid Services
Center for Medicare
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Part D Inflation Rebate Comments

Dear Dr. Seshamani:

340B Health represents over 1,400 public and private nonprofit hospitals that participate in the 340B federal drug discount program. We are writing to provide comments on the Centers for Medicare & Medicaid Services' (CMS) initial guidance regarding implementation of Medicare Part D drug inflation rebates paid by pharmaceutical manufacturers, specifically the requirement that CMS exclude 340B drugs from Part D inflation rebate requests beginning in 2026. In the initial guidance, CMS said it is soliciting comments on whether submission of a 340B identifier on the pharmacy claim is the preferred mechanism to identify 340B units dispensed in Part D, or if there is a better alternative.

As we explain below, 340B identifiers on Part D claims would be unworkable, effectively exclude covered entities from using 340B for Part D beneficiaries, raise concerns about potential discriminatory reimbursement by Part D plans, and raise the risk that 340B drugs might not be excluded from Part D inflation rebate requests. 340B Health urges CMS to instead adopt, as a more accurate and workable alternative, a methodology that would allow covered entities or their contractors to identify 340B claims retrospectively by sending at regular periods a file with 340B claim information directly to CMS or an agency vendor to ensure 340B claims are excluded from Part D inflation rebates.

I. 340B Identifiers on Claims Would Be Unworkable and Would Effectively Exclude Covered Entities from Using 340B for Part D Beneficiaries

CMS's Part D guidance mentions the National Council for Prescription Drug Programs' (NCPDP) Submission Clarification Code field value "20" ("SCC 20") for point-of-sale identification of a 340B claim. It would be impossible for the vast majority of pharmacies that dispense 340B drugs to 340B hospital patients to implement a point-of-sale 340B identifier on a Part D claim. A recent IQVIA study found that 81% of covered entity-owned pharmacies and 99% of pharmacies

that entities partner with do not use 340B claim modifiers for self-administered drugs.[1] This is because the overwhelming majority of pharmacies that dispense 340B drugs use a virtual 340B inventory system that determines 340B eligibility after the point of sale. NCPDP has stated that point-of-sale identification is impossible for 340B.[2] NCPDP explains that pharmacies start with a single, neutral physical inventory, and drugs are initially purchased at non-340B prices. Later, as patients are retrospectively determined to be 340B eligible, the pharmacy's inventory is replenished by purchasing drugs at 340B prices. Therefore, pharmacies with a virtual 340B inventory do not know until after the point of sale whether a claim is 340B. In addition, with a virtual 340B inventory, even if a patient is 340B-eligible, the claim might never officially become a 340B claim in the rare instances where the covered entity is not able to replenish the drug that was given to the patient at a 340B price.[3]

Although some hospitals have devised ways to provide free or discounted 340B drugs at the point of sale to certain patients by acting as a pharmacy benefit manager and providing patients with an "insurance card," this would not work all patients. Hospitals use these cards to offer free or discounted 340B drugs at the pharmacies they partner with for a subset of their patients that meet financial criteria established by the hospital. Under these arrangements, the hospital acts as the payer, allowing the pharmacy bill and receive in real time a determination of whether to provide the drug for free or at a discounted rate. Because of its unique circumstances, this model cannot be adapted to identify all 340B claims at the point of sale.

We also note that point-of-sale identification of 340B claims is not needed to implement the Inflation Reduction Act's requirement that manufacturers provide the "most favored price" (MFP) on certain Part D drugs. The MFP requirement would have no impact on pharmacies that dispense 340B drugs other than what the pharmacy gets paid for Part D drugs, which has nothing to do with whether a patient is 340B-eligible. If a pharmacy were to dispense to a Part D beneficiary a drug subject to the MFP requirement, then the pharmacy would be reimbursed based on the MFP. If the pharmacy were to dispense to a Part D beneficiary a drug not subject to the MFP requirement, then the pharmacy would be reimbursed at its negotiated rate, as they are now. Under either scenario, the covered entity will replenish the drug at a 340B price if the patient meets the 340B program's patient eligibility criteria. Manufacturers would not have to provide both the 340B price and the MFP because the entity can only purchase the drug at one price, not both. This is how the virtual 340B inventory system has been working for decades.

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[1] IQVIA, Can 340B Modifiers Avoid Duplicate Discounts in the IRA? 8 (Feb. 21, 2023), https://www.iqvia.com/locations/united-states/library/white-papers/can-340b-modifiers-avoid-duplicate-discounts-in-the-ira.

[2] National Council for Prescription Drug Programs, 340B Information Exchange Reference Guide 24 (June 2019), https://www.ncpdp.org/NCPDP/media/pdf/340B_Information_Exchange_Reference_Guide.pdf.

[3] For example, a patient might never pick up a prescription, a slow-moving drug might never reach a full package size, certain National Drug Codes might be discontinued, or there might an error by the prescriber or dispensing pharmacy where the "right" thing to do is reverse the claim because the medication should be destroyed.

A retrospective 340B identifier on a claim is also not a viable solution. CMS's Part D guidance mentions NCPDP's N1 transaction for retrospective identification of 340B claims. It is our understanding that no pharmacies or payers have used the N1 in the over 10 years since it was authorized by NCPDP. It would be inappropriate for CMS to require use of a completely untested 340B claim identification method. The only way to make a point-of-sale 340B identifier work would be to reverse and resubmit millions of claims, and an N1 requirement would require pharmacies to reidentify millions of claims. Both methods would be unworkable. If CMS were to require either approach, covered entities would be effectively excluded from dispensing 340B drugs to Part D beneficiaries. Nothing in the Inflation Reduction Act suggests that the law was intended to prevent covered entities from using 340B for Part D beneficiaries.

The loss of 340B for Part D beneficiaries would have a devastating impact on hospitals at a time that many hospitals are already under tremendous financial pressure. Hospitals rely upon the financial benefit they receive from using 340B to support and improve patient care. 340B hospitals are the backbone of the nation's safety net, providing 77% of the hospital care provided to Medicaid patients[4] and 67% of all hospital uncompensated care while having extremely tight operating margins.[5] These hospitals serve a greater share of Medicare patients who are low income or disabled,[6] which have a higher burden of illness and associated costs.[7] Seventy-one percent of rural hospitals rely on 340B, which helps maintain services in areas that have seen a growing number of hospital closures.[8]

II. 340B Identifiers on Claims Raise Concerns about Potential Discriminatory Reimbursement by Part D Plans

340B identifiers on claims also raise concerns about potential discriminatory reimbursement by Part D plans. Over the last 10 years, some payers have discriminated against covered entities and by reimbursing drugs at a lower rate simply because the entities participate in 340B, eroding their 340B benefit. Policymakers have become so concerned about this trend that nearly two dozen states have enacted laws prohibiting such policies and members of Congress have introduced legislation to address the problem. Allowing Part D plans to see which claims are 340B because of a requirement to use a 340B identifier on claims could inadvertently facilitate plan implementation of discriminatory rates and substantially harm covered entities and their patients.

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[4] Dobson DaVanzo, 340B DSH Hospitals Serve Higher Share of Patients with Low Incomes 12 (Sep. 26 2022), https://www.340bhealth.org/files/340B_and_Low_Income_Populations_Report_2022_FINAL.pdf.
[5] Dobson DaVanzo, 340B DSH Hospitals Increased Uncompensated Care in 2020 Despite Significant Financial Stress 4 (July 2020), https://www.340bhealth.org/files/Dobson_DaVanzo_Op_Margins_and_UC_FINAL.pdf.
[6] L&M Policy Research, Examination of Medicare Patient Demographic Characteristics for 340B and Non-340B Hospitals and Physician Offices 3-4 (July 28, 2022), https://www.340bhealth.org/files/LM-340B-Health-Demographic-Report-07-28-2022_FINAL.pdf.
[7] *Id.* at 4.
[8] The Cecil G. Sheps Center for Health Services Research, Rural Hospital Closures, https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.

III. 340B Identifiers on Claims Raise the Risk That 340B Drugs Might Not Be Excluded from Part D Inflation Rebate Requests

Requiring 340B identifiers on Part D claims might also be less effective in excluding 340B drugs from Part D inflation rebate requests than alternative methodologies, such as the one we propose below, because they necessitate Part D plans serving as intermediaries between pharmacies and CMS. By having 340B claim information go through multiple parties' systems, 340B identifiers may be dropped by the time they reach their final destination. We have been informed of situations where hospitals submitted claims with 340B modifiers to Medicaid managed care organizations, which submitted them to Medicaid without the modifier or otherwise identifying them as 340B. Hospitals have also raised concerns about CMS potentially not forwarding to state Medicaid programs 340B claim information provided by the hospitals using 340B identifiers on Medicare Part B claims for dual-eligibles. We are concerned that similar problems could arise with 340B identifiers on Part D claims.

IV. CMS Should Permit Covered Entities to Identify 340B Claims Retrospectively Using a Proven Methodology

For several years, Oregon Medicaid has used a proven model to identify 340B claims that relies upon covered entities or their contractors submitting at regular periods a file with 340B claim information directly to the state's Medicaid rebate vendor. [9] The Oregon model demonstrates that retrospective 340B claim identification is achievable without the use of 340B identifiers on claims. The rebate vendor matches the data in the file to other patient data to ensure the state excludes 340B claims from its Medicaid rebate requests to manufacturers. The Oregon model provides additional benefits by not giving Medicaid MCOs 340B claim information that could be used to implement discriminatory reimbursement rates for 340B drugs and decreasing the risk that the state does not get the 340B claim information it needs by removing MCOs from the process. We urge CMS to adopt a methodology based on the proven Oregon model to remove 340B claims from Medicare Part D inflation rebates.

If CMS were to decide to use a vendor to run the methodology as a federal contractor, it is important that the vendor be free of conflicts of interest. For example, the contractor should have no incentive to minimize covered entities' use of 340B drugs for Part D beneficiaries and should be prohibited from using 340B claim information for purposes other than ensuring that CMS does not request Part D inflation rebates for claims identified as 340B (e.g., selling the data to manufacturers or others).

[9] Retroactive 340B Claims File Instructions, https://www.oregon.gov/oha/HSD/OHP/Tools/340B%20Claims%20File%20Instructions%20and%20Design.pdf.

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Thank you for considering our comments. Please feel free to reach out to me if you have any questions or if we can provide any additional information.

Sincerely,

Maureen Testoni
President & CEO

cc: Carole Johnson, Administrator, Health Resources and Services Administration

Rear Admiral Krista Pedley, Director, Office of Special Health Initiatives, Health Resources and Services Administration

Dr. Emeka Egwim, Director, Office of Pharmacy Affairs, Health Resources and Services Administration

March 11, 2023

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Submitted via IRARebateandNegotation@cms.hhs.gov

RE: Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments; Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the Social Security Act, and Solicitation of Comments

Dear Deputy Administrator Seshamani,

The Association for Accessible Medicines (AAM) and its Biosimilars Council appreciates the opportunity to provide comments in response to the *Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments* and *Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the Social Security Act, and Solicitation of Comments*.

AAM is the nation's leading trade association for manufacturers of generic and biosimilar prescription medicines. AAM's core mission is to improve the lives of patients by advancing timely access to affordable, FDA-approved generic and biosimilar medicines. The Biosimilars Council works to increase patient access to lifesaving, high-value biosimilar medicines. Over the last ten years, generic and biosimilar medicines have provided more than $2.6 trillion in savings to U.S. patients and the healthcare system. In 2021 alone, these medicines provided more than $373 billion in savings, including more than $119 billion in savings for the Medicare program.[1] Because of their low cost and high value, generic and biosimilar medicines today account for more than 91% of all prescriptions dispensed in the US but only 18% of drug spending.

Our comments below fall in three main areas:

1. Appropriately identifying drugs subject to the rebate,
2. Providing time for manufacturers to review and respond to the rebate report and true up; and
3. Implementing the waiver or reduction in current or potential shortage situations to ensure stable supply consistent with Congressional' intent.

[1] AAM. (September 2022). "2022 Generic and Biosimilar Medicines Savings Report." Accessible at: https://accessiblemeds.org/resources/reports/2022-savings-report

1. We encourage CMS to take additional steps to appropriately identify drugs subject to the inflation penalty rebates

- **<u>Section 30. Identification of Part D Rebatable Drugs and Exclusions</u> – Recommendation: CMS should work directly with FDA to identify whether a drug approved under a 505(j) application meets the statutory criteria.**

The IRA narrows the scope of part D rebatable drugs to those approved under an ANDA when (1) the reference listed drug (RLD), including any authorized generics, is not being marketed; (2) there is no other drug approved and marketed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FFDCA) that is rated as therapeutically equivalent; (3) the drug product is not being marketed under the 180-day exclusivity period as a first applicant; and (4) the drug product is not being marketed by a "first approved applicant" for a competitive generic therapy. To evaluate if an approved drug meets these criteria, the memorandum notes that CMS intends to use the Drugs@FDA database, the FDA's Electronic "Orange Book", or other sources to obtain the necessary information.

However, these resources, while valuable, are not reliable, as they can be dated or can include inaccurate information due to delayed publication cycles or missing information. For example, the guidance requires CMS to determine eligible RLDs that are not actively marketed by identifying them using the FDA's National Drug Code Directory. This database may reflect that a manufacturer is currently marketing a drug product when, in fact, that is not the case. In that circumstance, the FDA's Orange Book would show an ANDA-approved drug product in the "Prescription Drug Product List" with a therapeutic equivalence code vis-à-vis the brand-name Reference Listed Drug (or other generic equivalents) instead of in the "Discontinued Drug Product List" where no therapeutic equivalence code is assigned. Certain marketing information is also provided directly by sponsors to their applications, in which case there may be delay in updating publicly available site. In addition, an ANDA-approved drug product may not be identified with the "PC" (Patent Certification) code for 180-day exclusivity. As a result of these types of issues, the Part D rebatable drug determination factors above could be in constant flux or inaccurate.

The only way a manufacturer can best predict how a rebatable drug might be identified they are dependent on when updated information is available through the FDA. The guidance does not indicate how CMS will determine the specific date on which agency will solicit data from the FDA. Also, because the generic drug market fluctuates regularly, eligible single source drugs in Part D could become a multiple source drug at the start of and/or during a calendar quarter.

To mitigate these concerns, we suggest that CMS work directly with the FDA Office of Generic Drugs to identify drugs that meet these conditions while also providing a tentative determination to manufacturers outlining which of their drugs are considered rebatable.

We also recommend CMS identify a specific date on which they will make their determinations while also using an approach that identifies a change in the status of a generic drug from single source to multi-source (or vice versa) and prorates the inflation penalty accordingly.

CMS should also provide manufacturers an opportunity to share confirmatory or contradictory details on the status and nature of their products.

- **<u>Section 30.2 Exclusion of Part D Rebatable Drugs Where Average Annual Total Cost of a Drug Under Part D Is Less than $100 Per Individual Using Such Drug per Year Adjusted by Changes in the CPI-U</u> – Recommendation: CMS should revise its methodology for "average annual total costs" to ensure that it only reflects costs determined by manufacturers.**

Section 1860D-14B(b)(1)(B)of the statute requires "With respect to an applicable period, not include a drug or biological if the average annual total cost under this part for such period per individual who uses such a drug or biological, as determined by the Secretary, is less than $100, as determined by the Secretary using the most recent data available or, if data is not available, as estimated by the Secretary." There are several different approaches that satisfy this exclusion. Under the draft guidance, CMS would calculate the average using total gross covered drug costs at the NDC-9 level and define gross covered prescription drug costs as the paid costs incurred including dispensing fees during the coverage year.[2]

Congress's intent was to hold drug manufacturers accountable for their pricing decisions. Calculating the average annual total costs based on gross spending is inconsistent with this objective. Using total gross covered drugs costs as reflected in the draft approach does not align with the actual behavior of manufacturers. Rather, the draft approach would show how much a pharmacy may have been *reimbursed* for a drug; it does not reflect the price for which a manufacturer *sold* the drug.

In fact, negotiated price (what a health plan agrees to pay a pharmacy) can vary significantly from a product's average manufacturer's price (AMP). According to a report released by the Brookings Institution "[h]ealth plans rely heavily on contracted pharmacy benefit managers (PBMs) to negotiate reimbursement terms on their behalf with retail pharmacies. However, PBMs also operate mail-order pharmacies, giving them knowledge of actual generic drug costs. To the extent that health plans pay similarly for retail and mail-order drugs, PBMs profit by keeping generic drug reimbursement generous. This disincentive to keep generic drug reimbursement low for their health plan clients poses an apparent conflict of interest for PBMs and increases health plan spending to the extent that a lack of information about actual generic drug costs leads to excessive reimbursement."[3]

Thus, we recommend CMS consider an alternative methodology that better aligns with the true cost of a unit. Since data regarding the AMP must already be available for the AnMP used to determine the total rebate amount and the number individual beneficiaries has an explicit definition, we suggest the following options:

- After CMS calculates gross covered drug costs, they could compare the average cost per script to the AMP for products close to the $100 threshold and exclude products within 10-15% of the threshold to ensure the inflated reimbursement which includes dispensing and administrative fees are not responsible for pushing a drug into the inflation rebate.
- Alternatively, CMS could calculate this as follows:
    - Average Annual Total Cost = [(AMP x total number of units)/number of individual beneficiaries]

[2] 42 CFR § 423.308

[3] Lieberman, S., Ginsburg, P (June 2017) Would Price Transparency For Generic Drugs Lower Costs For Payers And Patients?. The Brookings Institution. Accessible at: https://www.brookings.edu/wp-content/uploads/2017/06/es_20170613_genericdrugpricing.pdf

These approaches would better allow for the determination of which products are eligible for exclusion from the inflation rebates by aligning that determination directly with a manufacturer's pricing rather than dynamics driven by middlemen throughout the prescription drug supply chain.

- **<u>Section 40.2.7 Exclusion of 340B Acquired Units from Part D Rebatable Drug Requirements</u> – Recommendation: CMS should ensure that providers include a 340B indicator on the PDE.**

We commend CMS for their effort to ensure that manufacturers are not assessed rebates on products purchased by 340B entities. Avoiding this type of double-penalty is critical to program integrity. The proposed requirement that the pharmacy evaluate and identify all 340B-captured claims is a first step, but may not adequately accomplish its intended goal. We recommend CMS continue to evaluate options for manufacturers to exclude units acquired under the 340B program from the total number of rebatable units assessed, determine a process by which manufacturers have a basis to submit disputes to the agency, and to implement the process sooner than 2026.

2. We encourage CMS to provide flexible timelines for manufacturers to review and respond to reported information

- **<u>Section 50. Ensuring Integrity of Part D Drug Inflation Rebate Payments</u> – Recommendation: CMS should provide clarity for manufacturers on which products will be considered rebatable and the anticipated amount to allow for manufacturers to appropriately forecast their financial obligations.**

The memorandum discusses the transition period that allows CMS to delay sending invoices to manufacturers for the first two applicable periods (October 1, 2022, through September 30, 2023, and October 1, 2023, through September 30, 2024) until not later than December 31, 2025, however, it does indicate when CMS will provide such invoices. In order to accurately forecast and account for these potential payments, generic manufacturers will need to know in advance whether CMS has determined that a specific generic product will be subject to rebates and the amount of any potential rebate. We encourage CMS to provide notification to manufacturers in advance of any potential rebate obligations and to clarify when such notice will be provided, even if a formal invoice is not sent until closer to the 2025 statutory deadline.

- **<u>Section 50.1 Timing of Rebate Reports and Payment</u> – Recommendation: CMS should provide manufacturers with additional time to review and suggest calculation errors in the Preliminary Rebate Report**

Under the proposal, manufacturers would have only 10 days from the date of receipt of a Preliminary Rebate Report to review and suggest any calculation errors. Generic manufacturers have extensive portfolios with some managing between 500 and1000 SKUs. Because program participants will not be aware of which NDCs are considered rebatable until their initial Rebate Report is received, it would be challenging for a manufacturer to effectively assess the calculations within a 10-day timeframe. AAM recommends the manufacturer allowance to review potential errors and calculations be extended to at

least 30 days. This additional time is particularly important in the first invoice given the learning curve for manufacturers and CMS.

- **Section 50.2 Restatements of PDE Units Reported and True-Up Rebate Report – There are current best practices on when to submit information pursuant to a True-Up Rebate Report.**

In the Medicaid program, manufacturers must report their AMP monthly and quarterly, however, they have an obligation to correct AMPs for any error or change (other than lagged price concessions ratio) in the 3-year window. While it is feasible to submit true up data more than once in 3 years, after the 3-year threshold manufacturers are not permitted to modify previously reported AMPs absent exceptional circumstances and with CMS approval. With the proposed 1-year true up, changes submitted in year 2 or 3 would not be captured by CMS, or manufacturers would go through the true up process three times (once each year). To align with current best practices and to streamline the data submission requirement, we recommend CMS consider implementing a 3-year true up period.

3. We recommend CMS prioritize reduction of drug shortages or potential drug shortages in its implementation of the program

The Inflation Reduction Act grants the Secretary discretion to reduce or waive inflation penalty rebates when a drug is in shortage, has experienced a severe supply chain disruption, or is at risk of shortage. Congress intended to reduce the impact of drug shortages on patient care while still discouraging price increases exceeding inflation. We are concerned by portions of the memorandum that seem more concerned with avoiding "incentives for misuse" than with preventing shortages.

We commend CMS for noting some of the common causes of drug shortages, including delays in receiving raw materials and components from supplies, or discontinuations in product manufacturing. The FDA has conducted extensive work on the nature and causes of drug shortages as part of its efforts to reduce shortages. A consistent factor in drug shortages is inadequate reimbursement. Unpredictable, onerous penalties on low-margin medicines create significant risk for manufacturers to enter these markets and make it more challenging for manufacturers to continue to participate, which in turn harms patient access. Therefore, we encourage CMS implementation of this authority to prioritize reduction of factors that could extend a current drug shortage or lead to a new shortage.

- **Section 40.5 Reducing or Waiving the Rebate Amount for Part D Rebatable Drugs in Shortage and in Cases of Severe Supply Chain Disruptions – Recommendation: CMS should structure this policy in a manner that prioritizes the reduction of drug shortages**

Since the enactment of the Food and Drug Administration Safety and Innovation Act (FDASIA) in 2012, manufacturers have been required to notify FDA of changes in the production of certain finished drugs and biological products to assist the Agency in its efforts to prevent and mitigate shortages. Under section 506C of the FFDCA (as amended by FDASIA) and FDA's implementing regulations, manufacturers must notify FDA when the following occurs:

- Permanent discontinuance in the manufacture of such drug and biological products,
- Interruption in manufacturing that is likely to lead to a meaningful disruption in supply of the product in the United States

- A permanent discontinuance in the manufacturing of an active pharmaceutical ingredient (API) or
- An interruption in the manufacture of API for such drug and biological products that is likely to lead to a meaningful disruption in the supply of the API for those products

These notifications are required to include disclosure of reasons for the discontinuation or interruption and, where practical, must be submitted six months in advance.[4] The industry reports shortages, supply interruptions, recalls, and an increase in product demand through the Center for Drug Evaluation Research's Direct NextGen Portal and by submitting a copy of the 506E notification form. Upon receipt of these reports, FDA makes its own determination of whether to list a drug as being in shortage.

We appreciate CMS's intent to use those reports as a starting point for its waiver consideration. This builds on a well-understood set of reporting obligations and, in such, avoids new burdens on manufacturers and prevents misuse of the drug shortage reporting process.

However, we disagree with CMS's concern about misuse of these reporting processes. For a drug to appear on the FDA's drug shortage list, a manufacturer must engage in required correspondence with the FDA prior to the drug being added to the drug shortage list. The FDA also prospectively monitors the incidence of incoming drug shortage reports and can adjust policy if it believes a drug is no longer in shortage or if a manufacturer may be abusing this process. These are well-understood processes, and failure to report to FDA can expose a manufacturer to significant liability. Moreover, false statements designed to abuse these reporting processes would also be subject to enforcement action. Manufacturers have many commercial, operational, and compliance incentives to ensure their products do not end up in shortage. Fundamentally, the idea that a manufacturer might prefer to keep a drug in shortage simply for the purpose of avoiding an obligation to pay a rebate reflects a misunderstanding of the commercial incentives for that manufacturer to ensure an adequate supply of its product.

- **Section 40.5.1 Reducing or Waiving the Rebate Amount in the Case of a Part D Rebatable Drug Currently in Shortage on the FDA Shortage List – Recommendation: CMS should waive rebates for drugs in shortage unless unique extenuating circumstances apply.**

Section 40.5.1 solicits comments on the amount and duration of how a reduction should be applied and scenarios when a waiver may be considered. Specifically, CMS suggests a variable reduction in the rebate amount by length of time a drug is in shortage (decreasing the reduction over time) or a limited standard reduction with a reporting process whereby manufacturers may request a higher reduction or waiver. The memorandum goes on to request comment on the following:

1. How should CMS reduce or waive the rebate amount in the case of a Part D rebatable drug that is "current" on the shortage list?
2. How might CMS adjust the rebate amount in cases where not all of the NDC-11s for the Part D rebatable drug are "current" on the shortage list?
3. Are there specific types of Part D rebatable drugs where CMS might reduce or waive the rebate amount differently, and why would such an approach be necessary?

[4] US Food and Drug Administration. (December 2022) Drug Shortages. Accessible at: https://www.fda.gov/drugs/drug-shortages/frequently-asked-questions-about-drug-shortages

4. Are there specific causes for or types of a shortage where CMS might reduce or waive the rebate amount differently, such as drugs that treat certain conditions or address critical needs and how CMS would identify such drugs?
5. Are there certain scenarios where CMS should consider a greater or lesser reduction, or a waiver (e.g., due to the Part D rebatable drug's level of price increases over time, impact on manufacturer's solvency, or certain market factors)?
6. What safeguards would be necessary to ensure that a reduction or waiver of the rebate amount did not create incentives for a manufacturer to intentionally maintain a Part D rebatable drug on the shortage list so as to avoid a rebate obligation?

AAM strongly believes that the default approach for Part D rebatable drugs that are current on the FDA drug shortage list should be a full waiver of the inflation rebate. A waiver of the rebate obligation when any of these criteria are met best accomplishes the statutory intent to avoid or reduce drug shortages. Additional comments follow:

1. In cases where not all of the NDC-11s for the drug are "current" on the shortage list, CMS should limit the waiver to the portion of the rebate attributable to NDC-11s listed as "current".
2. As previously noted, there are a series of existing safeguards that already serve against potential incentives for a manufacturer to intentionally maintain a drug on the shortage list. These include:
    a. FDA/OIG scrutiny of false reporting and gamesmanship, including the ability to remove a drug from the shortage list.
    b. The waiver only applies to sales in Part D. Sales elsewhere (for example, in Medicaid) are still subject to inflation rebate penalties, regardless of whether the drug is in shortage or not.
    c. The nature of the generic market is such that a significant price increase often invites new competition that would (a) remove a drug from the rebate anyway as it would no longer be single source, (b) result in loss of market share for the first drug, and (c) result in a decline in prices, sometimes below where I the price initially started.
3. CMS should consider how to administer the rebate reduction and waiver program to take into account the repeating nature of drug shortages. For example, CMS should consider whether the drug has been in shortage multiple times during the relevant time period when considering a waiver or rebate reduction if the product is not currently on the drug shortage list.
4. That said, shortages are not solely limited to generic drugs. If CMS is concerned about abuse and instances where it should take a different approach, it may wish to consider how to tailor its approach to the unique differences between brand and generic/biosimilar market dynamics.

- **<u>Section 40.5.2 Reducing or Waiving the Rebate Amount for a Biosimilar or Generic Part D Rebatable Drug for When There Is a Severe Supply Chain Disruption</u> – Recommendation: CMS should lengthen the time period for a manufacturer to request a reduction or waiver in a severe supply chain disruption**

Under Section 40.5.2, CMS would reduce or waive the rebate amount in the case of a rebatable drug or biosimilar when CMS determines there is a severe supply chain disruption. There are additional

non-physical threats to consider, such as a cyberattack, that may impact one manufacturer or a smaller segment of the market and affect its ongoing ability to meet a demand. It would require a manufacturer to request a waiver or reduction within 60 days of the disruption but would require the disruption to last "at least 90 days". But a manufacturer might not know at 60 days whether the disruption will last "at least 90 days". We recommend CMS lengthen the time period for manufacturers to submit a request from 60 days to 90 or 120 days. That would provide manufacturers additional time in which to evaluate the situation and determine whether the "at least 90 days" threshold for the duration of the disruption would be met.

In addition, CMS should interpret this broadly. During the COVID-19 pandemic, generic manufacturers faced unprecedented increases in the cost of active ingredients and other supplies as well as shipping costs. CMS should implement this provision in such a way as to allow manufacturers to account for such cost increases as reflected in the waiver or reduction calculation.

Finally, CMS solicits comment on the amount and duration to reduce or waive the rebate amount in when there are supply chain disruptions. AAM encourages CMS to fully waive the rebate amount and to exercise flexibility in the duration to ensure that the severe supply chain disruption is fully resolved.

- **Section 40.5.3 - 40.5.3 Reducing or Waiving the Rebate Amount for a Generic Part D Rebatable Drug Where Without Such Reduction or Waiver, the Generic Part D Rebatable Drug is Likely to be Described as in Shortage on Such Shortage List During a Subsequent Applicable Period – Recommendation: CMS should update its guidance to conform with the statutory language applying the reduction or waiver where a generic is likely to be in shortage during a subsequent applicable period. CMS should also consider approaches to prevent shortage recurrence.**

Section 1860D-14B(b)(1)(C)(iii) states "the Secretary determines that without such reduction or waiver, the drug is likely to be described as in shortage on such shortage list *during a subsequent applicable period* (italics added)." However, the draft memorandum suggests that CMS would require that the drug is likely to be described as in shortage on the shortage list in *the next applicable period*. Not only is this contrary to the plain language of the statute, but it neglects the fluid and unpredictable nature of the generic drug market, in which a drug may be at risk of shortage in a subsequent, albeit not "next" period. For instance, a drug that experiences significant seasonal variation may be at risk of shortage due to challenges in acquiring API or other materials and ingredients. Although that shortage might not be a risk in the "next" applicable period, the manufacturer will nonetheless be racing to keep the drug out of shortage during its foreseen spike in demand. This scenario would clearly lend itself to a reduction or waiver. Accordingly, in alignment with the statutory language, we request that when a waiver or reduction is requested for a drug that is likely to be in shortage is approved, it applies to the "subsequent" applicable period.

In addition, the guidance document does not address CMS' approach to rebatable products that are coming out of shortage. There is a risk that a manufacturer has to take a price increase to help it recover from a drug shortage only to immediately incur a significant penalty the moment that FDA removes it from the drug shortage list. In fact, one of the predictors of a drug vulnerable to shortage is a previous shortage.

We recommend that CMS work with the FDA to further consider potential drug shortages. The FDA employs a Drug Shortage Staff (DSS) which resides in the CDER. It consists of a dedicated staff responsible for the coordination of all activities related to the prevention and mitigation of drug shortages. These individuals monitor reports of potential and actual drug shortages to prevent products from going into shortage.

To address the challenge of recurring drug shortages, we recommend CMS treat generic drugs exiting a shortage as being at risk of shortage and provide for a transitional period of a gradually declining rebate reduction. For instance, for a drug in shortage with a full rebate waiver, CMS could phase out the penalty through a 25% reduction for each quarter after the shortage ends (75% in the first quarter, 50% in the second quarter, etc.)

Overall, we appreciate CMS providing the industry guidance regarding the anticipated implementation of the inflation rebate program. As this is in response to recently passed legislation, we encourage continued flexibility and collaboration during the development and implementation of the program.

We look forward to continuing to engage with HHS and CMS on improving competition, care, and access for all Americans.

Sincerely,

Craig Burton

Craig Burton
Senior Vice President, Policy & Strategic Alliances
Executive Director, Biosimilars Council

March 10, 2023

The Honorable Meena Seshamani, MD, PhD
Director
Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 2020

Re: Medicare Prescription Drug Inflation Rebate Comments

Dear Dr. Seshamani:

AARP, on behalf of our nearly 38 million members and all older Americans nationwide, appreciates the opportunity to comment on initial guidance from the Centers for Medicare & Medicare Services (CMS) regarding implementation of the Medicare Prescription Drug Inflation Rebate Program. This important new program requires drug companies to pay a rebate if they increase the prices of certain drugs faster than the rate of inflation. The rebates are paid to Medicare and apply to drugs covered under Part B and Part D.

The Medicare Prescription Drug Inflation Rebate Program helps address brand name drug companies' long-standing practice of increasing their prices year after year—often at more than twice the rate of inflation. Drug price increases typically translate into higher out-of-pocket costs, especially for consumers who pay a percentage of drug costs (coinsurance) rather than a fixed dollar amount (copayment). Higher prices are also passed along to consumers in the form of higher deductibles and premiums.

While CMS does not plan to invoice drug companies for inflation-based rebates until 2025, the time periods for which drug companies will be required to pay rebates have already started and may already be having an impact on their pricing behavior. Further, under the initial guidance beginning April 1, 2023, Medicare Part B beneficiary coinsurance will be 20 percent of what the Medicare payment amount would have been if the price of the drug in question had not increased faster than inflation. AARP strongly supports the implementation of this change, which will effectively protect Medicare beneficiaries from the higher coinsurance that would normally result from drug price increases that exceed inflation.

AARP is also mindful that the Medicare Prescription Drug Inflation Rebate Program may already be providing benefits for people in Medicare Part D plans, as well. Medicare Part D enrollees are increasingly subject to deductibles and coinsurance that directly expose them to prescription drug price increases. For example, 70 percent of Part D enrollees in stand-alone plans (PDPs) were expected to be in a plan with the standard $505 deductible in 2023, and most

enrollees face coinsurance that can range from 15 to 50 percent. To the extent that the Medicare Prescription Drug Inflation Rebate Program is discouraging drug companies from making large price increases, Part D enrollees could see lower out-of-pocket costs than they would have experienced otherwise.

The Congressional Budget Office (CBO) estimates that the Medicare Prescription Drug Rebate Program will save billions of dollars. These savings are due to lower spending under Part D and Part B, as well as increased tax revenues due to spillover effects that will help suppress drug price and premium growth in the commercial market. CBO also expects that the lower drug prices that result from the inflation rebate provision means Medicare beneficiaries will be more likely to use prescription drugs and that will lead to declines in spending on other Medicare-covered services.

AARP would like to reiterate its strong support for the prescription drug provisions in the Inflation Reduction Act. The successful implementation of these improvements will lead to substantial savings for Medicare beneficiaries and the taxpayers who fund the Medicare program. More importantly, they will help ensure that Medicare beneficiaries can afford the prescription drugs they need.

Thank you for the opportunity to comment on the Medicare Prescription Drug Inflation Rebate Program. If you have any questions, please do not hesitate to contact me, or have your staff contact Glen Fewkes on our Government Affairs team at gfewkes@aarp.org.

Sincerely,

David Certner
Legislative Counsel & Legislative Policy Director
Government Affairs

abbvie

BY ELECTRONIC SUBMISSION
The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
IRARebateandNegotiation@cms.hhs.gov

March 10, 2023

RE: "Medicare Part D Inflation Rebate Guidance Comments"

Dear Administrator Brooks-LaSure:

AbbVie Inc. (AbbVie) appreciates the opportunity to provide feedback on the February 9, 2023, memorandum issued by the Centers for Medicare & Medicaid Services (CMS), entitled *Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of the Social Security Act, and Solicitation of Comments* (referred to below as the Part D Rebate Guidance).[1]

AbbVie is a biopharmaceutical company committed to discovering and delivering transformational medicines and products in key therapeutic areas, including immunology, oncology, neuroscience, eye care, virology, and women's health. AbbVie is also a leader in precision medicine, using genetic and molecular data, as well as companion diagnostic tests, to help target medicines to patients who are most likely to respond to and benefit from them. Through this patient-focused approach, AbbVie does more than just treat diseases—it aims to make a remarkable impact on people's lives.

AbbVie is concerned that the Inflation Reduction Act (IRA) does not provide sufficient time for the agency to implement the processes and procedures necessary to ensure compliance with constitutional requirements. AbbVie is also concerned that CMS is intending to employ guidance documents to impose substantive obligations and reorder rights that cannot be accomplished except through proper notice-and-comment rulemaking.[2] AbbVie therefore urges CMS to take the time that is required—and extend deadlines as appropriate—to ensure that the IRA is properly implemented consistent with basic administrative and constitutional law requirements. CMS must ensure that it complies with rulemaking procedures, allows for adequate public input, and responds meaningfully to comments and objections submitted by interested parties.

AbbVie appreciates this opportunity to provide feedback on portions of the Part D Rebate Guidance; however, we note that CMS has not requested public input on all portions of the guidance, jeopardizing a true, holistic process. Our requests, objections, and recommendations set forth below are intended to enhance the safeguards needed to achieve greater program integrity as

[1] Implementing section 1860D-14B of the Social Security Act (the SSA), as amended by section 11102(a) of the Inflation Reduction Act (codified at 42 U.S.C. § 1395w-114b).

[2] *See U.S. Steel Corp. v. EPA*, 595 F.2d 207, 213 (5th Cir. 1979) ("[T]he mere existence of deadlines for agency action, whether set by statute or court order, does not in itself constitute good cause for" an exception to the rulemaking requirements of 5 U.S.C. § 553.").

CMS works to implement a significant new federal program.

OVERVIEW AND SUMMARY

AbbVie's requests, objections, and recommendations are summarized below and set forth in more detail in the text that follows:

- **Benchmark Period Manufacturer Price, Where There Are No Sales in Benchmark Period (Section 40.1.2):**
    - CMS does not address how manufacturers would report reasonable assumption-based prices for use in determining the "benchmark period manufacturer price" for drugs that are approved or licensed on or before October 1, 2021, but where no sales data exist for the entire payment amount benchmark period.
    - One reasonable assumption in such a case would be to use the product's published wholesale acquisition cost (WAC) during the payment amount benchmark period, where available.

- **Removal of Excluded Units (Section 40.2.7):**
    - We support CMS's proposal to require an indicator on prescription drug event (PDE) records to identify 340B units. This important reform is necessary to comply with the statute and avoid abuse.
    - CMS should *also* require an indicator on PDE records to identify *non*-340B units, to determine statutorily excluded units more accurately.
    - CMS should ensure that Part D plans consistently and accurately reflect the 340B status of all utilization in PDE files.

- **Rebate Reports (Section 50):**
    - CMS should provide additional time for manufacturers to comment on such reports and should provide manufacturers a date certain in each rebate cycle when Rebate and True-Up Reports (preliminary and final) will be transmitted.
    - In addition, CMS should provide manufacturers with more detailed data in *all* Rebate and True-Up Reports (preliminary and final), to allow validation of calculations.
    - With respect to CMS's proposal to true up both underpayments and overpayments, we ask CMS to extend the time periods between the Preliminary Rebate Report and the Preliminary True-Up Rebate Report, and between the Rebate Report and the True-Up Rebate Report, to capture adjustments to and restatements of average manufacturer price (AMP) and other data more adequately.

abbvie

REQUESTS, OBJECTIONS, AND RECOMMENDATIONS

I. BENCHMARK PERIOD MANUFACTURER PRICE, WHERE THERE ARE NO SALES IN BENCHMARK PERIOD (SECTION 40.1.2)

A. CMS has not addressed how manufacturers would report reasonable assumption-based prices for use in determining the "benchmark period manufacturer price" for drugs approved or licensed on or before October 1, 2021, but where no sales data exist for the entire payment amount benchmark period. One reasonable assumption in such a case would be to use the product's published WAC during the payment amount benchmark period, where available.

The "benchmark period manufacturer price" is a critical component of the Part D inflation rebate calculation, because it is the dollar amount that will be inflation-adjusted and against which subsequent annual average manufacturer prices (AnMPs) will be compared to determine the amount of any Part D inflation rebate owed.[3] The "benchmark period manufacturer price" is based on the AMPs for the drug "and the *units sold* of the drug" reported by the manufacturer under the Medicaid Drug Rebate Program (MDRP) for each of the relevant calendar quarters in the "payment amount benchmark period."[4]

The Part D Rebate Guidance closely tracks the statute in providing for different "payment amount benchmark periods" based on when a product is approved or licensed:

- For a drug approved or licensed on or before October 1, 2021, the payment amount benchmark period is January 2021 through September 2021 (Q1 2021 through Q3 2021).

- For a drug approved or licensed after October 1, 2021 (a "subsequently approved drug"), the payment amount benchmark period is the first calendar year beginning after the day the drug is first marketed.[5]

However, the Part D Rebate Guidance does not address what amount, if any, will be used to determine the "benchmark period manufacturer price" for drugs that are approved or licensed by the Food and Drug Administration (FDA) on or before October 1, 2021, but with respect to which there were no AMP-eligible sales in Q1 2021 through Q3 2021 (the statutorily mandated "benchmark period"). CMS is silent on how manufacturers of such products would calculate and report AMPs and AMP units during a benchmark period that falls before the drug's market date. However, CMS must act consistently with the statute, which references a drug's FDA approval/licensure date as the date to which the benchmark period is linked.

With respect to subsequently approved drugs, CMS acknowledges that "reasonable

[3] Part D Rebate Guidance § 40; SSA § 1860D-14B(b). The benchmark period resets only where a drug ceases to be subject to a maximum fair price under the Drug Price Negotiation Program. SSA § 1847A(i)(4)(C).
[4] *See* Part D Rebate Guidance § 40 (emphasis added). CMS generally refers to this period as the "payment amount benchmark period" but the statute uses the term "benchmark period," and CMS in some places uses those terms interchangeably.
[5] *Id.*

assumptions" may be needed when there are no sales for one or more quarters in the benchmark period.[6] CMS indicates that, where "there are no sales of the drug for the entire payment amount benchmark period," the agency will average "the manufacturer's *reported price using reasonable assumptions*" over "the calendar quarters of the payment amount benchmark period in order to determine the benchmark period manufacturer price."[7]

We agree with CMS that calculations based on manufacturers' reasonable assumptions are needed for scenarios such as those described in Section 40.1.2 of the Part D Rebate Guidance, but *we urge CMS <u>also</u> to confirm the following*:

(1) This reasonable assumption policy applies to *both* subsequently approved drugs *and* drugs approved or licensed on or before October 1, 2021; where no AMP-eligible units are reported for the entirety of the benchmark period, no weighted averaging is needed;[8] and

(2) CMS will create a mechanism for a manufacturer to report a reasonable assumption-based AMP to the agency, given that MDRP pricing data cannot be submitted to CMS prior to the product's "market date," and thus such a price could not otherwise be reported. One reasonable assumption in such a case would be to use the product's published WAC during the payment amount benchmark period, where available.

II. REMOVAL OF EXCLUDED UNITS (SECTION 40.2.7)

A. We support CMS's proposal to require an indicator on PDE records to identify 340B units, but CMS should <u>also</u> require an indicator on PDE records to identify <u>non</u>-340B units to identify statutorily excluded units more accurately.

Units for which a manufacturer provides a 340B discount or rebate (referred to below as 340B units) are statutorily excluded from the Part D inflation rebate calculation beginning with Part D plan year 2026.[9] In the Part D Rebate Guidance, CMS acknowledges that (1) pharmacies dispensing 340B discounted drugs are not universally required to use the National Council for Prescription Drug Programs (NCPDP) 340B indicator to identify 340B units; and (2) 340B units are therefore not consistently identified on the PDE records submitted by Part D plans. CMS proposes to require use of a 340B indicator on PDE records prospectively and solicits feedback on how best to identify pharmacy claims for 340B units for purposes of excluding those units from Part D inflation rebate utilization.[10]

CMS indicates that requiring the use of a 340B indicator on PDE records is the most

[6] Part D Rebate Guidance § 40.1.2.
[7] *Id.* (emphasis added).
[8] Indeed, weighted averaging would be an impossibility, as a reasonable assumption-based price is needed solely in the absence of any reported sales units, such that there is no basis on which to calculate a weighted average.
[9] SSA § 1860D-14B(b)(1)(B). We note that our references to a Part D plan are as that term is used in the Part D regulations, including prescription drug plans and Medicare Advantage prescription drug plans. 42 C.F.R. § 423.4.
[10] Part D Rebate Guidance § 40.2.7.

reliable way to identify 340B units.[11] *AbbVie agrees and supports a requirement that a 340B identifier be included on each pharmacy claim under Part D such that PDE records identify such utilization for exclusion from Part D inflation rebates.* The PDE records submitted by Part D plans to CMS necessarily draw from the claims data submitted by pharmacies. As a result, the most accurate way for a Part D plan to identify 340B utilization in its PDE records is to require the pharmacies to do so with a 340B identifier.

AbbVie urges CMS to mandate the use of a 340B indicator in pharmacy claims data submitted to Part D plans, to better ensure the integrity of the PDE data used for administering the Part D inflation rebates. *CMS should require that a Part D plan PDE record will not be considered complete unless it indicates whether a claim was or was not dispensed with a 340B unit.* It may be helpful in this regard for CMS to work with NCPDP to ensure that available indicators are sufficient for this purpose (e.g., the indicator offers the choice of "Y" *or* "N" to indicate 340B or non-340B, but does not allow the field to be left blank) with respect to pharmacy claims dispensed to Part D beneficiaries. When necessary, it should develop more suitable indicators.

CMS should also engage in plan and pharmacy outreach to educate those entities on the use of appropriate indicators, as CMS has done when adding other PDE fields, given that 340B and non-340B indicators in the pharmacy billing and plan PDE processes will be new.

B. CMS should ensure that Part D plans consistently and accurately reflect the 340B status of all utilization in PDE files.

AbbVie urges CMS to take steps to ensure compliance with the claims modifier requirements discussed above. Compliance can be incentivized by CMS making clear that PDE records are not adequate if they do not indicate whether a claim is a 340B or a non-340B unit, and/or instructing Part D plans to reject claims if the applicable pharmacy claims modifier is not utilized. CMS can readily employ for this purpose its existing process that requires Part D sponsors to resolve errors—including incomplete submissions—via its PDE error reporting.[12] CMS should not accept PDE records that do not contain the 340B indicator (one way or the other). Sponsors should be permitted to take corrective action within the 90 days CMS allows for PDE record adjustments; absent correction, the utilization should be deemed ineligible for Part D inflation rebates.

Enforcing the use of 340B PDE identifiers and pharmacy claims modifiers is critical to ensuring payment accuracy and program integrity with respect to the Part D inflation rebating process. Studies have shown that 340B covered entities are unlikely to use such modifiers accurately and consistently in the absence of enforcement.[13] A recently published study by health information technology firm IQVIA found that 340B "modifier usage reached 90% in some segments when reporting was mandatory, fell below 20% when it was optional, and dropped below

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[11] *Id.*

[12] *See, e.g.*, Continuation of the Prescription Drug Event (PDE) Reports and PDE Analysis Reporting Initiatives for the 2022 Benefit Year, https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/Continuation_PDE_Reports_and_Analysis_Reporting_Initiatives_2022_508_0.pdf.

[13] *See* IQVIA, White Paper: Can 340B Modifiers Avoid Duplicate Discounts in the IRA? (2023), *available at* https://www.iqvia.com/locations/united-states/library/white-papers/can-340b-modifiers-avoid-duplicate-discounts-in-the-ira.

1% when it was impractical." Two factors were associated with the appropriate use of modifiers: (1) mandating modifier reporting, and (2) identifying the 340B status of the claim before or at the point of sale."[14] The same study found that use of 340B claims modifiers by commercial contract pharmacies is particularly low, but pharmacies are nevertheless able to identify 340B eligible patients at the point of sale, stating:

> In the current study, less than 1% of claims at contract pharmacies used a 340B modifier, which we think is because the 340B status of a claim was unknown to the pharmacy at the point of sale to the patient. However, it is possible to determine the 340B-eligibility of drugs at the point of sale at contract or entity-owned pharmacies, as demonstrated by the dozen or so vendors that offer 340B prescription discount cards. Previous studies by our group have shown 340B cards were able to reduce patient out-of-pocket costs by 92.9%. These 340B cards perform real-time checking such as confirming the presenter of the card is a patient of the covered entity, the prescribing provider is on an active list for the entity, and the drug written on the prescription is on the formulary of the covered entity. But this requires specialized systems and the sharing of patient and provider lists, neither of which is widespread yet in the 340B program.[15]

In addition, some states have contravening laws prohibiting certain entities from using 340B claims modifiers. We urge CMS to make clear that Part D billing requirements preempt any such state laws when pharmacies are billing Medicare (whether primary or secondary).[16]

III. REBATE REPORTS (SECTION 50)

A. CMS has proposed providing an impractical timeframe for manufacturers to comment on the Preliminary Rebate Reports and Preliminary True-Up Rebate Reports.

The IRA requires manufacturers to pay Part D inflation rebates within 30 days after receiving an invoice from the Secretary.[17] The Part D Rebate Guidance implements this requirement by creating a "Rebate Report" process, under which a series of preliminary, final, and true-up Rebate Reports are issued by CMS to manufacturers.[18] The Part D Rebate Guidance proposes that manufacturers will have only 10 calendar days to review preliminary Rebate Reports, and, if errors are identified, raise those concerns to CMS for its discretionary review.

CMS's proposed "Rebate Report" process does not allow for meaningful review, despite CMS's recognition that manufacturers need to review the underlying data and proposed rebate liability in advance of the issuance of an invoice. As proposed, CMS would be applying an

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[14] *Id.*at 10.
[15] *Id.*(footnote omitted).
[16] *See, e.g.*, *United States v. Idaho*, No. 1:22-CV-00329-BLW, 2022 WL 3692618, at *8–*10 (D. Idaho Aug. 24, 2022) (preempting state requirements where, among other things, it was "impossible" to comply with "obligations under EMTALA and Idaho statutory law"); *Krause v. Kimberly-Clark Corp.*, 749 F. Supp. 164, 168 (W.D. Mich. 1990) (state law claims regarding tampon packaging preempted to the extent they challenged the adequacy of warnings and labeling approved by FDA); *see also Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985) ("State laws can be pre-empted by federal regulations as well as by federal statutes.").
[17] SSA § 1860D-14B(a)(2).
[18] Part D Rebate Guidance § 50.

inadequate process for this critical obligation that is imposed upon manufacturers, given the significant dollar amounts anticipated to be paid in Part D inflation rebates, the civil monetary penalties associated with failure to timely pay such rebates, and the potential for error in light of the complexities under the rebate scheme. Proposing a mere 10 calendar days for manufacturers to review and respond to the Preliminary Rebate Reports and Preliminary True-Up Rebate Reports is patently deficient.

Fundamentally both CMS and manufacturers share a crucial interest to ensure that the underlying data and, ultimately, the invoiced rebate liability, are accurate, as later-identified inaccuracies may engender additional costs to true up. Especially in light of the severe penalties that CMS could impose upon manufacturers, CMS must provide sufficient time for review by the manufacturer of the preliminary reports. Ten days is grossly inadequate, especially when erroneous rebate requests can be reasonably foreseen, due, among other things, to inaccurate underlying data for this new IRA rebate program that CMS will be imposing on manufacturers. When a manufacturer identifies concerns or discrepancies, it will need to prepare a response to CMS, which will necessarily require appropriate development and internal review. There are helpful analogies to be found in similar programs administered by CMS, such as the MDRP and the Medicare Part D Coverage Gap Discount Program (CGDP). Each of these programs permits 37 days after receipt of an invoice to pay rebates prior to interest accruing, and each program also permits manufacturers to initiate a good faith unit dispute during—and in some cases after—that timeframe.

B. CMS should provide manufacturers a date certain in each rebate cycle when Rebate and True-Up Reports (preliminary and final) will be transmitted.

CMS should specify, with significant advance notice, a predictable date certain in each rebate cycle on which the Preliminary Rebate Reports for such cycle will be transmitted to manufacturers. Given the importance of the review process and the limited time available for review, manufacturers will need to plan and prepare for the review of a Preliminary Rebate Report, as well as any response thereto. Knowing such a date will help to ensure that a manufacturer can arrange for appropriate personnel and resources to be available to perform the necessary review and prepare an appropriate and timely response. We ask that CMS incorporate this same recommendation into the process for manufacturer review of the Preliminary True-Up Rebate Report, given that the reasoning discussed above is equally applicable to such Report.

C. CMS should provide manufacturers with more detailed data in Rebate and True-Up Reports (preliminary and final).

CMS has proposed that the Preliminary Rebate Report and the Rebate Report include: "(1) the total number of units for each dosage form and strength for the Part D rebatable drug for the applicable period; (2) the amount, if any, of the excess of the AnMP for each dosage form and strength of the Part D rebatable drug for the applicable period (the amount calculated per section 40.2); and (3) the rebate amount for each dosage form and strength of such Part D rebatable drug for the applicable period."[19] The Part D Rebate Guidance does not specify what information will

[19] *Id.*

be included in the Preliminary True-Up Rebate Report and the True-Up Rebate Report.

While the above-specified data are important, they are not sufficiently specific. In other CMS-administered programs, such as the MDRP and the CGDP, various claims-level data are available to assist manufacturers in identifying errors. Such data have long been properly used by manufacturers to analyze and identify unit discrepancies. Such data are equally critical to provide in connection with the Part D inflation rebate process.

Accordingly, CMS should provide additional detail as part of the Preliminary Rebate Reports and the Rebate Reports (initial as well as true-up). This data will help ensure that manufacturers can conduct their analyses in a fully informed manner, in service of the accuracy and integrity of rebate liability. CMS should also compile and publish for public comment a detailed description of the types of additional data that it intends to make available in connection with the Reports. That will help ensure that manufacturers understand the nature of the data that the agency intends to share, so that they can provide feedback accordingly, which, ultimately, will help ensure that CMS invoices rebates accurately.

D. We appreciate CMS's proposal to true up both underpayments and overpayments, but CMS should extend the time periods between the Preliminary Rebate Report and the Preliminary True-Up Rebate Report, and between the Rebate Report and the True-Up Rebate Report.

We appreciate that CMS has proposed adjustment and reconciliation methods for both underpayments and overpayments through the True-Up Rebate Report process. CMS proposes that the Preliminary True-Up Rebate Report will be sent "approximately 1 year" after the Preliminary Rebate Report is sent.[20]

CMS requires that drug manufacturers participating in the MDRP report any changes in AMP, which is the basis of the Part D inflation rebate calculation, within 12 quarters (three years) of when such data was originally due.[21] As a result, AMP may be restated beyond a one-year time horizon. AMPs are not restated solely based on lagged sales and price concession information (which are incorporated via smoothing), but they may be restated in connection with the identification of errors. In order to better align with the analogous restatement time frame under the MDRP, CMS should issue the True-Up Rebate Reports (preliminary and final) three years after the initial Rebate Reports (preliminary and final, respectively). Taking this approach would better ensure that restatements of AMP data (as well as other data) are accounted for, and thereby enhance the accuracy of any true-ups.

* * * * *

AbbVie appreciates this opportunity to provide input on the Part D Rebate Guidance. We understand that CMS has been tasked with implementing a major IRA-imposed undertaking in a short timeframe, but that does not mean that CMS may avoid notice-and-comment rulemaking or fail to respond to feedback by interested parties. As the above examples suggest, CMS's proposed guidance is incomplete and does not take into account all of the steps that will be necessary to

[20] *Id.* § 50.2.
[21] 42 CFR § 447.510(b)(1).

implement the statutory requirements faithfully and consistent with administrative and constitutional law requirements. If you have any questions, please feel free to contact Ashley Flint, Director, U.S. Policy & Analytics, at ashley.flint@abbvie.com.

Sincerely,

Hayden Kennedy

Hayden Kennedy
Vice President, Global Policy & U.S. Access Strategies
On behalf of AbbVie Inc.

Alkermes

BY ELECTRONIC DELIVERY

Meena Seshamani, M.D. Ph.D.
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
U.S. Department of Health & Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

March 9, 2023

Re: Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments

Dear Dr. Seshamani,

Thank you for this opportunity to comment on "Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments"[1] ("Initial Memorandum").

Alkermes, Inc. ("Alkermes" or "Company") is a biopharmaceutical company that applies its scientific expertise and proprietary technologies to research, develop, and commercialize pharmaceutical drugs that are designed to help address unmet medical needs of people living with addiction, serious mental illness, and cancer.

Alkermes has focused its comments on two issues in the Initial Memorandum of particular importance for the Company:

1. **The use of the terms "Approved" Versus "Marketed" in the Calculation of Part D Drug Inflation Rebate Amount**

Issue: Throughout certain sections of the Initial Memorandum, the terms "marketed" and "approved or licensed by the FDA" are used interchangeably and differently than how those terms are used in Section 1860D-14B of Social Security Act (the "Inflation Reduction Act"). For example, Section 40. *Calculation of the Part D Drug Inflation Rebate Amount* ("Section 40"), page 11, 3rd paragraph of the Initial Memorandum states:

> The inflation-adjusted payment amount for a dosage form and strength of a Part D rebatable drug for an applicable period would be determined by increasing the benchmark period manufacturer price by the percentage by which the applicable period CPI-U, which is the CPI-U for the October month of the applicable period, exceeds the benchmark

[1]Centers for Medicare and Medicaid Services (CMS). Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments. February 9, 2023.

> period CPI-U, ***which for drugs marketed on or before October 1, 2021***, is the CPI-U for January 2021, and ***for drugs first approved or licensed after October 1, 2021***, is the January CPI-U of the first calendar year beginning after the drug is first marketed. The statute defines the applicable period CPI-U at section 1860D-14B(g)(5) to mean, with respect to an applicable period, the consumer price index for all urban consumers for the first month of such applicable period. (Emphasis added).

This section uses the two different terms "marketed" and "approved" to identify the applicable period CPI-U, depending on whether the drug is "**marketed** on or **before** October 1, 2021" or "first **approved or licensed after** October 1, 2021". Similarly, Figure 1 in Section 40.3 *Treatment of Subsequently Approved Drugs for Part D Drug Inflation Purposes* ("Figure 1") of the Initial Memorandum refers to "Drugs **Marketed** on or **Before** 10/1/2021" and "New Drug **Marketed** 12/1/2021" in providing guidance on benchmark and applicable periods. As explained in more detail below, the use of the term "marketed" in Section 40 and in Figure 1 is inconsistent with the language of the Inflation Reduction Act.

In defining how rebates will be calculated, the Inflation Reduction Act draws a clear distinction between drugs "first ***approved or licensed*** by the Food and Drug Administration after October 1, 2021" (a "subsequently approved drug") and those drugs first approved or licensed on or before October 1, 2021. The Inflation Reduction Act specifically uses the terms "approved or licensed" in defining a subsequently approved drug. Because a drug may not be marketed immediately after approval, the date a drug is first approved or licensed may vary from the date a drug is first marketed by days, weeks, or months. Under the plain language of the Inflation Reduction Act, the date that a drug is first marketed is not relevant to determining whether the drug is a subsequently approved drug. Therefore, the references to "drugs marketed on or before October 1, 2021" in Section 40 and Figure 1 are inconsistent with the statutory text and should be revised to "drugs approved or licensed on or before October 1, 2021."

Suggestion: In accordance with the text of the Inflation Reduction Act, we ask CMS to utilize the term "approved or licensed" instead of "marketed" when referring to drugs first approved or licensed on or before October 1, 2021, throughout the agency's guidance on the calculation of Part D inflation rebates.

2. Calculation of the Part D Drug Inflation Rebate Amount for Drugs Approved on or before October 1, 2021, when there Are No Units Sold during the Benchmark Period

Issue: The Inflation Reduction Act provides that the benchmark period for Part D rebatable drugs approved or licensed by the Food and Drug Administration ("FDA") on or before October 1, 2021, is the first three quarters of 2021 (January 1 – September 30, 2021). The Initial Memorandum does not clarify how to determine a benchmark period price for a Part D rebatable drug approved on or before October 1, 2021, with no sales during the established benchmark period.

As stated above, drugs may not be marketed immediately following FDA approval. Alkermes is the manufacturer of LYBALVI® (olanzapine and samidorphan), a Part D rebatable drug that was first approved by the FDA on May 28, 2021. LYBALVI's first sale occurred on October 14, 2021, and therefore there were no reportable sales during the benchmark period (January 1, 2021 - September 30, 2021). The Inflation Reduction Act is clear that the benchmark CPI-U for LYBALVI is January 1, 2021. However, neither the statute nor the Initial Memorandum addresses how to establish a benchmark period price for products like LYBALVI.

The Initial Memorandum provides clarity in Section 40.1.2 *Situations in Which Manufacturers Do Not Report Units* on several scenarios in which manufacturers have no reportable units for a calendar quarter, however it does not address the specific scenario of a drug approved on or before October 1, 2021, with no sales during the benchmark period. We note that the second paragraph addresses the situation in which "a subsequently approved drug," does not yet have sales for a quarter and allows for the manufacturer to make reasonable assumptions. That paragraph does not speak to drugs first approved or licensed on or before October 1, 2021.

Further, in Section 40.2.2, *Calculation of Benchmark Period Manufacturer Price*, the Initial Memorandum clearly lays out how manufacturers are to calculate a benchmark period price for drugs first approved or licensed on or before October 1, 2021, but does not address how a manufacturer should calculate a benchmark period price if there are no sales during the benchmark period.

Suggestion: We ask that CMS extend the guidance in Section 40.2.2 to address how to determine the benchmark period price for those Part D rebatable drugs approved before October 1, 2021, with no sales in the benchmark period. CMS could utilize the AMP reported for the first three or four quarters of sales beginning with the quarter of the first sale date. For drugs such as LYBALVI, which had its first sale on October 14, 2021, this approach would mean that the benchmark period price would be calculated based on the weighted AMP of the three quarters of October 2021 through June 2022 or of the four quarters of October 2021 through September 2022. Following this approach, CMS could add a sentence to the end of Section 40.2.2. as follows (see bolded, italicized text):

> Benchmark Period Manufacturer Price for Part D Rebatable Drugs First Approved or Licensed On or Before October 1, 2021: As described above, the benchmark period manufacturer price would be calculated as the sum of the products of: (1) the AMP for the dosage form and strength of the drug for each of the three quarters (January through September 2021) reported by the manufacturer; and, (2) the total AMP units reported under section 1927(b)(3)(A)(iv) for each of the quarters divided by the total units reported for the three quarters. ***For products with no units reported for any of these three quarters, the benchmark period manufacturer price would be calculated as the sum of the products of: (1) the AMP for the dosage form and strength of the drug for each of the [three or four] quarters beginning with the quarter of the first sale date reported by the manufacturer; and, (2) the total AMP units reported under section 1927(b)(3)(A)(iv) for each of the quarters divided by the total units reported for the [three or four quarters]***.

Alternatively, CMS could address this scenario in Section 40.1.2, *Situations in Which Manufacturers Do Not Report Units* by adding the following language:

> ***For products approved prior to October 1, 2021, but with no units reported during the initial benchmark period of January 1 through October 1, 2021, the benchmark period manufacturer price would be calculated as the sum of the products of: (1) the AMP for the dosage form and strength of the drug for each of the [three or four] quarters beginning with the quarter of the first sale date reported by the***

manufacturer; and, (2) the total AMP units reported under section 1927(b)(3)(A)(iv) for each of the quarters divided by the total units reported for the [three or four quarters].

We thank the Administration for the opportunity to offer this comment and welcome any questions that you might have about it.

Sincerely,

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March 10, 2023

VIA ELECTRONIC DELIVERY
IRARebateandNegotiation@cms.hhs.gov

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue SW
Washington D.C. 20201

Re: Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act (SSA), and Solicitation of Comments

Dear Administrator Brooks-LaSure:

Amgen Inc. (Amgen) appreciates the opportunity to submit comments on the Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of SSA, and Solicitation of Comments posted on the Centers for Medicare & Medicaid Services (CMS) website on February 9, 2023.

Amgen is committed to using science and innovation to dramatically improve people's lives; improving access to innovative drugs and biologicals (collectively, "drugs," consistent with CMS's convention); and promoting high-quality care for patients.

Our comments on the Initial Memorandum are summarized as follows:

I. RECOMMENDATIONS REGARDING UNITS SUBJECT TO THE REBATE CALCULATION

A. We support the requirement to use a 340B indicator on the prescription drug event (PDE) record, but CMS should also implement this by requiring Part D plan

sponsors to use either a 340B or a non-340B indicator, as applicable, to identify units to be excluded from Part D inflation rebates.

II. RECOMMENDATIONS REGARDING SUBSEQUENTLY APPROVED DRUGS

A. We ask CMS to define the applicable period for subsequently approved drugs as the first year beginning October 1 after the payment amount benchmark period.

III. RECOMMENDATIONS REGARDING TIMELINES FOR REVIEWING AND COMMENTING ON PRELIMINARY REBATE AND TRUE-UP REPORTS AND THE TRUE-UP PROCESS

A. We applaud CMS for offering manufacturers an opportunity to comment on CMS's calculation of the rebates that it intends to invoice via the Preliminary Rebate Report but ask CMS to provide manufacturers with additional time for comment, a date certain in each rebate cycle for receipt of the report, and more detailed data in the report.
B. We applaud CMS for establishing a process for truing up both underpayments and overpayments but ask CMS to extend the time period between the Rebate Report and the True-up Rebate Report to three years to more fully capture adjustments to and restatements of average manufacturer price (AMP) and other data.

We discuss these comments below.

I. RECOMMENDATIONS REGARDING UNITS SUBJECT TO THE REBATE CALCULATION

A. We Support the Requirement to Use a 340B Indicator on the PDE Record, but CMS Should Also Implement This by Requiring Part D Plan sponsors to Use Either a 340B or a Non-340B Indicator, as Applicable, to Identify Units to Be Excluded from Part D Inflation Rebates

Effective Part D plan year 2026, the Part D inflation rebate statute carves out 340B units from the total units of Part D rebatable drug used to calculate the inflation rebate.[1] CMS indicates that it will require Part D plan sponsors to use an indicator on the PDE record to identify units of drugs or biologics acquired under the 340B program and dispensed to a Part D beneficiary for purposes of excluding those units from the Part D inflation rebate calculation.[2] Amgen supports CMS's required use of an indicator on the PDE record to help ensure that 340B units are excluded when calculating the inflation rebate, in accordance with the statute.

However, Amgen urges CMS to take additional steps to ensure that 340B units are appropriately identified and properly excluded from the Part D inflation rebate calculation. Specifically, CMS should:

- Require Part D plan sponsors to expressly identify units as *either* 340B units *or* non-340B units, as applicable, so that each unit is affirmatively identified as eligible to be included or excluded from the Part D inflation rebate calculation; and
- Specify that the use of a 340B or non-340B indicator, as applicable, is not only required but indeed necessary for a PDE record to be considered complete.

Requiring Part D plan sponsors to use either a 340B or non-340B indicator, as applicable, for every unit reimbursed will better ensure that each 340B unit is identified and reduce the risk that a unit is erroneously included in the Part D inflation rebate calculation. CMS should ensure Part D plan sponsors are complying with this requirement by rejecting PDE records as incomplete where they do not include a 340B or non-340B indicator.

To support the above requirements with respect to the PDE record, ***CMS should require Part D plan sponsors to require pharmacies to identify a given unit as either 340B or non-340B, as applicable, using National Council for Prescription Drug Programs (NCPDP) or other standards***. As noted by CMS, pharmacies dispensing 340B discounted drugs may not currently be required to use the available NCPDP 340B indicators to identify a 340B unit.[3] This requirement can be implemented by including 340B indicators on the PDE, as described above.

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[1] SSA § 1860D-14B(b)(1)(B).

[2] CMS, Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of SSA, and Solicitation of Comments, § 40.2.7 (Feb. 9, 2023) (hereinafter Part D Inflation Rebate Guidance).

[3] *Id*.

A recent IQVIA report found that "[t]wo factors appear to be associated with the increased usage of modifiers: mandating modifier reporting, and identifying the 340B status of the claim prior to or at the point of sale," with modifier usage reaching 90 percent in some cases where reporting of these modifiers was mandatory.[4] Thus, it is essential that CMS require Part D plan sponsors to use these indicators at the pharmacy level to support the ability of sponsors to appropriately identify 340B units. CMS could work with NCPDP or could otherwise seek to develop these standards to ensure that indicators are available at the pharmacy level to identify units as non-340B so that each unit can be affirmatively identified as either included or excluded in the Part D inflation rebate calculation. CMS should require the use of 340B or non-340B indicators on the PDE record and require Part D plan sponsors to require the same of pharmacies, regardless of whether NDPCP develops additional standards. Additionally, CMS should reject claims as incomplete where they do not include a 340B or non-340B modifier, as appropriate.

This approach is reasonable as pharmacies generally can know at the time a claim is billed whether a unit qualifies as a 340B unit. The parent covered entity retains responsibility for overall 340B program compliance under a contract pharmacy arrangement, and eligibility to be dispensed as a 340B unit at the pharmacy is tied to the same requirements incumbent on the parent covered entity.[5] Covered entities thus must ensure that the pharmacy can identify 340B-eligible patients before they are dispensed 340B units at the pharmacy. The IQVIA study reinforces the feasibility of this approach, finding that "it is possible to determine the 340B-eligibility of drugs at the point of sale at contract or entity-owned pharmacies."[6] Any unit identified as 340B or non-340B at point of sale necessarily can be so identified at the time the claim is billed to the Part D plan.

Thus, the above approach provides a means for CMS to accurately and reliably identify and exclude 340B units when calculating the inflation rebate. Amgen thus urges CMS to require Part D plan sponsors to use both 340B and non-340B indicators, as applicable, to identify drugs on PDE records and encourage plans to require pharmacies to do the same, working with NCPDP as appropriate.

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[4] *See* IQVIA, Can 340B Modifiers Avoid Duplicate Discounts in the IRA? At 10 (Feb. 21, 2023), *available at* https://www.iqvia.com/locations/united-states/library/white-papers/can-340b-modifiers-avoid-duplicate-discounts-in-the-ira (hereinafter IQVIA Report).

[5] Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010) (discussing the responsibilities of the parent covered entity as to oversight of contract pharmacy arrangements and noting that "[t]he covered entity has, and continues to bear, full responsibility and accountability for compliance with all requirements to prevent diversion of covered drugs to individuals other than patients of the covered entity, and to prevent situations in which a drug is subject to both the 340B discount and a Medicaid Rebate claim").

[6] *See* IQVIA Report at 10.

II. RECOMMENDATIONS REGARDING SUBSEQUENTLY APPROVED DRUGS

A. We Ask CMS to Define the Applicable Period for Subsequently Approved Drugs as the First Year Beginning October 1 After the Payment Amount Benchmark Period

Under the Part D inflation rebate statute, drugs that are first approved or licensed by the Food and Drug Administration after October 1, 2021, are subject to:

- A payment amount benchmark period defined as the first calendar year beginning after the drug is marketed; and
- A benchmark period consumer price index – urban tied to the first January of the calendar year beginning after the drug is first marketed.[7]

CMS is proposing to define the first applicable period for such drugs as "begin[ning] immediately after the payment amount benchmark period ends (i.e. December 31) and [extending] from January 1 to September 30 of the year following the payment amount benchmark period."[8] We urge CMS not to proceed with this proposal. The applicable period is defined by statute as "a 12-month period beginning with October 1 of a year," and, thus, the first applicable period for a subsequently approved drug cannot begin on January 1. We thus ask CMS to instead define the first applicable period for a subsequently approved drug as the 12-month period beginning the first October 1 after the end of the payment amount benchmark period, the period most consistent with the directives of the statute.

III. RECOMMENDATIONS REGARDING TIMELINES FOR REVIEWING AND COMMENTING ON PRELIMINARY REBATE AND TRUE-UP REPORTS, AND THE TRUE-UP PROCESS

A. We Applaud CMS for Offering Manufacturers an Opportunity to Comment on CMS's Calculation of the Rebates That It Intends to Invoice via the Preliminary Rebate Report, but Ask CMS to Provide Manufacturers with Additional Time for Comment, a Date Certain in Each Rebate Cycle for Receipt of the Report, and More Detailed Data in the Report

Under the Part D inflation rebate statute, manufacturers must pay inflation rebates on Part D rebatable drugs within thirty days of receipt of an invoice from the Secretary, which CMS's guidance denominates a Rebate Report.[9] The statute directs CMS to furnish the Rebate Report

[7] SSA § 1860-14B(b)(5)(A).
[8] Part D Inflation Rebate Guidance at 15.
[9] SSA § 1860D-14B(a); Part D Inflation Rebate Guidance, § 50.1.

to the manufacturer within nine months of the end of the rebate period.[10] The Rebate Report is to include (1) the total number of units for each dosage form and strength for the Part D rebatable drug for the applicable period; (2) the amount of the excess of the average annual manufacturer price (AnMP) for each dosage form and strength of the Part D rebatable drug for the applicable period; and (3) the rebate amount for each dosage form and strength of the Part D rebatable drug for the applicable period.[11]

In its guidance on the Part D inflation rebate, CMS indicates that it will provide a Preliminary Rebate Report to the manufacturer six months after the end of the rebate period, which will include the same information as that in the final Rebate Report and will give the manufacturer the opportunity to identify calculation errors and raise such concerns to CMS for discretionary review.[12] Manufacturers will be given ten calendar days to review the Preliminary Rebate Report and provide feedback to CMS.[13]

We applaud CMS for providing for an informal dispute resolution process through which manufacturers can evaluate the propriety of (1) CMS's assessment that a rebate is due and (2) the amount of the rebate that CMS intends to invoice, including the units on which it intends to invoice the rebate. There are, however, a number of steps CMS can and should take to ensure that this process more fully supports the accuracy of the final Rebate Report, and we ask that CMS revise the process accordingly.

First, we ask that CMS extend the review period from ten to thirty days. Ten calendar days is simply not sufficient to meaningfully review the information contained in the Preliminary Rebate Report and identify concerns and raise them to CMS's attention with appropriate support. Upon receipt of a Preliminary Rebate Report, a manufacturer will need to review whether:

- the drug is a Part D rebatable drug;
- the number of units of the drug on which CMS intends to invoice the rebate matches the manufacturer's assessment of the amount of rebatable utilization, given the exclusion of 340B units, relief for drugs determined to be in shortage, and relief for biosimilars in cases of severe supply chain disruptions; and
- the payment amounts and inflation adjustment on which CMS bases its rebate calculation are correct.

A manufacturer should instead be given at least ***thirty days*** to review and respond to a Preliminary Rebate Report. This would still allow CMS time to review and respond to the feedback before issuing the final Rebate Report by the six-month post-quarter statutory deadline. A thirty-

[10] SSA § 1860D-14B(a)(1); *see also* § 1860D-14B(a)(3) (permitting CMS to delay the time frame of Rebate Reports for rebate years beginning October 1, 2022, and October 1, 2023, until not later than December 31, 2025).
[11] *Id*.
[12] Part D Inflation Rebate Guidance, § 50.
[13] *Id* § 50.1.

day cycle would align with Medicaid state rebate invoice review period and is an industry business standard.

Second, CMS should specify the date in each rebate cycle on which the Preliminary Rebate Reports for such cycle will be issued, well in advance of their issuance. Given the importance of the review process and the limited time for review, manufacturers will need to plan and prepare for the review of a Preliminary Rebate Report. The serial identification of the exact date in each rebate cycle or the setting of a predictable date in each rebate cycle (e.g., the first day of the seventh month following the end of the applicable quarter) will ensure that a manufacturer can make arrangements to have appropriate resources available to perform the necessary review.

Third, CMS should include in each Preliminary Rebate Report all data that a manufacturer may need to meaningfully understand the basis for CMS's intended rebates and to identify potential concerns in a fully informed way. These data should include not only the amount by which the payment amount for the rebate quarter exceeds the inflation-adjusted payment amount as required by statute but also should include the number of units subject to the rebate, including 340B and Medicaid units excluded from the calculation, consistent with CMS guidance; the percent increase in inflation calculated by CMS; and the details of the calculation of the rebate for line extensions so that manufacturers can accurately understand the basis of the rebate calculation. To this end, CMS should provide a detailed description of the types of data that it intends to include in the Preliminary Rebate Report, and subject it to comment. This process will help ensure that manufacturers understand the nature of the data that CMS intends to share and provide feedback accordingly, which, ultimately, will help ensure that CMS invoices rebates accurately.

Finally, we ask that CMS make comparable adjustments to the process for manufacturer review of the Preliminary True-Up Rebate Report, discussed in Section II(B), as all of the reasoning discussed above applies equally to such Report.

We know that CMS shares manufacturers' interest in the accuracy and integrity of the inflation rebate invoicing process. The recommendations above will greatly enhance the safeguards needed to achieve that result.

B. CMS Should Extend the Time Period Between the Rebate Report and the True-up Rebate Report to Three Years to More Fully Capture Adjustments to and Restatements of AMP and Other Data

The Part D inflation rebate statute requires that CMS establish an adjustment and reconciliation process on the basis of restatements related to Part D units dispensed.[14] The statute does not mandate any adjustment or reconciliation process on the basis of restatements of AMP or other data.

[14] SSA § 1860D-14B(b)(6).

We applaud CMS for creating such an adjustment and reconciliation process for both underpayments and overpayments through the True-Up Rebate Report process, and for giving manufacturers an opportunity to review any proposed true-ups via a Preliminary True-Up Rebate Report, which CMS proposes to send approximately one year after the Preliminary Rebate Report is sent.[15] The True-Up Rebate Report will "capture any potential price and/or unit restatements of AMP data by manufacturers and revisions in reporting by Part D plan sponsors of the units dispensed that occurred after the rebate amounts were calculated and paid."[16] Manufacturers will be given ten calendar days to review the Preliminary True-up Rebate Report, and final True-Up Rebate Reports will be issued one year after the final Rebate Report is sent.[17]

CMS should extend the true-up period from one to three years, because one year is insufficient to appropriately capture restatements of AMP. CMS requires that manufacturers participating in the Medicaid Drug Rebate Program (MDRP) report any changes in AMP, which forms the basis for the Part D inflation rebate calculation, within 12 quarters (three years) of when such data were originally due.[18] Given this time frame under MDRP, CMS should issue the True-Up Rebate Report three years after the final Rebate Report, to greatly increase the likelihood that restatements of AMP data are properly accounted for, and thereby significantly enhance the accuracy of any true-ups.

* * * * *

We appreciate your consideration of our comments as you develop Part D inflation rebate policy. We look forward to continuing to work with CMS to ensure the Part D inflation rebates are implemented appropriately. Please contact Andy Swire by telephone at (202) 585-9611 or by email at aswire@amgen.com if you have any questions regarding our comments.

Regards,

Greg Portner
Senior Vice President
Global Government Affairs and Policy

[15] Part D Inflation Rebate Guidance, § 50.2.
[16] *Id*.
[17] *Id*.
[18] 42 CFR § 447.510(b)(1).

March 10, 2023

Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Administrator Brooks-LaSure:

Arnold Ventures welcomes the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the following guidance issued on February 9, 2023:

- *Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the Social Security Act, and Solicitation of Comments*
- *Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments*

Arnold Ventures is a philanthropy dedicated to investing in evidence-based policy solutions that maximize opportunity and minimize injustice. Our work within the health care sector is driven by a recognition that the system costs too much and fails to adequately care for the people it serves. Our work spans a range of issues including commercial-sector prices, provider payment incentives, prescription drug prices, clinical trials, Medicare sustainability, and complex care.

We want to thank you and CMS staff for your important and expeditious work implementing the prescription drug provisions of the Inflation Reduction Act (IRA), and for the opportunity to provide input. We recognize the difficulty of the task you face.

Our comments fall into three sections: (1) comments that apply to both Part B and Part D guidance documents, (2) comments that apply to the Part B guidance document, and (3) comments that apply to the Part D guidance document.

Section 1: Comments that Apply to both Part B and Part D Inflation Rebates

1. Removal of 340B Units
   - *Part B Guidance: 50.8.1 Removal of 340B Units*
   - *Part D Guidance: 40.2.7 Exclusion of 340B Acquired Units from Part D Rebatable Drug Requirements*

Arnold Ventures supports CMS's proposal to require that a modifier be added to the Part B and Part D claims data that indicates which drugs reimbursed by Medicare were acquired at 340B prices. This will ensure that all drugs purchased at a 340B discount are excluded from the Medicare inflation rebates as required by the IRA.

- *Medicare Part B.* For drugs purchased through hospitals (under the Outpatient Prospective Payment System), CMS can rely on a modifier that is already included in Medicare Part B claims data indicating when a 340B discount was provided to the hospital for the drug. Evidence suggests that hospitals account for most drug sales under Medicare Part B that are purchased at a 340B discount.[i] Other types of 340B providers do not

include a modifier on their claims data indicating whether the drug was purchased at a 340B discount. Arnold Ventures supports CMS's proposal to have the remaining 340B entities use these modifiers as soon as possible, and no later than January 1, 2024.

- *Medicare Part D.* To exclude 340B units from the Part D inflation rebate, CMS is also considering whether to require that Part D plans include an indicator on the PDE claims data in instances where the drug purchased was acquired at the 340B price by the pharmacy. Arnold Ventures supports this policy and believes Part D plans can work with pharmacies to provide this indicator in the Prescription Drug Event data.

2. Drug Shortages.
   - *Part B Guidance: 50.11 Reducing or Waiving the Rebate Amount in the Case of a Part B Rebatable Drug on the Shortage List*
   - *Part D Guidance: 40.5 Reducing or Waiving the Rebate Amount for Part D Rebatable Drugs in Shortage and in Cases of Severe Supply Chain Disruptions*

When deciding whether to modify the inflation rebate for drugs on FDA's shortage list, CMS should consider the drug's price. Lower priced drugs (typically generics) in shortage are less profitable and will be more likely to require a waiver or reduction in the inflation rebate in order help the manufacturer quickly address the shortage. CMS should be cautious modifying the inflation rebate for higher priced products in shortage for more than one rebate period.

The price used to determine whether to reduce or waive the rebate should be standardized so that it can be compared across drugs that come in different dosage forms. For Medicare Part D, this could be the cost per standardized prescription. For Medicare Part B this could be the cost per administration. Another useful measure is a drug's average annual cost per beneficiary.

3. Assuring the Integrity of Rebate Payments
   - *60. Ensuring Integrity of Part B Inflation Rebates*
   - *50. Ensuring Integrity of Part D Drug Inflation Rebate Payments*

CMS solicited comments with respect to approaches to ensure the integrity of the rebate determination process. Below we outline several items for consideration.

Rebate Reports. The "Rebate Reports" that CMS provides to the manufacturer will include (1) the number of units of the drug purchased by Medicare beneficiaries during the rebate period, (2) the amount of the excess price increase above inflation, and (3) the rebate amount owed per unit.

Arnold Ventures suggests that CMS include the total gross sales of the drug to Medicare in the Rebate Reports. CMS is likely to have the best available data on total sales of the drug to Medicare beneficiaries at the time the manufacturer receives the Rebate Reports. Providing this additional information at the dosage form/strength level in Part D and by HCPCS code in Part B will help all parties ensure that the total number of units in the Rebate Report is consistent with total Medicare payments for the drug during the rebate period.

Rebate Payment Integrity. To ensure the integrity of the Part D rebate payments, CMS will need to work with Part D plans to check the "quantity dispensed" field in the claims data. Part D plans do not have a financial incentive to populate this field carefully because they do not receive a share of the inflation rebates. For brand-name drugs, CMS can use the stable relationship

between gross part D sales per unit and AMPs, as well as the days supplied variable to check the accuracy of the "quantity dispensed" variable.

Section 2: Comments that Apply to Part B Inflation Rebate Guidance

4. Part B Inflation Rebates--Multiple Manufacturers in same HCPCS Code

- *50.13 Financial Responsibility for Part B Inflation Rebate Amount*

AV supports CMS's proposed methodology to allocate Part B inflation rebates across manufacturers in cases when multiple manufacturers of single source products are in the same billing code. This situation will likely occur infrequently when there is a separate labeler or an authorized generic version of a drug. This might also occur when a single source product faces competition from a similar drug approved under the 505b2 pathway.

5. Treatment of Part B Drug Purchases Made by Dual Eligibles

- *50.8.2 Removal of Units with a Rebate Under Section 1927 of the Social Security Act*

CMS requested comments on the exclusion of all drug units when an individual is enrolled in both Medicare and Medicaid (dual eligibles). Arnold Ventures is concerned that there is not enough information available to support CMS's proposed methodology.

States are likely paying dual eligibles' Medicare Part B co-insurance (usually 20 percent) for physician-administered drugs. It is not clear the extent to which the Medicaid statutory rebate is collected in these instances. If Medicaid rebates are collected, it is also unclear whether the entire rebate amount is collected by the state, or just a share. For example, if the state pays 20 percent of the drug's cost, there is little information to determine if the manufacturer only remits 20 percent of the total Medicaid rebate amount to the state.

Given the lack of information available, we encourage CMS between now and 2025 (when the first invoices for the rebates will be issued) to survey states to understand the extent to which Medicaid rebates are being paid for physician administered drugs used by dual eligibles before finalizing this methodology. We are concerned that the methodology outlined in the guidance overstates the extent to which Medicaid inflation penalties are paid on physician administered drugs purchased by dual eligibles.

6. Medicare Advantage and Part B Inflation Rebates

- *50.8.5 Operational Considerations Related to the Inclusion of Units Furnished to Beneficiaries Who are Enrolled in Medicare Advantage Plans*

Arnold Ventures supports the collection of inflation rebates on Part B drugs administered to beneficiaries in Medicare Advantage (MA) Plans. However, we also agree that there are significant operational complexities. For example, it will be challenging to obtain and analyze the data to implement these rebates in a timely manner.

Encounter data submitted to CMS by MA plans can be used to estimate the quantities of services used by MA beneficiaries.[ii] Therefore, Arnold Ventures suggests that CMS consider relying on encounter data submitted to CMS by MA plans to count the number of units of Part B drugs covered by MA plans during a rebate period.

The IRA requires CMS to invoice the manufacturer for the rebate within 6 months after the end of the calendar quarter. However, encounter data is currently submitted by MA plans to CMS roughly one year after the end of the plan service year. To invoice manufacturers in a timely manner while relying on encounter data, CMS could require that MA plans submit the encounter data for physician administered drugs earlier than they do today.

Since invoices do not need to be sent to manufacturers until September 30, 2025, CMS will have time to analyze the encounter data and invoice manufacturers for the inflation rebates owed on Part B drugs covered by MA plans in 2023. In future years—where CMS must invoice manufacturers within 6 months of the end of a calendar quarter—CMS could project the number of units of the drug used by beneficiaries in MA plans during the rebate period (based on utilization in the prior rebate period). Then update that estimate during the "true up" period roughly one year later by relying on the encounter data.

Additionally, CMS is required to back out the units purchased at a 340B discount from the inflation rebate calculations. To accomplish this, CMS could create a crosswalk between HRSA datasets that identify 340B entities and the provider identifiers in the encounter data to isolate claims administered by a 340B entity. CMS could then back out all claims administered by 340B entities from the estimated number of units of the Part B drug provided to beneficiaries in MA plans.

Section 3: Comments that Apply to Part D Inflation Rebate Guidance

7. Part D Rebates and Quantity Measures
    - *40.2.5 Use of PDE Data to Determine Total Units Subject to Rebate and Crosswalk to AMP Units*

Arnold Ventures supports CMS requesting from Part D plans detail that describes the "quantity dispensed" data. Currently, the PDE claims data includes the number of units dispensed and the number of days supplied by the prescription. But there is no data field to clarify how the units were measured by the pharmacist.

This additional information is especially important for non-oral solid dosage forms. For example, pharmacists may enter the number of syringes that were dispensed instead of the number of milliliters of the active ingredient that were dispensed. This will be problematic if the Average Manufacturer Price (AMP) is priced per milliliter. If the Part D plan captures the unit of measurement in Part D PDE claims data, that would supply Part D plans and CMS with more accurate information to help ensure the integrity of the inflation rebate program.

8. Part D Rebates and Line Extensions
    - *40.4 Treatment of New Formulations of Part D Rebatable Drug*

Arnold Ventures supports CMS's proposed methodology to estimate the Part D inflation rebates for line extensions of drugs that are oral solid dosage formulations. The proposed methodology is consistent with the methodology used in the Medicaid Drug Rebate Program.

This policy is important to stop line extensions from "resetting the clock" for the inflation rebate calculation. Under the proposed approach, if an extended-release capsule is introduced after a tablet has been on the market for many years, then the inflation rebate on the extended-release capsule can be linked to the original tablet's larger inflation rebate. For example, if the inflation

rebate on the original tablet were 20 percent of its AMP, then the inflation rebate on the extended-release version would be 20 percent of its AMP during its first rebate period (rather than a much lower amount because it is a newly launched product).

CMS will need to decide when the first rebate period begins for newly launched line extensions. The first rebate period could start earlier than for other types of new drugs because a benchmark price is not needed to estimate the inflation rebate owed. The inflation rebate for a new formulation could simply be calculated by tying it to the original formulation. CMS clarification is needed because if the first rebate period for line extensions were defined similarly to other new products, then line extensions would be on the market for 13 to 23 months before the first rebate period would begin.

AV supports the expansion of the line extension rebate to all types of drugs, not just drugs originally launched in oral solid dosage forms. Researchers have found that the exemption of non-oral solid products from this line extension policy has significantly reduced rebates collected on some drugs in the Medicaid program.[iii]

Conclusion

Arnold Ventures is prepared to assist with any additional information needed. Comments were prepared by Anna Anderson-Cook, Ph.D. with assistance from Mark E. Miller, Ph.D., Executive Vice President of Health Care at Arnold Ventures and Andrea Noda, Vice President of Health Care at Arnold Ventures.

Please contact Andrea Noda at anoda@arnoldventures.org or Mark E. Miller, Ph.D. at mmiller@arnoldventures.org with any questions. Thank you again for the opportunity to comment and for your important work to lower prescription drug prices for the Medicare program and its beneficiaries.

Sincerely,

Andrea Noda

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[i] Technical Assistance Brief: Implementation of Inflation-Indexed Rebates for Part B Drugs. February 2023, OEI-BL-23-00170 *https://oig.hhs.gov/oei/reports/OEI-BL-23-00170.pdf*

[ii] Jung, J., Carlin, C., and Feldman, R., Measuring Resource Use in Medicare Advantage Using Encounter Data, HEALTH SERVICES RESEARCH 57(1):172-181 (2022). doi: 10.1111/1475-6773.13879. Jung, J., Carlin, C., Feldman R., Tran, L., Implementation of Resource Use Measures in Medicare Advantage HEALTH SERV RES. 57(4):957-962 (Aug 2022). Doi:10.1111/1475-6773.13970. Here is a paper analyzing drug use in MA plans that relied on encounter data: Anderson, K. E., Polsky, D., Dy, S., Sen, A., Prescribing of Low- Versus High-Cost Part B drugs in Medicare Advantage and traditional Medicare, HEALTH SERVICES RESEARCH, November 2021, https://doi.org/10.1111/1475-6773.13912.

[iii] Hwang, T.J., Feng, J., Maini, L. et al. Medicaid Expenditures and Estimated Rebates on Line Extension Drugs, 2010–2018. J GEN INTERN MED 37, 3769–3771 (2022). https://doi.org/10.1007/s11606-022-07435-2

March 11, 2023

Dr. Meena Seshamani, MD, PhD
CMS Deputy Administrator and Director of the Center for Medicare
Department of Health & Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: 1) Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the Social Security Act, and Solicitation of Comments, and
2) Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments

Submitted electronically via IRARebateandNegotiation@cms.hhs.gov
(*"Medicare Part D Inflation Rebate Comments*" and *"Medicare Part B Inflation Rebate Comments"*)

Dear Dr. Seshamani,

The Association for Clinical Oncology (ASCO) is pleased to offer comments on the CMS guidance, *Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the Social Security Act, and Solicitation of Comments* and *Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments*.

Between them, the memoranda provide initial guidance to manufacturers, Medicare Part D Prescription Drug Plans, and Medicare Advantage-Prescription Drug Plans regarding the payment by manufacturers of inflation rebates for Part B and Part D rebatable drugs. CMS is voluntarily seeking comment on certain topics, including CMS' approach to waivers or reductions of rebates for drugs in shortage or, in some cases, at risk of being in shortage.

ASCO is a national organization representing nearly 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

Background

In calculating the estimated rebate amount for a Part B rebatable drug for a calendar quarter, the Secretary is required to reduce or waive the rebate amount for a Part B rebatable drug for a calendar quarter in two cases:

1. when a Part B rebatable drug is described as currently in shortage on the shortage lists established under section 506E of the Federal Food, Drug and Cosmetics Act (FD&C Act) at any point during the calendar quarter; or
2. for a biosimilar biological product when the Secretary determines there is a severe supply chain disruption during the calendar quarter, such as that caused by a natural disaster or other unique or unexpected event.

The statute provides that CMS reduce or waive the rebate amount with respect to a Part D rebatable drug for an applicable period in three cases:

1. for a Part D rebatable drug that is described as currently in shortage on the FDA drug shortage list in effect under section 506E of the FD&C Act at any point during the applicable period;
2. for a Part D rebatable drug that is a generic or biosimilar when CMS determines there is a severe supply chain disruption during an applicable period; and
3. for a generic Part D rebatable drug when CMS determines that without such a reduction or waiver in the rebate, the drug is likely to be described as in shortage on the FDA drug shortage list during a subsequent applicable period.

Applicability. The rebate provisions of the Inflation Reduction Act apply only to single source drugs. For Part B, single source drugs are defined as biologics and drugs marketed and distributed under new drug applications (NDAs). For Part D, single source drugs are defined as biologics, NDAs, and single source generics (with some exceptions). Inflation rebate requirements do not apply to single source drugs for which average Medicare annual charges are less than $100 per patient.

Current Shortage Landscape and CMS Considerations for Rebate Reductions and Waivers

According to the University of Utah Drug Information Service (UUDIS) and the American Society of Health-System Pharmacists (ASHP), in the fourth quarter of 2022 there were 295 active drug shortages, the highest in almost a decade.[1] In 2022, 48% of drugs newly in shortage were injectables.[2] (The Food and Drug Administration (FDA) lists approximately 125 drugs as currently in shortage; the FDA uses different criteria for its drug shortage list compared to ASHP. These differences have been well characterized previously.[3])

[1] University of Utah Drug Information Service. Available at https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics
[2] University of Utah Drug Information Service. Available at https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics
[3] FDA and ASHP Shortage Parameters. Contrasting the FDA (CDER) and ASHP Drug Shortage Websites: What Are the Differences? Available at https://www.ashp.org/drug-shortages/current-shortages/fda-and-ashp-shortage-parameters

For cancer therapies and supportive care drugs, it has been widely noted that for years, many of the most impactful drug shortages have been shortages of multi-source, generic, sterile injectables. These drugs are not subject to the inflationary rebate requirements, and thus are not impacted either by rebates or the reduction or waiver of such rebates. ASCO, in partnership with several stakeholder groups, has previously released recommendations for improvement in the resilience of drug and healthcare supply chains; we refer you to the most recent set of recommendations for further information.[4]

As CMS and others have noted, there is a balance to be achieved between providing flexibility to manufacturers in the form of reduced or waived rebates when a drug is in shortage or in danger of being in shortage, and not providing incentives for manufacturers to intentionally keep their drug or biological in shortage for the purpose of avoiding rebate payments. Many shortages occur due to "quality" issues and are under the control of the manufacturer: a UUDIS investigation found that in 2022, the reason for 56% of drug shortages as reported by manufacturers were characterized as "unknown/[manufacturer] would not provide."[5] Compared to circumstances outside of the manufacturer's control—natural disasters, other unexpected events—shortages due to quality issues at the level of the manufacturer will likely merit greater scrutiny of the rebate reduction level by CMS.

Currently, there appear to be a very small number of single source part D generic drugs that are in shortage. However, precisely because these drugs are single source, it will be important for CMS to assess the reason for these shortages as well as previous patterns of shortage. If, for example, a drug is extremely low margin and the cost of producing the drug is increasing, the manufacturer may realistically need to raise the price of the drug in order to just maintain these low margins and remain in the market. If the price increase is high enough, the manufacturer would then become subject to the inflationary rebate, and at that point may decide to withdraw from the market. These single source, low margin drugs likely merit more generous rebate reduction levels in order to keep them viable.

For Part B drugs and biologics subject to both inflationary rebates and the associated drug shortage provisions, CMS should consider the totality of the reason(s) for the shortage, the impact on patients, and efforts by the manufacturer to mitigate or resolve the shortage. In general, manufacturers of branded drugs have more of an incentive and ability to quickly resolve shortages of these drugs, due to higher margins and often more resilient supply chains. However, certain older branded drugs may lack generic competition for a variety of reasons. If these older single source branded drugs are low margin and facing increasing production costs, they may be risk of market exit as described above for single source generics and should be considered in a similar fashion.

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[4] Improving the Quality and Resilience of the United States Healthcare Supply Chain. Recommendations from the American Medical Association, American Society of Anesthesiologists, American Society of Health-System Pharmacists, Association for Clinical Oncology, and the United States Pharmacopeia. Available at https://www.ashp.org/-/media/assets/news-and-media/docs/Healthcare-Supply-Chain-Recommendations

[5] University of Utah Drug Information Service. Available at https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics

We thank you for the opportunity to comment on these initial memoranda. Please contact Karen Hagerty (karen.hagerty@asco.org) with any questions.

Sincerely,

Lori Pierce, MD, FASTRO, FASCO
Chair of the Board
Association for Clinical Oncology

JOHNS HOPKINS
BLOOMBERG SCHOOL
of PUBLIC HEALTH

Baltimore, March 11, 2023

To: Centers for Medicare and Medicaid Services
Re: Medicare Part D Inflation Rebate Comments

To Whom It May Concern:

This commentary addresses concerns with respect to the shortage exemption to the inflation rebate penalty. The Inflation Reduction Act (IRA) specifies that the **inflation rebate amount shall be reduced or waived for drugs with shortages** and severe supply chain disruptions, which includes drugs on the FDA shortage list (section 506E of the FDC Act) at any point during the quarter; generics and biosimilars with severe supply chain disruption during the quarter; and generics that, "without such reduction or waiver, the drug is likely to be described as in shortage on such shortage list during a subsequent applicable period." However, the IRA does not specify how the Secretary should determine whether to provide a waiver or reduction (and what level of reduction) to shortage drugs.

Our concern is that the IRA provisions of waived or reduced inflation penalties for shortage drugs may incentivize drug manufacturers to initiate or lengthen a drug shortage in order to benefit from waived or reduced inflation rebate penalties. The US legislation – namely, 21 USC 356e: Drug shortage list and Title X of FDASIA, 2012 – determines mandatory reporting requirements for manufacturers to the FDA regarding supply chain disruptions. The information provided by drug manufacturers provides the basis for the drug shortage list maintained by the FDA.

We contend that the majority of drug shortages occur due to reasons that are under drug manufacturers' control. In their investigations, both the GAO and the FDA agree:

- FDA - 62% of drug shortages are caused by manufacturing quality issues; an additional 3% are caused by product discontinuation, a manufacturer's decision[1]
- GAO - 70% of drug shortages are caused by quality problems or manufacturing delays; and additional 12% are caused by product discontinuation [2]

Our analysis of the FDA drug shortage list between 2020 and 2022 revealed that **67 drugs (30% of all 224 shortages reported 2020-2022) were single-source biologic and branded drugs, the drugs subject to the inflation rebate provision in the IRA.** On average, these single-source drug shortages lasted 19.6 months (min: 1.3, max: 71.7 months).

[1] FDA. Drug Shortages: Root Causes and Potential Solutions. Available from: https://www.fda.gov/drugs/drug-shortages/report-drug-shortages-root-causes-and-potential-solutions
[2] GAO Report. Drug Shortages: Public Health Threat Continues, Despite Efforts To Help Ensure Product Availability. February 2014. GAO-14-194

Those single-source drugs in the shortage list corresponded to $2 billion Medicare Parts B and D spending in 2020. The compound annual growth rate exceeded ~2% rate of inflation between 2016-2020 for 81 drugs (36% of all 224 shortages).

The table below summarizes the single-source drugs with highest compound annual growth rate of spending in the Medicare program between 2016-2020.

FDA Shortage Listing	Compound Annual Growth Rate (2016-2020)	Avg Spending Per Beneficiary (2016)	Avg Spending Per Beneficiary (2020)	Total Spending (2020)	Shortage duration
Erythromycin Lactobionate Injection	175.87%	$6,289.68	Small #	$119,503.99	2 years; resolved 2020
Cefotetan Disodium Injection	56.12%	$325.54	$538.89	$23,113.15	2014-ongoing
Ceftolozane and Tazobactam (Zerbaxa) Injection	38.87%	$6,073.08	$11,304.51	$1,572,928.46	1 year; resolved 2022
Triamcinolone Acetonide (Triesence) Injection	38.75%	$298.45	$254.02	$13,430.26	2019-ongoing
AVYCAZ® (ceftazidime and avibactam) Injection	34.80%	$11,300.55	$14,533.65	$1,378,666.71	<1 year, resolved 2020

Source: authors' analysis of Medicare Parts B and D dashboards[3] and FDA shortage list.[4]

We contend that the Secretary should provide a nominal level of reduction (say, 1%) in the inflation rebate penalty as a benchmark for all drugs in shortage that increase prices faster than the rate of inflation.

In order to qualify for greater reductions (or a waiver) of the penalty, the Secretary should, first, require that manufacturers of drugs in shortage provide significant evidence on the causes of the shortage and demonstrate that the cause of the shortage was outside of the manufacturer's purview. The clearest case of shortages that are not on the manufacturer's purview are shortages caused by natural disasters, such as hurricanes or floods, affecting production facilities. There may also be upstream shocks to the supply chain, such as transportation bans implemented by other countries or unavailability of active pharmaceutical ingredients, which may be outside of the manufacturer's purview. In a recent study, our team identified that one third of active pharmaceutical ingredients for US generic drugs are produced by only one facility, and another third of active pharmaceutical ingredients are manufactured by two to three facilities. [5] These findings reveal that most of the drug supply chains that depend on globally produced active pharmaceutical ingredients (which may include single-source products) are vulnerable to disruptions from active pharmaceutical ingredient production. It is important to

[3] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs

[4] https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages

[5] Socal MP, Ahn K, Greene JA, Anderson GF. Competition And Vulnerabilities In The Global Supply Chain For US Generic Active Pharmaceutical Ingredients. Health Aff (Millwood). 2023 Mar;42(3):407-415.

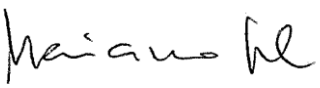
ensure that shortages have been caused by factors outside of the manufacturer's purview to prevent manufacturers from 'gaming' the system, by implementing product discontinuations for example, or product hopping (when the manufacturer reduces or stops the supply of a certain drug in order to incentivize the uptake of a new product).

Second, the Secretary should grant any reductions or penalties for a quarter only, and, for drugs granted a waiver or a reduction, the Secretary should review information every quarter, requiring that manufacturers demonstrate the steps that they are taking to mitigate or end the shortage. This is important to discourage manufacturers from prolonging shortages. The Secretary should require that any manufacturer of a drug in shortage that was subject to the rebate penalty but was granted a reduction or waiver greater than the benchmark must provide information demonstrating that the manufacturer is taking steps to mitigate or end the shortage. This should include information on actions taken by the manufacturer as well as actions taken by or together with the FDA.

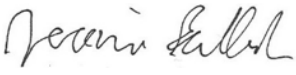
In sum, the Secretary should implement a nominal benchmark reduction of the inflation rebate penalty for all drugs in shortage that are subject to the inflation rebates (say, a 1% reduction) and should require that manufacturers provide extensive information in order to qualify for greater reductions. Waiver or reduction of the penalty should be reserved for the cases of shortages caused by external factors outside of the manufacturers' purview such as natural disasters or transport bans affecting the global supply of active pharmaceutical ingredients. **The Secretary should require that drug manufacturers provide extensive documentation, which may include contracts and communications with third parties such as active pharmaceutical ingredient manufacturers, as well as actions and communications with the FDA, to quarterly ensure that manufacturers are taking steps to mitigate or end the shortage while benefitting from inflation rebate penalty reductions or waivers.**

Please do not hesitate to let us know if you have any questions.

Sincerely,



Mariana Socal, MD PhD - Associate Scientist
410-502-9238 - msocal1@jhu.edu



Jeromie Ballreich, PhD MHS - Associate Scientist
814-599-6001 - jballre2@jhu.edu

Department of Health Policy and Management
Johns Hopkins Bloomberg School of Public Health
624 N Broadway, Baltimore, MD 21205

Via Electronic Submission

March 10, 2023

Dr. Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator, Director of the Center for Medicare
Centers for Medicare & Medicaid Services
200 Independence Avenue SW
Washington, DC 20201

Subject: Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of the Social Security Act, and Solicitation of Comments

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March 10, 2023

Brian Nagle
Head of Federal Gov't Affairs
for Healthcare and Policy
801 Pennsylvania Avenue NW
Washington, D.C. 20004

Tel. +1 202.756.3779
Brian.Nagle@bayer.com

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Dear Dr. Seshamani,

Bayer US ("Bayer") appreciates the opportunity to offer its input to the Centers for Medicare and Medicaid Services (CMS) on its initial memorandum addressing implementation of the inflation rebates under Medicare Part D issued on February 9, 2023.

Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture with nearly 25,000 employees in 300 sites across the United States. Our products and services are designed to benefit people and improve their quality of life. At the same time, we aim to create value through innovation and are committed to the principles of sustainable development and to our social and ethical responsibilities as a corporate citizen.

Many unanswered questions remain about the implementation of the Inflation Reduction Act (IRA) that present significant administrative complexity to manufacturers. We address several of these topics of particular importance to Bayer in this letter. Furthermore, we are generally supportive of input provided via our trade associations, including PhRMA and BIO. We offer these comments and welcome future opportunities to continue the dialogue with CMS and manufacturers as the program is implemented.

I. Exclusion of 340B Acquired Units from Part D Rebatable Drug Requirements (40.2.7)

As described under section 1860D-14B(b)(1)(B) (Excluded Units), the total number of dosage units for which manufacturers provide a discount are to be excluded from the rebate provisions starting in 2026. CMS notes the current National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard includes an optional field for pharmacies to indicate when a claim is for a 340B medication on a prospective basis. In addition, an "N1" indicator can be applied retrospectively, but as CMS states, it is very rarely used. CMS believes the requirement of a 340B indicator on the Part D Prescription Drug Event (PDE) record and all pharmacy claims would be a reliable means to identify drugs subject to the 340B discount.

We are supportive of the proposed requirement for a PDE claims identifier and believe some such approach is essential. However, we are concerned about compliance with such an approach given experience with certain claims currently. The claim is often left open and unidentified, leading to uncertainty about the disposition of the claim. In our experience, pharmacy benefit managers (PBMs) refuse to accept a drug manufacturer's assertion that a claim is a 340B excluded claim based on a single indicator. Thus, we support the use of two indicators, with the second noting the claim is for a "non-340B" drug. In this way, there will be greater certainty as to whether the claim is for a 340B medication. In the event the transaction fails to include such an indication, the claim could be rejected and resubmitted with a request for the needed information. For purposes of completion of the claim, the indicator could be made at the pharmacy level or when adjudicated between the Part D plan sponsor and the pharmacy.

One recent report suggests there may be compliance issues even when the inclusion of a 340B claims modifiers is required.[1] In an example for Medicare Part B, it was found that the percent of treatments for disproportionate share hospitals (DSH) under 340B was 89 percent. However, reporting for rural referral centers (RRC) and sole community hospitals (SCH) was at 61 percent. Each of these entities are currently required to provide 340B modifiers as part of their claims. Although there may be expected and inherent differences between these entities, the differential reported raises concerns about the lack of adherence to the requirements. Thus, CMS is encouraged to consider these challenges further.

Furthermore, the concept of 340B modifiers to prevent duplicate discounts does not work in cases when the 340B status of a claim was unknown to the pharmacy at the point of sale. A better approach to further ensure compliance with the provisions of the statute is the use of a clearinghouse-approach in which an entity would be designated to better identify and confirm those medications that were dispensed or administered to Part D patients via a 340B covered entity.

Alternatively, CMS could implement its own audit process to ensure adherence to the program on the part of covered entities.

[1] Martin R, Karne H, Duffy J. "White Paper: Can 340B Modifiers Avoid Duplicate Discounts in the IRA?" IQVIA White Paper. 2023. Accessed February 28, 2023 at: https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2023/can-340b-modifiers-avoid-duplicate-discounts-in-the-ira.pdf

II. Timing of Rebate Reports and Payment (50.1) and Restatements of Prescription Drug Event (PDE) Units Reported and True-Up Rebate Reports (50.2)

As stated in the initial memorandum, CMS plans to issue a Preliminary Rebate Report to manufacturers within 6 months of the end of each applicable period. Manufacturers would be granted 10 days following receipt of the Preliminary Rebate Report to review the report and provide feedback to CMS on any calculation errors as noted in section 50.2 of the memorandum. Information in the report, as proposed, would include the NDC of the Part D rebatable drug for the period for which the rebate is being sought, the rebate amount due, and the amount by which the Annual Manufacturers Price (AnMP) exceeds the inflation-adjusted payment amount for the dosage form and strength of the rebatable drug. Following the opportunity to provide input on potential calculation errors, manufacturers would receive a Rebate Report, serving as an invoice for payment within 30 days. We understand that additional guidance will be issued pertaining to how the Rebate Report will be sent to manufacturers.

CMS also indicates that manufacturer information submitted under section 1927(b)(3) of the Social Security Act will be used for the purpose of carrying out the Part D drug rebate program. Recognizing that changes take place over time with this reported data, CMS will reconcile these unit data as necessary, performing a one-time true up recalculation allowing for revisions. The resulting restatement would happen one year after the rebate amounts are invoiced under the Rebate Report to manufacturers. This process would address identified overpayments and underpayments by manufacturers as part of the reconciliation process.

In a manner similar to the initial payment made by manufacturers, there would be a Preliminary True-Up Rebate Report sent to manufacturers (approximately 1 year after the Preliminary Rebate Report is issued) followed by a 10-day opportunity for a manufacturer to identify and suggest calculation errors that may exist. The final True-Up Rebate Report would be sent to manufacturers serving as an invoice for which manufacturers will have 30 days to make payment.

We appreciate CMS giving manufacturers the opportunity to review for errors data developed in advance of the submission of a final invoice for rebates to manufacturers. However, we believe that a 10-day review period of either the Preliminary Rebate Report or the Preliminary True-Up Report is insufficient for manufacturers to conduct a proper review of the information to be submitted by CMS. The limited information provided by CMS will require additional data analyses of suspected errors to provide proper feedback to CMS to ensure that a final corrected Rebate Report or True-Up Report is provided to a manufacturer. Additional information provided by CMS may help to better ensure a proper review of the preliminary data provided to manufacturers. This might include data provided at the NDC-11 level, as well as information used by CMS, including the benchmark price, AnMP, and values of the benchmark and applicable period CPI-U. Information on the number of 340B units excluded from the preliminary invoice would also be helpful in assessing the preliminary invoice for errors.

However, even with additional data, a 10-day review period is too short. We believe a 30-day review period is the minimum time needed. Besides the anticipated requirements for data

analyses when errors are initially suspected, those that support these reviews are clearly challenged when a 10-day period may extend over times that conflict with staffing availability.

III. Manufacturer Suggestions of Calculation Errors in Preliminary Rebate Reports and Preliminary True Up Reports (50.3) and CMS Identification of Errors (50.4)

CMS notes it is providing for discretionary consideration of suggestions from manufacturers to calculation errors in its Preliminary Rebate Report and Preliminary True-Up Rebate Report in the event a calculation error is identified. As described, this input appears to be limited to the two 10-day periods for each of these reports for which we have provided input in the previous section of this letter.

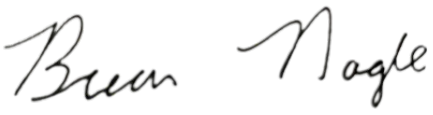
Conversely, CMS notes that it "…reserves the right to update or change the rebate amount and true-up amount due from manufacturers for applicable periods based on any calculation errors, or misreporting of manufacturer pricing or product data under section 1927(b)(3) that CMS identifies at any point after each applicable period ends." Clearly, this is different from the process allowed for manufacturers. However, it raises the prospect that additional adjustments could be made with the identification of errors beyond the time being considered for allotment to manufacturers.

Regarding the open-ended nature of this proposed provision, we believe a clearly defined end to potential liability for manufacturer rebates is needed, beyond those that may be the result of fraud. We recommend a 3 to 4-year limit on the reporting limits. Furthermore, we recommend that manufacturers be permitted to offer additional suggestions to CMS during this period should further calculation errors be identified. In this manner, manufacturers could serve as a source of information on any calculation errors "that CMS identifies at any point after each applicable period ends."

# # #

Again, Bayer appreciates the opportunity to offer these recommendations and hopes to continue its engagement with CMS as the program is implemented.

Sincerely,



Brian Nagle
Head of U.S. Federal Government Affairs
Healthcare and Policy
Bayer

CMS Desk Officers:

The Blue Cross Blue Shield Association (BCBSA) – a national federation of 34 independent, community-based and locally operated Blue Cross and Blue Shield (BCBS) companies (Plans) that collectively provide health care coverage for one in three Americans – would like to provide feedback on behalf of Plans. While individual Plans may submit their own questions or comments, our feedback reflects comments and concerns across the BCBS System.

We thank CMS for providing interested parties the opportunity to comment on the Medicare Part D Drug Inflation Rebates Paid by Manufacturers guidance. We appreciate consideration of BCBSA's comments, and we look forward to future collaboration on Inflation Reduction Act (IRA) implementation.

Reporting Obligations

- We understand the law authorizes HHS to use data supplied by Part D plans to carry out the inflationary rebate provisions of the IRA. We recommend that CMS use existing data sources (PDE, DIR, etc.) to gather data necessary to fully implement this new requirement and not apply new reporting requirements on Part D plans.
- Given the potential for additional plan burden, any increases in reporting requirements should have well evidenced justifications and should only be considered with a proper notice and comment period, long enough for stakeholders to provide feedback and engage in meaningful dialogue with CMS.

Identification of Rebatable Drugs and Exclusions

- CMS indicates it will exclude 340B units starting in January 2026, per the IRA. CMS suggests that requiring a 340B indicator in the PDE record (currently a 340B indicator is not included) is the most reliable way to identify drugs subject to a 340B discount and is soliciting feedback on this proposal.
- BCBSA requests CMS clarify its option, starting in 2026, for the inclusion of a 340B indicator in the PDE record. We are concerned about Part D sponsors having a role in determining or verifying 340B status, which is the responsibility of pharmacies. The challenge on pharmacy benefit claims is even if the SCC code of 20 is submitted that only captures 5-10% of 340B claims, as 340B status is often determined after claim adjudication, by one Blue Cross Blue Shield Plan metric.
- As CMS weighs its options, we ask the agency to consider the responsibility of the pharmacy and healthcare provider to verify 340B status. Pharmacies should be charged with identifying this information. Part D plans have no role in determining or verifying 340B status.
    - If CMS collects this data via PDEs, CMS should not require Part D plan sponsors to assess the accuracy of the 340B information supplied by pharmacies. Given the potential for variation and inconsistency in tracking 340B information by pharmacies, we do not believe that MA plans should be held responsible for potential external errors or omissions.

Waiver for Drug Shortages and Severe Supply Chain Disruptions

- BCBSA recommends CMS require drug manufacturers to report all NCDs to which a shortage applies in the 11-digit format. If manufacturers cannot report NCD-11, we request CMS crosswalk to NCD-11 and only apply waivers to those NDC-11 instead of the broader NDC-9. We are concerned the packaging code (the last two digits of the NDC) may determine a product's availability or if a product is in shortage; if certain NCDs are available and others not, CMS may be applying waivers too broadly.
- BCBSA supports CMS' proposed definition of "other unique or unexpected event" to mean "any exogenous, unpredictable event ***outside of a manufacturer's control*** *[emphasis added]*, including, but not limited to, a geopolitical disruption, pandemic, or act of terror." This would prohibit a waiver of rebates for supply chain disruptions that might be artificially created by the manufacturer in an attempt to avoid inflation rebate liability.

We appreciate the opportunity to provide feedback. If you have questions, please contact Jamal Bowleg at Jamal.Bowleg@bcbsa.com.

Sincerely,

Jamal Bowleg

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VIA ELECTRONIC DELIVERY to: IRARebateandNegotiation@cms.hhs.gov

March 10, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244–1850

RE: Medicare Part D Inflation Rebate Guidance Comments

Dear Administrator Brooks-LaSure:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Initial Medicare Part D Inflation Rebate Guidance issued by the Centers for Medicare & Medicaid Services (CMS) on February 9, 2023 *(Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 186D-14B of the Social Security Act, and Solicitation of Comments).*

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or prevent them in the first place. As a result, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers that have worked closely with stakeholders across the spectrum, including the public health and patient advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

We appreciate CMS putting forward an approach for addressing calculation errors through a preliminary rebate report process and for proposing a reconciliation ("true-up") process after final rebate reports are sent. Such processes are critical to ensuring program integrity. We offer detailed comments below on several timing and other process improvements that are needed to ensure that these processes work

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well for both CMS and manufacturers. We also note our appreciation for CMS taking initial steps toward excluding 340B units from the inflation rebate calculation but offer specific recommendations on additional action that CMS should take to ensure that inflation rebates are not paid on such units per the requirements set forth in the Inflation Reduction Act of 2022 (IRA). Finally, when CMS issues revised guidance on Part D inflation rebates, we urge the agency to outline in detail how its revised guidance has been updated based on stakeholder feedback – this is critical for transparency, which is particularly important as this is a new program. Our more detailed comments on these and other issues follow.

General – CMS Conflation of "Marketed" and "Approved"

In certain places in the guidance, CMS conflates the terms "marketed" and "approved." For example, in the last paragraph of page 11, CMS states the following (relevant language noted in bold/italics): "The inflation-adjusted payment amount for a dosage form and strength of a Part D rebatable drug for an applicable period would be determined by increasing the benchmark period manufacturer price by the percentage by which the applicable period CPI-U, which is the CPI-U for the October month of the applicable period, exceeds the benchmark period CPI-U, which ***for drugs marketed on or before October 1, 2021***, is the CPI-U for January 2021, and ***for drugs first approved or licensed after October 1, 2021,*** is the January CPI-U of the first calendar year… ."

> ***BIO Comment*:** CMS should consistently use the correct terminology throughout the guidance consistent with the statute. Specifically, the statute, in defining certain terms for purposes of calculating the inflation rebate amount, references Food and Drug Administration (FDA) approval/licensure date, not date when first marketed. CMS should substitute references to when a drug is marketed with references to when a drug is approved/licensed, as appropriate, to eliminate ambiguity. FDA approval/licensure cannot be used interchangeably with "marketed" – a product may be approved/licensed by FDA but may not be marketed until a later date.

Section 30 – Determination of Part D Rebatable Drugs and Exclusions

In Section 30.1., CMS outlines its proposed approach for identification of Part D rebatable drugs. Because of operational limitations, Part D rebatable drugs that do not have a Medicaid drug rebate agreement in effect under the Medicaid Drug Rebate Program (MDRP) would not be subject to inflation rebates. CMS notes that it will be assessing other means to collect needed information to subject such drugs to Part D inflation rebates in the future. In doing so, CMS notes that vaccines are excluded from the covered outpatient drug (COD) definition and manufacturers are not required to report pricing and drug product information on such products; as such, Part D vaccines will be excluded from Part D drug inflation rebate calculations "at this time."

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BIO Comment: We believe that vaccines should be permanently exempt from Part D inflation rebate liability. As CMS notes, it does not have access to Average Manufacturer Price (AMP) information for vaccines because such information does not exist for vaccines. Congress has authorized the collection of AMP information only for "covered outpatient drugs," as defined under Social Security Act (SSA) section 1927(k)(2). Congress explicitly excluded vaccines from the definition of a "covered outpatient drug" under section 1927(k)(2)(B), thereby excluding vaccines from AMP reporting. Therefore, there is no authority under section 1927 that permits CMS to collect AMP data for vaccines.

CMS indicates it intends to exclude Part D vaccines from Part D drug inflation rebate calculations at this time. However, CMS also indicates that it intends to assess other means to collect the needed information to subject these products to the Part D inflation rebate in the future. Without AMP data, CMS cannot calculate inflation rebates. Any means developed to collect the needed information would violate SSA section 1860D-14B(d), which expressly limits the sources of data from CMS may draw for purposes of the inflation rebate calculation to finite categories of information that, by their nature, do not include AMP information. (Again, information submitted under section 1927 (one such category of information) does not include AMP information for vaccines.)

In addition to the legal bar on invoicing Part D inflation rebates on vaccines, there are sound policy reasons for not doing so. Per the IRA, vaccines described in SSA section 1861(s)(10), i.e., influenza, pneumococcal, hepatitis B, and COVID-19 vaccines, are excluded from the Part B inflation rebate. Applying two different standards to vaccines based solely on how these products are covered by Medicare would create an arbitrary disincentive for new vaccine development. Medicare Part B covers only influenza, pneumococcal, hepatitis B, and COVID-19 vaccines. All other vaccines – vaccines that prevent the spread of all other diseases – are covered under Part D. This bifurcation exists because, with the establishment of the Part D benefit, Congress moved away from listing particular disease areas in statute in favor of a more flexible way to ensure prescription drug benefits meet the needs of the Medicare population and keep pace with medical advances. Applying penalties to Part D vaccines would create an arbitrary disincentive for exploration of new vaccine development, as only a small number of therapeutic areas with established vaccine options would be exempt from rebate liability. Applying a differential standard would also contradict efforts by Congress in the same law, the IRA, to standardize Medicare coverage of vaccines by extending cost-sharing protection to Medicare Part D.

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Further, the complexity of developing an alternative means for data collection, as well as verification, would create significant administrative burden and potentially flawed information. Should CMS proceed to develop any such means, despite the clear legal and policy reasons to not do so, it would be necessary to do so through notice-and-comment rulemaking.

For all these reasons, we ask CMS to clarify that vaccines are permanently exempt from Part D inflation rebate liability.

Section 40.2.7 – Exclusion of 340B Acquired Units from Part D Rebatable Drug Requirements

CMS acknowledges that SSA section 1860D-14B(b)(1)(B) requires that, beginning with plan year 2026, CMS is required to exclude from the total number of units of a dosage form and strength of a Part D rebatable drug those units for which a manufacturer provided a discount under the 340B Drug Pricing Program. CMS will exclude the 340B units starting in January 2026. CMS recognizes that requiring a 340B indicator to be included on the prescription drug event (PDE) record is the most reliable way to identify units that are subject to a 340B discount that are dispensed under Medicare Part D. Such an indicator would need to be included on all pharmacy claims where a drug subject to a 340B discount was dispensed to a Part D beneficiary so that units submitted on such claims can be excluded from the inflation rebate calculation. CMS is soliciting comment on the proposed 340B identifier.

BIO Comment: BIO agrees that a required 340B indicator on the PDE record and requiring such an indicator on all pharmacy claims is essential to ensuring that Part D inflation rebates are not paid on drugs dispensed under the 340B program, and we urge CMS to move forward with such an approach. In addition, we urge CMS to (1) establish a *non*-340B claims modifier (such that either a 340B claims modifier or a non-340B claims modifier is included on each claim), and (2) specify that, where a claim fails to accurately include either modifier, it will be deemed incomplete and unpayable.

It is also essential for 340B covered entities to provide CMS and manufacturers access to claims level data. Access to such data is necessary for manufacturers to validate that inflation rebate invoices reflect adherence to the statutory prohibition on inflation rebates on 340B units. The value of this approach is acknowledged in CMS's own guidance to states, "Best Practices for Avoiding 340B Duplicate Discounts in Medicaid" (January 2020). CMS should also consider further steps to help verify the accuracy of 340B claims modifiers. Such steps include the creation of a 340B claims data clearinghouse operated by an objective third party administrator, regular audits by manufacturers or by CMS, and penalties for inaccurate use of the modifiers.

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It is important to note that it would not be possible to identify 340B utilization by taking a percent of claims approach and generally identifying utilization. . . The approach would not be accurate enough, and manufacturers do not have access to validated claims data needed to conduct such an analysis. Specifically, manufacturers are blind to noncontracted Part D sales and thus could not accurately determine the total Part D sales needed for this ratio's calculation. Taking a percent of claims approach could result in CMS over or under identifying 340B claims, and could impact the accuracy of rebate. Such a negative impact becomes even more problematic absent procedural safeguards to help ensure information verification and correction as needed."

BIO urges CMS to move forward with all such requirements well in advance of 2026. Such requirements are necessary to enforce the statutory prohibition on inflationary rebates on 340B units, as well as the requirement that manufacturers offer eligible entities the lower of the 340B ceiling price or the "maximum fair price," but not both.

Finally, in light of certain state laws that seek to prohibit the use of a 340B claims modifier, CMS should clarify that its required use of a such a modifier preempts any such state law.

<u>40.5 Reducing or Waiving the Rebate Amount for Part D Rebatable Drugs in Shortage and Cases of Severe Supply Chain Disruption for Biosimilars or Generics</u>

To determine when a Part D rebatable drug is described as currently in shortage during an applicable year, CMS states that it intends to use the FDA drug shortage lists. CMS is soliciting comment on the amount and duration of the reduction that should be applied, and scenarios when a waiver should be considered. CMS notes that it is required to reduce or waive the rebate amount for an applicable period in the case of a generic Part D rebatable drug or biosimilar when CMS determines that there is a severe supply chain disruption during the applicable period, such as a severe supply chain disruption caused by a natural disaster, or another unique or unexpected event. CMS is soliciting comment on the amount by and duration for which CMS might reduce or waive the rebate amount in this scenario and a range of definitional issues.

BIO Comment: We support CMS's efforts to ensure inflation rebates will be waived or reduced during a shortage situation. We also support CMS's general approach as outlined and encourage CMS to consider flexible parameters in implementing these provisions. With respect to CMS's consideration of an approach where the amount of the reduction in the rebate amount would

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decrease over time, CMS's reasoning is unclear. If a shortage persists, rebate reductions (or waivers) should be maintained and not reduced.

50.1 Timing of Rebate Reports and Payment, 50.2 Restatements and True-up Rebate Report, 50.3 Manufacturer Suggestions of Calculation Errors, 50.4 CMS Identification of Errors

CMS intends to provide all manufacturers of Part D rebatable drugs with a Preliminary Rebate Report within 6 months of the end of each applicable period. Manufacturers would have 10 days from the date of receipt of a Preliminary Rebate Report to review and suggest any calculation errors. CMS also notes its intent to perform a one-time true up recalculation to allow for the revisions to occur based on changes in data reported by manufacturers. CMS intends to conduct a restatement process to true-up rebate amounts for all manufacturers one year after the rebate amounts are invoiced via the Rebate Report to manufacturers.

BIO Comment: We note CMS's reference to the IRA provision that allows rebate reports for 2023 and 2024 to be delayed until December 31, 2025. We also note that in CMS's February 9, 2023, press release, the agency states it intends to send first invoices to companies in 2025, but no specific date is provided. We urge the agency to provide clarity regarding its expected date of initial Part D invoicing, specifically whether invoicing will be delayed until December 31, 2025.

We appreciate CMS's recognition that a process will be necessary to rectify calculation errors in providing for the preliminary rebate report. We note that 10 days is an unduly short turnaround time for review of this report and urge more time for manufacturer review. Specifically, 45 days is preferred, and the review time should be no less than 30 days. This amount of time is necessary for several of reasons. Manufacturers will first have to run data and otherwise take steps to confirm that the drug is a Part D rebatable drug, to confirm whether the units identified in the preliminary report are rebatable, to confirm whether the payment amounts and inflation adjustment identified in the preliminary report are correct, and to verify whether the rebate amount set forth in the preliminary report is properly calculated. In addition, 10 days does not align with industry standards to allow for accurate reporting and invoicing. For example, 30 days is standard for reporting quarterly or monthly average manufacturer price. As another example, pharmacy benefit managers/health plans allow manufacturers to identify errors and withhold rebates on disputed utilization at the time of payment which is generally for 30 or more days.

In addition, to ensure timely review by manufacturers of these preliminary reports, we encourage CMS to establish a predictable date during each rebate cycle when the preliminary report will be provided. Further, to make this pre-invoice dispute resolution process

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meaningful, we urge CMS to include in the preliminary reports all information, calculations, and supporting documentation necessary for a manufacturer to be able to make an informed determination as to whether the intended invoicing is correct or incorrect. We also urge CMS to be flexible in its approach, particularly in the initial years of implementation.

We also appreciate CMS recognition of the need for a reconciliation ("true-up") process after final rebate reports are sent that accounts for both underpayments and overpayments. CMS proposes that such a process would occur one year after final rebate reports are sent. We support an approach that accounts for both underpayments and overpayments. We also recommend that CMS utilize a preliminary true-up report process comparable to the preliminary rebate report process recommended above. Such process should similarly ensure that, through the preliminary reports, manufacturers have access to all data necessary to ensure meaningful review (e.g., claims-level data).

Regarding timing of the "true-up" process, we urge CMS to provide for reconciliation up to three years after final rebate reports are sent. Oftentimes, manufacturer restatements of pricing data do not occur until well after the one-year mark. Thus, a true-up process at one year would not advance the goal of enhancing the accuracy of rebate liability. Allowing for restatement at the three-year mark would be consistent with restatement timelines under the Medicaid Drug Rebate Program.

We note that, in Sec. 50.5 (CMS Identification of Errors), CMS states that it reserves the right to update or change the rebate amount or the true-up amount at any point time – including after final rebate reports are sent or after the "true-up" process ends. In the interests of finality and fairness, any update or change to rebate liability should be limited to the true-up process recommended above. Notably, our recommended enhancements to the pre-invoice dispute resolution process and to the true-up process would greatly mitigate – if not eliminate – any errors and therefore any need for additional review.

Finally, CMS states that it may consider, at its own discretion, calculation errors identified by manufacturers in the preliminary rebate and true-up rebate reports. CMS also states it expects to issue additional information regarding how manufacturers may submit information on such errors. In the spirit of transparency, we strongly urge the agency to consider use of an informal dispute resolution process. Such an approach is critical in terms of resolving identified errors in a clear, consistent, and transparent manner.

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60. Enforcement of Rebate Amount Payments by Manufacturers: Civil Monetary Penalties (CMPs)
CMS states that a manufacturer of a Part D rebatable drug that has failed to comply with the requirement) to pay an inflation rebate would be subject to a CMP. CMS states that in accordance with section 1128A of the Act, it will provide notice to the manufacturer with information regarding the CMP, including the opportunity to request a hearing.

> ***BIO Comment:*** We urge CMS not to subject manufacturers to inflation rebate penalties until final regulations are issued and in place. Additionally, we stress the importance of due process, and suggest that CMS establish clear notice, procedures and timeframes for manufacturers to respond to CMP notices, request hearings before an administrative law judge (ALJ), and appeal ALJ decisions to the HHS Departmental Appeals Board before seeking review in the U.S. Court of Appeals, as is part of existing procedures for Medicare Advantage plans, Part D prescription drug plan sponsors, and CMP procedures issued by OIG.

Other Issues
We recommend that CMS monitor AMP fluctuations and impacts on patient access. AMP can fluctuate, in some cases quite significantly, in the absence of pricing changes by the manufacturer and in some cases for reasons outside the manufacturer's control. For example, if a major provider or payer terminates its contract with the manufacturer, AMP values can fluctuate dramatically, resulting in an inflation penalty even when the drug's list prices do not change. In some cases, it is possible that the inflation rebates owed for a product could exceed total net sales. This result is not only inconsistent with the intent of the statute, but we are also concerned that paying inflation rebates under these conditions may result in reduced patient access to therapy. We therefore recommend that CMS carefully monitor AMP fluctuations and identify any flexibilities to ensure the inflation rebate calculation does not harm patient access. We would be happy to work with the agency to identify potential solutions in that regard.

Thank you for the opportunity to comment. We look forward to ongoing discussions and engagement on these important issues.

Sincerely,

/s/
Crystal Kuntz
VP, Healthcare Policy & Research

/s/
Jack Geisser
Sr. Director, Healthcare Policy, Medicaid & State Initiatives

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March 10, 2023

Dr. Meena Seshamani, MD, PhD
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted by email to IRARebateandNegotiation@cms.hhs.gov

RE: Medicare Part D Inflation Rebate Comments

Dear Dr. Sheshamani,

On behalf of Bi-State Primary Care Association, thank you for the opportunity to provide input into CMS' plans for implementing the Medicare inflationary rebates established under the Inflation Reduction Act.

Established in 1986, Bi-State is a nonpartisan, nonprofit 501(c)(3) charitable organization promoting access to effective and affordable primary care and preventive services for all, with special emphasis on underserved populations in Vermont and New Hampshire. Bi-State's combined Vermont and New Hampshire membership includes 21 Federally Qualified Health Centers (FQHCs), one Look-Alike, Planned Parenthood of Northern New England, Vermont's Free and Referral Clinics, North Country Health Consortium, Community Health Access Network, and the Area Health Education Centers in New Hampshire.

As you know, FQHCs are the backbone of the health care safety net, providing high-quality, affordable care to over 30 million medically-underserved patients, regardless of whether they have insurance or their ability to pay. FQHCs serve nearly 1 in 3 Vermonters and 1 in 10 Granite Staters. We serve individuals in all counties within New Hampshire and Vermont providing care to all patients regardless of ability to pay.

Our FQHCs provide comprehensive, whole person care and offer a broad array of services to their patients. FQHCs offer a broad range of services, including primary care, dental, mental health and substance use disorder, and pharmaceuticals. Many of these services – and the sliding fee discounts that make them affordable for our patients -- are supported by savings generated through the 340B drug discount program. In New Hampshire and Vermont, the 340B program provides support for numerous services including, but not limited to: patient access to discounted prescriptions, dental programs, transportation services, to support medication assisted treatment, to provide language access services, to support management of chronic conditions, and to support mobile units to go out into the community. Nationally, FQHCs rely on contract pharmacy arrangements to dispense roughly 50-60% of the 340B drugs provided to their patients – the highest percentage of any type of 340B provider. FQHCs in NH and VT

endeavor to identify any pharmacy in their service area so that patients can get the prescriptions they need close to home. The 340B savings generated at contract pharmacies support many services that the FQHC would otherwise be unable to provide. Given the importance of 340B savings – including those generated by contract pharmacies – we were very concerned to hear that CMS is considering requiring an indicator (also known as modifier) on all claims for Part D prescriptions that were filled with 340B drugs.

As discussed in detail in comments submitted by other members of the FQHC community, FQHCs' experience clearly indicates that requiring a 340B indicator (also known as a modifier) on Part D drugs would:

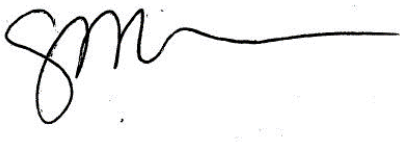
a. Result in data that are highly unreliable.
b. Force FQHCs to shut down many of their contract pharmacy arrangements for Part D drugs, leading to an overall loss in 340B savings and subsequent reduction in services provided to underserved patients.

Instead of a modifier, we recommend that CMS implement a "clearinghouse" model for identifying 340B drugs covered by Part D. Compared to a modifier requirement, a clearinghouse would:

a. Produce much more reliable data.
b. Be significantly less labor-intensive.
c. Preserve the ability of FQHCs and other 340B providers to rely on contract pharmacies to dispense 340B drugs to Part D enrollees, thereby avoiding reductions in access.
d. Could be expanded to include 340B drugs dispensed to Medicaid patients.

Thank you for your consideration of our serious concerns about the modifier model, and our proposed alternative. If you have any questions about our comments, please contact me at gmaheras@bistatepca.org or 802-229-0002 x 218.

Sincerely,



Georgia J. Maheras, Esq.
SVP, Policy and Strategy

Bristol Myers Squibb™

VIA ELECTRONIC DELIVERY to: IRARebateandNegotiation@cms.hhs.gov

March 10, 2023

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Part B and Part D Inflation Rebate Guidance Comments

Dear Dr. Seshamani:

Bristol Myers Squibb (BMS) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) *Medicare Part B Inflation Rebates Paid by Manufacturers Draft Guidance* ("Part B Draft Guidance") and *Medicare Part D Inflation Rebates Paid by Manufacturers Draft Guidance* ("Part D Draft Guidance").

At BMS, we are inspired by a single vision—transforming patients' lives through science. We are in the business of breakthroughs—the kind that transform patients' lives through lifesaving, innovative medicines. Our talented employees come to work every day dedicated to the mission of discovering, developing, and delivering innovative medicines that help patients prevail over serious diseases. We combine the agility of a biotech with the reach and resources of an established pharmaceutical company to create a leading global biopharma company. In oncology, hematology, immunology, and cardiovascular disease—with one of the most diverse and promising pipelines in the industry—we focus on innovations that drive meaningful change.

We bring a human touch to every treatment we pioneer. With great pride, we celebrate each time our patients take back their lives. Our shared values are central to who we are, what we do, and how we do it. Passion, innovation, urgency, accountability, inclusion, and integrity ground our work and unite our community. We never give up in our search for the next innovation that could mean new hope for patients who are urgently seeking new treatment options today.

BMS appreciates the opportunity to provide the following comments on the Part B and Part D Draft Guidance documents, with our comments intended to help CMS improve transparency and clarity of the program. Key comments include:

- We support both the proposed establishment of a pre-invoice dispute resolution process and the proposed true-up of both underpayments and overpayments, but we are concerned with CMS' proposed timelines for reviewing and verifying Preliminary Rebate and True-Up Reports. We urge CMS to provide as much clarity and flexibility as possible throughout this process, particularly for the initial rebate periods. We strongly encourage CMS to create a meaningful dispute resolution process to help provide for essential accuracy and transparency.

- We support CMS' proposed steps toward excluding 340B units from the rebate calculations, but we offer specific recommended enhancements to the Agency's proposed approach: mandatory and enforceable 340B *or* non-340B claims modifiers at the point-of-sale, visible claims data, a claims data clearinghouse, and a rebate.
- We encourage CMS to offer maximum flexibility with respect to drugs and biologicals experiencing shortages to limit patient access issues, as shortages are complex and highly disruptive to the marketplace.
- We urge CMS to exclude Medicare Advantage (MA) units from the inflation rebate calculation.
- Finally, we ask CMS to issue Final Guidance promptly after the Agency carefully considers, and publicly responds to, stakeholder comments.

I. Medicare Part D Guidance

Use of PDE Data to Determine Total Units Subject to Rebate and Crosswalk to AMP Units (40.2.5)
"CMS is exploring the option of adding a field to the PDE file layout to collect how the amount reported in the PDE 'quantity dispensed' field is measured (e.g., each, milliliter, gram). This additional data element would facilitate the identification of unit types for each NDC and add an additional level of assurance for CMS and manufacturers that the unit used to calculate inflationary rebates is accurate."

BMS agrees with the Agency's proposal to add a field to the Prescription Drug Event (PDE) file layout to collect how the amount reported in the PDE "quantity dispensed" field is measured for greater transparency. Ideally, this would occur through very specified implementation, and we encourage CMS to consider a standardized, transparent approach for reporting total units. For instance, CMS could consider specifying a particular unit of measure (UOM), not unlike what plans do today in various circumstances, and as the Agency does under the Medicaid Drug Rebate Program (MDRP). Then, CMS could convert this standardized unit to average manufacturer price (AMP) units in a transparent way that manufacturers could verify, and should be permitted to verify, as necessary to help ensure accuracy. We support CMS adding the new field as soon as possible, and, if Part D plans resubmit file information, such resubmissions should be done in a consistent manner.

From a process standpoint, we urge CMS to publish a recommended UOM in the Final Guidance or in a transmittal shortly thereafter. And we encourage front-end standard development to establish aligned processes prior to a drug launch, in order to avoid errors and avoid resubmission or reconciliation at a later time. Further, manufacturers working with the National Council for Prescription Drug Programs (NCPDP) framework can work to align on new and enhanced standards for the industry.

At the same time, while we support adding an additional field to the PDE, we acknowledge that we often see unit reporting errors in both the Medicare and Medicaid programs, particularly in determining total quantity units. BMS is concerned that, without proper safeguards in place, these types of errors in PDE will also carry over into this new reporting system. Additionally, even if conversion is still needed after this reporting requirement is implemented, this conversion and the accompanying crosswalk need to be clarified in the Preliminary Rebate Reports, in a manner that allows for sufficient manufacturer understanding and assistance in identifying calculation errors. Given the strong concern for potential errors, we request this process of converting billable units be as transparent as possible, especially if plans report in a different field measurement.

We also understand that, beginning in 2026, 340B units will be removed from the total units in the PDE. For reconciliation purposes by all stakeholders, BMS recommends, at a minimum, that the total volume of 340B units removed should be included in a supporting document with the Preliminary and Final Reports, and that these units be aligned in terms of the UOM. This recommendation is in addition to other 340B policy proposals noted elsewhere in our comments.

In summary, BMS supports the required new field in the PDE file layout to help ensure clarity on unit type, as this is a necessary step to ensuring that there are no over- or under-charges resulting from unit determination in the rebate calculation. We also urge the Agency to consider additional steps to create a standardized and transparent process.

Exclusion of 340B Acquired Units from Part D Rebatable Drug Requirements (40.2.7)

"Section 1860D-14B9(b)(1)(B) requires that beginning with plan year 2026, CMS shall exclude from the total number of units for a dosage form and strength for a Part D rebatable drug, with respect to an applicable period, those units for which a manufacturer provides a discount under the 340B Drug Pricing Program."

BMS appreciates CMS' proposal to require a 340B indicator be included on the PDE record as a way to help exclude 340B units from the total number of units on which a Part D rebate is invoiced beginning in 2026. We, too, believe that the use of a modifier is important, and we support CMS' directional approach in the Draft Guidance. However, BMS does not agree that a 340B indicator, alone, will adequately identify and exclude 340B units from the rebate calculation. As compelling evidence shows, far more is needed.

Given the size and scope of the potential 340B overlap, it is critical for CMS to establish a robust process to appropriately identify 340B-Medicare units at the outset of implementing the IRA. The Medicare-340B overlap is significant. According to a new analysis by IQVIA, for example, the estimated 340B overlap in Part D is 40.1% and in Part B is 36.3%, meaning that $34.0B to $37.5B of sales may be at risk for 340B-inflation rebate duplicate discounts.[1]

That same IQVIA analysis found that, for Medicare Part B claims of 340B hospitals involving pass-through and separately payable drugs where reporting was mandatory, 60-89% of drug treatments used modifiers. But, when reporting was optional, rates fell below 20%. For self-administered drugs across all payers, only 4% of branded, 340B-eligible pharmacy claims used a 340B modifier, rising to 50% for Medicaid claims at entity-owned pharmacies and falling to less than 1% at contract pharmacies. Also, 340B modifiers were sometimes used for products that were not 340B-eligible such as test strips, swabs, and vaccines.[2] The authors note: "[M]odifier usage . . . fell below 20% when it was optional, and dropped below 1% when it was impractical. Two factors appear to be associated with the increased usage of modifiers: mandating modifier reporting, and identifying the 340B status of the claim prior to or at the point of sale."[3]

BMS strongly asserts that addressing transparency challenges, such as those highlighted in the IQVIA report, is critical to successful IRA operationalization. It is important to note that it would not be

[1] IQVIA, "Can 340B Modifiers Avoid Duplicate Discounts in the IRA?" (February 21, 2023), *available at* https://www.iqvia.com/locations/united-states/library/white-papers/can-340b-modifiers-avoid-duplicate-discounts-in-the-ira.
[2] *Id.*
[3] *Id.*

possible to identify 340B utilization by taking a percent of claims approach and generally identifying utilization. While IQVIA estimated the overlap in the cited study, this analysis was extremely complicated and represents all-market data, and the approach has limitations cited in the study. The approach would not be accurate enough, and manufacturers do not have access to validated claims data needed to conduct such an analysis. Specifically, manufacturers are blind to noncontracted Part D sales and thus could not accurately determine the total Part D sales needed for this ratio's calculation. Taking a percent of claims approach could result in CMS over- or under-identifying 340B claims and could impact the accuracy of rebates. Such a negative impact becomes even more problematic absent procedural safeguards to help ensure information verification and correction as needed.

Accordingly, BMS strongly supports additional safeguards to help ensure that 340B units are identified: mandatory and enforceable 340B and non-340B modifiers at the point-of-sale; visible claims data; and a claims data clearinghouse. A robust process to prevent duplication and improve the integrity of the process must be in place to help ensure fairness and transparency in the program.

- **Mandatory and enforceable 340B and non-340B modifiers at the point-of-sale:** BMS suggests that CMS require indicators to identify *both* 340B *and* non-340B units in the PDE record at the point-of-sale. To better enable enforcement of the 340B indicator, we ask CMS to require pharmacies to accurately use either the 340B or the non-340B modifier for a claim to be considered complete and eligible for reimbursement. BMS notes that this approach would align with the approach taken by the Agency with respect to the discarded drug modifier, where providers and suppliers submitting claims for single-dose container or single-use package drugs under Part B must use the "JW" modifier to indicate the amount of a medicine that was discarded, or, effective July 1, 2023, use the "JZ" modifier to indicate that no amount of drug was discarded.[4]

  Additionally, CMS could support mandating 340B and non-340B modifiers on the PDE record for all claims (not just Part D claims). This may make it possible to reconcile that the total 340B volume sold by manufacturers is generally tracking with total 340B volume dispensed, which is otherwise difficult today. The benefit to CMS is that data would be available in the market to inform whether the 340B claims are completely being reported. If those totals between volume dispensed and claims volume are aligned, stakeholders can have greater confidence that the 340B claim volume in any payer channel is complete and accurate. This may in turn help provide much needed transparency across the entire 340B program.

- **Visible claims data:** We also believe it is essential for CMS to provide manufacturer access to visible claims level data, which would include the 340B and non-340B claims modifier. Claims-level data are essential to upholding the statutory prohibition to remove 340B units from the inflation rebate calculation, and for manufacturers to validate that invoices reflect adherence to that statutory prohibition.

- **Claims data clearinghouse:** BMS strongly encourages CMS to further create a robust approach to transparency by utilizing a claims data clearinghouse. BMS supports the ability of a claims clearinghouse, as well as the manufacturer, to have access to visible (not de-identified), minimally necessary claims. We note that a clearinghouse approach could allow for the

[4] CMS, "Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy: Frequently Asked Questions," *available at*: https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf.

necessary transparency via the Health Insurance Portability and Accountability Act (HIPAA) health care operations exception. The clearinghouse would act as a claims data verifier and determine whether a claim is subject to 340B pricing or not, furthering program integrity and accuracy.

While CMS is under no obligation to exclude 340B units prior to 2026, BMS strongly encourages CMS to begin implementing the necessary predicates for this exclusion as quickly as possible, and well in advance of 2026. BMS also recognizes that many states have banned the use of 340B modifiers; accordingly, we agree with PhRMA's comments and recommend that CMS make clear that the requirement for a 340B indicator preempts any state or local law or regulations that would conflict with or frustrate compliance with this requirement with respect to Part D prescription drug plans (PDPs) or Medicare Advantage prescription drug (MA-PD) plans, including state laws applicable to pharmacy benefit managers (PBMs) or other intermediaries. The Social Security Act (SSA) provides that the standards established under Part D shall "supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency)" with respect to PDPs offered by Part D sponsors and MA-PD plans.[5] Under this broad preemption authority, federal standards directly governing an entity's conduct with respect to PDPs and MA-PDs supersede state laws.[6]

Reducing or Waiving the Rebate Amount in the Case of a Part D Rebatable Drug Currently in Shortage on the FDA Shortage List (40.5.1)

"To determine when a Part D rebatable drug is described as currently in shortage on a shortage list under section 506E of the FD&C Act at any point during the applicable period, CMS intends to use the FDA drug and biological shortage lists, which are authorized under section 506E of the FD&C Act."

BMS appreciates CMS' intent to allow for financial relief for manufacturers with Part D products in shortage as reflected by the Food and Drug Administration's (FDA's) shortage list.[7] We request that the Part D and Part B approaches be the same.

To implement this requirement, BMS recommends that CMS waive the full rebate amount for the applicable period when a Part D rebatable drug is on a shortage list. We ask CMS to waive the rebate amount for the full year, but, at a minimum, CMS must waive the rebate for the quarter within which the shortage occurred and as long as the shortage lasts. We are concerned that any detrimental effects shortages may have on providers and patients would only be exacerbated by inflation rebate obligations.

BMS supports CMS' proposal to create a limited standard reduction in the rebate amount that would include a reporting process by which manufacturers could request an increased reduction or waiver for certain types of shortages (CMS' "second option").

In cases where not all the NDC-11s for the Part D rebatable drug are on the shortage list, BMS recommends that CMS waive the rebate amount for a drug for the applicable period regardless of

[5] SSA § 1860D-12(g) (incorporating SSA § 1856(b)(3)).

[6] *See, e.g., Uhm v. Humana, Inc.*, 620 F.3d 1134 (9th Cir. 2010) (Part D preemption extends to parent organization of Part D sponsor); *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 971–72 (8th Cir. 2021) (Part D preemption should be considered "field" preemption; state laws are preempted as applied to Medicare Part D plans if they "(1) regulate the same subject matter as a federal Medicare Part D standard (in which case they are expressly preempted), or (2) otherwise frustrate the purpose of a federal Medicare Part D standard (in which case they are impliedly preempted).").

[7] As established under section 506E of the Federal Food, Drug, and Cosmetics Act.

whether all NDC-11s are listed as "current" on the FDA shortage lists, as a shortage for one NDC-11 can have an effect on the availability of other NDC-11s. We further assert that factors that contribute to drug shortages are complex and multidimensional, and the uneven sales patterns of drugs in shortage can cause fluctuations in AMP outside of a manufacturer's control. Manufacturers should not be penalized for these unintended market distortions.

Finally, we disagree with CMS' assumption that reducing or waiving inflation rebates during a shortage period would incent a manufacturer to intentionally maintain a rebatable drug on the shortage list to avoid the inflation rebate obligation. Drug shortages are incredibly complex. Neither is intentionally extending a shortage economically advantageous for manufacturers nor, above all, would it be responsible to patients.

We thank CMS for consideration of this topic and appreciate CMS' intent to allow for financial relief for manufacturers with Part D products in shortage.

Ensuring Integrity of Part D Drug Inflation Rebate Payments (50)

"Manufacturers of Part D rebatable drugs that owe inflation rebates would be required to pay such rebates not later than 30 days after receiving an invoice, referred to as a Rebate Report, for an applicable period or shall be subject to a CMP equal to 125 percent of the rebate amount specified for each such drug in the Rebate Report in addition to the rebate itself."

BMS expresses serious concern with CMS' proposals related to invoicing, verifying, and paying inflation rebates. In general, BMS asks CMS for the maximum amount of flexibility possible, particularly in the initial rebate periods, to verify and pay inflation rebates. To further the goals of clarity and accuracy, we also urge CMS to establish a meaningful informal dialogue through which manufacturers can dispute and rectify rebate assumptions, data, and calculations. Our specific comments on these topics are below.

Timing of Rebate Reports and Payment (50.1) and Manufacturer Suggestions of Calculation Errors in Preliminary Rebate Reports and Preliminary True Up Reports (50.3)

"CMS intends to provide all manufacturers of Part D rebatable drugs with a Preliminary Rebate Report within 6 months of the end of each applicable period. Manufacturers would have 10 days from the date of receipt of a Preliminary Rebate Report to review and suggest any calculation errors . . . . Manufacturers should notify CMS, share the suggestion of a calculation error, and provide supporting documentation (if applicable) within 10 days after receiving their Preliminary Rebate Report or Preliminary True Up Rebate Report."

We appreciate CMS' recognition of the need for a pre-invoice dispute resolution mechanism. The Agency's guidance memorandum suggests that CMS will share Preliminary Rebate Reports with manufacturers no later than six months after the end of each rebate quarter,[8] yet manufacturers will have just 10 days to review the Report for potential errors and/or statutory exclusions that were not applied. CMS also notes its intention to take a similar approach with respect to the Preliminary True Up Rebate Reports—where approximately one year after CMS sends a final Rebate Report to manufacturers and rebate amounts have been paid, CMS plans to conduct a one-time true-up of the rebate amounts, and manufacturers again would only have 10 days to review for calculation errors,

[8] Under section 1860D-14B(a)(3) of the SSA, CMS may delay invoicing manufacturers until December 31, 2025 for applicable periods beginning October 1, 2022 and October 1, 2023.

which the Agency would consider at its discretion. While we appreciate and support the opportunity to report back with potential errors, BMS has serious concerns about the timeframe and process being proposed.

BMS maintains that 10 days is not sufficient to review the Preliminary Rebate Report. We would recommend, at a minimum, that manufacturers have at least 30 days to review and corroborate Preliminary Rebate Reports appropriately and accurately. We note that a 30-day review period would align with the time that manufacturers have to calculate AMP and Best Price under the MDRP. To accommodate this additional time, CMS likely would need to move the deadline for the Preliminary Rebate Report closer to four months after the end of the rebate period. BMS strongly urges CMS to clearly state, in advance, on what date the report will be furnished during a rebate cycle. Such predictability will allow manufacturers to be better prepared to review and respond to CMS with any recommended changes in the review time frame.

In the Draft Guidance, CMS notes that Preliminary Rebate Reports and Rebate Reports would identify only the following information: (1) the total number of units for each dosage form and strength for the Part D rebatable drug for the applicable period; (2) the amount, if any, of the excess of the annual manufacturer price (AnMP) for each dosage form and strength of the Part D rebatable drug for the applicable period (the amount calculated per section 40.2); and, (3) the rebate amount for each dosage form and strength of such Part D rebatable drug for the applicable period.

BMS asks CMS to disclose as much information as possible in the Preliminary Rebate Report about how it arrived at the anticipated rebate liability, to enable an informed response from the manufacturer and ensure greater transparency and rebate accuracy validation. For example, as this proposal currently is written, preliminary data reports would not identify rebate component information, such as details ensuring a clear understanding of the rebate calculation, the AnMP and benchmark AnMP, and units and unit type conversion/crosswalk. Additionally, the guidance offers no mention of supporting documentation such as a more detailed PDE/Units report, other than the aggregate total on the invoice. Without these critical data elements, the integrity of the program and transparency in invoice data cannot be achieved.

To that end, and at a minimum, BMS encourages the Agency to share with manufacturers:

- The benchmark price calculated by the Agency for each dosage form and strength, as well as the quarterly AMP and AMP unit figures used in calculating the benchmark price;
- The AnMP calculated by the Agency for the applicable period for each dosage form and strength, as well as the quarterly AMP and AMP unit figures used in calculating the AnMP;
- The benchmark and applicable period Consumer Price Index for All Urban Consumers (CPI-U) values used by the Agency;
- The billing unit reported on the FDA's Comprehensive NDC SPL Data Elements File;
- A summary of units dispensed during the applicable period; and
- Supporting claims-level data at the NDC-11 level with:
    - The number of units dispensed during the applicable period;
    - Dispense date;
    - Indicators for claims excluded due to being subject to 340B pricing as of 2026; and
    - Indicators for claims reduced or excluded due to product shortage.

Like with any new program, manufacturers will need a flexible transition period at the onset of this new program to ensure operational issues can be met. Accordingly, we hope that CMS provides greater flexibility with respect to verifying and paying rebate invoices.

BMS supports the proposed establishment of an informal dispute resolution process that occurs in advance of the issuance of a rebate invoice. The limitation on judicial and administrative review does not prevent CMS from establishing a process for manufacturers to dispute incorrect invoices, but this guidance does not address potential issues manufacturers may want to flag for the Agency beyond "calculation errors." We strongly advocate that the Agency implement a fulsome informal dispute process to ensure fairness and program integrity in the inflation rebate program.

CMS Identification of Errors (50.4)

"CMS is soliciting comments on section 50 of the memorandum regarding processes to ensure the integrity of the rebate amount determination process."

BMS strongly opposes the Agency's open-ended approach to continuously subjecting manufacturers to revisions without any statute of limitations or intent standard. Manufacturers deserve finality in determining how much will be owed in inflation rebates. As such, we would suggest that potential over/underpayments be clearly identified. In the case where there is an expected subsequent year invoice, the difference could be simply rolled into that next year's rebate invoice, which would align with the release of the True-Up Rebate Report language which comes "no later than a year" after initial invoice, while sections 50.1 and 50.2 indicate true-up would come "one year after" or "approximately one year after." CMS could otherwise resolve the disparity within the following year, in the absence of such a corrective invoice. In any event, clearly identifying these over/underpayments would help with the reconciliation of the total rebate amount.

BMS asks CMS to specify that the true-up would be conducted no later than three years after the invoice of the Part D inflation rebate amount to better align with MDRP restatement periods, which would also serve to enhance rebate liability accuracy. As the Agency builds out its reconciliation process, BMS supports the proposed true-ups of *both* underpayments *and* overpayments.

Enforcement of Rebate Amount Payments by Manufacturers: Civil Monetary Penalties (60)

"A manufacturer of a Part D rebatable drug that has failed to comply with the requirement at section 1860D-14B(a)(2) to pay an inflation rebate amount equal to the amount invoiced for each dosage form and strength with respect to such drug for an applicable period as reported by CMS in the Rebate Report and/or True Up Rebate Report would be subject to a CMP."

The Agency guidance on civil monetary penalties (CMPs) does not specify if the penalty would be applied only to the unpaid portion of the rebate amount. To the extent that CMS has the authority to do so, we support CMPs only applying to this unpaid portion and would request that CMS clarify this in the Final Guidance.

II. Medicare Part B Guidance

Removal of 340B Units (50.8.1)

"Section 1847A(i)(3)(B)(ii)(I) of the Act specifically excludes units of drugs for which the manufacturer provides a discount under the 340B program from the units of drugs for which a manufacturer may otherwise have a part B inflation rebate liability."

BMS appreciates CMS' proposal to require a 340B indicator to be included on the claims form by *all* 340B covered entities as a way to exclude 340B units from the total number of units for a Part B rebatable drug. We also support CMS' interim approach to excluding 340B units from the calculation with respect to those 340B covered entities to which such requirement will not apply until 2024, as well as support the proposed approach for 2023. We, too, believe that the use of a modifier is important, and we support CMS' directional approach in the Draft Guidance; however, BMS does not agree that a 340B indicator alone will adequately identify and exclude 340B units from the rebate calculation and urges CMS to implement mandatory and enforceable 340B and non-340B modifiers at the point-of-sale and share visible claims data through a claims data clearinghouse.

We ask that CMS refer to our comments in the Part D portion of this letter for BMS' response to the guidance regarding the exclusion of 340B units from the calculation.

Removal of Units with a Rebate Under Section 1927 of the Social Security Act (50.8.2)

"In order to receive payment under Medicaid for covered outpatient drugs, manufacturers must participate in the Medicaid Drug Rebate Program (that is, have a drug rebate agreement in effect) and are required to report certain pricing and drug product information and pay Medicaid drug rebates for covered outpatient drugs dispensed and paid for under the Medicaid state plan."

BMS supports CMS' proposal for excluding units where a Medicaid rebate is paid. The Agency should ensure identification and exclusion of Medicaid managed care (MCO) and fee-for-service (FFS) claims from the rebate calculation. BMS believes that it is unclear how dual eligible claims will be removed from inflation rebates, and CMS could consider requiring a mandatory field on claims to indicate Medicaid-Medicare dual eligibility. This field should not be left blank and must be populated as "yes" or "no."

Operational Considerations Related to the Inclusion of Units Furnished to Beneficiaries Who Are Enrolled in Medicare Advantage Plans (50.8.5)

"Section 1847A(i) of the Act requires the manufacturer of a Part B rebatable drug to pay a rebate that, generally speaking, is calculated on the basis of the total number of units of that drug that were furnished in a calendar quarter, multiplied by the excess payment amount for the drug over a statutorily-defined inflation-adjusted payment amount."

BMS strongly opposes CMS' implicit purported statutory interpretation in the Part B Draft Guidance that would include MA units in the inflation rebate calculation. CMS does not have the authority to include units furnished to MA enrollees in the calculation of Part B rebates, and, as such, we respectfully request that CMS clarify that the Part B inflation rebate calculation includes only units of drugs furnished under Part B, not those furnished under MA.

BMS notes that the statutory definition of a "Part B rebatable drug" is expressly limited to certain drugs "for which payment is made *under this part*" (emphasis added)—where "this part" refers to Medicare Part B.[9] Existing statutory provisions make clear that, when Congress refers to payment "under this part"

[9] SSA § 1847A(i)(2). *See also* SSA § 1847A(i)(3)(B)(ii)(II): "Moreover, the 'total number of units' considered in the Part B inflation rebate calculation specifically excludes 'units for such [HCPCS] code of such drug furnished during such calendar quarter. . . that are packaged into the payment amount for an item or service and *are not separately payable*'" (emphasis added). BMS supports PhRMA's comments on this point regarding MA units not being applicable for the inflation rebate calculation.

when discussing Part B, it means payment under the Part B benefit alone and not "payment under Part B or Part C." For example, the average sales price (ASP) statute applies to specified types of drugs furnished after 2004 "for which payment may be made *under this part*" (emphasis added).[10] CMS has correctly understood this language to apply only to drugs paid under Part B, and not as requiring that Part C plans use the ASP-based methodology to pay their network providers for Part B drugs furnished to plan enrollees. In light of the clarity of the statute, we urge CMS to remove MA units from the rebate calculation, consistent with plain Congressional intent.

BMS notes that the Part B inflation penalty was intended to address price growth exceeding inflation under the ASP payment methodology. As noted, however, MA plans are not required to use ASP-based payment, which further necessitates the need for CMS to revise its proposal to actually exclude MA units from the inflation rebate calculation.

In sum, BMS strongly opposes CMS' implicit proposal to include MA units in the inflation rebate calculation as a matter of law. In addition, we, too, agree with CMS that the inclusion of these units would pose "significant operational complexities," including data to determine the number of units and remove excluded units. For both of these reasons, CMS should abandon this approach, and exclude MA units from the calculation.

Reduction or Waiver of the Rebate Amount for Part B Rebatable Drugs in Shortage and in Cases of Severe Supply Chain Disruptions (50.10) and Reducing or Waiving the Rebate Amount in the Case of a Part B Rebatable Drug on the Shortage List (50.11)

"In calculating the estimated rebate amount for a Part B rebatable drug for a calendar quarter, section 1847A(i)(3)(G) of the Act requires the Secretary to reduce or waive the rebate amount for a Part B rebatable drug for a calendar quarter in two cases: (1) when a Part B rebatable drug is described as currently in shortage. . ."

BMS appreciates CMS' intent to allow for financial relief for manufacturers with Part B products in shortage as reflected by FDA's shortage list.[11] BMS supports a policy to fully waive the rebate amount for a shortage-defined drug (i.e., CMS' "second suggested approach" in the Draft Guidance). We would request that the Part D and Part B approaches be the same.

We ask that CMS refer to our comments in the Part D portion of this letter for BMS' response to the guidance on treatment of drugs currently in shortage on the FDA shortage list.

Financial Responsibility for Part B Inflation Rebate Amount (50.13)

"Because Part B rebatable drugs are single source drug or biological products, they typically will have one manufacturer. However, a single source Part B rebatable drug could have more than one manufacturer and there also is one or more manufacturer(s) that is a repackager or relabeler or markets an authorized generic product."

BMS is concerned with CMS' approach to this provision, as the approach outlined could result in manufacturers bearing a penalty due to pricing actions taken by competitors. BMS strongly believes that a manufacturer should not incur rebate liability because the ASP of another manufacturer's NDC has increased faster than the pace of inflation, but that of its own NDC has not.

[10] SSA § 1842(o)(1)(C).

[11] As established under section 506E of the Federal Food, Drug, and Cosmetics Act.

Should a manufacturer with an NDC of a single source drug that shares a HCPCS code with other such NDCs of distinct manufacturers, we suggest CMS come up with a methodology for ensuring that only the manufacturer(s) of the NDC(s) whose ASP has increased faster than the pace of inflation is subject to rebate liability.

Timing of Reports and Payment (60.1) and Manufacturer Suggestions of Calculation Errors in Preliminary Rebate Reports and Preliminary True-Up Reports (60.2)

"CMS intends to provide all manufacturers of Part B rebatable drugs with a Preliminary Rebate Report no later than five months after the end of each calendar quarter. . . Manufacturers would have 10 days to review the Preliminary Rebate Report for potential calculation errors. . . Manufacturers should notify CMS, share the suggestion of a calculation error, and provide supporting documentation (if applicable) within 10 days after receiving their Preliminary Rebate Report or Preliminary True Up Rebate Report."

The Agency's guidance memorandum suggests that CMS will share a Preliminary Rebate Report with a manufacturer no later than five months after the end of each rebate quarter, in which a manufacturer will have just 10 days to suggest potential errors.[12] As noted in and consistent with our Part D Guidance comments, BMS strongly urges CMS to extend the review period to 30 days, at a minimum, to align with similar reporting requirement timelines in the Medicaid program. BMS reiterates that CMS must provide sufficient information in the Preliminary Rebate Report to allow manufacturers to independently verify the rebate calculation, and to allow manufacturers to provide comment back to the Agency on more than "calculation errors," including statutory exclusions not applied.

As noted in our Part D Guidance comments, BMS does not believe that CMS' proposed approach to information sharing with respect to Preliminary Rebate Reports is sufficient information for manufacturers to verify the accuracy of the rebate calculation. BMS therefore, at a minimum, recommends that, for the Part B inflation rebates, the Agency should broaden the information shared with manufacturers to include:

- The benchmark payment amount calculated by the Agency for the billing and payment code;
- The applicable payment amount for the calendar quarter for the billing and payment code;
- The benchmark and rebate quarter CPI-U values used by the Agency;
- A summary of units administered during the calendar quarter;
- Supporting claims-level data at the NDC-11 level for the billing and payment code with:
    - The number of units administered during the calendar quarter;
    - Administration date
    - Indicators for units excluded due to being subject to 340B pricing;
    - Indicators for units excluded due to a Medicaid rebate being paid under section 1927 of the SSA;
    - Indicators for claims reduced or excluded due to product shortage;
- The dosage for the billing and payment code; and
- The date on which a Part B rebatable drug became a multiple source drug, as determined by CMS.

[12] Under section 1847A(i)(1)(C) of the SSA, CMS may delay invoicing manufacturers until September 30, 2025, for all calendar quarters in 2023 and 2024.

BMS also encourages similar flexibilities with timelines and data sharing for the Preliminary True Up Report.

Additionally, BMS supports the proposed establishment of an informal dispute resolution process that occurs in advance of the issuance of a rebate invoice. The limitation on judicial and administrative review does not prevent CMS from establishing a process for manufacturers to dispute incorrect invoices.

Restatements and True-Up Report (60.3)

"CMS would perform a single, subsequent reconciliation or 'true-up' for each applicable calendar quarter subject to Part B rebates approximately one year after sending Rebate Reports to manufacturers."

BMS is concerned with the guidance indicating that CMS plans to conduct a reconciliation or "true-up" each applicable calendar quarter approximately one year after sending Rebate Reports to manufacturers to capture potential revisions to ASP data, CMS revision of payment limits, revisions to CPI-U, or any updates to claims data that occurred after the rebate amounts were calculated.
Even more concerning is the Agency's suggestion that it can update or change the rebate amount and true-up amount based on any calculation errors or misreporting of manufacturer pricing or product data that CMS identifies "at any point." BMS is strongly against this proposal to continuously subject manufacturers to potential revisions without any statute of limitations. For any true-up process, we strongly suggest CMS provide reconciliations for both underpayments and overpayments. We would recommend CMS specify that the true-up be conducted three years after invoice of the Part B inflation rebate amount to enhance rebate liability accuracy and establish finality in the rebate invoice process.

Need for CMS to Meaningfully Consider and Respond to Comments

BMS appreciates the opportunity to comment on the proposals contained within the Draft Guidance, as well as other considerations before the Agency during implementation of the Inflation Reduction Act (IRA). Importantly, we ask CMS, in finalizing any proposals, to include responses to comments received, meaningfully explaining their consideration. Accordingly, BMS strongly urges CMS to consider and respond to comments in the Draft Guidance commensurate with notice-and-comment rulemaking in order to ensure that its policymaking is transparent and fair.

As CMS knows, "[t]he purpose of [a] comment period is to allow interested members of the public to communicate information, concerns, and criticisms to the [A]gency."[13] Equally important is the Agency's timely explanation of how such information, concerns, and criticisms factored into its final decision-making. This is what allows the comment process to serve its intended role of facilitating a "genuine interchange" of ideas between the agency and interested members of the public.[14] The process of responding to discrete points raised by commenters helps to ensure that the Agency is carefully considering the feedback it received from the public—"the interchange of ideas between the government and its citizenry provides a broader base for intelligent decision-making and promotes greater responsiveness to the needs of the people."[15]

[13] *Conn. Light & Power Co. v. NRC*, 673 F.2d 525, 530 (D.C. Cir. 1982).
[14] *Id.* (describing the purpose of notice-and-comment rulemaking).
[15] *Buschmann v. Schweiker*, 676 F.2d 352, 357 (9th Cir. 1982) (internal quotation marks and citations omitted).

The need for transparency is especially compelling here, given the novelty and complexity of the issues at hand. The IRA will have vast ramifications for patients, providers, pharmacies, manufacturers, and other stakeholders across the U.S., and these proposals represent the Agency's first significant endeavor to fill a largely blank slate. BMS is highly concerned that misinformed implementation could have especially sweeping negative repercussions with respect to Medicare beneficiary access to needed medicines. Given these circumstances, BMS asserts that it is absolutely vital that CMS make every effort to maximize transparency and fairness, including by ensuring that it meaningfully considers and responds to stakeholder feedback on its proposals.

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BMS appreciates the opportunity to comment on the Part B and Part D Draft Guidance. We would be pleased to discuss these comments in further detail. Should you have any questions or concerns, please contact Caroline Tucker, Director, Executive Branch Strategy, at caroline.tucker@bms.com.

Sincerely,

/s/

Amy Demske
Executive Director, U.S. Policy and Executive Branch
U.S. Policy & Government Affairs

March 3, 2023

Dr. Meena Seshamani, MD, PhD
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Concerns about modifier approach for identifying 340B drugs dispensed under Medicare Part D

Dear Dr. Sheshamani,

On behalf of the Colorado Community Health Network (CCHN), thank you for the opportunity to provide input into plans from CMS for implementing the Medicare inflationary rebates established under the Inflation Reduction Act. CCHN is the collective voice for Colorado's 20 federally qualified Community Health Centers (FQHCs or CHCs) and the patients they serve. Colorado CHCs provide a health care home to more than 855,000 of their community members – one in seven people in Colorado – from 63 of the state's 64 counties.

As you know, FQHCs are the backbone of the health care safety net, providing high-quality, affordable care to over 30 million medically underserved patients, regardless of whether they have insurance or their ability to pay. In 2021, at Colorado FQHCs 90% of patients had income below 200% of the Federal Poverty Level and 20% were uninsured.

FQHCs offer a broad range of services, including primary care, dental, behavioral health, and pharmaceuticals. Many of these services – and the sliding fee discounts that make them affordable for our patients -- are supported by savings generated through the 340B drug discount program. In Colorado, the savings go to support many programs including pharmacy, behavioral health, medication-assisted treatment, dental, case management and care coordination, primary care, community workers, outreach and enrollment, physical therapy, transportation, patient education services, telehealth, IT and equipment, translation, immunization clinics, residency programs, perinatal services, and school clinics.

Nationally, FQHCs rely on contract pharmacy arrangements to dispense roughly 50-60% of the 340B drugs provided to their patients – the highest percentage of any type of 340B provider. Thus, the 340B savings generated at contract pharmacies support many services that the FQHC would otherwise be unable to provide. Given the importance of 340B savings – including those generated by contract pharmacies – we were very concerned to hear that CMS is considering requiring an indicator (also known as modifier) on all claims for Part D prescriptions that were filled with 340B drugs.

As discussed in detail in comments submitted by other members of the FQHC community, FQHCs' experience clearly indicates that requiring a 340B indicator (also known as a modifier) on Part D drugs would:

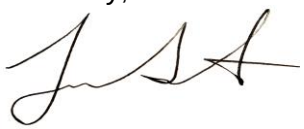
a. Result in data that is highly unreliable.
b. Force FQHCs to shut down many of their contract pharmacy arrangements for Part D drugs, leading to an overall loss in 340B savings and subsequent reduction in services provided to underserved patients.

Instead of a modifier, we recommend that CMS implement a "clearinghouse" model for identifying 340B drugs covered by Part D. Compared to a modifier requirement, a clearinghouse would:

a. Produce much more reliable data.
b. Be significantly less labor-intensive.
c. Preserve the ability of FQHCs and other 340B providers to rely on contract pharmacies to dispense 340B drugs to Part D enrollees, thereby avoiding reductions in access.
d. Could be expanded to include 340B drugs dispensed to Medicaid patients.

Thank you for your consideration of our serious concerns about the modifier model, and our proposed alternative. If you have any questions about our comments, please contact me at suzanne@cchn.org.

Sincerely,



Suzanne Smith
Health Center Operations Division Director

Center for Medicare Advocacy

Advancing Access to Medicare and Health Care

March 10, 2023

Submitted Electronically to IRARebateandNegotiation@cms.hhs.gov

The Honorable Meena Seshamani, MD, PhD
Director
Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 2020

Re: Medicare Prescription Drug Inflation Rebate Comments

Dear Dr. Seshamani:

The Center for Medicare Advocacy (the Center) is a national, non-profit law organization that works to ensure access to Medicare, health equity, and quality healthcare. The organization provides education, legal assistance, research and analysis on behalf of older people and people with disabilities, particularly those with long-term conditions. The Center's policy positions are based on its experience assisting thousands of individuals and their families with Medicare coverage and appeal issues. Additionally, the Center provides individual legal representation and, when necessary, challenges patterns and practices that inappropriately deny access to Medicare and necessary care. We appreciate the opportunity to submit these comments to the above referenced proposed rule.

The Center appreciates the opportunity to comment on initial guidance from the Center for Medicare & Medicare Services (CMS) for the Medicare Prescription Drug Inflation Rebate Program. This important new program requires drug companies to pay a rebate if they increase the prices of certain drugs faster than the rate of inflation. The rebates are paid to Medicare and apply to drugs covered under Part B and Part D.

The Medicare Prescription Drug Inflation Rebate Program helps address brand name drug companies' long-standing practice of increasing their prices year after year—often at more than twice the rate of inflation.[1] Drug price increases typically translate into higher out-of-pocket costs, especially for consumers who pay a percentage of drug costs (coinsurance) rather than a fixed dollar amount (copayment). Higher prices are also passed along to consumers in the form of higher deductibles and premiums.[2]

While CMS does not plan to invoice drug companies for inflation-based rebates until 2025, the time periods for which drug companies will be required to pay rebates have already started and may already be having an impact on their pricing behavior. Further, under the initial guidance

[1] http://www.aarp.org/rxpricewatch
[2] https://www.actuary.org/content/prescription-drug-spending-us-health-care-system

beginning April 1, 2023, Medicare Part B beneficiary coinsurance will be 20 percent of what the Medicare payment amount would have been if the price of the drug in question had not increased faster than inflation. The Center strongly supports the implementation of this change, which will effectively protect Medicare beneficiaries from the higher coinsurance that would normally result from drug price increases that exceed inflation.

The Medicare Prescription Drug Inflation Rebate Program may already be providing benefits for people in Medicare Part D plans, as well. Medicare Part D enrollees are increasingly subject to deductibles and coinsurance that directly expose them to prescription drug price increases. For example, 70 percent of Part D enrollees in stand-alone plans (PDPs) were expected to be in a plan with the standard $505 deductible in 2023, and most enrollees face coinsurance that can range from 15 to 50 percent.[3] To the extent that the Medicare Prescription Drug Inflation Rebate Program is discouraging drug companies from making large price increases, Part D enrollees could see lower out-of-pocket costs than they would have experienced otherwise.

The Congressional Budget Office (CBO) estimates that the Medicare Prescription Drug Rebate Program will save billions of dollars. These savings are due to lower spending under Part D and Part B, as well as increased tax revenues due to spillover effects that will help suppress drug price and premium growth in the commercial market. CBO also expects that the lower drug prices that result from the inflation rebate provision means Medicare beneficiaries will be more likely to use prescription drugs and that will lead to declines in spending on other Medicare-covered services.[4]

The Center would like to reiterate its strong support for the prescription drug provisions in the Inflation Reduction Act. The successful implementation of these improvements will lead to substantial savings for Medicare beneficiaries and the taxpayers who fund the Medicare program. More importantly, they will help ensure that Medicare beneficiaries can afford the prescription drugs they need.

We appreciate the opportunity to submit these comments. For additional information, please contact David Lipschutz, Associate Director at DLipschutz@medicareadvocacy.org or (202)293-5760.

Sincerely

David Lipschutz, JD
Associate Director/Senior Policy Attorney
Licensed in CA and CT

[3] https://www.kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-medicare-drug-plans-in-2023/
[4] https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf

Medicare Part D Inflation Rebate Comments

Peter J. Pitts

President, Center for Medicine in the Public Interest

Visiting Professor, University of Paris School of Medicine

Former FDA Associate Commissioner

February 10, 2023

Abstract:

When it comes to innovation in the development of new medicines, a key focus is on Real World Evidence – data based on what's really happening in the real world (aka: reality). Unfortunately, when it comes to healthcare policy, "real" seems to be conveniently ignored when it doesn't suit the shibboleths of political agendas. Case in point – the Inflation Reduction Act (IRA) and its call for partial biopharmaceutical price controls. The main consequence of these price controls will be to destroy the research-and-development system that makes America the world leader in medical innovation. In the words of Philip Dick, "Reality is that which, when you stop believing in it, doesn't go away." At the heart of the debate is whether we are going to improve our health care system using smart and evolving free-market principles, such as more focused regulation that addresses the exclusionary contracting that locks out savings from biosimilars or go down the sound-bite-laden path of government negotiation (today) and rationing care (tomorrow).

Introduction: Reality Isn't Negotiable

When it comes to innovation in the development of new medicines, a key focus is on Real World Evidence[i] – data based on what's really happening in the real world (aka: reality). Unfortunately, when it comes to healthcare policy, "real" seems to be conveniently ignored when it doesn't suit the shibboleths of political agendas. Case in point – the Inflation Reduction Act (IRA) and its call for government price controls for certain prescription medicines.[ii]

The IRA allows unelected federal officials to "negotiate" with drugmakers over the price Medicare will pay for what will become an ever-growing list of brand-name prescription drugs. In practice, these "negotiations" are federally mandated price controls. Under IRA, the government now has enormous power to name its own price for an increasing range of advanced medicines, and drugmakers would have little choice but to submit.

The main consequence of these price controls will be to destroy the research-and-development system that makes America the world leader in medical innovation. In the words of Philip Dick, "Reality is that which, when you stop believing in it, doesn't go away."[iii]

Will Direct Federal Negotiations Lower Costs?

According to the Congressional Budget Office (CBO), Part D plans "have secured rebates somewhat larger than the average rebates observed in commercial health plans"25. And the Medicare Trustees report that many brand-name prescription drugs carry substantial rebates, often as much as 20-30 percent and that on average, across all program spending, rebate levels have increased in each year of the program."[iv]

The argument is that Uncle Sam could do better. However, according to the CBO, revoking the Kennedy/Daschle Non-Interference Clause, "would have a negligible effect on federal spending because CBO estimates that substantial savings will be obtained by the private plans and that the Secretary would not be able to negotiate prices that further reduce federal spending to a significant degree. Because they will be at substantial financial risk, private plans will have strong incentives to negotiate price discounts, both to control their own costs in providing the drug benefit and to attract enrollees with low premiums and cost-sharing requirements."[v]

In 2007 after two years of experience with bids in the Part D program, the CBO found that striking noninterference "would have a negligible effect on federal spending because … the Secretary would be unable to negotiate prices across the broad range of covered Part D drugs that are more favorable than those obtained by PDPs under current law."[vi]

In 2009 after even further program experience, the CBO reiterated its previous views, stating that they, "still believe that granting the Secretary of HHS additional authority to negotiate for lower drug prices would have little, if any, effect on prices for the same reason that my

predecessors have explained, which is that…private drug plans are already negotiating drug prices." Importantly, the CBO says that no further savings are possible unless the government restricts beneficiary access to medicines or establishes market-distorting price interventions.[vii]

Price Controls Equal Choice Controls: Veterans Administration's Experience

The U.S. Department of Veterans Affairs plan illustrates the point. It offers 1,300 drugs, compared with 4,300 available under Part D, prompting more than one-third of retired veterans to enroll in Medicare drug plans. A study from Columbia University found that just 19 percent of all new drugs approved since 2000 were covered by the VA. And just 38 percent of drugs approved since 1990 were covered.[viii]

What's happening is that VA negotiating tactics are driving out some drug providers from the program, leaving patients with fewer treatment options.

Developing medicines is already a risky business. It costs, on average, nearly $3 billion over 10 to 15 years for each approved new medicine.[ix] That's partly due to the direct expense of the research-and-development activity itself — and partly because only 12% of potential medicines entering Phase I clinical trials ultimately win approval.[x] Private investors are willing to take such risks because a successful drug has the potential to earn back those costs and then some.

Artificially capping prices would have the unintended (but highly predictable) result of preventing companies from recouping their investments. President Biden, during his 2022 State of the Union, claimed that under a price control regime, "Drug companies will still do very well."[xi] In fact, such a policy could reduce the revenue of the innovative biopharmaceutical industry by $1.5 trillion over the next decade.[xii] These biopharmaceutical companies, on average, dedicate nearly one-fifth of revenue to research and development. Simple math suggests that price control legislation would cut funding for R&D spending by hundreds of billions of dollars. Economic modeling estimates that price control legislation would snuff out 56 new drugs — including 16 cancer treatments — that would have otherwise reached patients.[xiii]

Where Do Drugs Come From?

There seems to be a fundamental misunderstanding about the government's role in drug development. For example, Senator Elizabeth Warren (D, MA) and others mistakenly believe that pharmaceutical innovation is primarily driven by the National Institutes of Health, the federal medical research organization.[xiv] But that's never been true.

A study in the journal Health Affairs by two Columbia University scholars uses mounds of historical data to reveal the real role the NIH serves in drug development.[xv]
This study shows that fewer than 10 percent of drugs are covered by a public sector patent. And this slice of drugs only accounts for 2.5 percent of total annual drugs sales. Drugs that relied on federal funds for development, meanwhile, comprise only about a quarter of sales.

The primary engine of drug innovation is private industry, which spends more than $50 billion annually on research and development.

The NIH focuses on basic research — that is, the study of fundamental aspects of organic phenomena without regard to specific medical applications. The biopharmaceutical industry, on the other hands, directs most of its R&D toward clinical research. Private science is centered on the actual development of new medicines. Both the NIH and private firms provide research financing to academic institutions. But it is industry that employs most of the scientists that conduct the hands-on development work. Drug development is a team effort and mustn't be positioned by politicians, pundits, and agenda-driven advocates as an industry vs. government proposition.

Wither Innovation?

When the government attempts to put itself in charge of drug prices, the chances of recouping a medicine's development costs will plummet, and investment in new research will likewise dry

up. Everything from cancer breakthroughs to new treatments for Alzheimer's disease, ALS, cancers, COVID vaccines and heart medications would become rarer.

This predictable consequences of will leave the innovative biopharmaceutical industry in no position to compensate for the investment loss. A recent review led by University of Chicago economist Tomas Philipson notes that studies consistently show a 1% reduction in industry revenue leads to a 1.5% reduction in research-and-development activity. He finds this legislation would reduce industry revenue by 12% through 2039 and R&D activity by 18.5%, or $663 billion. He estimates the result will be 135 fewer medications being developed in that period — a crippling shortfall that will also be measured in lives lost.[xvi]

Are Drugs too Expensive? Follow the Money

The list price of a medicine is meaningless to patients. When Americans with health insurance say that their drugs are "too expensive," what they mean is that their co-pays and co-insurance rates are too high, and those rates aren't set by pharmaceutical companies. They're the domain of the pharmacy benefit managers and insurance companies. During the last few years, pharmaceutical spending has increased by 38% while the average individual health insurance premium has increased by 107%.[xvii] During the same period, rebates, discounts, and fees paid by the biopharmaceutical industry to insurers and pharmacy benefit managers have risen from $74 billion to $166 billion.[xviii] That's 37% of our nation's entire expense on drugs.

Government policies should encourage rebate dollars to flow back to patients who need to take prescription drugs. Will greater transparency of contracting practices on the state level drive better pharmacy benefit manager behavior? That's one theory. Such transparency efforts in New York and Connecticut, for example[xix], will be the bellwether. But greed often trumps shame and, without penalties, will PBMs choose to do the right thing by patients and reduce their hefty profits?

Pharmaceutical company rebates to pharmacy benefit managers that are tied to formulary restrictions create an incentive for entrenched market leaders to "bid" incremental rebates to prevent or limit access to competitive medicines. This model, coupled with escalating cost-sharing requirements, harms patients by driving up prices, which results in reducing access to innovative drugs.

Allowing pharmacy benefit managers to continue with business-as-usual means a continued disincentive to promote a more aggressive uptake of both biosimilars and less-expensive generic drugs. Worse, reinforcing the status quo moves us even further away from a health care ecosystem based on competitive, predictable, free-market principles.

Not following through on the proposed rule to ban rebates is harmful to patient health and the public purse. One of the biggest threats to the body politic is nonadherence to the medicines physicians have prescribed: It causes 125,000 deaths each year[xx] and is responsible for 10% of hospitalizations. Why don't people take their medicines? Often because their copays and co-insurance rates are too high.

Government policies should encourage rebate dollars to flow back to patients who need to take prescription drugs. Will greater transparency of contracting practices on the state level drive better pharmacy benefit manager behavior? That's one theory. Such transparency efforts in New York and Connecticut, for example, will be the bellwether. But greed often trumps shame and, without penalties, will payers choose to do the right thing by patients and reduce their profits?

At the heart of the debate is whether we are going to improve our health care system using smart and evolving free-market principles, such as more focused regulation that addresses the exclusionary contracting that locks out savings from biosimilars or go down the sound-bite-laden path of "free health care."

Perverse Incentives Deny Patient Options

Pharmaceutical company rebates to pharmacy benefit managers that are tied to formulary restrictions create an incentive for entrenched market leaders to "bid" incremental rebates to prevent or limit access to competitive medicines. This model, coupled with escalating cost-sharing requirements, harms patients by driving up prices, which results in reducing access to innovative drugs.

The FTC Weighs In

In June 2022, the Federal Trade Commission voted 5-0 conduct a study of pharmacy benefits managers' business practices.[xxi] The agency's inquiry will scrutinize the impact of vertically integrated pharmacy benefit managers on the access and affordability of prescription drugs. As part of this inquiry, the FTC will send compulsory orders to CVS Caremark; Express Scripts, Inc.; OptumRx, Inc.; Humana Inc.; Prime Therapeutics LLC; and MedImpact Healthcare Systems, Inc.

The inquiry is aimed at shedding light on several practices that have drawn scrutiny in recent years including:

- fees and clawbacks charged to unaffiliated pharmacies;[xxii]
- methods to steer patients towards pharmacy benefit manager-owned pharmacies;
- potentially unfair audits of independent pharmacies;
- complicated and opaque methods to determine pharmacy reimbursement;
- the prevalence of prior authorizations and other administrative restrictions;
- the use of specialty drug lists and surrounding specialty drug policies;
- the impact of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients.

"Although many people have never heard of pharmacy benefit managers, these powerful middlemen have enormous influence over the U.S. prescription drug system," said Federal Trade

Commission Chair Lina M. Khan**.** "This study will shine a light on these companies' practices and their impact on pharmacies, payers, doctors, and patients."

Sunshine is the Best Medicine: Reality-Based Legislation

In 2019, Senators Mike Braun (R, IN) and Mitt Romney (R, UT) introduced the *Prescription Drug Rebate Reform Act*.[xxiii] According to Senator Romney, "Patients in Utah and across the country are strapped with skyrocketing prescription drug costs, while insurance companies and drug manufacturers benefit from a complex system of rebates that results in higher drug costs. By changing the rules of cost-sharing, our bill aims to bring transparency to the prescription drug pricing system and lower out-of-pocket costs for medication."[xxiv]

And, per Senator Braun, "The current system of government-sanctioned rebates for prescription drugs has distorted the drug pricing market. Drug prices—and out of pocket expenses paid by consumers—seem to continually be on the rise. What is not talked about enough, however, is the inherent conflict of interest arising from negotiated rebates that affect the actual cost of drugs, which are paid by drug makers to pharmacy benefit managers (PBMs) in exchange for preferred status on insurers' health plan formularies. This creates a perverse incentive for drug *makers to continually increase drug list prices—at the expense of consumers. And even when drugs are covered by insurance—consumers with cost-sharing obligations are often required to pay 30 to 40 percent of high drug list prices out of their own pocket. These rebates are often hidden from consumers, contribute to high list prices for prescription drugs, and leave consumers with all, or a big part of the tab."*[xxv]

Rethinking the Inflation Reduction Act

At the heart of the debate is whether we are going to improve our health care system using smart and evolving free-market principles, such as more focused regulation that addresses the exclusionary contracting that locks out savings from biosimilars or go down the sound-bite-laden path of "government negotiation" (today) and "free health care" (tomorrow).

[i] https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence\

[ii] https://www.congress.gov/bill/117th-congress/house-bill/5376/text

[iii] https://en.wikipedia.org/wiki/Philip_K._Dick

[iv] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6994362/

[v] https://www.cbo.gov/sites/default/files/108thcongress-2003-2004/reports/fristletter.pdf

[vi] https://www.everycrsreport.com/reports/RL33782.html

[vii] https://www.help4seniors.org/wp-content/uploads/Downloads/newsletters/Noninterference%20Myth%20Fact%20(updated%208-22-16)%20FINAL.pdf

[viii] https://www.usatoday.com/story/opinion/2016/12/18/keep-feds-drug-pricing-second-look/95490280/

[ix] https://jamanetwork.com/journals/jama/fullarticle/2762311

[x] https://www.cbo.gov/publication/57126

[xi] https://www.whitehouse.gov/briefing-room/speeches-remarks/2022/03/01/remarks-of-president-joe-biden-state-of-the-union-address-as-delivered/

[xii] https://avalere.com/insights/impact-of-h-r-3-scenarioson-federal-spending-and-drug-manufacturerrevenues

[xiii] https://vitaltransformation.com/2019/11/internationalreference-pricing-under-h-r-3-would-devastate-theemerging-biotechnology-sector-leading-to-56-fewernew-medicines-coming-to-market-over-10-years/

[xiv] https://www.theatlantic.com/politics/archive/2015/01/elizabeth-warren-vs-big-pharma/440358/

[xv] https://www.ncbi.nlm.nih.gov/books/NBK553542/

[xvi] https://bfi.uchicago.edu/working-paper/the-evidence-base-on-the-impact-of-price-controls-on-medical-innovation/

[xvii] https://www.ncsl.org/research/health/health-insurance-premiums]

[xviii] https://www.aei.org/articles/assessing-the-effects-of-a-rebate-rollback-on-drug-prices-and-spending/

[xix] https://www.cga.ct.gov/2022/rpt/pdf/2022-R-0029.pdf

[xx] https://www.acpjournals.org/doi/10.7326/0003-4819-157-11-201212040-00538

[xxi] https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry

[xxii] https://healthpolicy.usc.edu/research/overpaying-for-prescription-drugs/

[xxiii] https://www.romney.senate.gov/romney-braun-introduce-legislation-ensure-drug-pricing-transparency/

[xxiv] https://www.romney.senate.gov/romney-braun-introduce-legislation-ensure-drug-pricing-transparency/

[xxv] Ibid

Community Health Center of Yavapai

Our Mission: "To contribute to the well-being of the people of Yavapai County by offering integrated primary health services."

03/06/2023

Dr. Meena Seshamani, MD, PhD
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Concerns about modifier approach for identifying 340B drugs dispensed under Medicare Part D

Dear Dr. Sheshamani,

On behalf of the Community Health Center of Yavapai, thank you for the opportunity to provide input into CMS' plans for implementing the Medicare inflationary rebates established under the Inflation Reduction Act. We are the only CHC/FQHC in Yavapai County Arizona we have three clinics offering Medial, Dental and Behavioral Health Services. Ancillary services include 340b, Care Coordination, and Certified Application Counselors.

As you know, FQHCs are the backbone of the health care safety net, providing high-quality, affordable care to over 30 million medically-underserved patients, regardless of whether they have insurance or their ability to pay. CHCY has 3 clinic sites the total in 2022 for Primary Care in is SFS 34%, Dental 36.42%, Behavioral Health 24% uninsured and low income, 200% and below of the Federal Poverty Level.

FQHCs offer a broad range of services, including primary care, dental, behavioral health, and pharmaceuticals. Many of these services – and the sliding fee discounts that make them affordable for our patients -- are supported by savings generated through the 340B drug discount program. We use 340B savings in many ways to deliver on our mission to advance health care to our community. Here are just a few examples:

- Pharmacy Discount Cards: These enable patients to purchase their prescriptions with a co-pay based on Federal Poverty Levels in accordance with a sliding fee scale.
- 340B Program Coordinator Position wages, ERE and indirect costs
- Balance transfer for any deficits caused by future HRSA approved projects (pharmacy startup costs for example)

Nationally, FQHCs rely on contract pharmacy arrangements to dispense roughly 50-60% of the 340B drugs provided to their patients – the highest percentage of any type of 340B provider. Thus, the 340B savings generated at contract pharmacies support many services that the FQHC would otherwise be unable to provide. Given the importance of 340B savings – including those generated by contract pharmacies – we were very concerned to hear that CMS is considering

requiring an indicator (also known as modifier) on all claims for Part D prescriptions that were filled with 340B drugs.

As discussed in detail in comments submitted by other members of the FQHC community, FQHCs' experience clearly indicates that requiring a 340B indicator (also known as a modifier) on Part D drugs would:

a. Result in data that is highly unreliable.
b. Force FQHCs to shut down many of their contract pharmacy arrangements for Part D drugs, leading to an overall loss in 340B savings and subsequent reduction in services provided to underserved patients.

Instead of a modifier, we recommend that CMS implement a "clearinghouse" model for identifying 340B drugs covered by Part D. Compared to a modifier requirement, a clearinghouse would:

a. Produce much more reliable data.
b. Be significantly less labor-intensive.
c. Preserve the ability of FQHCs and other 340B providers to rely on contract pharmacies to dispense 340B drugs to Part D enrollees, thereby avoiding reductions in access.
d. Could be expanded to include 340B drugs dispensed to Medicaid patients.

Thank you for your consideration of our serious concerns about the modifier model, and our proposed alternative. If you have any questions about our comments, please contact Sharon Rickman, Director CHCY.

Sincerely,

marketing@craneware.com
support@craneware.com
sales@craneware.com
training@craneware.com

3/8/2023

Dr. Meena Seshamani, M.D. Ph.D.,
CMS Deputy Administrator and Director of the Center for Medicare
5600 Fishers Lane
Rockville, MD 20857

RE:
Medicare Part B Inflation Rebate Comments
Medicare Part D Inflation Rebate Comments

Attention: IRARebateandNegotiation@cms.hhs.gov

Deputy Administrator Seshamani:

As Senior Vice President of Industry Relations for Sentry Data Systems, now The Craneware Group, I am pleased to have the opportunity to comment on the above referenced memorandums specific to the 340B Discount Drug Program administered by Health Resources and Services Administration (HRSA). Our comments emphasis is on claims identification for the purposes of excluding drugs purchased under the 340B Discount Drug Program and administered to a Medicare and/or Medicaid patient, whereby the manufacturer will not be subject to inflation rebate liability and how technology can be utilized.

Sentry Data Systems, a pioneer in automated pharmacy procurement, utilization management and 340B compliance, is leading the industry in helping healthcare organizations address their three biggest challenges: reducing costs, managing compliance and improving outcomes. More than 12,000 hospitals, clinics, integrated delivery networks (IDNs) and pharmacies across the country rely on our integrated platform for their procurement, drug utilization and compliance solutions.

In July 2021, Craneware announced the acquisition of Sentry Data Systems and Agilum Healthcare, optimizing an already-robust catalog of solutions. Now, after more than 20 years as the leading provider of revenue integrity solutions improving financial performance in U.S. hospital and health systems, together, we are The Craneware Group[1] and we deliver software applications across the value cycle.

We collaborate with U.S. hospitals, pharmacies, and clinics to plan, execute, and monitor operational and financial performance, so they can continue to deliver quality care and services to their communities. The Craneware Group's Trisus platform combines revenue integrity, cost management, 340B, and decision enablement into a single, SaaS-based platform,

[1] The Craneware Group accessed 3/8/2023 https://www.thecranewaregroup.com/company/our-story/

connecting actionable insights to deliver sustainable margin and operational efficiency – something no other single partner can provide.

Medicare Part B

In 2018, certain hospitals were required to apply modifiers (JG, TB, PO, PN) to separately billable drugs with a status indicator code of G and K. At The Craneware Group, we have worked with hospitals and other technology partners to develop a mechanism to place the appropriate modifiers when 340B purchased drugs are used for Medicare eligible patients[2]. This innovation resulted from technology we developed from the Deficit Reduction Act (2005) for Medicaid claims, that required certain state Medicaid programs add a UD modifier for physician administered medications.

Dual Eligible Patients

Today, dual eligible patients, Medicare and Medicaid, may require two of the three modifiers for the purposes of billing at a 340B covered entity. The ability to tie patient eligibility for 340B to the claim for billing is key to accurately determine whether a 340B purchased drug was used for a specific claim.

340B Eligibility

Some billing/technology solutions created operation challenges that automatically applied modifiers through the electronic health record or claim scrubber, regardless of whether the patient's 340B eligibility was known or determined at the time of billing. This automation could lead to a drug being purchased at wholesale acquisition cost (WAC) and not at a 340B discount and modified to reflect 340B acquisition, while it is not. In these cases, that drug would be eligible for a rebate, because it was not purchased at 340B, however because of automation to modify the claim; the drug would not be subject to the rebate. Undoubtedly, this has caused a significant overreporting in the number of 340B medication claims to CMS as well as under-capturing of non-340B rebates. Our technology solution is transformative and looks at each claim to determine the modifier that is appropriate based on the covered entities 340B purchasing. It is more common for 340B replenishment models to review patient eligibility to determine the correct account for drug purchasing. A patient alone, does not qualify for 340B and a covered entity alone, is not always able to purchase at 340B. Other factors, including but not limited to the healthcare provider, area of service on the Medicare Cost Report, eligible accumulations, and drug availability determine the account that is eligible for a particular patient. CMS should note this in their guidance to provide covered entities the ability to differentiate purchasing practices to ensure accurate application of 340B modifiers.

Reversals

It is important to note for timing of claims, that accumulations (package size) for certain drugs may take longer than one-quarter. CMS will need to identify a process that allows for reversals and provides quarterly adjustments or claim modifications up to a year from dispensation to move from WAC to 340B or vice-a-versa.

Maximum Fair Price

340B covered entities may not utilize 340B purchased drugs, if the maximum fair price is less than the 340B purchase price. In these instances, covered entities will not be required to utilize the JG or TB modifier, and those claims will need to be subject to inflation reduction rebates.

HRSA Office of Pharmacy Affairs information system (OPAIS)

Using the HRSA Office of Pharmacy Affairs information system (OPAIS) to determine which covered entities are 340B eligible in 2023 has limitations as described above in the 340B eligibility section. Not all claims that are processed by a covered entity are always purchased at 340B. Recently, manufacturers have placed unnecessary

[2] Sentry Data Systems, now The Craneware Group, https://www.sentryds.com/340b-solutions/claims-manager-plus/ accessed 3/6/2023

burden on covered entities to report data, which for some hospitals, they no longer have access to 340B pricing for the manufacturer, directly as a result of that manufacturer policy and not HRSA policy[3]. This may over-simplify the identification of claims to exclude, so long as CMS understands this is nowhere near 100% accurate and manufacturers may be excluded from rebates above and beyond the intent of CMS providing an advantage to manufacturers.

340B Federal Grantees

For 340B grantees (i.e. community health center, federally qualified health-centers, Ryan White), the application of these modifiers already does exist for some of these covered entities through the state Medicaid programs. While new for Medicare, the modifications to add a modifier that would be applied to eligible 340B claims could use existing technology to apply the modifier based on patient 340B eligibility for the most accurate reporting.

Medicare Advantage Plans (MA)

Per section 50.8.5 (MA) plans could follow a similar modifier requirement; however, we recommend that Medicare publish the qualified plans for providers to identify during the billing process that could be reported to Medicare directly by the covered entity to a central hub at CMS or through Health Resources and Services Administration (HRSA), that could also be used for Medicare Part D (which will be addressed in the next section). A serious concern that covered entities have over the Medicare advantage plans are the reduction in reimbursement they have experienced from discriminatory practices after alerting a plan that they are 340B eligible. The MA takes advantage of the 340B eligibility at the federal and state level, as well as the manufacturer requiring burdensome processes for the covered entity. A source of validation is needed at the federal level for claims to be provided in a secure manner, that removes any disadvantages to the 340B covered entities, while creating necessary transparency when the law requires it.

Medicare Part D

We have done extensive work with partners in the 340B community regarding claims identification at point of sale. As a thought-leader in the 340B community, we were invited to participate with the National Council for Prescription Drug Programs (NCPDP) 340B workgroup to review how NCPDP Version D.O standards[4] are utilized and the barriers to using 420-DK submission clarification code (SCC -value 20). Our perspective is based on a workgroup that included manufacturers, pharmacies, 340B technology companies, and covered entity representation.

Replenishment Model

The 340B contract pharmacy model operates under a replenishment model. This replenishment model assumes that at point of sale, drugs are considered purchased from "neutral" inventory and purchasing of 340B product is done retrospectively. Neutral inventory could be WAC or some other group purchasing price, and typically for a contract pharmacy model is not 340B. 340B entity owned pharmacies, that are "closed door pharmacy" may utilize a 340B neutral inventory. The replenishment model only allows for a full unit of purchase, after appropriate 340B eligible dispensations accumulate for a set amount of time. Once a set amount of time has passed, the claim will be reprocessed or reversed from 340B eligibility and the pharmacy will have ownership of the claim through their original "neutral" inventory, as opposed to the covered entity. Please review our diagram developed in collaboration with NCPDP.

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[3] Johnson and Johnson policy, https://340besp.com/JJHCS%20Notice%20to%20End%20Customers%20Regarding%20Updates%20to%20340B%20Delivery%20Limitations.pdf, accessed 3/6/2023.

[4] NCPDP Version D.0 Guide, https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwi_3v7L2cz9AhVgQjABHQFyDfkQFnoECAwQAQ&url=https%3A%2F%2Fwww.ncpdp.org%2FNCPDP%2Fmedia%2Fpdf%2F340B_Information_Exchange_Reference_Guide.pdf&usg=AOvVaw1mdVQAZ1DrRaHWYxvLuPrb accessed 3/8/2023

This replenishment model is based on two key attributes 1) accumulations must equal a package size and 2) accumulations meeting the package size threshold must be within a certain set amount of time as agreed upon by the covered entity and their contract pharmacy. The ranges in time can be from 30 days to 365 days, and more recently due to manufacturer policy demands, that are not 340B program requirements, have limited replenishment to within 45-60 days. The NCPDP standard was developed for point-of-sale (POS) claims modification of the 420-DK SCC. As demonstrated by the replenishment model, POS 340B eligibility may not be known by the pharmacy staff processing a claim. In order for a claim to have the SCC placed, it could be many days or months after the claim has been processed with Medicaid or in this case, Medicare. The process to place modifiers on the claim requires a manual reversal (340B N1) and a reprocessing of the claim. In some instances, this may result in a denial of a claim, due to the length of time from the original date of service, and in every case this requires an unnecessary, yet additional transaction fee, to the claims processor. Ultimately, the NCPDP process suggests no more than 30 days, which would eliminate 340B eligibility for many claims and impact covered entities and the patients they serve negatively.

Separate BIN/PCN for Medicare Part D Plans

We have seen examples, such as in New York, where the policy for NCPDP 340B identification failed, until the state Medicaid program mandated separate BIN/PCN numbers to assist covered entities carve out certain plans as appropriate. There is not a requirement for 340B covered entities or their contract pharmacy partners to place modifiers on commercial claims for the purpose of identifying a 340B purchased price, therefore we request that only Medicaid fee-for-service and Medicare Part D be subject to claims identification. What we have seen work, to avoid duplicate discounts in Medicaid, is for the states to provide a list of separate BIN/PCNs for the Medicaid plans. We would also recommend that for Medicare Part D, that CMS make available separate BIN/PCNs for Part D plans as opposed to shared BIN/PCNs that combine commercial and Medicaid/Medicare plans. This allows the covered entity and their 340B technology vendor to provide accurate reporting only to those required by law.

Batch Reporting to a Clearinghouse

One recommendation that worked in the state of Oregon, was batch 340B reporting retrospectively each quarter. While this model proved to be successful, it was one model that the state funded with minimal technology. Having a uniform submission process to a clearinghouse would allow for scales of efficiency and consistency. We suggest that CMS, in collaboration with HRSA, identify a government contractor that could act as a mediator for certain Medicaid and Medicare claims. The government contractor would carry out the inflation reduction act requirements effective in 2026 and 340B public service act to avoid duplicate discounts for Medicaid. Covered entities would have a secure, reoccurring report, that could be shared with the government to provide additional insights into 340B claims. We would recommend that the government contractor allow for 340B technology vendors to provide a conduit to share this data and reduce the burden on the covered entity to manually upload reports. The clearinghouse would eliminate burden on the covered entity to report to non-governmental organizations with varying policy criteria and limited transparency of all parties involved. This clearinghouse could be utilized to monitor manufacturer disputes with the state, as well as with the federal agency to better understand how rebates are impacted. The contractor could report to HRSA and CMS on a quarterly basis through both prospective and retrospective analysis on the impact of rebates assisting the states understand the value of 340B to their budget by reducing expenses. Manufacturers could work with the clearinghouse to connect disparate information and remove barriers that currently exist in a process that currently does not provide claims data. This clearinghouse would be limited to Medicaid fee-for-service and Medicare Part D, to assist with the current federal policy and intersection with 340B.

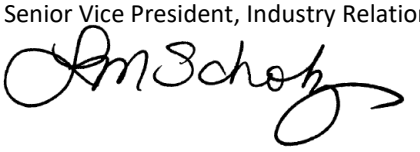
Thank you for the opportunity to provide comments on behalf of The Craneware Group and for your time to consider our recommendations. We welcome providing our insights into the IRA process to support covered entities manage the complexity of 340B in the current environment with a look to the future to make it accessible and fair for the safety net- the

ultimate beneficiary of the 340B program. The 340B program allows the covered entities to serve their communities offering more comprehensive care—therefore having a comprehensive and efficient revenue integrity process allows them to continue to focus on what they do best- care for patients.

We would be happy to provide more real-world operational information or answer any questions.

Regards,

Lisa Scholz, PharmD, MBA, FACHE
Senior Vice President, Industry Relations



1275 Pennsylvania Ave NW, Suite 700
Washington, D.C., 20004

Submitted electronically via IRARebateandNegotiation@cms.hhs.gov

March 10, 2023

Dr. Meena Seshamani, M.D. Ph.D.,
CMS Deputy Administrator and Director of the Center for Medicare

U.S. Department of Health and Human Services
Centers for Medicare and Medicaid Services
Attention: Medicare Prescription Drug Inflation Rebate Program Comment Solicitation
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on Medicare Part B and D Inflation Rebate Guidance

Dear Deputy Administrator Dr. Seshamani:

CVS Health appreciates the opportunity to respond to the Medicare Part B and D Inflation Rebate Guidance,[1] published via the Health Plan Management System on February 9, 2023.

CVS Health serves millions of people through our local presence, digital channels, and our nearly 300,000 dedicated colleagues – including more than 40,000 physicians, pharmacists, nurses and nurse practitioners. Our unique health care model gives us an unparalleled perspective on how systems can be better designed to help consumers navigate the health care system – and their personal health care – by improving access, lowering costs, and being a trusted partner for every meaningful moment of health. And we do it all with heart, each and every day.

We appreciate CMS' efforts to quickly implement the provisions of the Inflation Reduction Act (IRA). Despite the major changes to Medicare prescription drug pricing put into place by the IRA, CVS Health's strategy and what we do for our clients remains the same – to help make care more affordable and simpler. We're continuing to manage our clients' drug spend by getting the best possible price.

As CMS considers comments to this guidance, we recommend that the agency continue working with MAOs, PDPs, and other stakeholders to further understand the impact of these changes and to focus on those policies that will definitively strengthen the MA and Part D programs for the millions of beneficiaries they serve.

[1] CMS, Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the Social Security Act, and Solicitation of Comments; Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments. Health Plan Management System (February 9, 2023).

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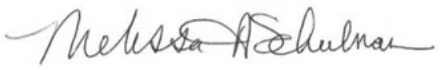
A more detailed discussion of our recommendations is provided in the attached Appendix.

Thank you for considering our recommendations and comments. CVS Health is committed to working with CMS as it formulates rules and policies that advance affordable, cost-effective care that provides beneficiaries with innovative choices of coverage that meets consumer needs. We welcome any follow-up questions you may have.

Sincerely,



Melissa Schulman
Senior Vice President, Government & Public Affairs
CVS Health

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Appendix

Specific Comments on Medicare Prescription Drug Inflation Rebate Guidance

I. Exclusion of 340B Acquired Units from Part D Rebatable Drug Requirements (Section 40.2.7)

CMS has requested comment on a potential future proposal to add a field to the PDE as a way to identify drugs purchased through the 340B program in order to exclude such units from rebate calculations beginning in 2026 as required in statute. However, we strongly recommend against adding this field in order to execute this provision. The field would be impractical from an operational perspective, overbroad in identifying the data CMS wishes to acquire, and places the burden of implementation on parties entirely unrelated to the inflation penalty itself. Recognizing that CMS is required by law to implement the 340B exclusion, they should strive to use existing data from manufacturers to calculate penalties.

Adding A Field To The PDE Is An Overbroad Approach

In its guidance, CMS contemplates requiring the identification of all drugs purchased through the 340B program on the PDE. However, this identifier goes far beyond what is statutorily required to implement the law. Pharmaceutical manufacturers are only required to pay inflationary penalties for drugs that: 1) have increased in price faster than inflation and 2) have been dispensed to a Medicare patient. Adding this field would identify all drugs purchased using the 340B program, irrespective of whether the drugs have had a price increase. While the PDE serves as a reasonable means of data collection for some policy goals, it is not suited for collection of the appropriate data for inflation penalties.

Manufacturers Are Best Suited For and Should Bear The Burden of Claim Identification

Manufacturers have made extensive efforts to develop the infrastructure to collect the data necessary to comply with the law. Over the last two years, numerous manufacturers have systemically conditioned participation in 340B covered entities' contract pharmacy networks on providing data to third party data collection companies like Kalderos and 340B ESP. Through these data collection companies, manufacturers have compiled what is likely the most comprehensive source of all 340B claims on their drugs, including the patients' Medicare status. Further, the inflation penalties included in the IRA were intended to address manufacturer pricing practices. It therefore makes logical sense to place the burdens of compliance on those manufacturers, particularly when they have so heavily invested in creating the largest source of data on relevant claims.

Pharmacies Cannot Identify 340B Claims At The Time of Dispensing

Most pharmacies do not have sufficient data at the time of filing a claim to identify whether a drug was purchased with a 340B discount. The majority of pharmacies participating in the 340B program are "contract pharmacies" that rely on their covered entity partners to identify whether patients they've served were eligible under the 340B program. The pharmacies are then able to "replenish" their stock retroactively based on having served a patient from the covered entity. Due to the lag between dispensing the drug and the covered entity facilitating a replenishment, there is rarely sufficient data when the claim is filed to complete out another PDE field. Also, when the contract pharmacy receives information on which drugs it can replenish, it may not be able to link drugs to individual patients and instead rely on data provided by the covered entity and its vendors.

Plans Cannot Identify 340B Claims In Real-Time

For similar reasons to the pharmacies, Part D plans do not have sufficient data to complete an additional PDE field to be submitted to CMS. While contract pharmacies receive data from the covered entities that they are associated with, Part D plans do not receive updates from the pharmacies at any point on whether a prescription was filled with a 340B drug. Additionally, by the time the pharmacy had replenished its stock it could be months after the initial transaction, and it is entirely possible that the plan would have already submitted the PDE and should not be expected to bear the burden of retrospectively updating the PDE after submission.

CMS Can Extrapolate 340B Claims Based On Manufacturer Data

Even without leveraging data collected by manufacturers through third-party entities like Kalderos and 340B ESP, manufacturers have significant data that could be used to extrapolate approximately how many drugs are dispensed to Part D beneficiaries using 340B discounted drugs. Manufacturers have complete records of how many 340B discounts they provided and to what covered entities. Additionally, manufacturers have data approximating what percentage of any drug is used by Part D patients. Those two data sources combined could provide CMS with an approximation of how many sales should be exempt from inflation penalties. While we recognize this is not claims-level data, it is a reasonable approximation and could potentially be the lowest burden, most efficient method of adjusting penalty amounts when considering there is no member of the supply chain with complete, accurate data. It also provides the benefit of having the data managed by the party with the most immediate direct interest in providing accurate information.

CMS Should Not Share Claims Data With Manufacturers

Finally, any data collected by CMS that goes beyond what is immediately necessary to implement statutorily required inflation penalties should not be provided to

manufacturers. Any data beyond what is immediately necessary has additional commercial applications that should not be freely provided to any commercial entities. Manufacturers have regularly expressed an interest in reducing their liability to commercial and Medicare payers based on 340B claims. Providing unnecessary data that could be used by manufacturers in negotiations with payers creates the risk of increasing costs for patients and plans. These increased costs would be felt directly by patients in the form of increased drug costs and premiums and would be in direct opposition of the IRA's goals of reducing drug costs.

Recommendations:

- **For purposes of implementing this provision, manufacturers are best suited for an should bear the burden of 340B claim identification.**
- **CMS should not add a field to the PDE or require any additional information from Part D sponsors in order to implement this provision.**
- **In implementing this provision, CMS should not share any claims data with manufacturers other than what is immediately necessary, in order to prevent any unintended consequences from a commercial pricing perspective.**

II. Identification of Part B Rebatable Drugs (Section 30.1) and Computation of Beneficiary Coinsurance and Amounts Paid Under Section 1833(a)(1)(EE) of the Social Security Act (Section 40)

CVS Health understands that with respect to this section, CMS is issuing final guidance on this section and intends to use the processes described in this section to determine the Part B rebatable drugs for a calendar quarter. However, we seek clarification on the timing of the process laid out in this section and comments made by CMS on the IRA User calls.

In the guidance, CMS states, "approximately two months before the start of a calendar quarter, CMS will identify Part B rebatable drugs using available information in order to determine the beneficiary coinsurance percentage that is applicable for the calendar quarter," however, according to that statement, for the quarter beginning April 1, 2023, CMS should have announced the Part B rebatable drugs and its associated coinsurance adjustment by February 1, 2023 which did not occur. Further, in Section 40 of this guidance CMS notes that, "beginning with the April 2023 quarterly pricing files, the applicable beneficiary coinsurance percentage would be shown for each HCPCS code in the pricing files that are posted on the CMS website." From our understanding, these files are only released about two weeks in advance of the start of a quarter. This is in line with comments made by CMS at the Monthly CMS Part C&D User Call on the IRA on February 8, 2023, where CMS stated that CMS could not, "promise to get you that real price file earlier than two weeks. Maybe it could be even later…"

The timing of this process laid out in various guidance referenced previously is conflicting and we request clarification on when stakeholders should expect for CMS to release the Part B rebatable drugs and the associated coinsurance adjustment for each quarter. While we understand that CMS would like to base the coinsurance adjustment on the latest data possible, we remind CMS that a two-week timing is not feasible from a systems perspective for plan sponsors or PBMs to reprogram and be ready to adjudicate claims at the adjusted coinsurance by the beginning of the quarter. We would request that CMS clarify whether the two-month lead time is the process timing they will follow starting with the July 1, 2023 quarter.

Recommendations:

- **CVSH recommends that CMS clarify that they will release the Part B rebatable drugs and the associated coinsurance adjustment for each quarter two months in advance of each quarter.**

March 6, 2023

Dr. Meena Seshamani, MD, PhD
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Concerns about modifier approach for identifying 340B drugs dispensed under Medicare Part D

Dear Dr. Sheshamani,

On behalf of the El Rio Health, thank you for the opportunity to provide input into CMS' plans for implementing the Medicare inflationary rebates established under the Inflation Reduction Act. El Rio Health is a Federally Qualified Health Center (HQHC) in Southern Arizona that serves nearly 130,000 patients, most of them underserved.

As you know, FQHCs are the backbone of the health care safety net, providing high-quality, affordable care to over 30 million medically-underserved patients, regardless of whether they have insurance or their ability to pay.

FQHCs offer a broad range of services, including primary care, dental, behavioral health, and pharmaceuticals. Many of these services – and the sliding fee discounts that make them affordable for our patients -- are supported by savings generated through the 340B drug discount program.

Nationally, FQHCs rely on contract pharmacy arrangements to dispense roughly 50-60% of the 340B drugs provided to their patients – the highest percentage of any type of 340B provider. Thus, the 340B savings generated at contract pharmacies support many services that the FQHC would otherwise be unable to provide. Given the importance of 340B savings – including those generated by contract pharmacies – we were very concerned to hear that CMS is considering requiring an indicator (also known as modifier) on all claims for Part D prescriptions that were filled with 340B drugs.

As discussed in detail in comments submitted by other members of the FQHC community, FQHCs' experience clearly indicates that requiring a 340B indicator (also known as a modifier) on Part D drugs would:

a. Result in data that is highly unreliable.
b. Force FQHCs to shut down many of their contract pharmacy arrangements for Part D drugs, leading to an overall loss in 340B savings and subsequent reduction in services provided to underserved patients.

Instead of a modifier, we recommend that CMS implement a "clearinghouse" model for identifying 340B drugs covered by Part D. Compared to a modifier requirement, a clearinghouse would:

a. Produce much more reliable data.
b. Be significantly less labor-intensive.
c. Preserve the ability of FQHCs and other 340B providers to rely on contract pharmacies to dispense 340B drugs to Part D enrollees, thereby avoiding reductions in access.
d. Could be expanded to include 340B drugs dispensed to Medicaid patients.

Thank you for your consideration of our serious concerns about the modifier model, and our proposed alternative. If you have any questions about our comments, please contact Ocie Wilson at 520-309-3923.

Sincerely,

Ocie Wilson, Pharm D
Pharmacy Director
El Rio Health
T. (520) 309-3923 F. (520) 670-7560
OcieW@elrio.org
www.elrio.org

March 6, 2023

Submitted via email to IRARebateAndNegotiation@cms.hhs.gov[1]

Meena Seshamani, MD, PhD
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
Dept. of Health and Human Services
ATTN: Medicare Part D Inflation Rebate Comments
7500 Security Boulevard
Baltimore, MD 21244

RE: Medicare Part D Inflation Rebate Comments: Concerns About Modifier Approach for Identifying 340B Drugs Dispensed Under Medicare Part D

Equitas Health is a federally designated community health center and one of the largest LGBTQ+ and HIV/AIDS serving healthcare organizations in the country. Each year, we serve tens of thousands of patients in Ohio, Texas, Kentucky, and West Virginia, and since 1984, we have been working to advance "care for all." Our mission is to be the gateway to good health for those at risk of or affected by HIV; for the lesbian, gay, bisexual, transgender, and queer/questioning (LGBTQ+) community; and for those seeking a welcoming healthcare home. In doing so, we offer primary and specialized medical care, pharmacy services, dentistry, mental health and recovery services, HIV/STI prevention and treatment services, Ryan White HIV case management, overall care navigation, and a number of community health initiatives.[2] On behalf of Equitas Health, thank you for the opportunity to provide input into CMS' plans for implementing the Medicare inflationary rebates, as established under the Inflation Reduction Act.

As you are aware, federally qualified health centers (FQHCs) and FQHC look-alikes are the backbone of our country's healthcare safety net. By providing high-quality, affordable care to over 30 million medically underserved patients, FQHCs and FQHC look-alikes are able to increase access to care, regardless of whether a patient has access to an insurance plan. During 2021, Equitas Health served more than 15,000 patients via 31,500 total in-person patient visits and 47,000 telehealth appointments; of these visits, 51,500 were medical visits, 21,500 were mental health visits, and 5,500 were dental visits. In 2021, nearly one-third (28.9%) of our patients were people of color, roughly 15% were transgender and/or non-binary, and nearly one-fifth (19%) were over 50 years old. Regarding payment for healthcare services in 2021, one-

[1] Document prepared by Rhea Debussy, Ph.D. (she/her), Director of External Affairs with assistance from the Ohio Association of Community Health Centers (NACHC). Document reviewed by Sam Brinker (he/him), General Counsel; Adrianna Udinwe, Associate General Counsel; and Sarah Green (they/she), Administrative Assistant – Advancement.
[2] https://equitashealth.com/about-us/

fourth (25%) of our patients used Medicaid, 5% used Medicare, and roughly 16% self-paid (i.e. including people who utilized our sliding scale fee options).[3]

Beyond just our agency and speaking more broadly, FQHCs and FQHC look-alikes offer a broad range of services, including primary care, dental, behavioral health, and pharmaceuticals. Many of these services – and the sliding fee discounts that make them affordable for our patients – are supported by savings generated through savings gained from the 340B Drug Pricing Program. This program is critical to our ability to provide comprehensive services to our medically underserved and often uninsured or underinsured patients, and the same is very much true of our fellow FQHC and FQHC look-alikes across the country.

The savings and resources that we generate by participating in the 340B Drug Pricing Program allow us to provide the services our patients most need and for which there is no other source of funding. In fact, the savings for this program help us to offer a number of crucial resources to underinsured and/or uninsured LGBTQ+ people across the state of Ohio. Such resources include some of the following: our pharmacies, gender affirming healthcare program, gender affirming legal clinics, non-grant funded HIV/STI prevention resources and programs, crucial advocacy work at the state and federal level, community events across the state, and much more. Like our fellow FQHCs and FQHC look-alikes, we strive to follow all requirements for the 340B Drug Pricing Program, and of course, we continue to expect the same of all other covered entities and participating drug manufacturers.

Nationally, FQHCs and FQHC look-alikes rely on contract pharmacy arrangements to dispense roughly 50-60% of the 340B drugs provided to their patients – the highest percentage of any type of 340B provider. Thus, the 340B savings generated at contract pharmacies support many services that the community health center would otherwise be unable to provide. Given the importance of 340B savings – including those generated by contract pharmacies – we were very concerned to hear that CMS is considering a proposal that would require an indicator (also known as modifier) on all claims for Part D prescriptions that were filled with 340B drugs.

As discussed in detail in comments submitted by other members of the FQHC and FQHC look-alike community, the experiences from FQHCs and FQHC look-alikes clearly indicate that requiring a 340B indicator (also known as a modifier) on Part D drugs would:

a. Result in data that is highly unreliable;
b. Force FQHCs and FQHC look-alikes to shut down many of their contract pharmacy arrangements for Part D drugs, leading to an overall loss in 340B savings;
c. Force FQHCs and FQHC look-alikes to reduce critical services – due to the lost 340B savings – for their already underserved patients; and
d. Contribute to less equitable health outcomes for medically underserved patients enrolled in Medicare Part D programs.

Instead of a modifier, we *strongly* recommend that CMS implements a "clearinghouse" model for identifying 340B drugs covered by Part D. Compared to a modifier requirement, a clearinghouse model would:

a. Produce much more reliable data;
b. Be significantly less labor-intensive for FQHC, FQHC look-alike staff, and CMS staff;

[3] https://equitashealth.com/wp-content/uploads/2022/04/722265148_Annual-Report-2021.pdf

c. Preserve the ability of FQHCs and FQHC look-alikes to rely on contract pharmacies to dispense 340B drugs to Part D enrollees;
d. Retain existing 340B savings that help to provide critical services for underserved patients;
e. Retain and/or increase access to healthcare for medically underserved patients, which would avoid reductions in access;
f. Potentially expand the amount of 340B drugs dispensed to Medicaid patients; and
g. Contribute to more equitable health outcomes for medically underserved patients enrolled in Medicare Part D programs.

Thank you for your consideration of comments, including our serious concerns about the modifier model and our proposed alternative. Should you have any questions about our comments, please feel free to contact Dr. Rhea Debussy (she/her), Director of External Affairs at Equitas Health.

FamilyHealthCare
OF NORTHWEST OHIO

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3/6/2023

Dr. Meena Seshamani, MD, PhD
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Concerns about modifier approach for identifying 340B drugs dispensed under Medicare Part D

Dear Dr. Sheshamani,

On behalf of the Family Health Care of Northwest Ohio, Inc. (FHC), thank you for the opportunity to provide input into CMS' plans for implementing the Medicare inflationary rebates established under the Inflation Reduction Act. FHC is a Federally Qualified Health Center (FQHC), located in Van Wert Ohio. FHC serves about 4,600 patients annually. FHC provides medical, dental and behavioral health services.

As you know, FQHCs are the backbone of the health care safety net, providing high-quality, affordable care to over 30 million medically-underserved patients, regardless of whether they have insurance or their ability to pay. Of the 4,600 patients that FHC serves, 69% are below 200% of the FPL. 43% of the population is at 100% and below FPL. About 7% of the population is uninsured.

FQHCs offer a broad range of services, including primary care, dental, behavioral health, and pharmaceuticals. Many of these services – and the sliding fee discounts that make them affordable for our patients -- are supported by savings generated through the 340B drug discount program. FHC rely on the 340B savings to help provide services to the patients that we serve. Dental services are very expensive to provide and many of our patients are on the sliding fee scale for dental and come in for services and only pay $35.00. We are so fortunate that we can provide this service to these patients at a reduced rate, but we would not be able to do it without the 340B savings.

Nationally, FQHCs rely on contract pharmacy arrangements to dispense roughly 50-60% of the 340B drugs provided to their patients – the highest percentage of any type of 340B provider. Thus, the 340B savings generated at contract pharmacies support many services that the FQHC would otherwise be unable to provide. Given the importance of 340B savings – including those generated by contract pharmacies – we were very concerned to hear that CMS is considering requiring an indicator (also known as modifier) on all claims for Part D prescriptions that were filled with 340B drugs.

As discussed in detail in comments submitted by other members of the FQHC community, FQHCs' experience clearly indicates that requiring a 340B indicator (also known as a modifier) on Part D drugs would:

a. Result in data that is highly unreliable.

b. Force FQHCs to shut down many of their contract pharmacy arrangements for Part D drugs, leading to an overall loss in 340B savings and subsequent reduction in services provided to underserved patients.

Instead of a modifier, we recommend that CMS implement a "clearinghouse" model for identifying 340B drugs covered by Part D. Compared to a modifier requirement, a clearinghouse would:

a. Produce much more reliable data.
b. Be significantly less labor-intensive.
c. Preserve the ability of FQHCs and other 340B providers to rely on contract pharmacies to dispense 340B drugs to Part D enrollees, thereby avoiding reductions in access.
d. Could be expanded to include 340B drugs dispensed to Medicaid patients.

Thank you for your consideration of our serious concerns about the modifier model, and our proposed alternative. If you have any questions about our comments, please contact Jennifer Smith. Below is my contact information.

Sincerely,

Jennifer Smith, CEO

Phone: 419-771-1903
jsmith@familyhealthnwo.org

March 10, 2023

Via email (IRARebateandNegotiation@cms.hhs.gov)

Dr. Meena Seshamani
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments

Dear Dr. Seshamani:

Gilead Sciences, Inc. (Gilead) appreciates this opportunity to comment on the above-captioned memorandum providing initial guidance (Guidance) regarding the payment by manufacturers of inflation rebates on Part D rebatable drugs (Part D inflation rebates) pursuant to Section 11102 the Inflation Reduction Act (IRA).[1]

Gilead is a research-based biopharmaceutical company that discovers, develops, and commercializes innovative medicines in areas of unmet medical need. We endeavor to transform and simplify care for people with life-threatening illnesses around the world. Our portfolio of products and pipeline of investigational drugs includes treatments for HIV/AIDS, liver diseases, cancer, inflammatory and respiratory diseases, and cardiovascular conditions. Our portfolio of marketed products includes a number of category firsts, including complete treatment regimens for HIV infection available in a once-daily single pill, the first oral antiretroviral pill available to reduce the risk of acquiring HIV infection in certain high-risk adults, and the first Hepatitis C virus (HCV) treatment to provide a complete regimen in a single tablet. Gilead is committed to ensuring that people have access to our medicines.

We appreciate the efforts of the Centers for Medicare & Medicaid Services (CMS) to provide initial guidance to pharmaceutical manufacturers regarding the payment of Part D inflation rebates and to solicit stakeholder comments on this guidance. We support the comments of our trade associations, the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Innovation Organization (BIO). The comments herein are intended to further build on suggestions included in PhRMA's and BIO's comments. Together, we believe that our suggestions will help promote efficiency, accuracy, and reliability in Part D inflation rebate calculations and help ensure that the law is implemented consistent with Congress' intent.

[1] Memorandum from Dr. Meena Seshamani, M.D. Ph.D., CMS Deputy Administrator and Director of the Center for Medicare to Pharmaceutical Manufacturers of Part D Rebatable Drugs and Other Interested Parties (Feb. 9, 2023), https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-initial-guidance.pdf.

Gilead's specific comments can be summarized as follows:

- Gilead strongly supports the use of a prescription drug event (PDE) indicator to identify 340B-acquired units of drug, in order to exclude such units from the scope of Part D inflation rebates. In order for the PDE indicator to accurately identify which units of a Part D drug are subject to 340B discounts, however, the dispensing pharmacy must know whether a given unit of drug is subject to a 340B discount at the time the claim is submitted. This is seldom the case under the "replenishment" model system, in which contract pharmacies identify whether a patient is 340B-eligible (i.e., eligible to receive drugs purchased under the 340B program) after the point of dispense, and subsequently replenish the bottle or units at the 340B price through the covered entity. Therefore, Gilead recommends that HHS prohibit the use of the 340B replenishment model by 340B covered entities or, at the very least, require guardrails around use of the replenishment model so that it does not undermine the accuracy and reliability of a 340B PDE indicator. Such guardrails should include, at a minimum, requiring covered entities to place replenishment orders within a reasonable time frame following the date of dispense to a 340B patient, and (a) requiring rebilling of the claim with a 340B indicator, (b) establishing a mechanism for covered entities to resubmit the 340B indicator field for the claim without rebilling the claim, or (c) implementing a claims clearinghouse model. Additionally, Gilead recommends that HHS establish a mechanism for manufacturers to submit corrected claims information and otherwise identify claims that were not properly identified as 340B drugs and for CMS to adjust the Part D drug inflation rebate amounts owed to exclude such units.

- Gilead supports defining "line extension" and "new formulation" for purposes of Part D inflation rebates in a way that will exclude combination products, and we urge CMS to also define a "new formulation" for the purposes of the government's "Drug Price Negotiation Program" set forth in Section 11001 of the Inflation Reduction Act (the Section 11001 Program) to exclude combination products.

Our more detailed comments on the Guidance are set forth below. We hope CMS will incorporate these suggestions when developing the revised guidance.

I. Gilead Supports Using a PDE Indicator to Identify Units Acquired Under the 340B Program and Recommends Changes to the 340B Replenishment Model to Facilitate the Collection of Accurate Data About 340B Units

A. CMS Should Issue Clear Guidance to Stakeholders on the 340B Indicator Requirement

Beginning in 2026, the IRA requires CMS to exclude "units of each dosage form and strength of [a] part D rebatable drug for which the manufacturer provides a discount under the [340B program]."[2] Section 40.2.7 of the Guidance solicits comments on whether to require that a 340B indicator be included on the PDE record, which CMS believes "is the most reliable way to identify drugs that are subject to a 340B discount that were dispensed under Part D." Gilead supports including a 340B indicator on the PDE record as a threshold step for identifying 340B

[2] Social Security Act (SSA) § 1860D-14B(b)(1)(B).

units. However, given the inconsistency in current 340B modifier usage and the varying approaches to identifying 340B claims, we believe it is important that CMS issue clear and detailed guidance clarifying the role of each 340B stakeholder in identifying 340B units of Part D rebatable drugs.

Currently, covered entities do not consistently include 340B modifiers on insurance claims, particularly if use of such modifiers is not mandatory. A recent study found that "[m]odifier usage reached 90% in some segments when reporting was mandatory, fell below 20% when it was optional, and dropped below 1% when it was impractical."[3] Therefore, it is important that CMS establish a uniform, mandatory standard for reporting 340B units on the PDE record. This would reduce potential confusion among 340B stakeholders about applicable reporting requirements. It would also provide CMS with the information that the Agency needs to comply with its statutory obligation to exclude 340B units from the Part D inflation rebate calculation.

We understand that certain stakeholders have identified an alternative approach under which CMS would exclude 340B units based on a ratio that is intended to estimate the volume of Medicare sales purchased under the 340B program. That ratio would be calculated based on the percentage of a drug's sales that are subject to a 340B discount and the percentage of a drug's sales under Medicare. Gilead opposes this approach, as it may not accurately estimate the portion of a drug's Medicare sales purchased at a 340B discount if the proportion of 340B utilization is higher or lower in Medicare than in other segments. Moreover, we believe this approach is inconsistent with CMS' statutory obligation to exclude 340B units from the Part D inflation rebate calculation, starting in 2026. The statute requires CMS to exclude 340B units without qualification. Congress did not give CMS the authority to estimate or extrapolate the number of 340B units for a drug.

B. CMS Should Eliminate the Replenishment Model and Require the 340B Indicator be Applied at the Point-of-Sale, or at a Minimum Establish Guardrails on the Replenishment Model to Facilitate Accurate Use of the 340B Identifier

The same study cited in Section I.A. found that 340B claims modifier usage was higher when the 340B status of the claim was known prior to or at the point-of-sale.[4] However, under the current system, covered entities often claim a 340B discount on a unit of a drug long after the point-of-sale. It is less common for covered entities (and in particular, their contract pharmacies) to use a pre-purchased inventory model, where product pre-purchased at the 340B price is kept on the pharmacy shelf to fill the prescriptions for the covered entity's patients. Instead, contract pharmacies frequently use what is known as a "replenishment model." Under the replenishment model, when filling a prescription, the contract pharmacy initially dispenses product purchased at

[3] Rory Martin, et al., Can 340B Modifiers Avoid Duplicate Discounts in the IRA?, IQVIA White Paper (Feb. 2023), https://www.iqvia.com/locations/united-states/library/white-papers/can-340b-modifiers-avoid-duplicate-discounts-in-the-ira10.

[4] *Id.* (The "340B status of a drug must be known at the point of sale to the patient in order to apply the modifier to the claim prior to adjudication. While this is possible for pharmacies that identify 340B transactions at the point of sale, which may occur in entity-owned pharmacies and often in those that use physical inventory, the drug's 340B status is unknown for pharmacies using the 340B replenishment model and virtual inventory which is used by almost all contract pharmacies.").

a non-340B price. The pharmacy sends an electronic record of its claim to a third-party administrator (TPA), which reviews the claims to determine which prescriptions were filled by an eligible patient of the covered entity. Once the TPA has made its determinations, it transmits that information back to the pharmacy. After the covered entity has dispensed a full bottle of a given drug, the covered entity purchases that quantity of drug at the 340B price and has it delivered to its contract pharmacies to "replenish" the number of prescriptions filled for 340B-eligible patients. Because a pharmacy using the replenishment model does not know the 340B status at the point of sale, the replenishment model poses significant challenges to the consistent use of a 340B indicator.[5]

Therefore, in response to CMS' question about the "most reliable way to identify Part D claims filled with 340B units," Gilead recommends that the Department of Health and Human Services (HHS) require that all covered entities and contract pharmacies identify a patient as 340B-eligible at the point of sale and dispense product purchased under the 340B program to that patient. This would help ensure that a pharmacy knows the 340B status of a particular unit of drug at the time the product is dispensed to the patient and thus can include a 340B indicator as appropriate on the claim, resulting in accurate claims information submitted in real time and prior to adjudication. Such a requirement should also apply regardless of the insurance that the patient presents at the time of dispense, since pharmacies may not be able to accurately determine whether a patient's health plan is a Medicare Part D plan at the point of sale. With respect to Medicare Part D claims, HHS also should require pharmacies to populate 340B identifier on the claim at the point of sale to identify the claim as either 340B or not 340B and require Part D plan sponsors to deny claims that do not have the field populated with one of these values.

If HHS nevertheless permits covered entities and their contract pharmacies to identify product as 340B-eligible after the product is dispensed (which can result in identification of the patient as 340B-eligible *after* the insurance claim is submitted), it is critical that HHS establish robust guardrails around the replenishment model to enable the accurate submission of 340B indicators. First, HHS should limit the timeframe for replenishment, so that covered entities must determine whether a particular unit of product is subject to a 340B discount within a specified period after the product is dispensed. For example, for NDCs representing a thirty-day supply or less of product, HHS should limit replenishment claims to only those submitted within forty-five days after a prescription has been dispensed to the patient, which is a sufficient timeframe for the covered entity to dispense a full bottle to the patient and submit a replenishment order at the 340B price.[6] Second, HHS should create a process for covered entities to identify product as subject to a 340B discount following replenishment (which is typically after the claim has been submitted).

[5] The HHS Office of Inspector General also has found that the replenishment model creates complications in preventing diversion and duplicate discounting under the 340B program. *See* OIG, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431 (Feb. 4, 2014), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.

[6] We recognize that there are certain situations where additional time may be necessary. For example, for products dispensed in containers with fills that last longer than 30 days, this timing would need to be adjusted appropriately, *e.g.*, to 105 days for a 90 day fill, depending upon the frequency of dispense and the size of the container used by the pharmacy.

HHS has several options for how it could require drugs to be identified as subject to a 340B discount after the original claim is submitted:

(1) Require covered entities to rebill the claim for the corresponding unit(s) dispensed to a 340B patient with the 340B indicator. We recognize that some pharmacies have expressed concerns about that such an approach, however, as it could require re-adjudicating a claim which may lead to a slight increase in denials if plan policies have changed since the initial claim was submitted.

(2) Establish a mechanism for covered entities to resubmit the 340B indicator field for the claim to plans without rebilling the claim (such as through the N1 transaction or another similar mechanism) and instruct plans not to reprocess claims that are resubmitted with only the 340B indicator changed within the specified time period (*e.g.*, forty-five days).

(3) Create a 340B claims clearinghouse to promote the integrity of the 340B PDE indicator data. We further outline this potential approach below.

In establishing a claims clearinghouse, HHS could refer to the Oregon Medicaid program's model as an example of a claims clearinghouse that generally works effectively today.[7] Under this model, covered entities (and any 340B vendors or contract pharmacies that submit claims on their behalf) must identify and submit 340B claims for each calendar quarter to the clearinghouse within thirty days after the end of that quarter, and the state rebate vendor uses the 340B claims files to match up the original paid encounter and exclude the claim from the quarterly drug rebate process.[8] If there is an error and a validation fails, it is sent back to the trading partner for correction.[9]

The Oregon model could be adapted to apply to Medicare Part D instead of Medicaid claims (recognizing that HHS would need to update the data collected by the clearinghouse to include data applicable to the Medicare Part D program). Any claims clearinghouse should, at a minimum, include the following data fields:

- Part D Contract ID and Part D Plan Benefit Package ID
- Prescription Number
- Prescribed Date
- Fill Date (i.e., date of service)
- 9-digit National Drug Code (NDC)
- Quantity dispensed
- Pharmacy ID
- Prescriber ID
- Wholesaler Invoice Number
- 340B Covered Entity ID/NPI

[7] Oregon Health Authority, Retroactive 340B Claims File Instructions, https://www.oregon.gov/oha/HSD/OHP/Tools/340B%20Claims%20File%20Instructions%20and%20Design.pdf.

[8] *Id.*

[9] *Id.*

- 340B claims identifier

HHS could consider using a TPA to manage the clearinghouse program, similar to the agency's use of a TPA for the Part D Coverage Gap Discount Program. The TPA could collect Medicare Part D PDE data from HHS in addition to 340B claims information from providers as specified above. The claims data could be used to validate and update as needed the information provided on the bill. In addition, if a manufacturer reviews the claims data and identifies a unit that was not correctly identified as subject to a 340B discount, and the covered entity agrees that the claim should have been billed as a 340B claim, that manufacturer should have the ability to submit this information to the clearinghouse, including appropriate documentation of the covered entity's agreement, and the clearinghouse should update the claim information to reflect the 340B status. This will help increase the accuracy and integrity of the clearinghouse model.

If HHS implements a clearinghouse model, Gilead encourages HHS to clearly set forth applicable claims submission requirements for all 340B stakeholders. HHS should also establish penalties for covered entities that do not submit claims data to the clearinghouse in the specified time frame. For example, a covered entity's repeated failure to comply could result in losing eligibility for participating in Medicare Part D or the 340B program. Additionally, if HHS establishes a clearinghouse, Gilead encourages HHS to employ the same clearinghouse to comply with other statutory requirements that involve identifying 340B claims, such as the prohibition against Medicaid duplicate discounts[10] and the non-duplication provision of the Section 11001 Program.[11]

C. CMS Should Permit Manufacturers to Submit Information Regarding 340B Units and Adjust Part D Inflation Rebates to Exclude Such Units

The Guidance provides that "Manufacturers of Part D rebatable drugs that owe an inflation rebate could submit a suggestion of a calculation error if they identify . . . an exclusion of a Part D rebatable drug specified in a statute that was not applied in their Preliminary Rebate Report and Preliminary True-Up Rebate Report."[12] As part of this process, regardless of whether CMS implements a clearinghouse model, CMS should establish a mechanism for manufacturers to identify drug units that were not correctly identified as subject to a 340B discount. Today Gilead generally does not have the data needed to identify which claims are 340B. One approach would be for CMS to provide for a similar process to the one that manufacturers currently use to dispute 340B units subject to Medicaid rebate claims.

To facilitate this process, CMS should provide access to the claims-level data underlying the Preliminary Rebate Report and the Preliminary True Up Rebate Report so that manufacturers can identify 340B units that were not excluded. The claims data provided should, at a minimum, include the following data fields:

- Part D Contract ID and Part D Plan Benefit Package ID

[10] Public Health Service Act § 340B(a)(5)(A).

[11] SSA § 1193(d).

[12] Guidance § 50.3.

- Prescription Number
- Prescribed Date
- Fill Date (i.e., date of service)
- 9-digit National Drug Code (NDC)
- Quantity dispensed
- Pharmacy ID
- Prescriber ID
- Wholesaler Invoice Number
- 340B Covered Entity ID/NPI
- 340B claims identifier

Importantly, if a manufacturer identifies 340B units that should have been, but were not, excluded from Part D rebatable drug units, CMS should then exclude such units from the amounts invoiced on the Rebate Report or the True Up Rebate Report, as applicable, consistent with CMS' statutory obligation to exclude "units of each dosage form and strength of [a] part D rebatable drug for which the manufacturer provides a discount under the [340B program]."[13] In such cases, CMS may not invoice for Part D inflation rebates on such units while directing manufacturers to resolve their disputes with the covered entities that submitted the underlying claims. Our experience is that some state Medicaid programs currently follow this type of process, and many duplicates are never fully resolved. The IRA does not permit CMS to collect Part D inflation rebates from manufacturers on 340B units, whether or not the covered entity appropriately identified the unit as subject to a 340B discount.[14]

II. Gilead Supports Defining "Line Extension" and "New Formulation" to Exclude Combination Products

A. Combination Products are Not New Formulations for Purposes of Part D Inflation Rebates

As Gilead commented in response to CMS' 2020 proposed rule regarding the definition of "line extension" and "new formulation" for purposes of the Medicaid Drug Rebate Program (MDRP),[15] the text and legislative history of Section 1927(c)(2)(A)(ii) of the Medicaid rebate statute make clear that Congress intended this provision to encompass only "slight" alterations that could serve as an easy means for manufacturers to avoid the additional, inflation-based Medicaid rebate.[16] Congress circumscribed the scope of a line extension by citing a type of slight alteration

[13] SSA § 1860D-14B(b)(1)(B).

[14] SSA § 1860D-14B(b)(1)(B).

[15] Letter from Brett Fletcher, EVP, Corporate Affairs and General Counsel, Gilead to Seema Verma, Administrator, Centers for Medicare & Medicaid Services, RE: CMS-2482-P; Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements (July 20, 2020), https://www.regulations.gov/comment/CMS-2020-0072-21730.

[16] *See Ipsen Biopharmaceuticals, Inc. v. Azar*, No. 16-CV-2372 (DLF), 2020 WL 3402344, at *11 (D.D.C. June 19, 2020) (quoting S. REP. NO. 111-89, at 92 (2009)) (alteration in original) (emphasis added) ("Congress enacted the

— an "extended release formulation" — as the sole example of a line extension in the statute,[17] and in the legislative history, Congress repeatedly describes this provision as applying to "slight alterations" of a manufacturers' drugs.[18]

We therefore agree with CMS' decision to exclude combination products from the definition of a "new formulation" at 42 CFR § 447.502,[19] and we believe it is important to define "line extension" and "new formulation" for purposes of Part D inflation rebates to also exclude combination products. Like the Medicaid rebate statute, Section 11102 of the IRA defines a "line extension" for purposes of Part D inflation rebates to mean "with respect to a part D rebatable drug, a new formulation of the drug, such as an extended release formulation, but does not include an abuse-deterrent formulation of the drug."[20] This language refers to the original drug in the singular only, and does not recognize the possibility of a line extension being formulated from multiple original drugs, as must be the case with a combination therapy. Moreover, a combination product combines "the drug" represented by each active ingredient with other "drugs" and therefore creates a new discrete drug that can no longer be a new formulation of "the drug" represented by any component.

Like the Medicaid rebate statute, Section 11102 of the IRA also defines a line extension by reference to an extended release formulation, which is a slight alteration quite unlike a combination product. Combination drugs — particularly those containing new molecular entities — involve significant alterations from existing products. They treat conditions in novel ways and are expensive to research and develop. For example, the standard of care for treating infectious diseases like HIV and HCV involve multiple drugs that attack different parts of the viral lifecycle

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provision to prevent manufacturers from "avoid[ing] incurring additional rebate obligations by making *slight alterations* to existing products, sometimes called line extensions.").

[17] *AK Steel Corp. v. United States*, 226 F.3d 1361, 1372 (Fed. Cir. 2000) ("When Congress makes such a clear statement as to how categories are to be defined and distinguished, neither the agency nor the courts are permitted to substitute their own definition for that of Congress.").

[18] *See* America's Affordable Health Choices Act of 2009, H.R. 3200, 111th Cong. (2009) (defining "line extension" exclusively as "an extended release formulation of the drug"); Senate Committee on Finance Chairman's Mark, America's Healthy Future Act of 2009, S. 1796, 111th Cong., at 54-55 (Sept. 2009) (referring only to extended release products and indicating concern with the fact that "drug makers can avoid incurring additional rebate obligations by making slight alterations to existing products…while significantly increasing the price on these products" and noting that extended release products would be treated as if they were original products for purposes of calculating rebates); 21 S. Rep. No. 111-89, at 92 (2009) (documenting that Congress' focus was on ensuring that manufacturers no longer could "avoid incurring additional rebate obligations by making slight alterations to existing products").

[19] The final definition of "new formulation" excludes the phrase: "provided that the new formulation contains at least one active ingredient in common with the initial brand name listed drug," which CMS had proposed to include. 85 Fed. Reg. 37286, 37319 (June 19, 2020). *See also* 85 Fed. Reg. 87000, 87039 (Dec. 31, 2020) (explaining that, based on the comments received, CMS "decided not to include a new combination of drugs…as a new formulation" in the definition of "new formulation").

[20] SSA § 1860D-14B(b)(5)(B)(ii).

to suppress viral replication and slow the progression of disease.[21] Fixed-dose single-tablet regimens (STRs) require complex clinical development to combine these multiple drugs into a single pill. Physical compatibility, dosage strength, pill size, solubility, permeability, and stability differences among the components necessitate many attempts to develop one single combination product. Unlike, for example, extended release formulations, combination therapies require complex chemistry and years of development. To ensure that all of the medicines in a pill are delivered to a patient and made bio-available, Gilead typically develops and tests between five and ten formulations of our medicines before identifying a combination that works for patients. This is one of the principal reasons that the Food and Drug Administration (FDA) treats combination drugs as entirely new products subject to full review under an original new drug application (even when a combination drug consists only of previously approved active moieties).[22]

Once combination products are successfully developed, approved, and brought to market, they have proven significant clinical benefits to patients. For example, STRs help in simplifying dosing frequencies, reducing pill burden, and lowering the risk of selective non-adherence, where a patient takes part of a regimen but not the full regimen.[23] Studies have shown that compared to patients on STRs, patients on multi-tablet regimens (MTRs, regimens of two or more pills per day) have poorer persistence, with a 60% higher rate of discontinuation.[24] A 2020 analysis of real world claims data found that among adult Medicaid beneficiaries newly initiating antiretroviral therapy, adherence and persistence was better among patients initiating STRs compared to those initiating MTRs.[25] Patients on STRs also achieved greater viral suppression compared to MTRs.[26] Improved viral suppression leads to better control of HIV, significantly decreases rates of hospitalization and

[21] The DHHS states that "Monotherapy for the treatment of HIV is not recommended outside of a clinical trial." The optimal regimen for initial treatment of HIV includes multiple antiretroviral (ARV) drugs from at least two different HIV drug classes." U.S. Department of Health and Human Services, AIDSinfo, HIV/AIDS Glossary: Monotherapy, https://aidsinfo.nih.gov/understanding-hiv-aids/glossary/1605/monotherapy.

[22] FDA, *Guidance for Industry: Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees*, at 3 (Dec. 2004) ("Every . . . combination of two or more different active ingredients should be submitted in a separate original application.").

[23] Yager J, Faragon J, McGuey L, et al., *Relationship Between Single Tablet Antiretroviral Regimen and Adherence to Antiretroviral and Non-Antiretroviral Medications Among Veterans' Affairs Patients with Human Immunodeficiency Virus*, 31 AIDS PATIENT CARE AND STDS 370-76 (2017).

[24] Hines D., et al., *Persistence Among Treatment-Native HIV-1 Patients: Single Versus Multiple Table Regimen Comparison*, Academy of Managed Care Pharmacy NEXUS 2017 (Oct. 2017).

[25] Cohen, J., Beaubrun, A., Bashyal, R. et al., *Real-World Adherence and Persistence For Newly-Prescribed HIV Treatment: Single Versus Multiple Tablet Regimen Comparison Among US Medicaid Beneficiaries*, AIDS RES THER 17, 12 (2020), https://doi.org/10.1186/s12981-020-00268-1 (finding that the proportion of Medicaid patients who were adherent was nearly double for those initiating STRs compared to MTRs).

[26] *See e.g.*, Hanna, D.B., et al., *Increase in STR Use and Associated Improvements in Adherence-Related Outcomes in HIV-Infected Women*, 65 J. ACQUIRED IMMUNE DEFICIENCY SYNDROME 587-96 (2014) (noting that MTRs are not less effective if they are also taken daily as prescribed); Sutton SS, Magagnoli J, and Hardin JW, *Odds of Viral Suppression by Single-Tablet Regimens, Multiple-Tablet Regimens, and Adherence Level in HIV/AIDS Patients Receiving Antiretroviral Therapy*, 37 PHARMACOTHERAPY 2014-13 (2017); Yager J et al., *supra* note 21.

lower healthcare costs,[27] reduced risk of treatment discontinuation, and avoids adverse consequences such as drug resistance. [28]

Widespread partial adherence to treatment regimens, where a patient takes some of their HIV medications but not all, poses a significant public health threat because it can lead to the development of resistant forms of the virus.[29] Drug resistance can lead to treatment failure and eliminates any further treatment from the class of drugs that the resistance impacts, thus requiring patients to switch to alternative treatment regimens that may be more limited and expensive. In addition, the drug-resistant form of the virus can then infect other patients, which further undermines efforts to end the HIV epidemic.[30] Furthermore, studies now show that individuals living with HIV who take their medicine daily as prescribed and suppress their viral load to undetectable levels have effectively zero risk of transmitting HIV to their sexual partners.[31] In other words, adherence to HIV treatment helps prevent the spread of HIV and is consistent with the National HIV/AIDS Strategy and Ending the HIV Epidemic in the U.S. (EHE) initiative.[32] Therefore, developing and formulating novel combination products such as STRs is critical.

Treating combination products as "line extensions" would penalize the life-changing innovation provided by combination therapies and create a new financial incentive for manufacturers to bring any new molecule to market separately. Because combination therapies are so important to successful treatment of infectious diseases, this could result in worse outcomes for patients and increased costs to the healthcare system. Gilead therefore supports defining a "line extension" and "new formulation" for purposes of Part D inflation rebates in a way that excludes combination products.

B. Combination Products are Not New Formulations for Purposes of the Section 11001 Program

It is similarly critical that CMS recognize that combination products are distinct from new formulations for purposes of the Section 11001 Program, which outlines what the government considers to be the primary "negotiation" process. Section 11001 of the IRA provides that "[i]n determining whether a qualifying single source drug satisfies any of the criteria [for a "negotiation-

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[27] Sutton S, Magagnoli J, Hardin J., *Impact of Pill Burden on Adherence, Risk of Hospitalization, and Viral Suppression in Patients with HIV Infection and AIDS Receiving Antiretroviral Therapy*, 36 PHARMACOTHERAPY 385-401 (2016); Sutton S, Hardin JW, Bramley TJ, D'Souza AO, Bennett CL, *Single- versus multiple-tablet HIV regimens: adherence and hospitalization risks*, 22 AMERICAN JOURNAL OF MANAGED CARE 242-48 (2016).

[28] Yager J et al., supra note 21, Cohen C et al., *supra* note 23, Bangsberg DR, Acosta EP, Gupta R, et al., *Adherence-Resistance Relationships For Protease And Non-Nucleoside Reverse Transcriptase Inhibitors Explained By Virological Fitness*, 20 AIDS 223-32 (2006).

[29] Von Wyl V, Klimkait T, Yerly S, Nicca D, Furrer H, et al., *Adherence as a Predictor of the Development of Class-Specific Resistance Mutations: the Swiss HIV Cohort Study*, 8 PLOS ONE e77691 (2013).

[30] Guyer B, et al., AMCP NEXUS, Abstract #17 (2010).

[31] NIH News Releases, *The Science Is Clear: With HIV, Undetectable Equals Untransmittable* (Jan. 10, 2019), https://www.nih.gov/news-events/news-releases/science-clear-hiv-undetectable-equals-untransmittable.

[32] National HIV/AIDS Strategy (2022-2025), https://www.hiv.gov/federal-response/national-hiv-aids-strategy/national-hiv-aids-strategy-2022-2025/.

eligible drug"], [CMS] shall use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug."[33] In addition, CMS is directed to "establish procedures to compute and apply" the price under the Section 11001 Program across "different strengths and dosage forms of a selected drug and not based on the specific formulation."[34] For the reasons described above with respect to Part D inflation rebates, combination products cannot be considered "new formulations" for purposes of the Section 11001 Program.

In addition, Section 11001 of the IRA specifically references "dosage forms and strengths of the drug, *including* new formulations of the drug, such as an extended release formulation…."[35] Because this provision uses the word "including" as a bridge between "dosage forms and strengths" and "new formulations," it makes clear that "new formulations" are a subcategory of "dosage forms and strength" changes for purposes of the Section 11001 Program.[36] The only listed example of a new formulation in Section 11001 — "extended release formulations" — further reinforces this reading because it involves precisely that kind of change: Extended release formulations "typically involve changes to the dosage form or strength of a drug."[37] Combination drugs, by contrast, are *not* merely changes in the "dosage form" or "strength" of an existing drug. Rather, they include the addition of an entirely different active ingredient. They thus cannot be treated as new formulations and aggregated with other drugs for purposes of determining whether they satisfy the criteria for a "negotiation-eligible drug" or applying the price determined under the Section 11001 Program.

We therefore urge CMS to define a "new formulation" for purposes of the Section 11001 Program to exclude combination products. Doing so will help promote the development of combination products that can improve patient adherence and health outcomes, which ultimately could lower costs overall for patients, the Medicare program, and other healthcare entities.

* * *

[33] SSA § 1192(d)(3)(B).

[34] *Id.* at § 1196(a)(2).

[35] *Id.* at § 1192(d)(3)(B) (emphasis added).

[36] *See, e.g., Hincapie-Zapata v. U.S. Att'y Gen.*, 977 F.3d 1197, 1202 (11th Cir. 2020) ("Sometimes the listed examples are broader than the general category and need to be limited in the light of that category. For example, the phrase 'any American automobile, including any truck or minivan,' would not naturally be construed to encompass a foreign-manufactured truck or minivan." (citation, quotation marks, and brackets omitted)).

[37] *Ipsen Biopharmaceuticals, Inc. v. Azar*, No. 16-CV-2372 (DLF), 2020 WL 3402344, at *11 (D.D.C. June 19, 2020).

Thank you for the opportunity to provide feedback on the Guidance regarding Part D inflation rebates. If you have any questions, please do not hesitate to contact Michelle Drozd at Michelle.Drozd2@gilead.com.

Sincerely,

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March 11, 2023

Via email to IRARebateandNegotiation@cms.hhs.gov

Dr. Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Department of Health & Human Services

RE: Medicare Part D Inflation Rebate Comments

Dear Dr. Seshamani:

On behalf of over 300 340B Covered Entities that have come together to form the Hall Render 340B Collaborative ("**Collaborative**"), we appreciate the opportunity to submit comments in response to the Medicare Part D Drug Inflation Rebates guidance document dated February 9, 2023 ("**Initial Guidance**").[1]

The Collaborative's members are safety-net government or non-profit hospitals and grant-funded clinics that provide vital access to care for our nation's uninsured, underinsured, and impoverished communities. Congress created the 340B drug discount program ("**340B Program**") to provide safety-net providers with statutory discounts on specified covered outpatient drugs ("**SCOD**" or "**340B Drugs**"), ensuring that these providers and their patients are not "unprotected against manufacturer price increases."[2] Meanwhile, CMS and third-party payor reimbursement in the ordinary course for drugs that may have been acquired using a 340B Program discount ensures that participating safety-net providers ("**Covered Entities**") can continue to reach more eligible patients and provide more comprehensive services, again consistent with Congressional intent.[3]

We recognize that CMS has a statutory obligation to exclude drugs 340B Drugs from its Part D Inflation Rebate requests beginning in 2026. However, we believe that the mechanism for identifying ineligible 340B Drugs described in the Initial Guidance is unlikely to lead to CMS's

[1] *See* Inflation Reduction Act Initial Program Guidance, 88 Fed. Reg. 9293 (available at: https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-initial-guidance.pdf) (Feb. 13, 2023);

[2] H.R. Rep. 102-384(II), at 11.

[3] *See id.* at 12.

desired result and could have severe unintended consequences for safety-net 340B Covered Entities.

Instead of mandating how pharmacies identify 340B Drugs, CMS should provide a framework that allows market actors to develop solutions that fit within the mature 340B contract pharmacy environment while protecting Covered Entities and their pharmacy partners from discriminatory practices by the manufacturers, insurers and pharmacy benefit managers that facilitate and administer the Part D program on CMS's behalf.

340B Covered Entities, Contract Pharmacies and Retrospective Replenishment

It is important to recognize that 340B pharmacies are site of service extenders for 340B Covered Entities, who are the Program's intended beneficiaries. Thus, the cost of complying with any requirement CMS imposes on Part D Plan Sponsors regarding the identification of 340B Drugs will eventually flow down to those Covered Entities via "direct and indirect remuneration" ("**DIR**") fees charged by pharmacy benefit managers ("**PBMs**"). The 340B contract pharmacy system is a mature, if evolving, market, and CMS can achieve its goal of obtaining the information necessary to exclude 340B Drugs from its Part D rebate invoices without imposing burdensome new requirements that increase costs for Covered Entities. Similarly, CMS's requirements should not unnecessarily limit Covered Entities' ability to benefit from 340B contract pharmacy arrangements.

Covered Entity 340B community pharmacies[4] (sometimes referred to as "**Contract Pharmacies**") facilitate the provision of 340B Drugs to that Covered Entity's "Eligible Patients". These Contract Pharmacies generally do not maintain dedicated, separate physical inventories of 340B Drugs to dispense to Covered Entity patients. Rather, pre-existing inventory is dispensed to Covered Entity patients and subsequently replenished at the required 340B price. This means that it is not feasible to include a 340B identifier on claims real time at the point-of-sale. That is, determining the 340B status of a drug occurs through a retrospective data-matching process. Under this process, specialized software ingests information from the Covered Entity and the pharmacy, then identifies dispenses that resulted from a patient's encounter with the Covered Entity. When enough dosing units have accumulated, the Covered Entity orders a package of drugs at the 340B price and directs the manufacturer or wholesaler to ship it to the pharmacy. Because the shipment is replenishing stock that the pharmacy already dispensed, it is returned back to the neutral stock. This virtual inventory, retrospective replenishment model is well known to, and accepted by, the Health Resources & Services Administration ("**HRSA**").[5]

CMS proposes to require pharmacies to include a 340B identifier on all pharmacy claims where a Part D beneficiary received a 340B Drug, stating that the identifier would be "the most reliable way to identify drugs that are subject to a 340B discount that were dispensed under Medicare Part

[4] We intend this term to mean any pharmacy that dispenses drugs to patients for administration at home, such as retail, specialty, and mail-order pharmacies.

[5] *See, e.g.*, Declaration of Krista M. Pedley, Director, Office of Pharmacy Affairs (June 16, 2021), Docket No. 53-2 in Novo Nordisk Inc. & Novo Nordisk Pharma, Inc. v. U.S. Dep't of Health & Human Servs. No. 21-cv-806 (D.N.J. filed Jan. 15, 2021)

D."[6] The retrospective replenishment model means that this identifier can only be appended to claims retrospectively, we believe only by using the N1 Information Reporting transaction type. CMS would not be the first, or even the largest, entity to impose such a requirement. In August 2020, Express Scripts PBM, the pharmacy benefit manager for more than 100 million Americans,[7] updated its Provider Manual to require pharmacies to identify 340B Drugs at the point of sale or retrospectively using the exact same transaction types that CMS described in the Initial Guidance.[8] Yet, due to the limitations associated with retroactive claims identification, CMS's understanding that "few pharmacies use this transaction" is still accurate.[9]

As explained below, we believe there are several reasons behind the low uptake of N1 transactions that CMS should consider when deciding how to identify 340B Drugs dispensed to Part D beneficiaries. Ultimately, we believe that CMS is much more likely to achieve its stated goals and prevent unintended harm from coming to Covered Entities and their patients if it establishes guidelines for reporting 340B Drug data on an aggregated, retroactive, basis rather than a rigid mandate which has proven to be unworkable. We also requested that CMS affirmatively state that it will keep this data confidential in order to prevent the inappropriate monetization and aggregation of that information by third party, for-profit organizations.

Challenges in Requiring 340B Drug Identification

Implementing an effective 340B Drug identification system will require CMS to address numerous challenges within the 340B retail pharmacy system. These challenges can be characterized as informational and operational, as well as legal.

Informational and Operational Challenges

CMS Should Not Require Pharmacies to Use the N1 Transaction Type

Pharmacies are unable to identify claims filled with 340B Drugs at the point of sale because of a necessary, and ultimately efficient, information lag. 340B-qualifying pharmacy encounters are identified retrospectively by comparing Covered Entity encounter data with pharmacy dispense data. This structure facilitates a robust and efficient 340B contract pharmacy system. Without it, community pharmacies would face materially burdensome challenges associated with maintaining the transaction history, transaction information and transaction statement ("**T3**") data required

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[6] Initial Guidance, § 40.2.

[7] *See* Express Scripts website, *About* (https://www.express-scripts.com/corporate/about) (last accessed Mar. 9, 2023). In contrast, about 49 million Americans were enrolled in Part D plans in 2022. Kaiser Family Foundation, *An Overview of the Medicare Part D Prescription Drug Benefit* (Oct. 19, 2022) (https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/) (last accessed Mar. 9, 2023).

[8] Express Scripts, *Frequently Asked Questions, 340B Reporting Requirement (N1 Transactions)* (https://www.express-scripts.com/art/prc/340B_Drug_Discount_Program_N1_Transaction_FAQ.pdf) (last accessed Mar. 9, 2023).

[9] Initial Guidance, § 40.2.

under the federal Drug Supply Chain Security Act ("**DSCSA**"),[10] and diversion of 340B Drugs may increase due to human error.[11]

As a result, CMS's 340B Drug identification mandate should permit pharmacies to identify claims filled with 340B Drugs retrospectively and on a batched basis, without requiring the use of a specific tool to do so. While one might assume the N1 Information Reporting transaction would allow for this, we understand that industry-standard point-of-sale pharmacy software systems used by many pharmacies do not permit them to use the N1 transaction type, or at least use it in the way that the Initial Guidance would require. The impending adoption of the NCPDP F6 Telecommunications Standard[12] may be a natural point for software providers to add this functionality, but it is not clear if they will do so. If they do, it can be expected that software vendors and others will charge Covered Entities for configuring the software in this way.

To avoid placing this financial burden on Covered Entities, CMS's Drug identification mandate should be flexible enough to permit pharmacies to identify claims filled with 340B Drugs in various ways at the pharmacies' reasonable discretion. This could include, for instance, batch data uploads in industry-standard formats such as .csv or .xlsx files that are transmitted through appropriately secure channels. To ensure consistency and efficiency across the regulated industry, CMS should provide template .csv or .xlsx files that pharmacies may use for this purpose and require that they be used to submit data directly to a CMS clearinghouse and not through a PBM or other third party, to the extent permissible under the Inflation Reduction act. Our concern with direct uploads to PBMs and other third parties is that they could scrape and monetize that data consistent with what manufacturers have been, we believe, illegally compelling as part of their 340B Program Contract Pharmacy restrictions.

> **Recommendation: CMS should permit pharmacies to identify claims filled with 340B Drugs using methods other than the N1 transaction, such as batch uploads in .csv or .xlsx format. CMS should provide template files and require Part D Plan sponsors and their PBMs to accept them.**

CMS Should Not Require Pharmacies to Identify 340B Drugs Within an Unreasonably Short Time Period

The Initial Guidance does not state that CMS intends pharmacies to identify claims filled with 340B Drugs within any specific period of time after the claim was submitted. However, PBMs and manufacturers have required data submission within certain periods of time, such as 45 days from the date of dispense, without any legal justification for these deadlines. In addition, Section 1860D-14(a)(1) requires the Secretary to submit its invoices to manufacturers within nine months of the close of any applicable period. As a result, it is reasonable to assume that in follow-up guidance, CMS would set a deadline for 340B transaction reporting. If it does so, CMS should not set a deadline of less than 18 months from the date of dispense. This would permit CMS to

[10] Codified at 42 U.S.C. § 360eee *et seq*.

[11] *See* 42 U.S.C. § 256b(a)(5)(B).

[12] *See* 87 Fed. Reg. 67,634 (Nov. 9, 2022).

collect the data it needs to comply with the Inflation Reduction Act while avoiding unnecessary limitations on the 340B Program.

It is not the case that every dosing unit that a contract pharmacy dispenses to an eligible patient will be replenished at the 340B price. Instead, enough dosing units have to accumulate such that the Covered Entity can order an entire package of the drug. If the packages are large or the drugs have low volumes, it can take months for enough dosing units to accumulate. In many cases, agreements between Covered Entities and their contract pharmacies set a cutoff date of one year after the date of dispense for a drug to count toward these accumulations. Notably, this is a market-developed solution to this problem; slow-moving drugs are not addressed in the 340B statute or HRSA regulations.

We also note, as CMS is aware, that PBMs have continued their practice of retroactively charging direct and indirect remuneration ("**DIR**") fees. These DIR fees can be charged to 340B pharmacies up to a year after the date of dispense, which is many cases can result in recharacterization of claims from 340B-eligible to non-340B. In order to prevent manufacturers and PBMs from benefitting by not being subject to a CMS rebate *or* offering a 340B price, a sufficient period of time between dispense and claims identification is required.

Although the Inflation Reduction Act requires CMS to furnish manufacturers with their Part D Inflation Rebate invoice within nine months of the end of an applicable period, it also requires CMS to establish a method to reconcile overcharges and undercharges that are identified based on updated information received from Part D Plan sponsors.[13] If it were to require pharmacies to identify claims filled within 340B Drugs within any timeline, CMS would create a new restriction on Covered Entities' use of contract pharmacies, because such a timeline currently does not exist within the 340B statute or regulations. As a result, if CMS does deem it necessary to set such a deadline, the deadline should comport with prevailing practices within the industry. Our recommendation is that the deadline be not less than 18 months after the date of dispense and to reconcile any amounts owed to or from a manufacturer through an adjustment on each year's invoice. An 18-month period would fully encompass the DIR fees process unilaterally compelled by PBMs and manufacturers, as well as the common one-year "slow-moving drug" provisions contained within many contract pharmacy agreements. Even in the most extreme cases this would give CMS 3 months to calculate adjustments to the next invoice.[14] In addition, it would avoid creating a new, shorter period that could be harmful to 340B Covered Entities.

> **Recommendation: CMS should permit pharmacies to identify Part D claims filled with 340B Drugs for at least 18 months following the date of dispense.**

[13] 42 U.S.C. § 1395w-114b(b)(5)(C).

[14] If applicable periods from October 1 through the following September are defined as periods 1, 2, 3, etc., a drug dispensed on September 30 of period 1 would have to be identified as 340B no later than March 31 of period 3. The invoice for the dispenses occurring during period 1 is due no later than June 30 of period 2. As a result, CMS would have 3 months to calculate an adjustment to the invoice for period 2, which would be due no later than June 30 of period 3.

We would be happy to discuss any of these concerns at your convenience.

Very Truly Yours,

HALL, RENDER, KILLIAN, HEATH & LYMAN, P.C.

Todd A. Nova

James Junger

www.HaystackProject.org

March 11, 2023
The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244–1850

VIA ELECTRONIC DELIVERY to: IRARebateandNegotiation@cms.hhs.gov

Re: Medicare Part D Inflation Rebate Comments

Haystack Project appreciates the opportunity to submit its comments in response to the Centers for Medicare & Medicaid Services' (CMS') Medicare Part D Inflation Rebate Guidance.

Haystack Project is a 501(c)(3) non-profit organization enabling rare and ultra-rare disease advocacy organizations to highlight and address systemic access barriers to the therapies they desperately need. Our core mission is to evolve health care payment and delivery systems, spurring innovation and quality in care toward effective, accessible treatment options for Americans living with rare or ultra-rare conditions. Haystack Project is committed to educating policymakers and other stakeholders about the unique circumstances of extremely rare conditions with respect to product development, commercialization, and fair access to care.

Haystack Project supports health policy refinements that make it possible for all patients to receive the medications they need without compromising the financial sustainability of our payer systems or chilling innovation in disease states with high unmet needs. Our comments offer insights and recommendations from Haystack Project's over-130 ultra-rare disease patient advocacy organization members so that CMS can continue to build upon its efforts to ensure that Medicare coverage and benefits confer equally to individuals regardless of the rarity of their health condition(s).

Background

Of the approximately 7,000 rare diseases identified to date, 95% have no FDA-approved treatment option. Advances in research and development such as regenerative medicine, gene

therapy, and other targeted therapy innovations offer a renewed hope for Haystack Project's patient and caregiver communities that a treatment might be on the horizon for any disease, no matter how rare. Unfortunately, treatments targeted to extremely rare conditions are, by necessity, associated with high costs when compared to drugs developed for more common, well-understood disease states. We have significant concerns that unless CMS fully considers the unique challenges associated with developing and manufacturing rare disease treatments as it implements provisions of the Inflation Reduction Act (IRA), our patients will suffer disproportionately from its unintended consequences.

As you know, Congress tackled the incentive framework for orphan drugs to counter the commercial realities associated with research and development toward treatments for serious medical conditions affecting small populations. Countless lives have been improved or saved by new therapies since then. The economic calculation of research and development costs, projected risk, and population-based revenue estimates must include a realistic assessment of reimbursement mechanisms and payment structures that can tip the scales for or against pursuing a specific drug candidate for an orphan indication.

While the Orphan Drug Act (ODA) clearly boosted interest in pursuing rare disease treatments, its incentives are a fixed set of counterbalances to the inherent risk associated with rare disease research and development. When patient populations approach the 200,000 orphan disease limit, the ODA incentives may be sufficiently robust to mitigate clinical trial and reimbursement risks. As affected populations dwindle below 20,000 or even into and below the hundreds, however, the balance is far more fragile. Innovators newly considering a pipeline candidate in an ultra-rare disease state face substantial uncertainties on whether Medicare and other payers will maintain sufficient payment to ensure commercial viability. The inflation rebates will add an additional layer of uncertainty and risk.

Haystack Project and its member organizations appreciate that CMS must implement the inflation rebate provisions of the IRA within an extremely limited timeframe. We generally support many of the policies outlined in CMS' guidance as applied to most treatments covered under Medicare Part D. We are, however, concerned that the unique circumstances associated with treatments for extremely rare diseases will drive risks and uncertainties that will not only discourage new product development but threaten financial viability of existing treatments. This would be catastrophic for our patient communities.

Reducing or Waiving the Rebate Amount in the Case of a Part D Rebatable Drug on the Shortage List

Section 1847A(i)(3)(G) provides that CMS reduce or waive the rebate amount with respect to a Part D rebatable drug for an applicable calendar quarter in two cases: (1) when a Part D rebatable drug is described as currently in shortage on the shortage lists authorized under section 506E of the Federal Food, Drug, and Cosmetic Act (FD&C Act) at any point during the calendar quarter; or (2) for a biosimilar biological product when the Secretary determines there

is a severe supply chain disruption during the calendar quarter, such as that caused by a natural disaster or other unique or unexpected event.

CMS states that it intends to structure this policy to provide a period of financial relief for manufacturers in certain circumstances without creating incentives for manufacturers to intentionally maintain their drug or biological in shortage for the purpose of avoiding an obligation to pay a rebate.

Haystack Project supports broad application of CMS' authority to adjust and/or waive imposition of rebates on drugs impacted by shortages. We also appreciate that CMS has asked whether there are "specific causes for or types of a shortage where CMS might reduce or waive the rebate amount differently, such as drugs that treat certain conditions or address critical need, and how CMS would identify such drugs."

We ask that CMS fully consider the impact of its guidance on rare disease treatments and urge the Agency to implement a set of safeguards and/or exceptions to address the realities associated with small population treatments, including, for example:

- New requirements for manufacturing and/or quality assurance can introduce significant costs that are allocated over a smaller volume of product. Manufacturers facing these challenges must increase prices to account for increased cost, attempt to "sell" the asset to a manufacturer able to accommodate the requirements, or stop manufacturing the treatment.

- Shortages and/or price increases in ingredients will present more of a challenge to manufacturers producing low-volume treatments as they do not have the purchasing power of their high-volume counterparts. This could result in a real-world ingredient shortage well in advance of official product shortage reporting.

- Introduction of new products to address an ultra-rare disease can have an enormous impact on the per-unit costs of continuing to manufacture an older treatment. For example:

    - If rare disease X impacts 20,000 patients and is associated with 5 acute "attacks" per patient each year, a drug addressing the attacks could expect volume of 100,000 treatment episodes per year.
    - A new treatment option that reduces the incidence of these attacks would be valuable to patients but would not eliminate the need for the older product.
    - Unfortunately, many of the manufacturing costs for the older product are fixed regardless of volume. Without the ability to increase the product price, a manufacturer could not continue to offer the product.

Haystack Project urges CMS to implement a limited set of guardrails applicable to rare disease products that would protect manufacturers of products addressing small populations from

punitive rebates when (and to the extent that) increases in the costs of manufacturing a unit of product exceed the applicable CPI-U. Without this protection, Haystack Project fears that it will become increasingly difficult to protect or project the commercial viability of the treatments many within our patient communities rely on and most hope will be developed in the future.

Value-Based Arrangements Should Not Trigger or be Subject to Inflation Rebates.

The Administration has prioritized a set of innovation models focused on further reducing the costs of drugs and biologics, including value-based arrangements for cell and gene therapies. These arrangements are likely to be increasingly adopted among commercial payers as a coverage and payment mechanism for high-cost treatments. Haystack Project expects that treatments for rare and ultra-rare conditions will be disproportionately impacted by value-based payments that rely on patient-specific outcomes for determining the actual price received for the treatment.

These arrangements are inherently associated with dips and peaks in drug "price" over time without any further manufacturer decision or action. In fact, it is likely that payers and manufacturers could improve their ability to identify likely responders over time. This could lead to imposition of a penalty in the form of inflation rebates based on improved patient selection, increased provider experience managing the patient, and other factors associated with real-world "value" to patients and payers.

We urge CMS to revise its guidance to accommodate and protect pricing arrangements aligned with value and improved patient outcomes.

CMS Should Enable Manufacturers to Avoid Inflation Rebates When AMP Fluctuations Are Outside their Control.

Haystack Project expects that AMP fluctuations from quarter to quarter are particularly common for drugs treating rare and ultra-rare conditions. These fluctuations can occur for many reasons beyond the manufacturer's control. For example, a greater number of patients being covered (or ceasing coverage) by a major payer, introduction or removal of mail-order pharmacy options, and other factors can have a significant impact on the AMP – the smaller the total patient population, the greater impact a single patient or payer will have.

We are concerned that patient access to necessary treatments will be impeded if CMS imposes inflation penalties on manufacturers when they have not increased their list price (or even changed contract terms). This was not the intent of the statute.

Haystack Project is similarly concerned with the interaction between inflation rebates and the increasing interest among Medicare, Medicaid, and other payers in reducing payment for accelerated approval treatments. Haystack Project has voiced its objection to this policy and

will continue to do so. If, however, payers subject accelerated approval treatments to a discount until confirmatory studies demonstrate clinical benefit, it would be unfair and counter-intuitive to impose an inflation penalty when the product receives traditional approval.

Conclusion

Haystack Project appreciates the opportunity to provide feedback on this important guidance. We believe that our 130+ ultra-rare disease member community is uniquely positioned to offer CMS important insights it will need to implement the inflation rebates without compromising rare disease patient access to life-saving treatments. If you have any questions or need additional information, please contact me or our policy consultant, M Kay Scanlan, JD at 410-504-2324.

Very truly yours,

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Dr. Meena Seshamani, MD, PhD
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Concerns about modifier approach for identifying 340B drugs dispensed under Medicare Part D

Dear Dr. Seshamani,

On behalf of Regional Health Care Affiliates DBA Health First Community Health Center, thank you for the opportunity to provide input into CMS' plans for implementing the Medicare inflationary rebates established under the Inflation Reduction Act. We represent one of the 30 Federally Qualified Health Centers in the state, compromising 8 clinic sites in 6 counties in Western Kentucky.

I begin this letter with a summary of our comments, followed by background on FQHCs and 340B, and then a detailed discussion of each comment.

SUMMARY OF COMMENTS

1. FQHCs' experience clearly indicates that requiring a 340B indicator (also known as a modifier) on Part D drugs would:
   a. Result in data that is highly unreliable.
   b. Force FQHCs to shut down many of their contract pharmacy arrangements for Part D drugs, leading to an overall loss in 340B savings and subsequent reduction in services provided to underserved patients.

2. Instead of a modifier, FQHCs recommend that CMS implement a "clearinghouse" model for identifying 340B drugs covered by Part D. Compared to a modifier requirement, a clearinghouse would:
   a. Produce much more reliable data.
   b. Be significantly less labor-intensive.
   c. Preserve the ability of FQHCs and other 340B providers to rely on contract pharmacies to dispense 340B drugs to Part D enrollees, thereby avoiding reductions in access.
   d. Could be expanded to include 340B drugs dispensed to Medicaid patients.

BACKGROUND INFORMATION ON FQHCs, 340B, and CONTRACT PHARMACIES

Federally Qualified Health Centers (FQHCs) are the backbone of our nation's health care safety net. By law and by mission, FQHCs focus on serving medically underserved patients, and ensure that nobody is

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denied care, regardless of ability to pay. In our state, 17.2% of the population have incomes below the Federal Poverty Level. These patients are cared for by the FQHC's of our state.

FQHCs offer a broad range of services, including primary care, dental, behavioral health, and pharmaceuticals. Many of these services – and the sliding fee discounts that make them affordable for our patients -- are supported by savings generated through the 340B drug discount program. At RHCA, we help patients with Medications, Continuing Glucose Monitoring Devices, Women's Health, Dental, Primary Care, and general health needs. For many FQHCs, 340B savings are more important to their financial viability than the Federal grant they receive.

Nationally, FQHCs rely on contract pharmacy arrangements to dispense roughly 50-60% of the 340B drugs provided to their patients – the highest percentage of any type of 340B provider. Thus, the 340B savings generated at contract pharmacies support many services that the FQHC would otherwise be unable to provide to their medically-underserve patients.

Given the importance of 340B contract pharmacy arrangements to our FQHCs and their patients, ***we are deeply concerned about the following statement on page 18 of the preliminary guidance that CMS shared on February 9, 2023:***

> ***"CMS believes that requiring that a 340B indicator be included on the PDE record is the most reliable way to identify drugs that are subject to a 340B discount that were dispensed under Medicare Part D."***

While we understand and support the need for CMS to collect accurate data on which Part D prescriptions were filled with 340B drugs, requiring an indicator (aka modifier) on claims would not only produce unreliable data; it would also undermine FQHCs' 340B savings – and the services they support, particularly at contract pharmacies. Fortunately, there is an alternative way for CMS to collect that data that would yield more reliable data without threatening the financial support that FQHCs rely on. These concerns and recommendations are discussed in detail below.

DETAILED COMMENTS

1. A modifier requirement under Part D would produce highly unreliable data.

Requiring pharmacies to include a 340B modifier on Part D claims filled with 340B drugs would produce highly unreliable data for a combination of two reasons:

- Determining whether a prescription can and should be filled with a 340B drug can be a very complicated, data-intensive process that often cannot be completed reliably at the time that the prescription is being filled and the claim submitted to the payer (aka the point-of-sale.)
- Because of this complexity, most prescriptions that are filled with 340B drugs ("340B prescriptions") are not identified by the pharmacy until after the drug has been dispensed. Therefore, adding a 340B modifier would require pharmacies to reopen and update every claim for every Medicare 340B prescription – a laborious process which many pharmacies (particularly large chain pharmacies) have been unwilling to do.

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The complex decision-tree for determining whether a dispensed prescription should be filled with a 340B drug. As illustrated in the attached flowchart (see Attachment) determining if a prescription can be filled with a 340B drug requires evaluating each of the following issues:

- Does the payer allow for a 340B drug to be dispensed?
- Is the individual a patient of the FQHC?
- Has the patient been seen at the FQHC recently enough to qualify for a 340B drug?
- Was the prescription written by a provider who works for the FQHC?
  - If yes, was the provider:
    - moonlighting when the prescription was written?
    - providing a service that is under the FQHC's scope of project?
  - If no, can the FQHC demonstrate that it has assumed responsibility for the care that generated the prescription?
- Is it more cost-effective to dispense a non-340B drug?

(Note that this decision tree does not apply to clinically-administered drugs – i.e., Part B drugs – as they are clearly 340B-eligible. For that reason, FQHCs do not have the same concerns about using a modifier to identify Part B drugs.)

Many 340B prescriptions cannot reliably be identified at the point -of-sale. To make an accurate assessment for each prescription, the pharmacy needs access to patients Electronic Health Records and to the FQHCs' administrative records regarding in-scope services, contracted providers, moonlighting providers, etc. Because of the amount of work and data involved, FQHCs (and other 340B providers, known as covered entities) hire Third Party Administrators (TPAs) to conduct these assessments. Every evening, the TPAs sync extensive data between the FQHC and the pharmacies. The TPA then reviews all prescriptions to identify those that can be filled with 340B drugs. Due to the volume of data involved, it is not technically feasible for this data to be downloaded and synced in "real time", as would be required for 340B-eligibility to be determined at the point-of-sale. Thus, it is impossible to reliably identify 340B prescriptions at the point-of-sale.

For many 340B prescriptions, adding a modifier would require amending a submitted claim – a very labor-intensive process that most contract pharmacies refuse to do.
As discussed above, many 340B prescriptions cannot be identified until after the claim has been submitted to the payer. Therefore, including a modifier requires that the pharmacy amend the submitted claim for each 340B Medicare prescription, which is a very labor-intensive and time-consuming process. Also, some payers will not accept amended claims, and instead require the pharmacy to first rescind the original claim, and then submit a new one – further increasing the workload.

Given the additional work involved, it is not surprising that most contract pharmacies – particularly the large chains – refuse to apply a modifier on 340B claims. To demonstrate this, we encourage you to review what happened when Express Scripts (ESI) – one of the three largest Pharmaceutical Benefits Managers (PBMs) in the US – announced a modifier requirement in February 2021.

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In summary, a modifier requirement under Part D would yield unreliable data on 340B prescriptions, as a modifier often cannot be added to a claim in real time, and most contract pharmacies are unwilling to amend or rescind a previous claim in order to add the modifier.

2. A modifier requirement would force FQHCs to shut down many of their contract pharmacy arrangements for Part D drugs, leading to an overall loss in 340B savings and subsequent reduction in services provided to underserved patients.

As described above, FQHCs rely on contract pharmacies to fill 50% to 60% of their 340B prescriptions and use the resulting savings to support a range of services for underserved populations. A CMS requirement to include a modifier on all claims for Part D 340B prescriptions would jeopardize these contract pharmacy arrangements, and the services they support. As discussed above, large chain pharmacies have made it clear that they are unwilling to apply a modifier. Thus, to ensure compliance with Federal rules, FQHCs would be forced to shut down their contract pharmacy arrangements for Part D drugs. This would be harmful to FQHCs' finances (and the services they support) in its own right; also, a CMS modifier requirement would encourage other payers to impose their own modifier requirements, further eating away at the contract pharmacy savings that FQHCs rely on.

3. Instead of a modifier, FQHCs recommend that CMS implement a clearinghouse model for identifying 340B drugs covered by Part D.

Fortunately, there is an alternative to the modifier approach that avoids the challenges outlined above. This model – which has been used successfully for years by Oregon Medicaid and is now being implemented by Hawaii Medicaid – is called a "clearinghouse" or "flat file" model. Under this model, covered entities send a Medicaid contractor a "flat file" that lists every Medicaid claim filled with 340B drugs during a recent time period (e.g., the past two weeks, or month). The file contains the NDC code and BIN/ PCN number for each claim, but no Protected Health Information. The contractor aggregates the data by NDC, BIN, and PCN, and shares the totals with the Medicaid agency, so that it can deduct them from the number of units on which it claims Medicaid Drug Rebates.

This clearinghouse approach has multiple benefits compared to a modifier requirement:

- **A clearinghouse approach produces much more reliable data.** Unlike a modifier approach, the clearinghouse approach allows covered entities to submit 340B data on a retrospective basis. Thus, it gives the covered entity and pharmacy the additional time they need (after the point-of-sale) to conduct a thorough analysis of whether each prescription should be filled with a 340B drug. Also, it does not require rescinding or amending claims in order to provide accurate data.
- **A clearinghouse approach is much less labor-intensive.** The modifier approach requires that every claim for every 340B drug be either amended or rescinded in order to have the modifier added – an extremely time-consuming and labor-intensive process. In contrast, the clearinghouse approach allows thousands of 340B prescriptions to be identified at once, through a flat-file that can be produced automatically by a covered entity or their TPA.

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- **A clearinghouse approach preserves the ability of FQHCs and other covered entities to rely on contract pharmacies, thereby avoiding reductions in access.** By taking the burden of identifying Part D 340B prescriptions off of contract pharmacies, a clearinghouse approach would preserve FQHCs' contract pharmacy relationships, for Part D and likely for commercially insured patients. This preserves FQHCs' ability to retain savings generated by contract pharmacies – and to continue using them to support the range of services for underserved populations.
- **Could be expanded to incorporate Medicaid 340B data.** A clearinghouse for Part D 340B data could easily be expanded to receive data on Medicaid 340B drugs. This would provide a streamlined and consistent national approach for avoiding duplicate discounts under Medicaid.

Thank you for your consideration of our serious concerns about the modifier model, and our proposed alternative. If you have any questions about our comments, please contact Ronnah Alexander 270-667-2533.

Sincerely,

DocuSigned by:
Ronnah Alexander
0B77CB1DE07C4F4...

Ronnah Alexander, RPh. MBA, CPO/340B
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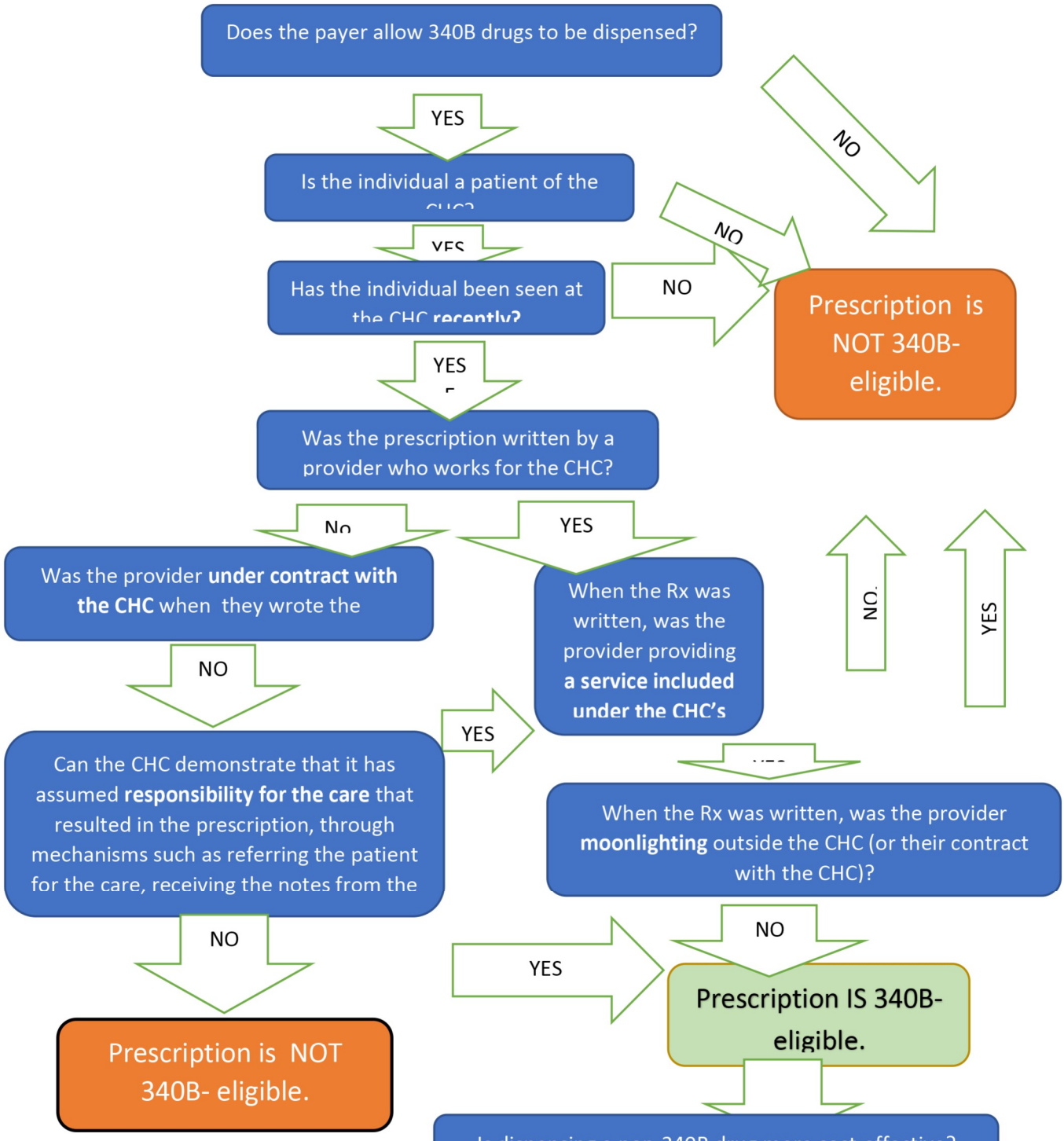
Process for a Pharmacy to Determine if a Prescription Should be Filled with a 340B Drug



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March 8, 2023

Dr. Meena Seshamani, MD, PhD
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Concern about modifier approach for identifying 340B drugs dispensed under Medicare Part D

Dear Dr. Sheshamani,

On behalf of HealthSource of Ohio, thank you for the opportunity to provide input into CMS' plans for implementing the Medicare inflationary rebates established under the Inflation Reduction Act. Healthsource of Ohio is a Federally Qualified Health Care center (FQHC) located in Southwest Ohio that receives federal grant funds under Section 330 of the Public Health Services Act. We have 359 full time employees and served 59,682 patients in 2022 through 238,048 visits. In 2022 we filled over 145,000 prescriptions for patients from our in-house pharmacies. HealthSource of Ohio offers the following primary care services: Family Medicine, Pediatrics, Ob/Gyn, Optical, School Based Health, Dentistry, Behavioral Health, and Pharmacy in offices located in eight rural and semi-rural counties.

As you know, FQHCs are the backbone of the health care safety net, providing high-quality, affordable care to over 30 million medically underserved patients, regardless of whether they have insurance or their ability to pay. Eighty percent (80%) of HealthSource of Ohio patients have income levels below 200% of Federal Poverty Levels. Fifty-one percent (51%) of our patients have income levels below 100% of Federal Poverty Levels.

FQHCs offer a broad range of services, including primary care, dental, behavioral health, and pharmaceuticals. Many of these services – and the sliding fee discounts that make them affordable for our patients -- are supported by savings generated through the 340B drug discount program. In addition, our 340B savings have allowed HSO to expand our School Based Health (SBH) programs, including SBH dental and vision. We have also been able to utilize 340B savings to invest in our infrastructure, providing greater access to more patients and offering more services in the communities we serve.

Nationally, FQHCs rely on contract pharmacy arrangements to dispense roughly 50-60% of the 340B drugs provided to their patients – the highest percentage of any type of 340B provider. Thus, the

340B savings generated at contract pharmacies support many services that the FQHC would otherwise be unable to provide. Given the importance of 340B savings – including those generated by contract pharmacies – we were very concerned to hear that CMS is considering requiring an indicator (also known as modifier) on all claims for Part D prescriptions that were filled with 340B drugs.

As discussed in detail in comments submitted by other members of the FQHC community, FQHCs' experience clearly indicates that requiring a 340B indicator (also known as a modifier) on Part D drugs would:

a. Result in data that is highly unreliable.
b. Force FQHCs to shut down many of their contract pharmacy arrangements for Part D drugs as 340B determination is completed post point of sale, making it impossible for contract pharmacies to add this type of claim modifier. This would lead to a devastating loss in 340B savings and subsequent reduction in services provided to underserved patients.

Instead of a modifier, we recommend that CMS implement a "clearinghouse" model for identifying 340B drugs covered by Part D. Compared to a modifier requirement, a clearinghouse would:

a. Produce much more reliable data.
b. Be significantly less labor-intensive.
c. Preserve the ability of FQHCs and other 340B providers to rely on contract pharmacies to dispense 340B drugs to Part D enrollees, thereby avoiding reductions in access.
d. Could be expanded to include 340B drugs dispensed to Medicaid patients.

Thank you for your consideration of our serious concerns about the modifier model, and our proposed alternative. If you have any questions about our comments, please feel free to contact me at contact information listed within signature.

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March 11, 2023

Dr. Meena Seshamani, M.D. Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Email to: IRARebateandNegotiation@cms.hhs.gov

Re: Medicare Part D Inflation Rebate Comments

On behalf of H-E-B, thank you for the opportunity to comment on *Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860-D-14B of Social Security Act*. H-E-B is a regional grocery chain operating over 295 pharmacies operating in Texas.

40.2.7 Exclusion of 340B Acquired Units from Part D Rebatable Drug Requirements

As one of the smallest chains in the United States to operate our own pharmacy dispensing system (PDS), we have serious concerns with the proposed mechanism for capturing 340B purchases. We disagree with the PDE record being the most reliable way to identify 340B discounts for Part D drugs and believe the proposed mechanism will place a tremendous burden on small regional and, likely, independent pharmacies.

Burden on Small and Regional Pharmacies

The NCPDP "N" transaction is used to capture non-essential "information" unrelated to patient care after POS (i.e. not in "real time"). H-E-B does not utilize the N/N1. Further, we are not aware of this transaction being commonly utilized by other community pharmacies except in rare instances where mandated by local or state governmental agencies.

Requiring all pharmacies to begin using N1 transactions would be an intensive and costly technology effort with no offsetting revenue gains or improvement in patient outcomes. It is also likely smaller pharmacies would need to hire outside administrators to identify and report Part D 340B transactions after POS.

Use of Pharmacy Data to Determine 340B Manufacturer Discounts is Not Reliable or Accurate

A 340B contract pharmacy does not generally know at POS whether an individual prescription will result in a discounted purchase for several reasons. The covered entity, or their administrator, determines 340B eligibility well after POS.[1] Once qualified, a dispensing record may or not become part of a 340B rebatable sale for several reasons. First, many covered entities utilize a virtual inventory for contract pharmacies to ensure compliance and prevent diversion,.[2] In a virtual inventory model, contract

pharmacies use their own inventory to dispense a potential 340B prescription. A pharmacy is later replenished when the sum of dispensed, eligible prescriptions aggregates to a "full-bottle threshold." In many cases, this means only a portion of a prescription is used to hit the threshold. The remaining portion may or may not contribute to a future 340B replenishment.

340B is also not unique to Medicare, so determining which part of individual discounted purchases resulted from Part D prescriptions would be challenging in the proposed manner particularly when adjustments are made a later date (such as for claim disqualification or audits). Finally, the actual 340B discounted purchase can occur weeks or months after dispensing. In summary, use of pharmacy Part D claims and the PDE to determine rebatable 340B drugs would not be reliable, timely or accurate. Ultimately, the actual sell/invoice is the only accurate record of a 340B discount.

Thank you again for the opportunity to comment on CMS' proposed requirements for implementing Inflation Rebates. If we can further clarify any comments or assist in any way please, contact us.

Respectfully,

Jay Bueche, R.Ph.
H-E-B
Managing Director,
Pharmacy Supply Chain, Managed Care & Payment Policy
Bueche.jay@heb.com

1. *Which Prescriptions Are 340B Eligible;* National Association of Community Health Centers; https://www.nachc.org/wp-content/uploads/2018/04/Which-Rx-are-elig-for-340B-updated-March-2018.pdf
2. https://www.hudson340b.com/news/inventory-monitoring-with-the-virtual-replenishment-model/#:~:text=Virtual%20replenishment%2C%20also%20known%20as,340B%20and%20non%2D340B%20drugs; viewed 3/11/2023

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March 10, 2023

VIA EMAIL — IRARebateandNegotiation@cms.hhs.gov

Dr. Meena Seshamani
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments

Dear Dr. Seshamani:

Incyte Corporation ("Incyte") writes to submit comments on the Centers for Medicare and Medicaid Services' ("CMS") February 9, 2023 memorandum to pharmaceutical manufacturers providing initial guidance on the Medicare Part D Drug Inflation Rebate program, codified under section 1860D-14B of the Social Security Act ("SSA") ("the Initial Guidance").[1] Incyte supports the comments submitted by our trade associations, the Pharmaceutical Research and Manufacturers of America ("PhRMA") and the Biotechnology Innovation Organization ("BIO") on the Initial Guidance. We write separately to voice our concerns with the approaches CMS is considering regarding "line extension" and relatedly "new formulation." Our concerns stem from our deep experience in pharmaceutical research and development ("R&D") and in commercializing our drug products. We also write to recommend how CMS should treat "subsequently approved drugs" and drugs without Average Manufacturer Price ("AMP") eligible sales, and to recommend that CMS increase transparency regarding its Part D inflation rebate calculations.

At Incyte, we exist to positively affect the lives of patients through heavy investment in biopharmaceutical R&D. To this end, we employ more than 800 world-class scientists who are committed to finding solutions for some of the most critical unmet medical needs. In 2022 alone, Incyte invested $1.6 billion on R&D, representing nearly 47% of the company's total net revenues during that time. Revenue from sales of our approved products, chiefly Jakafi® (ruxolitinib), fuel Incyte's clinical development program of 25 investigational medicines intended to transform the treatment of cancer and inflammatory and autoimmune conditions.[2]

Most recently, Incyte's significant R&D investments produced Opzelura™ (ruxolitinib) cream, which FDA approved in September 2021 for the short-term and non-continuous chronic treatment of mild to moderate

[1] CMS, Letter to Pharmaceutical Manufacturers of Part D Rebatable Drugs and Other Interested Parties (Feb. 9, 2023) [hereinafter "Initial Guidance"].
[2] Incyte Corporation Pharmaceutical Portfolio, https://www.incyte.com/what-we-do/pharmaceutical-portfolio (last visited March 6, 2023).

atopic dermatitis ("eczema") in non-immunocompromised patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Opzelura is the first and only topical Janus kinase inhibitor ("JAK") inhibitor approved in the United States, and FDA granted Opzelura Priority Review in recognition of its potential as a major treatment advancement. In 2022, Opzelura became the first and only FDA-approved topical treatment for repigmentation in patients with vitiligo, again after FDA granted Priority Review for the new indication.

I. CMS Should not Extend the Medicaid Drug Rebate Program Definitions of "line extension" and "new formulation" to Identify Line Extensions for Part D Inflation Rebate Purposes

Given Incyte's commitment to pharmaceutical innovation, we are concerned that CMS is considering applying its overbroad Medicaid drug rebate program ("MDRP") definitions of "line extension" and "new formulation" to identify line extensions for Part D inflation rebate purposes. Specifically, CMS writes: "Regulatory definitions of 'line extension' and 'new formulation' were adopted through rulemaking for the MDRP and can be found at 42 CFR section 447.502. These are the definitions that would be used for the purposes of identifying new formulations of Part D rebatable drugs."[3]

These MDRP definitions are inconsistent with the Medicaid rebate statute, exceed CMS's authority, and would cause significant harm both to Incyte specifically and to pharmaceutical innovation more broadly by undermining the incentives to produce innovative new drugs. For this reason, Incyte has filed suit against the U.S. Department of Health and Human Services ("HHS"), CMS, and their officers, seeking a declaratory judgment that the Medicaid rebate statute does not require Incyte to treat its topical dermatological drug, Opzelura, indicated to treat eczema and vitiligo, as a line extension of another Incyte drug, Jakafi, an oral product indicated to treat certain cancers.[4] We urge CMS not to exacerbate this legal problem by extending the MDRP's definitions of "line extension" and "new formulation" to the Part D inflation rebate program.

The MDRP definition of line extension that CMS now proposes to apply to the calculation of Medicare Part D inflation rebates goes well beyond what is permitted by the statutory text. In this regard, the Medicaid rebate statute provides that "the term 'line extension' means, with respect to a drug, a new formulation of the drug, such as an extended release formulation, but does not include an abuse-deterrent formulation of the drug . . . , regardless of whether such abuse-deterrent formulation is an extended release formulation."[5] The CMS MDRP regulations, by contrast, define a line extension more broadly as a "new formulation" (other than an abuse deterrent formulation) and a "new formulation" as "a change to the drug, including, but not limited to: an extended release formulation or other change in release mechanism, a change in dosage form, strength, route of administration, or ingredients."[6]

The regulations find no support in the Medicaid rebate statute's text, structure, history, or purpose – all of which instead make clear that "line extensions" are "minor alterations" to existing drugs, meaning changes like extended-release formulations that generally treat the same indications and the same patient populations. The plain and understood meaning of a "line extension" is the *extension* of a drug *line*, one where the two drugs treat the same pathologies and the patients overlap. This is why, for example, Congress singled out extended release formulations and abuse deterrent formulations as examples of a "line extension" – both types of drug reformulations virtually always treat the same conditions and patients as the original drug, but with formulation

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[3] Initial Guidance, § 40.4.

[4] Incyte Corp. v. Becerra, 1:21-cv-03378 (D.D.C. 2021) (Complaint for Declaratory and Injunctive Relief).

[5] SSA § 1927(c)(2)(C).

[6] 42 C.F.R. § 447.502.

properties that permit less frequent dosing or that address safety concerns. Moreover, the legislative history reinforces that Congress intended the line extension provision to reach only drugs involving "slight alterations."[7] There is no indication that Congress intended the line extension provision to apply to innovative new drugs that provide new and different therapeutic benefits for different patients with different diseases.

The Medicaid rebate statute also makes clear that line extension rebates apply only to a "line extension of a single source drug or innovator multiple source drug that is an oral solid dosage form."[8] This provision means what it plainly says: only a line extension that is itself an "oral solid dosage form" is subject to the line extension rebate requirements. On the other hand, CMS' MDRP approach, which would treat any subsequent form of a product as a line extension so long as the initial formulation was an oral solid dosage form, is at odds with the statutory text, purpose, and history. For these same reasons, CMS should not apply its MDRP "line extension" and "new formulation" definitions to the calculation of Medicare Part D inflation rebates.

II. CMS Should Address whether Certain Drugs Represent Subsequently Approved Drugs and Define Applicable Periods for Subsequently Approved Drugs Consistent with the Statute

A. CMS's Policy Should Address Drugs Approved on or before October 1, 2021, but not Marketed until after October 1, 2021

Under the Medicare statute, the benchmark period for a drug approved on or before October 1, 2021 is January 1, 2021 to September 30, 2021, and the benchmark period CPI-U for such a drug is January 2021.[9] The Medicare statute also includes a special rule for a drug approved after October 1, 2021, or a "subsequently approved" drug, defining the benchmark period as the first calendar year beginning after the day on which the drug was first marketed, and the benchmark period CPI-U for such a drug as January of the first calendar year beginning after the day on which the drug was first marketed.[10]

However, it is unclear what the benchmark period and benchmark period CPI-U would be for a drug approved on or before October 1, 2021, but not marketed until October 1, 2021 or later. The special rule for subsequently approved drugs does not apply, as the drug was approved prior to the specified date. But, as the drug was not marketed during the benchmark period, there is no AMP or AMP-eligible units available during the benchmark period. This is the case for Incyte's drug Opzelura, which was approved in September 2021 but not marketed until after October 1, 2021.

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[7] The legislative history of the Medicaid rebate statute amendment, which added the concept of line extension, shows that Congress was concerned that manufacturers were releasing "slight" or "minor" alterations to existing drugs to obtain a new base date AMP (for Medicaid rebate purposes)—and thus avoid paying higher rebates—when the price growth for the preexisting product was outpacing inflation. *See* H.R. REP. NO. 111-299, at 635 (2009) (Congress intended to target "*slight alterations* to existing products") (emphasis added); *see also, e.g.*, *Financing Comprehensive Health Care Reform: Proposed Health System Savings and Revenue Options*, SENATE FIN. COMM., at 12 (May 20, 2009), https://bit.ly/3iR6GzO (expressing intent to prevent manufacturers from reducing rebate obligations by making "*slight alterations* to existing products" (emphasis added)); *Chairman's Mark, America's Healthy Future Act of 2009*, S. 1796, 111th Cong., SENATE FIN. COMM., at 54 (Sept. 22, 2009), https://bit.ly/3yYAovp (expressing concern that "drug makers can avoid incurring additional rebate obligations by making *slight alterations* to existing products" (emphasis added)); *Budget Options, Volume I: Health Care*, CONG. BUDGET OFF., at 143 (Dec. 2008), https://bit.ly/3w58xGq (setting out a proposal to impose alternative rebates on drugs with "*slight alteration[s]*" designed to "avoid incurring an additional rebate" (emphasis added)).

[8] SSA § 1927(c)(2)(C)(i).

[9] SSA § 1860D-14B(g)(3)-(4); Initial Guidance § 40.3.

[10] SSA § 1860D-14B(g).

CMS' Initial Guidance does not address what the benchmark period and benchmark period CPI-U would be for drugs that are not considered subsequently approved drugs and that do not have any sales during the benchmark period. The guidance acknowledges that "[f]or Part D rebatable drugs first approved or licensed after October 1, 2021, the benchmark period manufacturer price would require a different calculation," and provides an alternative calculation, but it does not acknowledge that the same is true of a drug approved but not yet marketed prior to October 1, 2021, and it does not provide a corresponding alternative calculation.[11]

Incyte requests that CMS address the benchmark period and benchmark period CPI-U for drugs like Opzelura, which were approved before October 1, 2021, but not marketed until after that date. We suggest that CMS treat such a drug as if it were a subsequently approved drug for purposes of determining the benchmark period and benchmark period CPI-U. In other words, the benchmark period for such drugs would be the first calendar year beginning after the day on which the drug was first marketed, and the benchmark period CPI-U would be January of the first calendar year beginning after the day on which the drug was first marketed. For Opzelura, this would mean that its benchmark period would be January 1, 2022 to December 31, 2022, and its benchmark period CPI-U would be January 2022.

B. CMS's Proposed Definition of "First Applicable Period" for Subsequently Approved Drugs is Not Consistent with the Statutory Language Defining the Part D Inflation Rebate "Applicable Period"

The Medicare statute defines the "applicable period" for which the manufacturer of a part D rebatable drug must provide a rebate to CMS to mean "a 12-month period beginning with October 1 of a year."[12] However, in the Initial Guidance, CMS states that for "subsequently approved drugs," (i.e., drugs approved after October 1, 2021) "the first applicable period after the benchmark period ... would begin immediately after the payment amount benchmark period ends (i.e. December 31) and would extend from January 1 to September 30 of the year following the payment amount benchmark period."[13] CMS further states that, after this first applicable period, the "regular applicable period, meaning a 12-month period beginning with October 1 of a year, as defined at section 1860D-14B(g)(7) would apply."[14] Therefore, CMS is considering that the first applicable period for a subsequently approved drug would last for less than 12-months and begin on January 1 (not October 1).

Incyte opposes CMS's approach to defining the first applicable period of a subsequently approved drug. The statute does not give CMS the authority to redefine the first "applicable period" to mean a nine-month period or a period that begins on any date other than October 1. Therefore, consistent with the statute, the first applicable period for a subsequently approved drug should begin October 1 of the year immediately following the benchmark period for the relevant drug. For example, for a drug approved November 1, 2023, the benchmark period would be January 1, 2024 through December 31, 2024. The first applicable period should be October 1, 2025 through September 30, 2026.

III. Drugs without AMP-Eligible Sales: CMS Should Provide A Proposed Solution for Manufacturers to Determine Benchmark Period Price and Annual Manufacturer Price

The Initial Guidance does not address how CMS intends to treat drugs that lack any AMP-eligible sales during the benchmark period and foreseeable applicable periods. This circumstance can arise because MDRP guidance

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[11] Initial Guidance, § 40.2.2.
[12] SSA § 1860D-14B(g)(7) (emphasis added).
[13] Initial Guidance, § 40.2.1 (emphasis added).
[14] *Id.*

instructs that if the manufacturer has no AMP-eligible sales, it should report zero AMP units,[15] even where the manufacturer adopts a reasonable assumption allowing it to report a non-zero value for AMP. This circumstance occurs, for example, for oral drugs – which are subject to the narrow definition of AMP for drugs that are not inhaled, infused, instilled, implanted, or injected (i.e., that lack a "5i" route of administration) – that are sold only to customers that are not "retail community pharmacies."[16]

Under the Medicare statute, a Part D rebatable drug's AMP-reported units are key inputs in the calculation of the drug's "benchmark period manufacturer price" and "annual manufacturer price" ("AnMP"). Also under the Medicare statute, the benchmark period manufacturer price is calculated as "the sum of the products of – (A) the average manufacturer price . . . of such dosage form and strength, as calculated for a unit of such drug, with respect to each of the calendar quarters of the payment amount benchmark period . . . ; and (B) the ratio of – (i) the total number of units reported under section 1927 of such dosage form and strength with respect to each such calendar quarter of such payment amount benchmark period; to (ii) the total number of units reported under section 1927 of such dosage form and strength with respect to such payment amount benchmark period."[17] Similarly, the Medicare statute provides that the AnMP equals "the sum of the products of (A) the average manufacturer price ... of such dosage form and strength, as calculated for a unit of such drug, with respect to each of the calendar quarters of such period; and (B) the ratio of (i) the total number of units of such dosage form and strength reported under section 1927 with respect to each such calendar quarter of such period; to (ii) the total number of units of such dosage form and strength reported under section 1927 with respect to such period."[18] Both a benchmark period manufacturer price and AnMP are required to calculate the inflation rebate, and AMP units for at least one calendar quarter during each of the benchmark period and applicable period are required to calculate the benchmark period manufacturer price and AnMP.

CMS' Initial Guidance acknowledges that "the primary data elements ... used to calculate the Part D drug inflation rebates are AMP data" and "unit data" reported by manufacturers, and that "[t]hese AMP units that the manufacturers report represent the total units of a drug sold by the manufacturer for each month to retail community pharmacy purchasers."[19] While the Initial Guidance acknowledges that "when there may not yet be any sales for a quarter, the MDRP also allows a manufacturer to make 'reasonable assumptions' for the quarter with respect to pricing for their drug,"[20] it does not acknowledge the possibility that a drug may have no AMP units under CMS' MDRP guidance. Similarly, while the Initial Guidance expresses CMS' intention to "only use the AMP for a calendar quarter in the calculation of an AnMP if there are units associated with the reporting of the

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[15] *See, e.g.*, 81 Fed. Reg. 5169, 5300 (Feb. 1, 2016) ("For purposes of drug manufacturer monthly reporting and the calculation of the FUL, in the case where a drug product does not have any utilization prior to the drug product's actual termination date, the drug manufacturer is responsible for reporting the drug product's AMP, and that drug product's AMP units would be correctly reported as zero.") (emphasis added); *see also, id.* ("When a manufacturer has had no product sales in a given month, the manufacturer should not carry forward the last reported positive AMP units. Instead, in this instance, the manufacturer should report to us via the DDR system an AMP based on the most recent prior month's positive AMP and an AMP units value of zero. . . . [I]n the event that there is a negative AMP units value, manufacturers should enter a zero and not enter a previous month's AMP unit value.").

[16] 42 C.F.R. § 447.504(a) (defining AMP for such drugs as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer"); *see also* 42 C.F.R. § 447.510(d)(6) (defining AMP units as "the total number of units that are used to calculate the monthly AMP . . .").

[17] SSA § 1860D-14B(b)(4).

[18] SSA § 1860D-14B(b)(2).

[19] Initial Guidance at §§ 40.1 and 40.1.1.

[20] *Id. at* § 40.1.2.

AMP in the calendar quarter of an applicable period,"[21] CMS does not address what it plans to do if there are no AMP units for any calendar quarter of the applicable period or benchmark period.

For drugs with no AMP-eligible sales, it is mathematically impossible to calculate the AnMP according to the statutory formula because both the total number of units reported for each quarter and the total number of units reported with respect to the four calendar quarters are equal to zero. The AnMP and benchmark period manufacturer price calculation for this drug would require dividing zero by zero, which produces an undefined result.

Accordingly, Incyte recommends that CMS develop an alternative methodology for calculating benchmark period manufacturer prices and AnMPs for applicable periods that lack any AMP units. For example, if there are no AMP units but there are reported AMPs (based on reasonable assumptions) during a benchmark or applicable period, the AMPs could simply be averaged with equal weighting (e.g., the sum of the four quarterly AMPs divided by four).

IV. CMS Should Increase the Transparency of its Part D Inflation Rebate Calculations

Incyte requests that CMS provide manufacturers with the mathematical values for the components of CMS's inflation rebate calculations when providing manufacturers with any rebate report, including: Preliminary Rebate Reports, Rebate Reports, Preliminary True Up Rebate Reports, True Up Reports, and any subsequent revision to the rebate assessment under section 60.4 of the Initial Guidance. Providing these data to manufacturers will improve the efficiency and accuracy of any suggestions the manufacturers may make to CMS regarding possible calculation errors, by allowing the manufacturers to identify and isolate what aspect of CMS's calculation led to an unexpected and possibly erroneous result. This, in turn, should reduce CMS's time needed to process these suggestions, because manufacturers with access to these data could pinpoint to CMS those aspects of the calculation believed to be incorrect, rather than just stating that the end result is surprising. Providing these calculation component data elements to manufacturers will also speed manufacturers' own analyses, which will help them to meet the Initial Guidance's compressed 10-day deadline for manufacturers to suggest calculation errors to CMS.

The Initial Guidance already provides that the Preliminary Rebate Report and Rebate Report "would list each NDC of a drug that has been determined to be a Part D rebatable drug for the applicable period; the total number of units for each dosage form and strength for the Part D rebatable drug for the applicable period; the amount, if any, of the excess of the AnMP for each dosage form and strength of the Part D rebatable drug for the applicable period; and, the rebate amount for each dosage form and strength of such Part D rebatable drug for an the applicable period."[22] For the reasons noted above, Incyte requests that CMS share the following additional calculation component data with each manufacturer in a manner that maintains the confidentiality of the manufacturer-specific component data:

- AnMP for the Part D rebatable drug;
- Benchmark Period Manufacturer Price for the Part D rebatable drug;
- Both CPI-U values used calculate the Inflation-Adjusted Payment Amount;
- Inflation-Adjusted Payment Amount for the Part D rebatable drug;
- Total Part D-dispensed units;

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[21] *Id.*

[22] Initial Guidance, § 50.1.

- Starting in 2026, the number of 340B units that were excluded;

- For any line extension;
  - Initial drug selected;
  - AnMP for the initial drug;
  - Both CPI-U values used to calculate the Inflation-Adjusted Payment Amount for the initial drug;
  - Inflation-Adjusted Payment Amount for the initial drug; and
  - Alternative Inflation Rebate Amount.

* * * * *

We appreciate the opportunity to submit these comments for CMS's consideration. We would be happy to provide any additional feedback on these topics, at your request. Thank you.

Sincerely,

Barry Flannelly
Executive Vice President & General Manager, North America

Hello,

I'm personally commenting on the concepts in both Part B and Part D and submitting them separately under the appropriate subject lines.

I support the Part B inflation rebate plan as laid out and encourage CMS to even more closely consider equity and the disproportionately high costs of drugs in the US as compared to the EU or elsewhere. We pay more and receive less for our healthcare, and drug pricing is a significant part of that. As CMS is both a payor and regulator, it is in the unique position of being enabled to make changes that could improve equitable health outcomes and treatments for all Americans.

I know that CMS will receive drug industry pushback for the stronger provisions of this proposed policy and I'm writing to urge CMS to stand strong, **center the equitable distribution of federal health care dollars to those most impacted by the harms our system puts on people (i.e. poor, disabled, black and brown, LGBTQi+, indigenous people, and anyone with a uterus)**. While I don't have EU sources to point to for drug pricing, **CMS should adopt proven, efficacious, and impactful drug policies (rebates and future policy) that are in practice in countries with lower drug costs.**

This would fulfill the intent of Congress's passage of the Inflation Rebate legislation. **Prioritizing clarity and eliminating loopholes** would decrease or eliminate the armies of drug industry lawyers employed to discover and expand exceptions and discounts for themselves. These loopholes and unclear policy language harm ordinary Americans like our grandmothers. Ordinary, unexceptional, hard-working Americans, especially those on fixed incomes, cannot continue to fund investor payouts, executive salaries, contractors, and legal teams who argue for keeping and expanding loopholes.

The arguments the **drug industry has made about the costs of R&D are false, amply demonstrated by far lower drug prices elsewhere in the world**. In addition, the industry's profit motive is clear when you look at where they spend R&D dollars – certainly not on new antibiotics to combat multiply drug resistant organisms unless they are explicitly incentivized to do so. Instead, their massive resources are focused on development (and marketing!) of optional therapies aimed at well-off individuals who can afford high out of pocket costs and have private insurance.

CMS should not be swayed by drug company arguments about R&D funding. Basic research is NIH funded and far more productive, especially since industry simply buys promising academic-spinoff small molecule development companies. The slow, expensive, and difficult part of drug R&D is being publicly funded already and this should be increased and expanded.

While the cap on insulin is welcome, it does not go far enough – insulin should be no-cost. Given the crisis of diabetic neuropathy and amputation we are experiencing, especially in places that are rural, south, poor, and/or brown or black, insulin and other diabetes treatments should be free to patients. The equity issue here is unavoidable and could be the center of CMS's strategy if it is willing to center disproportionately-impacted populations in this and future regulation. Explicit support and consideration of equity, like the analysis of costs to implement should be included in policy publications. This **should include examination of expected outcomes of all proposed policy looking explicitly at health outcomes of groups impacted inequitably** by policies today and this **should be conducted and published for all CMS policies, like implementation analysis now in NPRMs**.

The impact of those changes could have saved my uncle who recently died (in a rural flyover state) after sepsis and then amputation that were secondary to poorly managed diabetes. His veterans' benefits helped later in life, but could not mitigate years of inconsistent and insufficient diabetes management due to out of pocket insulin and other drug costs. He was only 62, was otherwise healthy, and leaves behind a daughter, younger sister, grandkids, and nieces and nephews whose lives he positively impacted and now is gone from. This isn't a unique story.

CMS should regulate all drug pricing. Starting with Medicare and Medicaid rebates is welcome, but CMS needs to include descriptions of harms of our current and past systems in the NPRM. This will build support and lay the groundwork for future regulation required to protect Americans from harmful and predatory drug companies. While I'm glad that CMS has developed this Medicare rebate program for pricing that outpaces inflation, efficiencies in production and scale should be factored in too. Drug prices should track with less than the rate of inflation – perhaps as much as half of the inflation rate. This could also dis-incentivize drug companies to aggressively extend their monopoly period by publishing new treatments and other techniques used to extend patient protections beyond the 'generics cliff'.

While the desire to give CMS flexibility in issuing wavers is laudable, CMS should explicitly list the circumstances for which drug companies may receive a waiver, and while it should include situations such as the example given about destruction of one factory that is the single source of a particular drug, it should also factor in profitability of the industry as a whole and the drug company in question. If CMS does not do this, it will be buried in requests for rebate/discounts to the proposed policies for decades to come. In addition, the costs to CMS of hiring lawyers and staff to respond to industry lawsuits intended to expand and increase the availability of the exceptions/waivers will be costly. CMS should clearly specify the limited conditions under which an exception can be submitted and should include consideration of industry and company profits over the last 10 years in the exception.

That might look like a company who wants a waiver only being eligible if health care industry profits are under some percentage set like inflation rates with the drug company profits under some different percentage. Including health care industry in this calculation will account for the entire impact to patients from health care costs, not only drug costs as patients don't consider drug costs separately from health care. This would let CMS avoid what we saw with PPP payments to large companies who later posted incredible revenue and profits for that and the following several years.

Finally, **CMS should include more language addressing the impact of health care consolidation on patient and Medicaid and Medicare costs** similar to the work the FTC has been doing recently to address monopolization and the repeated pattern we see (across industries) of consolidation that results in companies essentially owning provision of health care in towns and even cities, then **raising prices, decreasing quality, reducing services, and decreasing pay of workers in those areas**. I realize this is outside the scope of the regulation CMS is developing related to drug pricing, **but it is impacting the same consumers in the same way they're already impacted by out-of-control drug prices. Patients on fixed incomes should be special considerations. CMS should examine recent FTC actions and consider how it could use those tactics, rules, or strategies to address health care costs.**

My sincere thanks for your hard work in the area of equity (thank you for discussing health technology literacy in recent HIT policy – my apologies for not recalling which RFI or NPRM that was included in, but it was a surprising and welcome acknowledgement!), health care costs, consumer protection, and aiming at the unconscionable profits of drug companies that are forcing Americans to go without

treatment due to high health care and drug costs. I look forward to the strength CMS describes, and more policy aiming in this direction:

The Inflation Reduction Act makes Medicare stronger for current and future enrollees. It makes health care more accessible, equitable, and affordable by lowering what Medicare spends for prescription drugs and limiting increases in prices.

Thank you,
[redacted]

[redacted]

White Paper

Can 340B Modifiers Avoid Duplicate Discounts in the IRA?

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Abstract

In August 2022, the Biden administration passed the Inflation Reduction Act (IRA) which introduced provisions requiring the identification of 340B transactions. 340B modifiers — a system of codes used on some pharmacy and medical claims to identify 340B drugs — have been required by the Centers for Medicare & Medicaid Services (CMS) for Medicare Part B reimbursement, and more recently, to identify 340B drugs[1]. Descriptive data about the usage of 340B modifiers has not been reported publicly and would provide useful insight into their potential to support implementation of 340B-related provisions of the IRA.

This study examined 340B modifier usage data using a national sample of physician-administered and self-administered products, providers, pharmacies, and payers. For Medicare Part B claims in 340B hospitals involving pass-through and separately payable drugs where reporting was mandatory, 60-89% of drug treatments used modifiers. But when reporting was optional, rates fell below 20%. For self-administered drugs across all payers, only 4% of branded, 340B-eligible pharmacy claims used a 340B modifier, rising to 50% for Medicaid claims at entity-owned pharmacies and falling to less than 1% at contract pharmacies. Also, 340B modifiers were sometimes used for products that were not 340B-eligible such as test strips, swabs, and vaccines.

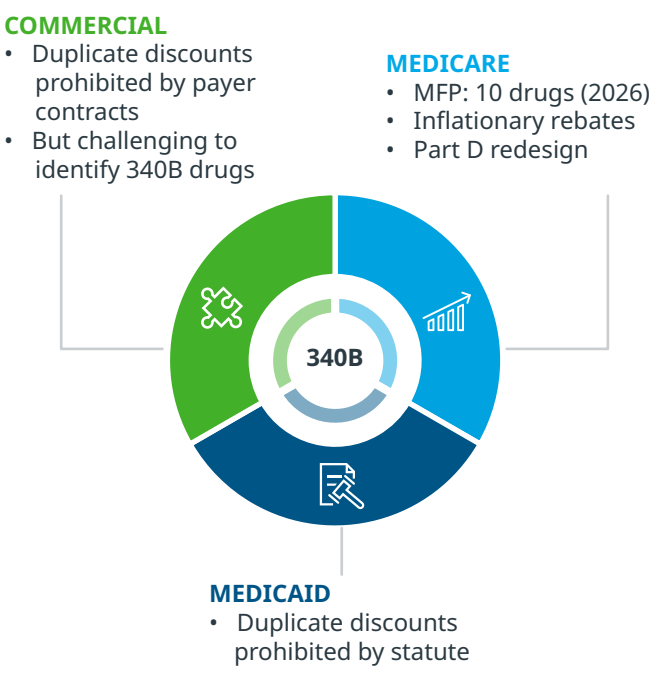
Medicare Part D represents 40.1% of business for 340B-eligible, branded drugs while Medicare Part B is 36.3%, meaning that $34.0B to $37.5B of sales at wholesale acquisition cost (WAC) pricing may be at risk for IRA/340B duplicate discounts. These findings suggest that 340B modifiers provide visibility to 340B transactions in some segments of payers, pharmacies, and products but not others. Further thought needs to be given to determine the optimal methods for consistently identifying 340B drugs in order to support implementation of non-duplication and inflationary rebate provisions of the IRA.

Introduction

The Inflation Reduction Act of 2022[2] is comprehensive legislation intended to reform and lower Medicare drug prices. It applies to both self-administered and physician-administered drugs, and employs drug price negotiation, introduces inflationary rebates somewhat like those used in Medicaid, and restructures Medicare Part D by introducing a patient out-of-pocket limit, shifts costs from Medicare to insurers, and assesses patient out-of-pocket costs over a year to help seniors[3]. These changes are being phased in over seven years beginning with inflationary penalties and a price cap on insulins. One of the act's major components — price negotiation for Part D — will begin the process for negotiation in 2023, with negotiated prices offered in 2025.

The IRA identifies a few specific scenarios of overlap with the 340B program, such as (1) manufacturers must offer the Maximum Fair Price (MFP) in Part B and Part D or the 340B price, but not both (non-duplication), and (2) manufacturers must pay separate inflationary rebates on Part B and Part D volume, but 340B drugs must be removed. The interaction of various discounts is illustrated in Figure 1.

Figure 1: Drug discounts and their interaction with 340B



CMS has not yet issued comprehensive instructions for how those provisions will be implemented. It recently announced it would require modifiers for all 340B providers for the purpose of excluding 340B drugs from Part B inflationary rebates[1]. However, it is unclear if 340B modifiers can be used successfully for this purpose, and it is unknown how CMS will address provisions for Part D inflationary rebates or non-duplication for Part B and Part D. There has not been a published analysis of the potential significance of these particular 340B-related IRA provisions. Specifically, the percentage of 340B drugs that overlap with Medicare, and the corresponding drug spend subject to non-duplication and inflationary rebates, is unknown.

340B MODIFIERS

Modifiers are a system of codes applied to pharmacy claims and medical claims to share information between providers, pharmacies, and payers. Although there are hundreds of modifiers which are used to transmit information about anything from drug pricing to claim rejections, the half dozen of interest for the current study are called 340B modifiers.

340B MODIFIERS: SELF-ADMINISTERED DRUGS

In July 2011[4], followed by an update in June 2019[5], the National Council for Prescription Drug Programs (NCPDP) released a standard for 340B information exchange designed to support the sharing of information between pharmacies and payers. In version 2.0 released in June 2019, three 340B modifiers were defined as described in Table 1.

Table 1: NCPDP 340B modifiers for self-administered drugs

Field	Value	Description
Submission Clarification Code (SCC)	20	The pharmacy reports the drug was purchased under the 340B drug discount program
Basis of Cost Determination (BCD)	08	The pharmacy reports the Ingredient Cost Submitted field was based on the 340B price of the drug
Basis of Reimbursement Determination (BRD)	12	The payer indicates how the Ingredient Cost Paid field was calculated

The first two — SCC 20 and BCD 08 — are submitted by the pharmacy and indicate the drug was purchased under the 340B program (there are some rare exceptions to this for BCD 08 which will be ignored for the current study). The third — BRD 12 — is submitted by the payer, and indicates reimbursement information based on 340B pricing.

NCPDP 340B modifiers have been adopted by several dozen state Medicaid agencies as well as some commercial payers. Their Achilles' heel is the 340B status of the drug must be known at the point of sale to the patient in order to apply the modifier to the claim prior to adjudication. While this is possible for pharmacies that identify 340B transactions at the point of sale, which may occur in entity-owned pharmacies and often in those that use physical inventory, the drug's 340B status is unknown for pharmacies using the 340B replenishment model and virtual inventory which is used by almost all contract pharmacies.

340B MODIFIERS: PHYSICIAN-ADMINISTERED DRUGS

A separate system of modifiers exists to identify 340B physician-administered drugs in medical claims, one which has important differences versus the previously-described NCPDP system.

CMS introduced TB and JG modifiers so it could lower reimbursements for Medicare Part B. Previously, CMS reimbursed 340B physician-administered drugs at ASP +6%, but on January 1, 2018, it reduced reimbursements to ASP - 22.5% for certain types of 340B drugs used for Medicare beneficiaries by non-exempt hospitals paid under the Hospital Outpatient Prospective Payment System (OPPS)[6].

Several complexities exist in how 340B modifiers are used for physician-administered drugs: only some types of covered entities have been required to report them for reimbursement purposes, until recently there was a financial disincentive to do so[7], and reporting rules are complex. Reporting requirements depend on the payer channel, entity type, OPPS payment status, and drug type[6], as described in Table 2. For example, TB or JG modifiers are required for Medicare Part B beneficiaries by providers reimbursed under the OPPS, which includes most 340B hospitals except for those that are exempt from the payment adjustment. Some commercial payers also require these modifiers although publicly available data is lacking, and a separate UD modifier is used to bill Medicaid for 340B drugs. TB or JG modifiers are required for pass-through drugs, which include biosimilars and the newer CAR-T therapies, and for separately payable drugs which include blockbuster IV products for oncology and immunology. Reporting for packaged drugs is optional.

Methods

DATA

Medical claims may span multiple products administered on multiple days. For a given claim, each administration of each product on a different day was counted separately, which we call "drug treatments". Drugs were identified using J-codes and Q-codes, and mapped to status indicators using the method described in reference 6 using OPPS Addendum B drug lists available at the CMS website[8]. The study was limited to pass-through drugs (status indicator G, Table 2) and separately payable drugs (status indicator K); these categories contain the majority of branded products and biosimilars that are likely to be 340B-eligible and subject to Part B inflationary rebates.

Table 2: Medicare Part B reporting for TB and JG modifiers. CAH: critical access hospital. CAN: cancer hospital. PED: children's hospital. SCH: sole community hospital. DSH: disproportionate share hospital. RRC: rural referral center.

Hospital type	Drug type (Status indicator)		
	Pass-through (SI=G)	Separately payable (SI=K)	Packaged drugs (SI=N)
CAH	Optional	Optional	Optional
CAN, PED, Rural SCH	TB	TB	Optional
DSH, RRC, Non-rural SCH	TB	JG	Optional

For self-administered drugs, the study was limited to branded products because many 340B-eligible generic drugs are not converted to 340B[9]. Claims were included whether they were paid, rejected, or reversed since the pharmacy didn't know the final status of the claim when it was submitted and all are valid observations of modifier usage. The study period was 2022-Q3, chosen to minimize the impact of contract pharmacy restrictions, since by this time many entities had regained access to contract pharmacy pricing through the use of submitted data.

Physician-administered drugs were sourced from two reference data assets for medical claims: the CMS Medicare Standard Analytical File (SAF) for Medicare Part B institutional claims, and IQVIA medical claims for all other payer channels. Self-administered drugs were sourced from IQVIA pharmacy claims. For further details, see Data Sources (page 11).

The study period for IQVIA medical claims was 2021-Q4 to 2022-Q4, and for SAF it was 2021-Q4 to 2022-Q4. This was chosen to ensure at least two quarters of data for both types of claims, since there is a data lag for SAF of up to 9 months.

340B-ELIGIBILITY

For physician-administered drugs, 340B-eligibility was determined by the billing provider on the claim (or the facility provider if populated), combined with the drug type and with Office of Pharmacy Affairs Information System (OPAIS) 340B participation data for the quarter in question.

There is no publicly available data for the actual 340B status of pharmacy claims, so we estimated their 340B eligibility using the algorithm described in reference 10. In brief, the 340B-eligibility of each claim was a likelihood measuring two conditions representing the 1996 patient definition[11]:

C1. Was the prescription written at a covered entity?

C2. Was the script filled at an entity-owned pharmacy or at one of the entity's contract pharmacies?

Condition C1 was measured using billing provider and rendering provider information on medical claims, supplemented by affiliation data for HCPs not captured in medical claims. This was merged with OPAIS-covered entity participation data. Condition C2 was measured using the pharmacy NCPDP on the claim merged with OPAIS data.

LIMITATIONS

A handful of limitations apply to our approach. First, the 340B status of pharmacy claims used 340B-eligibility since the actual 340B status of pharmacy claims is not publicly available. Second, contract pharmacy restrictions were not explicitly accounted for, since there is no publicly available information to understand which claims from specific manufacturers are or are not 340B-eligible. Thus, the study period for self-administered drugs was made as late as possible (2022-Q3) by which time we estimate the majority of 340B pricing had been restored. Third, Medicare SAF claims lag by up to 9 months.

Studying 340B modifier usage by state is of interest, but is problematic. For example, some states have reporting requirements for 340B modifiers for Medicaid claims, but states may also have legislation prohibiting administrative requirements such as 340B modifiers for pharmacies[12], and it's unclear which prevails. Also, there doesn't appear to be publicly available data for the existence of state legislation involving 340B modifiers, and while Apexus — the 340B Prime Vendor — maintains a database containing state reporting requirements[13] it is incomplete. For example, it lacks data for at least 10 states, and it's unclear how to interpret the absence of a reporting requirement for a state/modifier pair.

Findings

OVERLAP OF MEDICARE AND 340B

To quantify the overlap between Medicare and 340B, we estimated payer mix for the 340B channel. 340B-eligible volume was broken out by payer channel using the primary payer on claims. For self-administered drugs, "Medicare" was Part D, while for physician-administered products it represented both Medicare Part B and Medicare Advantage, since most Part D changes also apply to Medicare Advantage prescription drug plans[14].

For self-administered and physician-administered drugs, Medicare represented 40.1% and 36.3% of 340B-eligible volume respectively, as shown in Figure 2. "Cash & Cards" contains cash claims, cash discount cards, and 340B discount cards. For physician-administered drugs, Medicare comprised 15.2% Part B and 21.1% Medicare Advantage. In 2021, the 340B program generated $93.6B of sales (WAC dollars)[15], thus $34.0B to $37.5B of business may be at risk from IRA/340B duplicate discounts.

Figure 2: Payer mix for 340B-eligible branded drugs. Self-administered drugs: WAC. Physician-administered drugs: ASP.

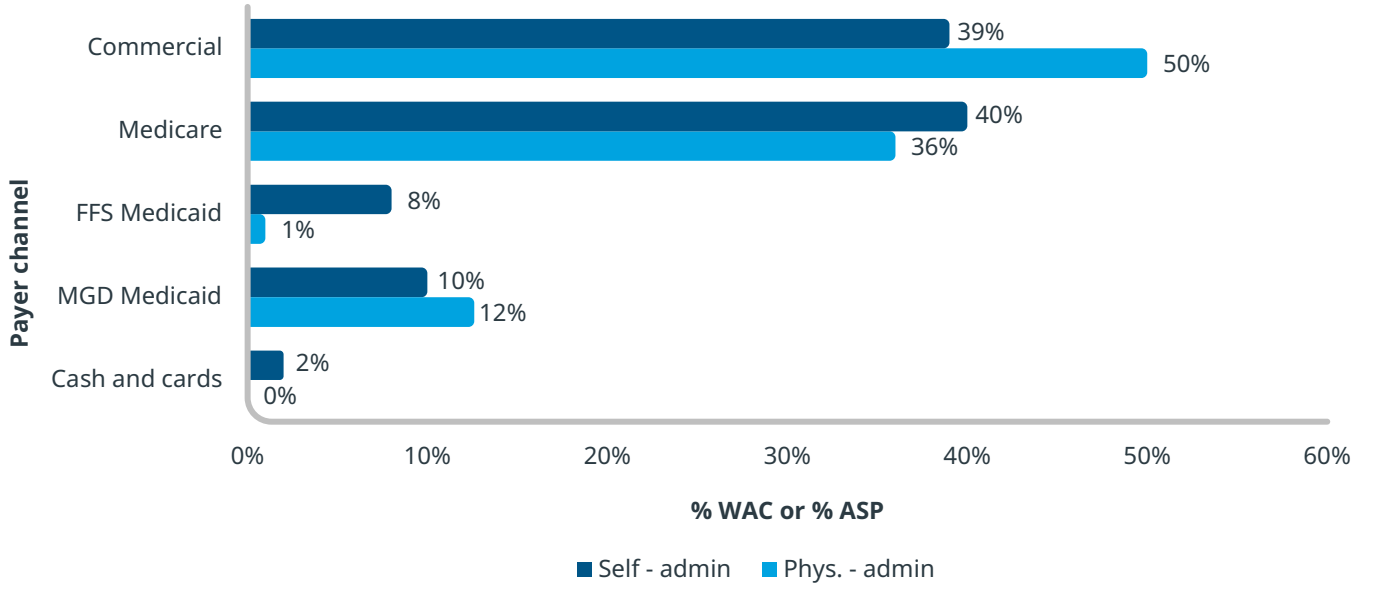


Figure 3: Modifier frequency for drug treatments by payer channel and entity type for pass-through and separately payable drugs

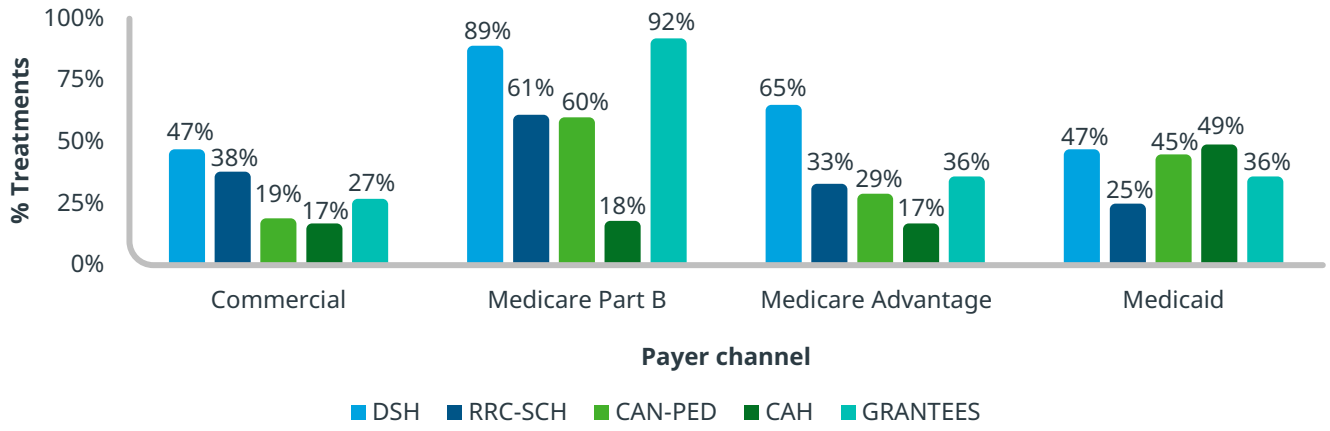
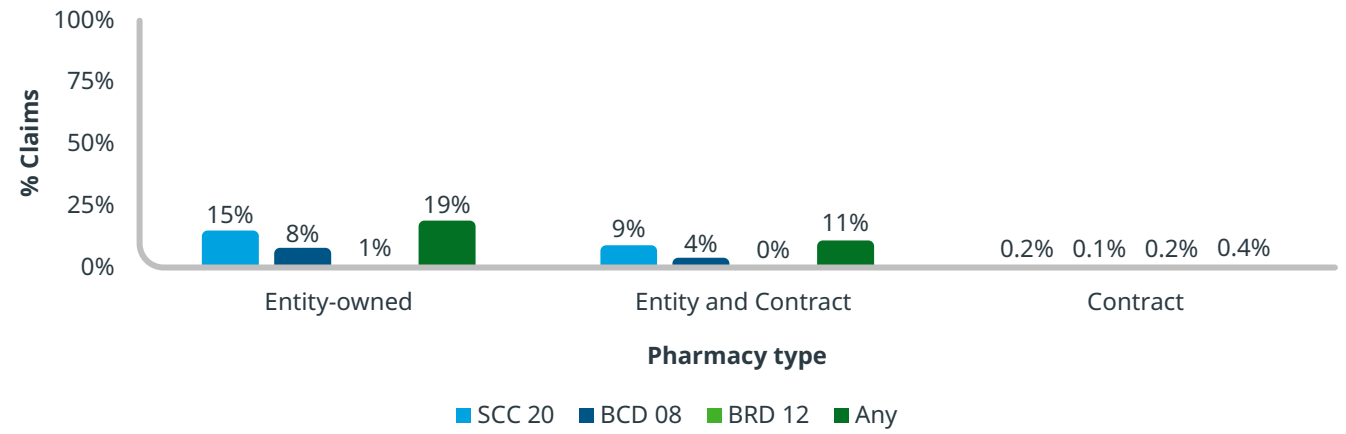


Table 3: 340B modifier frequency by entity type and drug type for Medicare Part B physician-administered drugs. Mandatory reporting for Part B is indicated by a bold font, while modifier rates are shown using shading. There were no reporting requirements for federal grantees during the period of the study.

Drug type	DSH			RRC-SCH			CAN-PED			CAH			GRANTEES		
	TB	JG	UD	TB	JG	UD	TB	JG	UD	TB	JG	UD	TB	JG	UD
Pass-through	**82%**	2%	6%	**72%**	2%	7%	**57%**	0%	17%	21%	1%	2%	82%	1%	26%
Sep. payable	9%	**82%**	6%	14%	**46%**	5%	**60%**	0%	8%	13%	4%	2%	1%	92%	20%
Packaged	3%	6%	5%	8%	4%	4%	30%	0%	9%	4%	0%	2%	6%	3%	15%

Figure 4: Frequency of 340B modifiers by pharmacy type for self-administered drugs. EOP: entity-owned pharmacy. CP: contract pharmacy.



PHYSICIAN-ADMINISTERED DRUGS

Overall, around 25% of 340B-eligible, physician-administered drug treatments used a 340B modifier, where any combination of TB, JG, or UD modifier was counted as a positive report. There were large effects by payer channel and by entity type, as shown in Figure 3, with up to 90% of drug treatments using a modifier for Medicare Part B, where required, falling to 18% when reporting was optional.

Modifier rates for Medicare Part B were closely aligned with reporting requirements, as shown in Table 3.

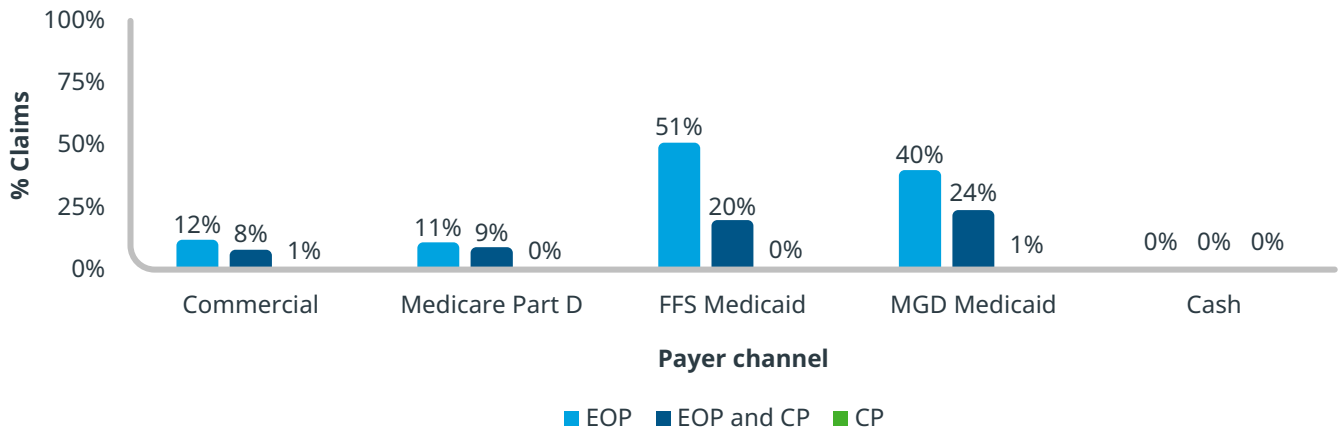
SELF-ADMINISTERED DRUGS

On average, 4.1% of branded, 340B-eligible, self-administered drugs used at least one NCPDP 340B modifier, meaning either SCC 20, BCD 08, or BRD 12.

There were large differences in usage by pharmacy type, with rates at entity-owned pharmacies approaching 19% and dropping to less than 1% for contract pharmacies, as shown in Figure 4. Hybrid pharmacies that are entity-owned but also contract with other covered entities fell in between at 11%.

Further differences were seen when usage was broken out by payer channel, as shown in Figure 5. Over half of branded, 340B-eligible products in FFS Medicaid used a 340B modifier, versus only 11-12% in commercial or Medicare claims. Medicare Advantage had low sample size at entity-owned pharmacies and entity-owned/contract pharmacies, and modifier rates could not be calculated. At contract pharmacies, rates for Medicare Advantage were close to 0%.

Figure 5: % 340B modifiers by payer channel and pharmacy type for self-administered drugs. COM: commercial. MGD Medicaid: managed Medicaid.



MODIFIERS AND NON-COVERED OUTPATIENT DRUGS

Some products, such as diabetic test strips, monitoring systems, alcohol swabs and pads, lancets, and vaccines, are not covered outpatient drugs under the 340B program, but appeared in claims containing 340B modifiers. The usage rates of 340B modifiers for these products was relatively low, ranging from 0.01% to 3.9%, with an average of 0.1%.

WHY WASN'T MODIFIER USAGE 100% WHEN MANDATED?

There are a handful of possible explanations for why the usage of 340B modifiers wasn't 100% when mandated, as illustrated, for example, in Table 3 and Figure 4 (for Part B). These include (1) some entities failed to report modifiers; (2) entities reported modifiers but some were removed before claims were reported to IQVIA (this is unlikely to be widespread for physician-administered products as modifier rates were above 90% in some segments), (3) entities chose not to convert some 340B-eligible drugs, e.g., the entity was able to buy product for less than the 340B price, or Medicaid carve-outs were in place, or the entity chose not to convert some low-cost branded products, and, (4) the 340B status of self-administered products was estimated algorithmically and was not 100% accurate.

Discussion

A remarkable finding of this study was the variety and complexity of the 340B modifier reporting patterns displayed. Modifier usage reached 90% in some segments when reporting was mandatory, fell below 20% when it was optional, and dropped below 1% when it was impractical. Two factors appear to be associated with the increased usage of modifiers: mandating modifier reporting, and identifying the 340B status of the claim prior to or at the point of sale.

On February 9, 2023, CMS released inflation rebate guidance for Medicare Part B and Part D as part of the Medicare Prescription Drug Inflation Rebate Program[16]. CMS described the guidance as "initial", added a 30-day comment period seeking stakeholder feedback, and said revised guidance will follow in Q4 2023. For Part D, the guidance documents stated 340B modifiers should be used on pharmacy claims to identify 340B drugs[17]. In the current study, less than 1% of claims at contract pharmacies used a 340B modifier, which we think is because the 340B status of a claim was unknown to the pharmacy at the point of sale to the patient.

However, it is possible to determine the 340B-eligibility of drugs at the point of sale at contract or entity-owned pharmacies, as demonstrated by the dozen or so vendors that offer 340B prescription discount cards. Previous studies by our group have shown 340B cards were able to reduce patient out-of-pocket costs by 92.9%[10]. These 340B cards perform real-time checking such as confirming the presenter of the card is a patient of the covered entity, the prescribing provider is on an active list for the entity, and the drug written on the prescription is on the formulary of the covered entity. But this requires specialized systems and the sharing of patient and provider lists, neither of which is widespread yet in the 340B program.

Our finding that 340B modifiers are sometimes being used for products that aren't 340B-eligible may suggest a wider problem, namely that some providers and pharmacies aren't clear how 340B modifiers should be used. This may warrant further investigation.

A recent report[18] from the Office of Inspector General (OIG) discussed a handful of challenges implementing inflation index rebates for Part B drugs, including drugs purchased under the 340B program. It observed that provisions for inflationary rebates took effect on January 1, 2023, but mandatory reporting of 340B modifiers for federal grantees and some types of 340B hospitals only begins on January 1, 2024, a year later. As a solution, it recommended monitoring 340B modifier usage for Part B drugs, especially for providers for which reporting isn't yet mandatory.

Based on the findings of the current study, consideration should be given to broadening OIG's recommendation. First, monitoring of 340B modifiers needs to include Part D as well as Part B. Second, thought should be given to how to make certain providers and pharmacies are clear about using 340B modifiers the right way. This should include addressing state laws which appear to be interfering with their use. Third, a system could be evaluated, possibly similar to the process used by 340B prescription discount cards, to support the identification of 340B drugs at the point of sale. Finally, given the complexity and challenges involved in identifying 340B product, it's likely that 340B modifiers alone will not be enough to ensure transparency. This becomes critically important given that CMS has not yet incorporated other transparency solutions as part of the invoice process described in its initial instruction, and manufacturers have limited ability to dispute in this area. For example, additional 340B transparency measures that are being used or contemplated in the marketplace include requiring the submission of claims data and the use of a clearinghouse.

The study estimated that $34.0B to $37.5B of business may be at risk of IRA discounts and other types of discounts, however the actual cost to manufacturers may be *higher* than this. Consider for example a drug that the manufacturer sells for $100, and which commands a $70 340B chargeback and a (prohibited duplicate discount of a) $60 maximum fair price (MFP) discount. The manufacturer sells the drug for $100, pays $130 of discounts, and loses $30. This example, although hypothetical, would not be unusual, and further underlines the importance of the right approach in this area.

Data sources

Pharmacy claims were sourced from IQVIA's Longitudinal Access and Adjudication Dataset (LAAD) reference data. Claims spanned all branded U.S. pharmaceutical products and all disease areas. The sample size was approximately 9.9M claims (2022-Q3).

Medical claims were sourced from two reference data assets: the CMS Medicare Standard Analytical File (SAF) for Medicare Part B institutional claims, and LAAD institutional medical claims for all other payer channels. The sample size for LAAD was 44.9M drug treatments (2021-Q4 through 2022-Q4), of which 3.0M were for pass-through or separately payable drugs.

For the payer mix analysis, volume for self-administered drugs was measured using days of therapy (also called days of supply), which accounts for the fact that the quantity of medication in a prescription can vary. Here, a prescription for a 90-day supply of drug has three times the weight as a 30-day prescription. For physician-administered drugs, volume was based on ASP (average sales price)[19].

ACKNOWLEDGEMENTS

We thank Luke Greenwalt, Shiraz Hasan, and an anonymous reviewer for suggestions on an earlier draft.

This study was published in response to questions from participants in the U.S. healthcare system, after conducting an initial, related analysis for Bristol Myers Squibb. Bristol Myers Squibb had no role in data collection, analysis, or decision to publish.

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Rory uses advanced analytics to create innovative Gross to Net strategies and solutions to help manufacturers accelerate portfolio growth. He has been an invited speaker at the FDA's Center for Drug Evaluation and Research (CDER) and is the author of several analytics texts.

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Jeff has 30 years of experience using advanced analytics to solve pharmaceutical sales and marketing problems, with recent focus on Managed Care profitable market access.

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Fact Sheet

IQVIA has conducted a study[1] of the usage of 340B modifiers using a national sample of providers, payers, pharmacies, and products

RORY MARTIN, PHD, IQVIA Market Access Center of Excellence
HARISH KARNE, MS, IQVIA Market Access Center of Excellence
JEFF DUFFY, PHD, IQVIA Market Access Center of Excellence

1. Why did IQVIA conduct a study of 340B modifiers?

- The IRA has introduced provisions requiring 340B drugs to be identified, but it is unclear how best to do so accurately and consistently
- There's up to $37.5B of potential 340B/Medicare overlap in the IRA, and drugs in this overlap will be subject to multiple increasing discounts (e.g., 340B, MFP, inflationary rebates, commercial Part D rebates, and Part D redesign)

2. What are 340B modifiers and why are they important?

- They're flags on claims indicating product was purchased at 340B pricing
- Although they've been required by CMS for Part B reimbursement since 2018, no publicly reported study about their usage exists

3. How are 340B modifiers expected to be used for 340B-eligible drugs?

- Reporting requirements are complex and only some entity types report them
- For physician-administered drugs, reporting depends on the payer channel, entity type, and drug type
- For self-administered drugs, the 340B status of the claim must be known at the point of sale to the patient to use 340B modifiers

The full IQVIA white paper can be found here:

https://www.iqvia.com/locations/united-states/library/white-papers/can-340b-modifiers-avoid-duplicate-discounts-in-the-ira

4. How were 340B modifiers used for 340B-eligible, physician-administered drugs?

- For Part B claims when 340B hospitals used separately payable and pass-through drugs where reporting was mandatory
- When reporting was optional (e.g., packaged drugs), rates fell below 20%

5. How were 340B modifiers used for 340B-eligible, branded, self-administered drugs?

- Only 4% of pharmacy claims for branded, 340B-eligible, self-administered drugs used 340B modifiers
- At entity-owned pharmacies, up to 50% of claims used a 340B modifier, but only 1% of claims at contract pharmacies used one

6. What are some key takeaways?

- Monitoring of 340B modifiers should include Part B and Part D
- A system could be evaluated to support identification of 340B drugs at the point of sale
- Additional transparency measures should be considered: 340B modifiers alone likely won't be enough

[1]Martin R, Karne H, Duffy J. Can 340B modifiers avoid duplicate discounts in the IRA? February 2023.

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WORLDWIDE GOVERNMENT AFFAIRS & POLICY

March 11, 2023

Dr. Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator, Director of the Center for Medicare
Centers for Medicare & Medicaid Services
200 Independence Avenue SW
Washington, DC 20201

Re: Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of the Social Security Act, and Solicitation of Comments

Dear Dr. Seshamani,

On behalf of Johnson & Johnson (J&J) we appreciate the opportunity to provide feedback to the Centers for Medicare & Medicaid Services (CMS, the Agency) on the initial guidance regarding the implementation of the Medicare Part D drug inflation rebate. J&J is the world's most comprehensive and broadly-based manufacturer of health care products for pharmaceutical, medical devices, and diagnostics markets. For nearly 130 years, we have supplied a broad range of products and have led the way in innovation and are continuing this heritage today by bringing important new pharmaceutical products to market in a range of therapeutic areas. In addition, we are advancing beyond current innovation at J&J MedTech to help save lives and create a future where healthcare solutions are smarter, less invasive, and more personalized to enhance the value for all consumers of health care around the world, including Medicare, Medicaid, and Marketplace beneficiaries. We are engaged members of BIO and PhRMA and support their comments also submitted in response to this initial guidance.

We appreciate the opportunity to continue our ongoing dialogue with CMS on implementation of the Inflation Reduction Act (IRA), and we offer the following comments for CMS' consideration. Of note, we would like to underscore that transparency is fundamental in ensuring program integrity. The economic impact of the inflation rebate program is substantial – estimated at $9billion in 2031 by CBO[1]. Adequate financial controls must be in place to ensure the accurate implementation this significant program. At a minimum, this includes a needed level of transparency into the data used by CMS to determine rebate amounts so that manufacturers can sufficiently replicate calculations and verify the accuracy of rebate payments. Such reconciliation is consistent with stakeholders' fiduciary responsibilities and in support of financial reporting obligations.

Section 40 – Calculation of the Part D Drug Inflation Rebate Amount

Section 40.1: Components of the Part D Drug Inflation Rebate Amount Calculation
CMS notes that the law requires the agency to report to manufacturers (1) the amount, if any, by which the "annual manufacturer price" (AnMP) for each dosage form and strength of a Part D rebatable drug exceeded the inflation-adjusted payment amount; and (2) the rebate amount for each dosage form and strength of the Part D rebatable drug for the applicable period. J&J strong requests CMS provide visibility to manufacturers as to this process, including the specific data that will be used to calculate these amounts to promote transparency and program integrity. Specifically, we ask CMS to provide visibility to manufacturers to quarterly AMP and AMP units used to determine the AnMP (benchmark and applicable), the "amount" in excess of the inflation adjusted amount, as well as the eligible Part D units associated the total rebate amount at each NDC11 level.

[1] https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf

Section 40.1.1: Units Used for Determination of AnMP and Benchmark Period Manufacturer Price

In this section CMS states that manufacturer-reported monthly AMP units would be the appropriate units to use in the calculation of the AnMP and the benchmark period manufacturer price for the Part D drug inflation rebates. J&J disagrees and notes that the accurate calculation of the weighted average AnMP is possible only if both actual sales and units are used to calculate the weighted average AnMP. Therefore, to ensure accuracy J&J recommends that CMS require manufacturers to calculate and submit in the MDP system the AnMP based on actual transactions over 12 months. Alternatively, CMS could require manufacturers to submit AMP value and units "as calculated."

Section 40.1.2: Situations in Which Manufacturers Do Not Report Units

CMS states that for quarters in which a manufacturer does not have sales or units to report (i.e., because of the lack of sales), the agency would not use that calendar quarter's data in calculating the AnMP or the benchmark period manufacturer price. We note that this supports our recommendation that manufacturers calculate and submit AnMP to reflect actual transactions.

Section 40.2.1: Calculation of the AnMP

The inflation rebates payable under the IRA are intended to address Congress's concern with drug price increases, specifically price increases that exceed the rate of inflation. To effectuate a penalty for price increases that exceed the rate of inflation, the law references calculations under the Medicaid program, specifically the AMP calculation. We are concerned that there are instances in which a naked application of the statutory text would not meet Congress' intent. In certain instances, employing reported AMPs will lead to illogical outcomes and unjustified inflation rebates. This can occur in at least two situations, including related to MDRP regulations and the 5i calculation methodology. Under the Medicaid program, AMP "as calculated" or "reported" is often adapted to make it fit for purpose under the requirements of the Medicaid program. To calculate inflation rebates meaningfully and correctly in these differing circumstances, CMS will need to make technical adjustments when relying on metrics reported under other programs (i.e., the Medicaid Drug Rebate Program).

For example, certain technical requirements and point in time methodologies under the MDRP regulations and manufacturer release guidelines will result in increases in AMP in situations where the manufacturer has not increased price. In these scenarios, manufacturers should not be subject to inflation rebate penalties. Below are several illustrative examples that demonstrate AMP increases independent from, or absent manufacturer price actions.

1) CMS has indicated it intends to calculate the AnMP itself based on the AMP "as calculated" and "reported" to CMS. (Section 1860D-14B(b)(2)). While CMS has "as reported" AMP data, it is not always equal to "as calculated" AMP based on *actual* transactions. For example, as required by MDRP guidance, there are quarters in which manufacturers report the last positive quarter AMP (for example, when there are zero gross sales or negative sales), and this is not reflective of actual transactions. CMS currently does not have access to the "as calculated" AMP under this scenario.

2) As required by the Medicaid regulation that defines how AMP should be calculated, the applicable AnMP calculation can result in a higher AnMP even when no price action has occurred.[2] For example, this can happen due to lagged price concessions and changes in eligible sales and units. This is more evident with respect to low-cost drugs because of the highly competitive dynamic market. **See Figure 1** for a low-cost product example. As illustrated below, AnMP can increase period over period due to timing of lagged price concessions and changes in eligible sales and units. In this case, the increase in AnMP is due to technical calculation, and this change will generate a higher AMP, even when list price remains the same.

[2] Medicaid Final Rule § 447.510 Requirements for manufacturers.

Figure 1

	Benchmark	Y1 Applicable
Low Cost Drug	1Q-3Q21	4Q22-3Q23
List Price	$25.00	$25.00
aAMP	$1.00	$2.00
AMP Increase %		*200%*
Allowable AMP % (Jan21 Oct22)		*114%*
Inflation Penalty %		86%

3) 5i drug AMP calculation method could vary for the reporting periods within the applicable year (5i AMP or Standard AMP) due to the Medicaid required quantitative measurement. Identification of a 5i drug "not generally dispensed through retail community pharmacy" (RCP) must be completed and reported to CMS monthly based on the percentage of sales units sold to entities other than RCPs using the 70/30 "not generally dispensed through RCP" threshold (Medicaid Final Rule § 447.507). Consequently, CMS has visibility to the methodology applied to calculate AMP for a particular month.

   The AMP calculation method for a product may change from 5i to Standard when the 5i product did not meet the 70/30 "not generally dispensed through RCP" threshold. Solely because of the difference in calculation methods, this change will generate a higher AMP, even when list price remains the same. See Figure 2 below as an example.

Figure 2

	1Q21	2Q21	3Q21	Benchmark 1Q-3Q21	4Q22	1Q23	2Q23	3Q23	Y1 Applicable 4Q22-3Q23
5i Measurement									
Non Retail %	71%	70%	70%		69%	70%	71%	70%	
AMP Method	5i	5i	5i	5i	**Standard**	5i	5i	5i	Mix Methods
List Price	$100	$100	$100	$100	$100	$100	$100	$100	$100
aAMP	$51	$50	$53	$51	$99	$51	$52	$53	$63.8
AMP Increase %									*124%*
Allowable AMP % (Jan21 Oct22)									*114%*
Inflation Penalty %									10%

Note: 5i Measurement is determined monthly. Quarterly AMP Method determination above is for illustrative purposes and assumes monthly "AMP Method" designation is consistent within the quarter.

J&J recommends that CMS require manufactures to submit the two key components that were used to generate the "as calculated" AMP (Eligible Dollars and Eligible Units) over the applicable twelve months/four quarter periods. This allows CMS to calculate the AnMP for the benchmark and applicable measurement periods using relevant and accurate data CMS did not previously have visibility to when "as calculated" and "as reported" AMP values are not the same.

In cases where the list price action, if any, is not the key driver of an increase in AMP in excess of the allowable inflation percent, CMS should not apply the inflation rebate penalty. Determination of "key driver" would involve a

comparison of baseline list price to applicable period end of month list price (Jan21 vs. Oct22). If the increase is not directionally in alignment within the allowable increase (114% in Figure 1), it would be appropriate for CMS to conclude that list price is not the key driver of the AMP change. This will require manufacturer to submit applicable list prices to CMS. Because AMP increases beyond the allowable limit it can be driven by causes other than list price increases, CMS should consider a threshold. For example, see Figure 3 below.

Figure 3 (Assumes Allowable Inflation is 3%)

Product A	**AMP Base**	**AMP Applicable Period**	**% Change**	**Conclusion**
	10.00	12.65	27%	Price action is likely the primary driver of the AMP increase. Apply inflation penalty (27% less 3%)
	List Price (LP) Base	**LP Applicable Period**	**% Change**	
	17.00	21.10	24%	
Product B	**AMP Base**	**AMP Applicable Period**	**% Change**	**Conclusion**
	10.00	15.30	53%	Price action is not the primary driver of the AMP increase. Do not apply inflation, list price change is within the allowable 3% increase
	List Price (LP) Base	**LP Applicable Period**	**% Change**	
	17.00	17.40	2%	
Product C	**AMP Base**	**AMP Applicable Period**	**% Change**	**Conclusion**
	10.00	15.30	53%	Price action is not the primary driver of the AMP increase. However, list price change exceeds the allowable limit of 3%. Apply modified inflation penalty (5% less 3%)
	List Price (LP) Base	**LP Applicable Period**	**% Change**	
	10.00	10.50	5%	

Applying inflationary penalty due to AMP flux when there are no list price actions or minimal list price actions could unintentionally disadvantage the marketability of lower price drugs that are subject to unique market dynamics (example in Figure 1).

With respect to 5i products and possible inconsistency with AMP calculation methodology across Benchmark and Applicable periods, J&J suggests that CMS consider application of a “normalization” process when determining the inflation penalty where there is a change in methodology between the measurement periods (Wholesaler vs. Primary method). This is similar in concept to the VHCA mandated process to “normalize” the NFAMP calculation in the year over year comparison. Two potential normalization solutions are outlined below for CMS’ consideration.

1. Preferred solution (simplest): If a product meets the definition of a 5i product (infused, injectable, inhaled, instilled, implanted), under the normalization process, the manufacturer will recalculate and report to CMS any outlier quarter (such as 4Q22 in Figure 2) using the 5i AMP calculation methodology, despite the results of the quantitative 70/30 Not Generally Dispensed to Retail Community Pharmacy threshold.

2. Alternative solution: If there are two or more quarters that were calculated by the Standard AMP methodology, the normalization process would require the manufacturer to recalculate the quarters that were previously reported using the 5i AMP methodology, thus normalizing to a consistent comparison. Conversely, if there are three or more quarters that were calculated by the 5i AMP methodology, the normalization procedure would require the manufacturer to recalculate the quarters that were previously reported using the Standard AMP methodology.

40.2.5: Use of PDE Data to Determine Total Units Subject to Rebate and Crosswalk to AMP Units

J&J supports CMS’ proposal to add a "Quantity Dispensed" unit of measure field to the PDE file layout, which would add an additional level of “assurance” for CMS and manufacturers. We further recommend CMS enforce use, while providing sufficient visibility to this data to manufacturers. We encourage CMS to allow manufacturers the opportunity to review and reconcile the agency's collected data to support accuracy and completeness. We note that “Quantity Dispensed” as a data field by itself is not sufficient. For example, without knowing the claim status, it is difficult to know if it was a valid quantity dispensed, or if it was reversed. Therefore, we urge transparency with manufacturers to support accuracy including at a minimum that relevant data fields are included on invoices for manufacturer review.

Additionally, CMS notes its intent to compare the Part D rebatable drug units reported in the PDE record to the units reported in MDP for the monthly AMP. J&J urges CMS to provide manufacturers with visibility to the unit of measure conversion and critical data fields within the invoice details so that manufacturers can verify the accuracy of the conversions. J&J would welcome the opportunity to partner with CMS to help verify and confirm conversions.

40.2.7: Exclusion of 340B Acquired Units from Part D Rebatable Drug Requirements

J&J is concerned that all prescriptions subject to a 340B agreement may not be adequately accounted for, as required by statute. However, we support CMS' proposed approach to including a 340B indicator on the PDE record and requiring its use on all pharmacy claims and urge CMS to move forward with implementation prior to 2026. We also recommend that CMS include a non-340B modifier and require its use by rejecting claims that do not contain a 340B or non-340B modifier. To enforce use, we recommend CMS reject claims submitted without a 340B or non-340B modifier. Compliance with these required modifiers is critical in enabling CMS to accurately identify and exclude 340B units as required by statute. While the addition of a required non-340B modifier will help CMS to more accurately remove 340B units, we further recommend that CMS conduct periodic audits to enforce covered entities' compliance with required modifiers and ensure these units are appropriately excluded as required. CMS should provide manufacturers with claims level data for transparency and to enable manufacturers to validate that 340B units are not included in inflation rebate calculations.

Section 50 – Ensuring Integrity of the Part D Drug Inflation Rebate Payments

Section 50.1: Timing of Rebate Reports and Payment

J&J supports the establishment of a process which provides manufacturers the opportunity to review preliminary rebate and true up reports and identify calculation errors to the agency. However, we are concerned that 10 days for review of these preliminary reports, as proposed by CMS in this initial guidance, is wholly insufficient for an adequate review. We ask CMS to extend this timeframe to 45 days, but no less than 30 days. Consistent with their fiduciary responsibilities, manufacturers will need to validate and confirm the accuracy of information included in the preliminary rebate and true up reports. To illustrate, some steps manufacturers will need to take in this process include confirming product eligibility, normalizing report data to be compatible with manufacturers' systems, confirmation of accurate application of exclusions, AnMP, CPI-U and allowable amount, and inflation-adjusted amount; perform reasonability analysis of billing units based on internal sales data, and calculate the total invoice amount based on billing units. This is further complicated for large manufacturers who may have over 100 products that meet the definition of a rebatable drug, and they will need to ensure appropriate levels of review. As noted above, we underscore that manufacturers will need visibility to the data informing CMS' determinations and calculations to conduct this validation process.

In addition, CMS states that manufacturers will have 30 days from the date of receipt of the Rebate Report to pay the rebate owed. We ask CMS to clarify how it will determine the date of receipt. 30 days is already a short timeframe, and we note that the issue date for the Rebate Report is not necessarily the same as the date of receipt. We ask CMS how it plans to determine this precise date to ensure that manufacturers are allotted the full 30 days.

While not addressed in this initial guidance, we ask CMS to clarify the format for the rebate reports. J&J recommends a computer readable file format within a modern spreadsheet application, such as ASCII delimited for fixed file format.

50.2: Restatements of PDE Units Reported and True Up Rebate Report

While we support the establishment of a true up process to reconcile under and overpayment, we ask CMS to provide this process for up to three years after final rebate reports are submitted to account for restatements that occur after the one-year mark.

50.4: CMS Identification of Errors

J&J acknowledges that CMS reserves the right to update or change the rebate amount and true up the amount due from manufacturers based on calculation errors, or misreporting issues that the agency identifies at any point after each applicable period ends. While we appreciate the need to address errors and issues, we urge CMS to specify a maximum amount of time during which the agency may make such corrections. We ask CMS to avoid an open-ended approach, and to define a period of three to four years in which it may true up rebate amounts based on CMS identification of errors.

Section 60: Enforcement of Rebate Payments by Manufacturers: Civil Monetary Penalties

Consistent with the statute, CMS notes its intent to establish a process for Part D inflation rebate CMPs pursuant to regulations. J&J urges CMS not to subject manufacturers to inflation rebate penalties until final regulations are issued and in place, as we would have concerns if manufacturers could only rely on this short guidance before CMS imposes CMPs on manufacturers. Additionally, we stress the importance of due process, and suggest that CMS establish clear notice, procedures and timeframes for manufacturers to respond to CMP notices, request hearings before an administrative law judge (ALJ), and appeal ALJ decisions to the HHS Departmental Appeals Board before seeking review in the U.S. Court of Appeals, as is part of existing procedures for the Medicare Advantage organizations, Part D prescription drug plan sponsors, and CMP procedures issued by OIG.

Section 70 – Formulas

70.7: Calculation of Total Rebate Amount Owed by Manufacturer per Dosage Form and Strength of a Part D Rebatable Drug
CMS outlines that Total Rebates Owed = Total PDE Units of a dosage form and strength of a Part D Rebatable Drug dispensed under Part D and covered and paid for by Part D sponsors for an applicable period **multiplied by the Per Unit Rebate Amount**. However, we note that Total PDE Units may not align to the "amount rebate" per unit based on Medicaid Unit of Measure. J&J suggests that CMS revise the definition to clarify Total Rebates Owed = Total Converted PDE Units of a dosage form and strength of a Part D Rebatable Drug dispensed under Part D and covered and paid for by Part D sponsors for an applicable period multiplied by the Per Unit Rebate Amount.

We thank the agency for the opportunity to provide feedback on this initial guidance document and would be happy to answer any questions about these comments. Please contact Jacqueline Roche @ jroche@its.jnj.com.

Sincerely,

Jacqueline Roche, DrPH
Head Payment and Delivery & Global Policy Institute
Johnson & Johnson Worldwide Government Affairs & Policy (WWGA&P)

kalderos

Via email to IRARebateandNegotiation@cms.hhs.gov

March 10, 2023

Dr. Meena Seshamani, M.D. Ph.D.,
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Part D Inflation Rebate Comments

Dear Deputy Administrator Seshamani:

Kalderos appreciates the opportunity to submit comments on the Centers for Medicare & Medicaid Services' ("CMS") Initial Memorandum on the Implementation of Section 1860D-14B of the Social Security Act concerning Medicare Part D Drug Inflation Rebates Paid by Manufacturers (hereinafter, "Part D Initial Guidance" or "Guidance"). Kalderos has also submitted corresponding comments on CMS' Initial Memorandum on the Implementation of Section 1847(A)(i) of the Social Security Act concerning Medicare Part B Drug Inflation Rebates Paid by Manufacturers.

Kalderos is building unifying technologies that bring transparency, trust, and equity to the entire healthcare community. We are on a mission to solve systemic problems of the healthcare system, redefining how the business of healthcare performs. Kalderos seeks to solve the problems in drug discount and rebate programs by connecting the stakeholders; enabling simple, streamlined communication; and applying machine learning to create smart data science tools. We are genuinely committed to being an honest broker administering a fair, balanced process assisting payers, providers, and manufacturers to ensure the right drug price is applied to the right transaction, in compliance with laws and contract terms.

I. Kalderos's Role in Discount and Rebate Compliance

Kalderos builds solutions to ensure that stakeholders comply with all statutory and regulatory requirements of discount and rebate programs, including those imposed by the Inflation Reduction Act of 2022 ("IRA") and other federal and state laws concerning drug pricing and reimbursement. To that end, Kalderos supports the goals outlined by CMS in the Part D Initial Guidance, particularly those goals related to program integrity and error identification.

Beginning in 2016, Kalderos sought to develop solutions to fix a broken 340B program. The essence of Kalderos's honest-broker approach is to be fair to payers, providers, and manufacturers in a manner that is consistent with the 340B statute. To that end, Kalderos evaluated and developed solutions to facilitate coordination between 340B Covered Entities and manufacturers, including those using contract pharmacies, while simultaneously ensuring that there are systems in place to identify duplicate discounts and diversion. Kalderos's principles reflect the balance at the core of the 340B statute.

However, despite our efforts and the efforts of other key stakeholders, hundreds of millions of dollars continue to be in dispute each year with state Medicaid agencies as a result of duplicate discount concerns. Accordingly, it is of vital importance to us that CMS' future guidance regarding the Part D Inflation Rebate adequately addresses the manner by which duplicate discount issues will be identified and resolved. Failure to address these issues will result in significant duplicate discount claims between Inflation Rebates, 340B discounts, and, potentially MDRP rebates for dual eligible entities. These deficiencies weaken the 340B Program for payers, providers, and manufacturers alike. Without adequate mechanisms to address these duplicate discounts, which the Guidance does not address, the duplicate discount problem will only increase. CMS must act to prevent the further weakening of the 340B Program.

It is with this experience that we offer the following comments:

- Inflation Rebate Dispute Process: While we support CMS allowing manufacturers the opportunity to dispute incorrect data, CMS must revise the process by which manufacturers may dispute CMS' calculation of the Inflation Rebate owed. Specifically, the Part D Initial Guidance frames the dispute process as a "suggestion" that an error may exist, which is not sufficient to ensure that Part D Inflation Rebates are accurate. We believe that an administrative dispute process similar to the MDRP dispute resolution process is consistent with the statute and is necessary to provide manufacturers an adequate opportunity to dispute incorrect calculations.

- Claims Data Sharing: We are deeply concerned with the process, or lack of process, by which CMS intends to share the data it uses to calculate the Part D Inflation Rebate with manufacturers. The sharing of claims data is a critical tool in the dispute process as it allows manufacturers to quickly and accurately identify incorrect data. Without claims data, manufacturers will have no ability to verify that the Inflation Rebates owed are accurate.

- Identification and Exclusion of 340B Products: The method currently outlined in the Guidance does not adequately address how 340B discounted drugs will be identified and excluded from the calculation of the Part D Inflation Rebate. Specifically, we are concerned that the proposed method of identifying such products—using a 340B claim indicator—will be insufficient to properly identify claims. As a result, duplicate discount can be expected to be a significant problem that CMS must address.

- Incentivizing Covered Entities to Ensure Appropriate Claim Identification: We are concerned that the Guidance does not provide an adequate process for 340B Covered Entities to proactively and appropriately identify 340B claims for exclusion or to participate in the dispute resolution process, as needed. We urge CMS to implement a process that encourages 340B Covered Entities and other stakeholders to identify 340B claims and facilitate Covered Entity participation in the dispute resolution process.

II. CMS Must Provide Manufacturers an Adequate Opportunity to Dispute Incorrect Data or Calculations

We are deeply concerned that the Guidance, as currently written, does not provide manufacturers the opportunity to engage in meaningful and effective disputes concerning the data from which CMS calculates the Part D Inflation Rebates. The Part D Initial Guidance merely provides:

> Manufacturers of Part D rebatable drugs may provide CMS, for its discretionary consideration, with suggestions of calculation errors in their Preliminary Rebate Report and Preliminary True- Up Rebate Report for Part D drug inflation rebate amounts owed . . . if the manufacturer believes that there is a calculation error to be corrected before the Rebate Report or True-Up Rebate Report is finalized . . . Manufacturers of Part D rebatable drugs that owe an inflation rebate could submit a suggestion of a calculation error if they identify a mathematical error in the calculation by CMS or an exclusion of a Part D rebatable drug specified in statute that was not applied in their Preliminary Rebate Report and Preliminary True-Up Rebate Report, which CMS may consider at its discretion. Manufacturers should notify CMS, share the suggestion of a calculation error, and provide supporting documentation (if applicable) within 10 days after receiving their Preliminary Rebate Report or Preliminary True Up Rebate Report.[1]

The guidance points to the statutory language barring administrative or judicial review of CMS' inflation rebate calculations as a reason for not implementing a dispute resolution process[2], but such a process can be established without formal administrative or judicial review, consistent with the statute. Namely, CMS can, and must, establish a process by which manufacturers can address concerns about data accuracy directly to CMS and such a process must involve more than the mere "suggestion" of incorrect data. For example, under the 340B Program, manufacturers and Covered Entities are required to respond to good faith inquiries of duplicate discounts and, if unresolved, may pursue an audit to validate and address duplicate discounts. This process is fully separate from the formal administrative dispute resolution process governed by a panel of government officials and requiring formal complaints and a hearing. Relatedly, under the MDRP, manufacturers may dispute a rebate claim through the filing of specified forms, again outside of a formal administrative or judicial dispute process. A similar dispute process is absolutely critical here and can be established consistent with the statute.

Incorrect data has long been a prevalent issue impacting rebates paid by manufacturers to state Medicaid programs under the MDRP. Indeed, since the creation of the MDRP via the Omnibus Budget Reconciliation Act of 1990, recurring systemic issues have created challenges with accurately invoicing manufacturers for MDRP rebates. These systemic issues have been the

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[1] *See* CMS, "Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments" at 31 (Feb. 9, 2023).
[2] *See* 42 U.S.C. 1395w-31(g).

subject of multiple reports[3] by the Department of Health and Human Services Office of the Inspector General ("OIG"). For example, a 2005 OIG study of the Medicaid drug rebate programs of 49 states and the District of Columbia revealed that:

> Seventeen States had weaknesses in their rebate collection systems that resulted in inaccurate and/or insufficiently detailed rebate collection information. Eleven of these States did not maintain a rebate general ledger control account. Other States did not make rate adjustments to the system, make billing and payment adjustments to the National Drug Codes level, or maintain records throughout the history of the rebate program. As a result, these States could not be assured that all drug rebate revenue was collected.[4]

Over a decade later, in 2016, OIG once again found that states lacked the ability to collect accurate claims level data, noting that, "States' use of provider-level methods creates a risk of duplicate discounts and forgone rebates. States using provider-level methods are likely to either erroneously include some 340B claims in rebate invoices (resulting in duplicate discounts) or erroneously exclude some non-340B claims from rebate invoices (resulting in forgone rebates)."[5]

Each year, manufacturers continue to dispute inaccurate claims for hundreds of millions of dollars' worth of rebates under the MDRP. In fact, Kalderos alone has assisted in disputes totaling hundreds of millions of dollars in the past six years. Given that the Part D inflation rebates are, in part, modeled after the MDRP rebates, we can expect similar levels of inaccurate claims here. Further, since issues have yet to be solved for MDRP rebates, it is reasonable to assume that the same issues regarding data accuracy will occur with Part D Inflation Rebates. We urge CMS to implement a dispute resolution process for Part D Inflation Rebates. As a starting point, CMS should consider drawing from the dispute resolution process provided under the MDRP. Kalderos supports a Part D Inflation Rebate dispute process that would:

1. **Extend the time for manufacturers to report inaccuracies**: Given that manufacturers must analyze millions of claims for each product subject to an Inflation Rebate, CMS should allow manufacturers at least 38 days, consistent with the period allowed currently in the MDRP program, to review the Preliminary Reports, analyze the claims data, and identify inaccurate claims.

2. **Require claim-submitting entities involvement in ensuring data accuracy**: CMS should require that claim-submitting entities engage in a mandatory good faith inquiry process, in which they are required to respond to data inquiries and to confirm certain information. Revised guidance should clarify that providers, pharmacies, and states, to the

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[3] *See* OIG, "Multistate Review of Medicaid Drug Rebate Programs" (July 2005) https://oig.hhs.gov/oas/reports/region6/60300048.pdf; OIG, "Nationwide Rollup Report for Medicaid Drug Rebate Collections" (Aug. 2011) https://oig.hhs.gov/oas/reports/region6/61000011.pdf; OIG, "Medicaid Drug Rebate Dispute Resolution Could Be Improved" (Aug. 2014) https://oig.hhs.gov/oei/reports/oei-05-11-00580.pdf; OIG, "State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates" (June 2016) https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf.

[4] OIG, "Multistate Review of Medicaid Drug Rebate Programs" at 5.

[5] OIG, "State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates" at 11.

extent MDRP claims are not appropriately excluded for dual eligible individuals,[6] must assist in reviewing and validating claims data.

3. **Require CMS to review all reports of inaccurate data**: The Part D Initial Guidance currently allows CMS discretion to review a manufacturer's claim of incorrect data. Given the high likelihood that the data provided to CMS will be inaccurate in many cases, CMS should review each report of inaccurate claims that it receives and adjust the rebate amount owed, as appropriate.

Kalderos's experience as a transparent and honest broker managing dispute resolution between parties has given us insight into the ease in which duplicate discounts and data errors occur. Ensuring the program integrity of the Inflation Rebate process should be a tantamount concern for manufacturers, claim-submitting entities, states, and CMS alike. We welcome CMS' further guidance on the dispute resolution process and are hopeful that future guidance will mitigate the issues outlined above.

III. Claims Data Must be Provided to Manufacturers as a Default

Currently, the Part D Initial Guidance includes no provisions requiring that claims data be provided to manufacturers at any point before, during, or after the Inflation Rebate calculation. Without claims data, manufacturers cannot meaningfully and effectively dispute CMS' Inflation Rebate Calculation. We urge CMS to look to the lessons learned from other rebate or refund programs, such as the MDRP, and to provide claims data to manufacturers in the Preliminary Reports so that manufacturers can quickly and accurately validate such data in compliance with the limited time frame CMS has proposed for the manufacturers' review.

As we briefly discussed above, in Section II of this comment letter, information asymmetry has plagued other rebate programs, such as the MDRP. In the context of the MDRP, stakeholders have repeatedly discussed the need for the transparent provision of robust claims data to improve dispute resolution processes. In fact, CMS itself has repeatedly emphasized the importance of claims data in disputes. In 2020, CMS issued guidance setting forth "best practices" for avoiding 340B duplicate discounts. As one such "best practice," CMS encouraged states to provide manufacturers with claims level data and drug rebate invoices to facilitate compliance with the no duplicate discount provision and to minimize the number of disputes.[7] Namely, CMS stated that "when states provide claims level data to manufacturers, we would expect there to be a reduction in number of disputes due to more accurate information being provided."[8] The best practices guidance goes on to state that "manufacturers likely need claims level data for true invoice validation purposes."[9] CMS noted that providing claims level data may reduce the state's administrative burden and expense of researching manufacturer dispute issues.

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[6] While MDRP rebate claims should be uncommon for dual eligible claims in Part D, Kalderos has found instances where the states have asked for rebates for dual eligible claims. We previously shared this data with CMS via email in 2017.

[7] CMS, Best Practices for Avoiding 340B Duplicate Discounts in Medicaid (Jan. 8, 2020), available at https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib010820.pdf.

[8] *Id*.

[9] *Id*.

Such guidance is not new. As far back as 2001, CMS encouraged the provision of claims data, stating:

> We are taking this opportunity to ask all states to continue to share data necessary for dispute resolution with pharmaceutical manufacturers through the DRP process. Data such as third-party reimbursement amounts, zip code and pharmacy level data very often provide information that leads to resolution of rebate disputes. . . . [W]e have learned through hundreds of DRP meetings that, for purposes of dispute resolution, **this information is frequently necessary**.[10]

Similarly, in 2015, CMS issued an MDRP program notice to states that, again, encouraged states to provide claims data to address disputes, stating that "we continue to encourage states to respond to reasonable requests for [claims level data or] CLD."[11] A separate CMS "Hot Topics and Best Practices" guidance from 2020 similarly states that the agency "received feedback from states, manufacturers, and industry groups that have shared with CMS the CLD they have found useful in preventing or resolving disputes [sic] Medicaid Drug Rebate disputes."[12] These repeated statements make clear that CMS itself recognizes the critical nature of claims data in disputes.

Finally, other government stakeholders have similarly identified claims data as a critical part of effective disputes. For example, a report published in a 2014 by OIG studied the dispute resolution process under the MRDP.[13] OIG studied data from 31 states to determine the extent to which rebate amounts were disputed and surveyed 12 states to determine the frequency of the disputes. States reported to OIG that poor-quality claims data lead to disputes regarding unit-of-measure conversions and physician-administered drugs. OIG ultimately recommended that CMS work with states to improve quality of claims data submitted by providers and pharmacies and establish a stronger role in dispute resolution.

Accordingly, in order for the Part D Inflation Rebate and its dispute resolution process to be efficient and to prevent the obstacles found in the dispute resolution process of the MDRP, CMS should provide claims data to manufacturers in the Preliminary Reports for validation purposes. Without manufacturers receiving claims data and using the claims data to identify and report inaccurate or duplicate claims to CMS, accurately calculating Part D Inflation Rebates owed by manufacturers will be impossible.

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[10] CMS, State Release No 108 (Aug. 15, 2001), available at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-108.pdf (emphasis added).
[11] CMS, State Release No 173 (Dec. 31, 2005), available at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-173.pdf.
[12] CMS, Hot Topics and Best Practices (Aug. 2020), available at https://www.medicaid.gov/sites/default/files/2020-09/drp-hottopics-bestpractices.pdf.
[13] OIG, Medicaid Drug Rebate Dispute Resolution Could be Improved (Aug. 2014), available at https://oig.hhs.gov/oei/reports/oei-05-11-00580.pdf.

IV. Claim Indicators Will not be Effective in Identifying and Removing Claims for 340B Discounted Products

We support CMS' intent to remove 340B claims from the calculation of Part D Inflation Rebates, however, we are concerned that CMS' method of identifying and removing such claims will be ineffective. Identifying 340B claims is a challenging task and has resulted in significant time, money, and resources spent to appropriately identify 340B claims. Over the years, states have implemented several different approaches to prevent 340B duplicate discounts, all of which have failed to be effective.

The most common approach involves the Medicaid Exclusion File ("MEF"), which is designed to be used to exclude utilization purchased by Covered Entities at 340B prices from the MDRP rebate process.[14] This MEF process was intended by the U.S. Department of Health and Human Services' Health Resources and Services Administration ("HRSA") to be the mechanism to ensure that Covered Entities comply with the duplicate discount prohibition, but, unfortunately, that mechanism is not effective in prohibiting duplicate discounts. As the Medicaid and CHIP Payment and Access Commission stated in a 2018 report, "states have raised concerns that the MEF can be inaccurate or outdated,"[15] and "the MEF does not apply to drugs dispensed by contract pharmacies or to drugs paid for by Medicaid managed care, both of which have expanded significantly over the past decade."[16]

Another approach used by states involved the submission clarification code exclusions. Under this approach, 340B Covered Entities must submit a code when seeking reimbursement from a state to tell the state when the entity dispensed a 340B drug. If a code were used on a claim, the state would exclude that claim when seeking rebates from the manufacturer. Despite the apparent benefits of using claims-level code data rather than providers claim data, modifiers have been largely ineffective in preventing duplicate discounts. For example, even if a 340B Covered Entity correctly identifies a claim as a 340B claim, which does not occur consistently, that modifier may be removed before it makes it to CMS given the many touchpoints of a pharmacy, third-party administrator, or pharmacy benefit manager, among others. As of March 9, 2023, we understand that thirty-eight (38) states require claims modifiers from covered entities when submitting claims to Medicaid for reimbursement. For these states, Kalderos has identified approximately $150,000,000 of 340B duplicate discounts over the last six years.

Accordingly, relying on an ineffective modifier, particularly without a dispute resolution process, will result in significant errors and overpayments by manufacturers on their Inflation Rebates. Failing to adequately address this issue would be contrary to the statutory exclusion of 340B claims from the Inflation Rebate calculation and would be arbitrary and capricious.

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[14] *See* HRSA, Notice Regarding the Section 340B Drug Pricing Program—Program Guidance Clarification, 65 Fed. Reg. 13983, 13984 (Mar. 15, 2000) (stating with respect to the clarification of the use of the MEF to prevent duplicate discounts that"[t]his policy release does not apply to the prevention of duplicate discounts that may occur under MCOs.").

[15] MACPAC, Issue Brief, The 340B Drug Pricing Program and Medicaid Drug Rebate Program: How They Interact (May 2018), available at https://www.macpac.gov/wp-content/uploads/2018/05/340B-Drug-Pricing-Program-and-Medicaid-Drug-Rebate-Program-How-They-Interact.pdf.

[16] *Id.*

We urge CMS to adopt a 340B identification and exclusion method based on a clearinghouse model. Under this model, claims data for 340B transactions, MDRP rebates, Inflation Rebate transactions, and maximum fair price transactions would be collected and validated to ensure that the proper discount or rebate is provided to the proper party. Kalderos has developed such a model for 340B and MDRP rebates and can quickly expand to cover the Inflation Rebate and maximum fair price transactions once in place. Consistent with our comments above, such a model requires transparency and claims data to be effective.

V. Covered Entity Participation

We are concerned that the Part D Initial Guidance does not provide an adequate process for 340B Covered Entities to participate in identifying and resolving duplicate discount issues. Covered Entities have historically been reluctant to engage in duplicate discount disputes, in part due to a lack of a clear process from CMS requiring Covered Entities to identify 340B claims and to respond to good faith inquiries regarding duplicate 340B claims. To effectively exclude duplicate discounts from the Inflation Rebate calculation, CMS must provide a process for Covered Entities and manufacturers to work together when a manufacturer believes a duplicate discount has occurred. Establishing a collaborative process between Covered Entities and manufacturers would recognize Covered Entities as stakeholders in the Inflation Rebate process and encourage Covered Entities' participation. Without this collaboration CMS would be unable to exclude 340B duplicate discounts from the Inflation Rebate calculation.

We urge CMS to issue guidance establishing a process for Covered Entities to engage in duplicate discount disputes between 340B claims and Inflation Rebates. Without such a process, it is likely that many Covered Entities may elect not to work with manufacturers to identify and proactively resolve duplicate discount disputes.

* * *

Kalderos appreciates this opportunity to provide input about the Part D Guidance. If you have any questions about these comments, please do not hesitate to contact me at 773-934-3672 or jdocken@kalderos.com.

Sincerely,

Jeremy G. Docken.

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March 11, 2023

BY E-MAIL (IRARebateandNegotiation@cms.hhs.gov)

Dr. Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Part D Inflation Rebate Comments

Dear Deputy Administrator Seshamani:

Eli Lilly and Company (Lilly) is pleased to respond to the Initial Guidance on Medicare Part D Inflation Rebates (Guidance).[1] Lilly is one of the country's leading innovation-driven, research-based pharmaceutical and biotechnology corporations. Our company is devoted to seeking answers for some of the world's most urgent medical needs through discovery and development of breakthrough medicines and technologies and through the health information we offer. Ultimately, our goal is to develop products that save and improve patients' lives.

We appreciate the time constraints under which CMS has been tasked with implementing this new statutory program but have some concerns that, in its haste, CMS is neglecting to address several key issues. As a member of both the Pharmaceutical Researchers and Manufacturers Association of America (PhRMA) and the Biotechnology Industry Organization (BIO), Lilly largely joins those groups in their comments on the Guidance and encourages CMS to carefully consider the input of those organizations. Lilly takes this opportunity to offer the following comments to highlight matters of specific concern and Lilly-specific positions.

I. CMS Needs to Create a Meaningful Manufacturer Error Resolution Framework to Ensure that Manufacturers Only Pay Part D Rebates on Eligible Units of Part D Rebatable Drugs

Lilly has decades of experience participating in drug rebate and refund programs administered by various federal agencies. Our experience has been consistent across all these programs: despite clear statutory commands that manufacturers are only required to pay rebates or refunds under certain circumstances, agencies routinely rely solely on "front end" controls that seem "good enough" at the time of initial program implementation but that prove insufficient as the years go by. Our concern is that federal authorities are simply not concerned about whether manufacturers overpay rebates or refunds. This view disregards statutory mandates and is shortsighted, as manufacturers will

[1] CMS, Center for Medicare, "Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the Social Security Act, and Solicitation of Comments." (Feb. 9, 2023)

eventually factor erroneous rebate and refund claims into their decision to continue participation with federal healthcare programs.

For example, in the Medicaid Drug Rebate Program, Lilly has years of accumulated evidence of ineligible 340B duplicate discounts and other instances of ineligible utilization. These claims sit for years, unacted upon, in an amorphous dispute resolution process. Similarly, in the Part D Coverage Gap Discount Program, Branded Prescription Drug Fee excise tax, and the TRICARE Retail Pharmacy Refund Program manufacturers have clear evidence of erroneous claims but few – if any - options on the backend for resolving these.

To avoid and minimize erroneous claims, **Lilly urges CMS, as a threshold matter, to provide Part D invoice documentation that makes available claim-level details to support Part D rebate invoices. Specifically, we request CMS provide the following data elements in their invoice reports:**

- Date of Service
- Prescription ID Number
- Part D Contract ID and Part D Plan Benefit Package ID
- De-identified Part D Beneficiary ID
- De-identified Beneficiary ID Number
- National Prescriber Identified (NPI)
- Pharmacy NPI
- National Drug Code
- Days Supply
- Quantity Dispensed
- Fill Number
- Paid Date (by the Part D plan)

As Lilly has reviewed this draft Part D Inflation Guidance, we have identified several foreseeable examples where manufacturers are likely to seek resolution of fact-specific requests to correct or amend Part D rebate invoices. Specifically:

- Errors Related to Variable AMP Methodologies: Section 40.1.1 of the Guidance notes that "[m]anufacturers may include under certain circumstances non-retail community pharmacy sales units in the calculation of their AMPs for 5i AMP drugs as described in 42 CFR section 447.507." CMS goes on to state that it "believes that these manufacturer-reported monthly AMP units under section 1927(b)(3)(A)(iv) would be the appropriate units to use in the calculation of the Annual AMP (AnAMP) and the benchmark period manufacturer price for the Part D drug inflation rebates because using the total units sold by the manufacturer for the dosage form and strength of the drug as reported will allow for the accurate calculation of both a weighted average AnAMP as well as a benchmark period manufacturer price, as prescribed by the statute." However, CMS fails to address or acknowledge that a drug product may "flip" from being a 5i AMP drug to being a retail community pharmacy (RCP) drug if fewer than 70% of the units of that drug are dispensed by non-RCPs. This will almost certainly lead to confusion and error in the AnAMP calculation and in comparisons between the benchmark AnAMP and current period AnAMP. How should manufacturers present these issues to CMS?

- Errors Identified in Preliminary Rebate Reports: In sections 50.1 and 50.2 of the Guidance, CMS notes its intention to send manufacturers a Preliminary Rebate Report no later than six (6) months after the end of each rebate period. Manufacturers would then have ten (10) days to review the Preliminary Rebate Report for potential errors in the calculation of the rebate amount for the Part D rebatable drug for the quarter or for a statutory exclusion that was not applied. CMS would have "discretion" to review a manufacturer's suggestions about the Preliminary Rebate Report. What recourse do manufacturers have if CMS abuses its discretion or ignores the manufacturer's identification of the erroneous invoice amount? What recourse do manufacturers have if they miss the (unreasonably short) ten (10) day turn around time? Statutorily ineligible rebates are statutorily ineligible, and there is no provision in the statute that allows CMS to claim rebates if a manufacturer does not catch CMS's error within 10 days.

- Errors Identified in True-Up Reports: Lilly appreciates CMS's acknowledgment that some form of "true ups" will be necessary to accommodate lagged data or changes due to restatement or calculation errors (either by the government or the manufacturer). CMS proposed to send a one-time true-up report of the rebate amounts, which would allow for updated AnAMP and other data by manufacturers, revisions to the CPI-U, and updates to claims data that occurred after the rebates were calculated. CMS plans to provide a Preliminary True-Up Rebate Report and again provide ten (10) days for manufacturers to review for calculation errors which the Agency would consider at its "discretion." Again, what recourse do manufacturers have if they miss the (unreasonably short) ten (10) day turnaround time? Again, statutorily ineligible rebates are statutorily ineligible, and there is no provision in the statute that allows CMS to claim rebates if a manufacturer does not catch CMS's error within 10 days.

- Errors Related to Ineligible Duplicate Discounts: Section 1860D-14B(b)(1)(B) prohibits duplicate discounts on units subject to 340B ceiling prices. While we appreciate that this Guidance proposes methods to identify and exclude these units from the invoicing process, Lilly remains concerned that there may be unforeseen data complexities that CMS is not anticipating and where, over time, manufacturers may develop techniques to scrub for duplicates that CMS had not considered or deployed. CMS should welcome these efforts as they advance program integrity and ensure that the statute commands are heeded.

Lilly hopes that all these sources of potential errors – and others not yet contemplated – can be addressed through rational and open dialog with the agency. We highly recommend, at a minimum, establishing and staffing an email address for manufacturers to communicate concerns or perceived discrepancies with CMS.

II. CMS Needs to Provide Additional Guidance Related to Penalties for Covered Entities That Fail to Include 340B Claims Modifiers

Under section 1860D-14B(b)(1)(B), the SSA also prohibits duplicate rebates in on Part D rebatable units. We support CMS's proposed approach to using "N1" identifiers, but **Lilly believes this requirement must be supplemented by a legally binding requirement that covered entities identify 340B eligible prescriptions at point-of-sale and at the time of dispense.** CMS may need to engage in joint rulemaking with its sister agency, the Health Resources and Services Administration (HRSA), to implement this control. Please note, this control is also long overdue in the context of avoiding statutorily prohibited Medicaid duplicate discounts and is forward looking as

it will address the requirement for "Maximum Fair Price" (MFP) units, which are also statutorily barred from giving rise to duplicate discounts. All these statutes represent categorical prohibitions to duplicate discounts. Lilly continues to observe ample evidence in its own review of claim-level 340B data of rampant noncompliance and urges CMS action.

Specifically, the current National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard, the HIPAA compliant standard for Part D transactions, allows for, but does not require, the identification of units subject to a 340B agreement via a submission clarification code that can be populated and sent during claims adjudication. And while NCPDP does permit the retrospective identification of 340B units under the "N1" transaction, it is very rarely utilized. As such, Lilly believes the most reliable way to identify drugs subject to a 340B discount that are dispensed under Part D is requiring a 340B indicator be included on the Prescription Drug Event (PDE) record and included on all pharmacy claims for such drugs and that can only be done accurately if there is a requirement for patients to identify (or be identified) at point-of-sale and time of dispense.

We believe that CMS and HRSA should work together to undertake a holistic review of all the statutory prohibitions against duplicate discounts on 340B units. These non-duplication requirements extend to Part B rebate, Part D rebate units, Medicaid rebate units (fee-for-service and managed care), and Maximum Fair Price (MFP) unit.

Finally, Lilly urges CMS to establish a robust audit process for 340B covered entities to confirm the appropriate identification of units subject to 340B agreements, or to establish a clearinghouse-type organization to identify 340B units administered to Medicare enrollees. The 340B clearinghouse would act as a claims verifier, reviewing data submitted by 340B covered entities (or entities acting on their behalf) to determine the likelihood that a claim is subject to a 340B agreement, similar to the role attempted by 340B third-party administrators (TPAs) and split-billing vendors today.[2] Units marked as subject to 340B agreements on either the claim or by the 340B clearinghouse would be excluded from calculation of the Part D inflation rebate.

III. CMS Should Extend Its Timeframes for Manufacturer Review and Payment of Part D Rebate Invoices and True-Up Reports

In sections 50.1 and 50.2 of the Guidance, CMS notes its intention to send manufacturers a Preliminary Rebate Report within six (6) months after the end of each applicable rebate period. Manufacturers would then have ten (10) days to review the Preliminary Rebate Report for potential errors in the calculation of the rebate amount for the Part D rebatable drug for the quarter or for a statutory exclusion that was not applied. Similarly, CMS proposes to provide manufacturers with only ten (10) days to review any true-up reports. These are an unreasonably compressed timeframes for individuals in the payment processing team to receive, route to the appropriate person, analyze, and document any questions or concerns related to the invoices.

We respectfully request that CMS extend both deadlines to at least thirty (30) days.

[2] 340B TPAs and split-billing vendors assist 340B CEs in managing prescriptions. These entities track electronic data feeds (such as inpatient or outpatient status, prescriber eligibility, clinic location, Medicaid payer status, drug identifier, and quantity dispensed) so 340B patient eligibility can be assessed and to virtually separate inventory dispensed to 340BCE patients from inventory dispensed to individuals who are not CE patients.

IV. CMS Should Advocate for a More Equitable and Straightforward Metric for Assessing Inflation for Purposes of Assessing Part D Inflation Rebates

Lilly unsuccessfully advocated that any Medicare Part D inflation rebate program should be based on changes to the wholesale acquisition cost (WAC, also sometimes call the "list price") rather than the AnAMP for several reason. First, WAC and change to WAC are fixed, definite, and easy to determine. Second, WAC is completely controlled by the manufacturer, whereas AMPs are dictated by varying purchase and discount patterns controlled AMP eligible customers, not the manufacturer. Third, as described above, there are **two** different AMP calculation methodologies –RCP AMP and 5i AMP. Because some products – again, based on customer purchase patterns – might flip back and forth between using the RCP AMP and 5i AMP methodologies. We expect this will give rise to "illusory" inflation for such products.

We invite CMS to consider whether a WAC-based inflation rebate would be preferable and, if so, to work with HHS's Office of Legislative Affairs to petition Congress for this revision.

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Lilly is grateful for the opportunity to comment on the Part D Inflation Rebate Initial Guidance. We sincerely appreciate your thoughtful consideration of the issues discussed in this letter and look forward to working with you in the future to help ensure that patients have meaningful access to affordable health care benefits and prescription drug coverage. Please do not hesitate to contact Derek Asay at Asay_Derek_L@Lilly.com with any questions.

Sincerely,

Derek L. Asay
Senior Vice President, Government Strategy

Shawn O'Neail
Senior Vice President, Government Affairs

March 7, 2023

Dr. Meena Seshamani, MD, PhD
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Concerns about modifier approach for identifying 340B drugs dispensed under Medicare Part D

Dear Dr. Sheshamani,

On behalf of the Mid-Atlantic Association of Community Health Centers (MACHC), thank you for the opportunity to provide input into CMS' plans for implementing the Medicare inflationary rebates established under the Inflation Reduction Act. MACHC is the federally designated primary care association for Maryland and Delaware's twenty federally qualified health centers (FQHCs).

I begin this letter with a summary of our comments, followed by background on FQHCs and 340B, and then a detailed discussion of each comment.

SUMMARY OF COMMENTS

1. FQHCs' experience indicates that requiring a 340B indicator (also known as a modifier) on Part D drugs would:
   a. Result in data that is highly unreliable.
   b. Force FQHCs to shut down many of their contract pharmacy arrangements for Part D drugs, leading to an overall loss in 340B savings and subsequent reduction in services provided to underserved patients.

2. Instead of a modifier, FQHCs recommend that CMS implement a "clearinghouse" model for identifying 340B drugs covered by Part D. Compared to a modifier requirement, a clearinghouse would:
   a. Produce much more reliable data.
   b. Be significantly less labor-intensive.
   c. Preserve the ability of FQHCs and other 340B providers to rely on contract pharmacies to dispense 340B drugs to Part D enrollees, thereby avoiding reductions in access.
   d. Be able to be expanded to include 340B drugs dispensed to Medicaid patients.

BACKGROUND INFORMATION ON FQHCs, 340B, and CONTRACT PHARMACIES

Federally Qualified Health Centers (FQHCs) are the backbone of our nation's health care safety net. By law and mission, FQHCs serve medically-underserved patients and ensure that no one is denied care, regardless of ability to pay. More than two-thirds (67%) of FQHC patients in Maryland and Delaware are uninsured or Medicaid beneficiaries.

FQHCs offer a broad range of services, including primary care, dental, behavioral health, and pharmaceuticals. Many of these services – and the sliding fee discounts that make them affordable for our patients -- are supported by savings generated through the 340B drug discount program. For many FQHCs, 340B savings are more important to their financial viability than the Federal grant they receive.

Nationally, FQHCs rely on contract pharmacy arrangements to dispense roughly 50-60% of the 340B drugs provided to their patients – the highest percentage of any 340B provider. Thus, the 340B savings generated at contract pharmacies support many services that the FQHC would otherwise be unable to provide to their medically-underserve patients.

Given the importance of 340B contract pharmacy arrangements to our FQHCs and their patients, ***we are deeply concerned about the following statement on page 18 of the preliminary guidance that CMS shared on February 9, 2023:***

> ***"CMS believes that requiring that a 340B indicator be included on the PDE record is the most reliable way to identify drugs that are subject to a 340B discount that were dispensed under Medicare Part D."***

While we understand and support the need for CMS to collect accurate data on which Part D prescriptions were filled with 340B drugs, requiring an indicator (aka modifier) on claims would not only produce unreliable data; it would also undermine FQHCs' 340B savings – and the services they support, particularly at contract pharmacies. Fortunately, there is an alternative way for CMS to collect that data that would yield more reliable data without threatening the financial support that FQHCs rely on. These concerns and recommendations are discussed in detail on the following pages.

DETAILED COMMENTS

1. A modifier requirement under Part D would produce highly unreliable data.

Requiring pharmacies to include a 340B modifier on Part D claims filled with 340B drugs would produce highly unreliable data for a combination of two reasons:

- Determining whether a prescription can and should be filled with a 340B drug can be a very complicated, data-intensive process that often cannot be completed reliably when the prescription is being filled and the claim submitted to the payer (aka the point-of-sale.)
- Because of this complexity, most prescriptions filled with 340B drugs ("340B prescriptions") are not identified by the pharmacy until after dispensing the drug. Therefore, adding a 340B modifier would require pharmacies to reopen and update every claim for every Medicare 340B prescription – a laborious process that many pharmacies (particularly large chain pharmacies) have been unwilling to do.

The complex decision tree for determining whether a dispensed prescription should be filled with a 340B drug. As illustrated in the attached flowchart (see Attachment), determining if a prescription can be filled with a 340B drug requires evaluating each of the following issues:

- Does the payer allow for a 340B drug to be dispensed?
- Is the individual a patient of the FQHC?
- Has the patient been seen at the FQHC recently enough to qualify for a 340B drug?
- Was the prescription written by a provider who works for the FQHC?
  - If yes, was the provider:
    - Moonlighting when the prescription was written?
    - Providing a service that is under the FQHC's scope of project?
  - If not, can the FQHC demonstrate that it has assumed responsibility for the care that generated the prescription?
- Is it more cost-effective to dispense a non-340B drug?

(Note that this decision tree does not apply to clinically-administered drugs – i.e., Part B drugs – as they are 340B-eligible. Therefore, FQHCs do not have the same concerns about using a modifier to identify Part B drugs.)

Many 340B prescriptions cannot reliably be identified at the point of sale. To accurately assess each prescription, the pharmacy needs access to patients' Electronic Health Records and the FQHCs' administrative records regarding in-scope services, contracted providers, moonlighting providers, etc. Because of the amount of work and data involved, FQHCs (and other 340B providers, known as covered entities) hire Third Party Administrators (TPAs) to conduct these assessments. The TPAs sync extensive data between the FQHC and the pharmacies every evening. The TPA then reviews all prescriptions to identify those that can be filled with 340B drugs. Due to the volume of data involved, it is not feasible for this data to be downloaded and synced in real-time, as would be required for 340B eligibility to be determined at the point of sale. Thus, it is impossible to reliably identify 340B prescriptions at the point of sale.

For many 340B prescriptions, adding a modifier would require amending a submitted claim – a labor-intensive process that most contract pharmacies refuse to do.

As discussed above, many 340B prescriptions cannot be identified until the claim has been submitted to the payer. Therefore, including a modifier requires the pharmacy to amend the submitted claim for each 340B Medicare prescription, which is very labor-intensive and time-

consuming. Also, some payers will not accept amended claims and instead require the pharmacy to rescind the original claim and then submit a new one – further increasing the workload.

Given the additional work involved, it is unsurprising that most contract pharmacies – particularly the large chains – refuse to apply a modifier on 340B claims. To demonstrate this, we encourage you to review what happened when Express Scripts (ESI) – one of the three largest Pharmaceutical Benefits Managers (PBMs) in the US – announced a modifier requirement in February 2021.

In summary, a modifier requirement under Part D would yield unreliable data on 340B prescriptions, as a modifier often cannot be added to a claim in real-time, and most contract pharmacies are unwilling to amend or rescind a previous claim to add the modifier.

2. A modifier requirement would force FQHCs to shut down many of their contract pharmacy arrangements for Part D drugs, leading to a loss in 340B savings and a subsequent reduction in services provided to underserved patients.

As described above, FQHCs rely on contract pharmacies to fill 50% to 60% of their 340B prescriptions and use the savings to support services for underserved populations. A CMS requirement to include a modifier on all Part D 340B prescriptions claims would jeopardize these contract pharmacy arrangements and the services they support. As discussed above, large chain pharmacies have made it clear that they are unwilling to apply a modifier. Thus, FQHCs would be forced to shut down their contract pharmacy arrangements for Part D drugs to ensure compliance with Federal rules. This would be harmful to FQHCs' finances (and the services they support) in its own right; also, a CMS modifier requirement would encourage other payers to impose their modifier requirements, further eating away at the contract pharmacy savings that FQHCs rely on.

3. Instead of a modifier, FQHCs recommend that CMS implement a clearinghouse model for identifying 340B drugs covered by Part D.

Fortunately, an alternative to the modifier approach avoids the challenges outlined above. This model – which has been used successfully for years by Oregon Medicaid and is now being implemented by Hawaii Medicaid – is called a "clearinghouse" or "flat file" model. Under this model, covered entities send a Medicaid contractor a "flat file" listing every Medicaid claim filled with 340B drugs during a recent period (e.g., the past two weeks or month). The file contains each claim's NDC code and BIN/ PCN number but no Protected Health Information. The contractor aggregates the data by NDC, BIN, and PCN and shares the totals with the Medicaid agency to deduct them from the number of units on which it claims Medicaid Drug Rebates.

This clearinghouse approach has multiple benefits compared to a modifier requirement:

- **A clearinghouse approach produces much more reliable data.** Unlike a modifier approach, the clearinghouse approach allows covered entities to submit 340B data retrospectively. Thus, it gives the covered entity and pharmacy the additional time they need (after the point-of-sale) to thoroughly analyze whether each prescription should be filled with a 340B drug. Also, it does not require rescinding or amending claims to provide accurate data.
- **A clearinghouse approach is much less labor-intensive.** The modifier approach requires that every claim for every 340B drug be either amended or rescinded to have the modifier added – an extremely time-consuming and labor-intensive process. In contrast, the

clearinghouse approach allows thousands of 340B prescriptions to be identified at once through a flat file that can be produced automatically by a covered entity or their TPA.

- **A clearinghouse approach preserves the ability of FQHCs and other covered entities to rely on contract pharmacies, thereby avoiding reductions in access.** By taking the burden of identifying Part D 340B prescriptions off of contract pharmacies, a clearinghouse approach would preserve FQHCs' contract pharmacy relationships for Part D and likely for commercially insured patients. This keeps FQHCs' ability to retain savings generated by contract pharmacies – and to continue using them to support the range of services for underserved populations.
- **Could be expanded to incorporate Medicaid 340B data.** A clearinghouse for Part D 340B data could easily be expanded to receive data on Medicaid 340B drugs. This would provide a streamlined and consistent national approach to avoiding duplicate Medicaid discounts.

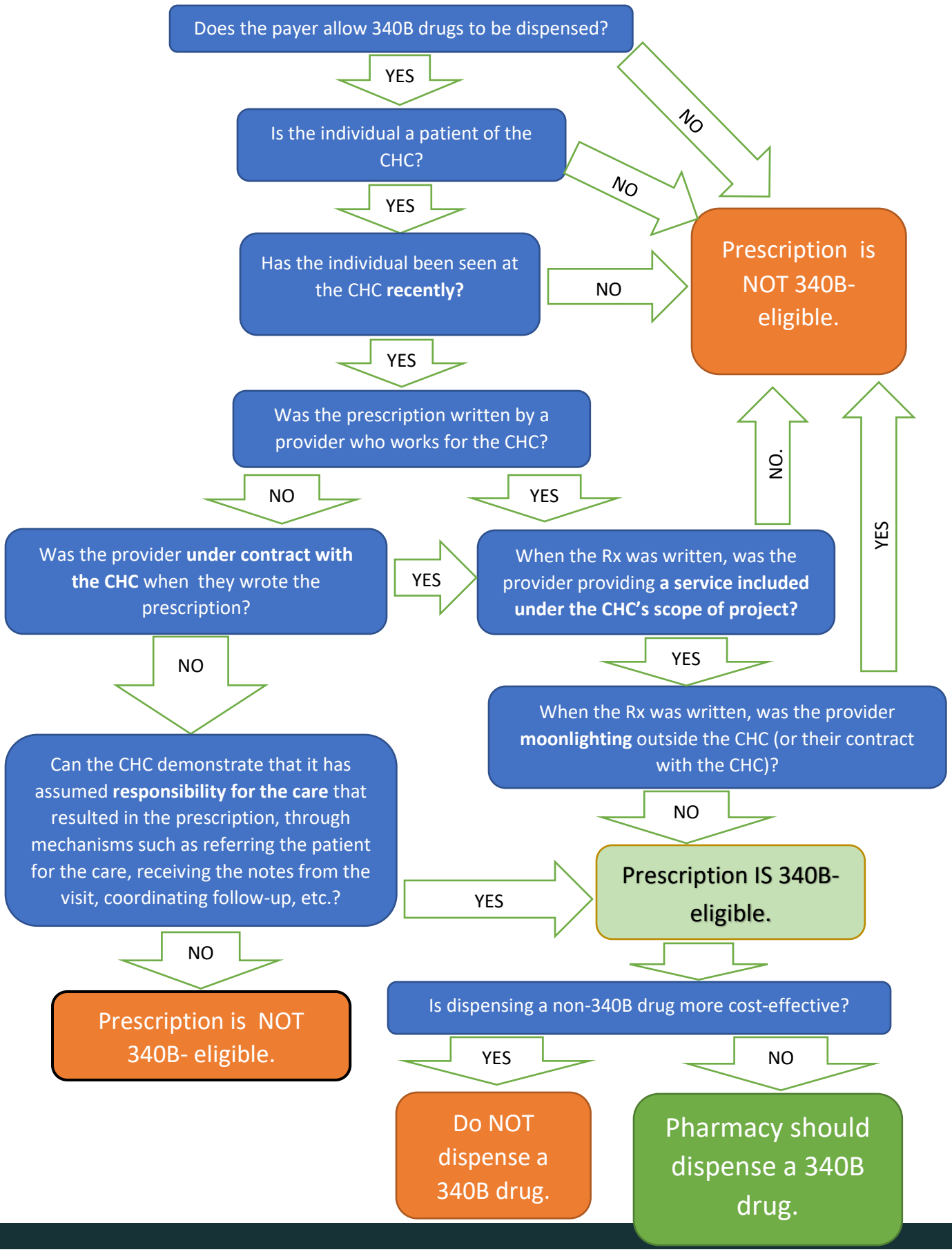
Thank you for considering our serious concerns about the modifier model and our proposed alternative. If you have any questions about our comments, please contact me at dmcgonegal@machc.com.

Sincerely,

Delaney McGonegal

Delaney McGonegal
Director of Health Policy & Analytics
Mid-Atlantic Association of Community Health Centers

Process for a Pharmacy to Determine if a Prescription Should be Filled with a 340B Drug



MEDICARE RIGHTS CENTER
Getting Medicare right

266 West 37th Street, 3rd Floor
New York, NY 10018
212.869.3850/Fax: 212.869.3532

March 11, 2023

The Honorable Meena Seshamani, MD, PhD
Director, Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Prescription Drug Inflation Rebate Comments

Dear Dr. Seshamani:

The Medicare Rights Center (Medicare Rights) appreciates this opportunity to comment on initial guidance from the Center for Medicare & Medicare Services (CMS) for the Medicare Prescription Drug Inflation Rebate Program (Rebate Program). Medicare Rights is a national, nonprofit organization that works to ensure access to affordable and equitable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Each year, Medicare Rights provides services and resources to nearly three million people with Medicare, family caregivers, and professionals.

Based on this experience, we know that people with Medicare are uniquely impacted by high and rising drug prices. This is partly due to utilization and health status; for example, Part D enrollees take an average of 4 to 5 prescriptions per month,[1] and over two-thirds of all enrollees have multiple chronic conditions.[2] At the same time, many live on fixed or limited incomes that cannot keep pace with rapidly escalating drug prices. Half of all Medicare beneficiaries—nearly 30 million people—live on $29,650 or less per year, and one quarter have less than $8,500 in savings.[3] Health care costs comprise a large and disproportionate share of beneficiaries' limited budgets: nearly 30% of Medicare households spend 20%

[1] Leigh Purvis, *et al.,* "Rx Price Watch Report: Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans, 2006 to 2020" AARP Public Policy Institute (September 28, 2021) http://www.aarp.org/rxpricewatch.
[2] Centers for Medicare & Medicaid Services, "Multiple Chronic Conditions" https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/MCC_Main.
[3] Wyatt Koma, *et al.,* "Medicare Beneficiaries' Financial Security Before the Coronavirus Pandemic" Kaiser Family Foundation (April 24, 2020) https://www.kff.org/medicare/issue-brief/medicare-beneficiaries-financial-security-before-the-coronavirus-pandemic/.

or more of their income on health care, compared to only 6% of non-Medicare households.[4] Out-of-pocket costs for prescription drugs represent a significant share of this amount, accounting for nearly one out of every five beneficiary health care dollars.[5] Put simply, most people with Medicare cannot afford to pay more for care. Yet, costs continue to climb—price hikes on brand name drugs have exceeded the rate of inflation every year since at least 2006.[6]

The Inflation Reduction Act's (IRA) Rebate Program will provide much-needed relief. It will require drug companies to pay a rebate if they raise certain Part B and Part D drug prices faster than inflation, curbing the industry practice of sky-high annual price adjustments.[7] This deterrent will drive down individual and program costs. Drug price increases usually translate into higher out-of-pocket consumer payments, especially for people who pay coinsurance, as do most Medicare enrollees. They are also passed along to Medicare and the taxpayers who help fund the program, and to all beneficiaries in the form of higher deductibles and premiums.[8] Better controlling the drug prices on which these costs are based will lower spending and improve access to care.

We commend CMS for its attention to prompt implementation of the Rebate Program, including this timely initial guidance. As CMS explains, although full implementation will appropriately span multiple years, the program is expected to have an impact much sooner. For example, while CMS does not plan to invoice drug companies for Part D inflation-based rebates until 2025, the first yearly period for which drug companies will be required to pay those rebates began October 1, 2022. Companies may have already adjusted current and future pricing behaviors as a result.

This could translate into direct savings for Part D enrollees this year. Most pay coinsurance, leaving them exposed to high and rising drug prices. Individual risk can vary; in 2023, coinsurance rates range from 15 to 50 percent.[9] To the extent the Rebate Program is already discouraging drug companies from making large price increases, Part D enrollees could experience lower out-of-pocket costs than they would have otherwise, saving them money and undue stress.

The savings are just beginning. The nonpartisan Congressional Budget Office (CBO) estimates the Rebate Program will save billions of dollars for beneficiaries, taxpayers, and Medicare over the next ten years. Importantly, CBO notes the IRA will generate these savings while bolstering outcomes and solvency:

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[4] Juliette Cubanski, *et al.*, "The Financial Burden on Health Care Spending: Larger for Medicare Households than for Non-Medicare Households" Kaiser Family Foundation (March 1, 2018) https://www.kff.org/medicare/issue-brief/the-financial-burden-of-health-care-spending-larger-for-medicare-households-than-for-non-medicare-households/.

[5] Kaiser Family Foundation, "10 Essential Facts about Medicare and Prescription Drug Spending" (January 29, 2019) https://www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending/.

[6] Leigh Purvis, *et al.,* "Rx Price Watch Report: Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans, 2006 to 2020" AARP Public Policy Institute (September 28, 2021) http://www.aarp.org/rxpricewatch.

[7] *Id.*

[8] American Academy of Actuaries, "Prescription Drug Spending in the U.S. Health Care System" (March 2018) https://www.actuary.org/content/prescription-drug-spending-us-health-care-system.

[9] Juliette Cubanksi and Anthony Damico, "Medicare Part D: A First Look at Drug Plans in 2023" Kaiser Family Foundation (November 10, 2022) https://www.kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-medicare-drug-plans-in-2023/.

lower drug costs will increase medication adherence, improving beneficiary health and reducing the need for—and Medicare spending on—more costly care.[10]

Thank you again for the opportunity to provide comment. Medicare Rights strongly supports the IRA's Rebate Program. These long overdue reforms will strengthen Medicare as well as beneficiary health and financial security. For additional information, please contact me at LCopeland@medicarerights.org or 202-637-0961 and Julie Carter, Counsel for Federal Policy JCarter@medicarerights.org or 202-637-0962.

Sincerely,

Lindsey Copeland
Federal Policy Director
Medicare Rights Center

[10] Congressional Budget Office, "How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act" (February 2023) https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf.

Maine Primary Care Association

March 8, 2023

Dr. Meena Seshamani, MD, PhD
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Concerns about modifier approach for identifying 340B drugs dispensed under Medicare Part D

Dear Dr. Seshamani:

Maine Primary Care Association (MPCA) is a non-profit membership organization representing the collective voices of Maine's 20 Federally Qualified Health Centers (FQHCs), which provide high-quality and equitable primary and preventive medical, behavioral, and dental health services for 1 in 6 Maine people at over 70 service sites across the state. MPCA's mission is to champion and maximize the value of Maine's FQHCs for the health and well-being of all Maine people. For more than 40 years, MPCA has provided technical assistance and training, housed relevant programs and services, and advocated on behalf of Maine's health centers and the hundreds of thousands of patients they serve each year.

Thank you for the opportunity to provide input into CMS' plans for implementing the Medicare inflationary rebates established under the Inflation Reduction Act. We would also like to lend our strong support to comments submitted by other members of the FQHC community, including the National Association of Community Health Centers and various other state and regional Primary Care Associations.

In Maine, FQHCs are the backbone of the health care safety net. They provide care to over 200,000 people, regardless of whether they have insurance or their ability to pay, ensuring that comprehensive services are available to medically underserved and often uninsured or underinsured patients. The broad range of services provided by FQHCs[1] – and the sliding fee discounts that make them affordable for patients – are often supported by savings generated through the 340B Drug Pricing Program. This program is an essential source of support for FQHCs, allowing them to stretch federal resources and reinvest in patient care. The program allows health centers to purchase outpatient drugs at significantly reduced costs. FQHCs are then required to pass the savings on to their patients through reduced drug prices and invest additional savings to expand access and improve health outcomes.

The savings and resources generated by participating in the 340B program allow FQHCs to provide the assistance to patients in the most need and for which there is no other source of funding. Examples of what the 340B program allows Maine FQHCs to accomplish include setting up food pantries to support food insecure patients, providing care to those experiencing homelessness, integrating substance use disorder treatment, and funding critical workforce positions beyond the clinical care team.

[1] MPCA - Community Health Center Profiles

Nationwide, FQHCs rely on contract pharmacy arrangements to dispense roughly 50-60% of the 340B drugs provided to their patients – the highest percentage of any type of 340B provider. Thus, the 340B savings generated at contract pharmacies support many services that the FQHC would otherwise be unable to provide. Given the importance of 340B savings – including those generated by contract pharmacies – we are very concerned that CMS is considering requiring an indicator (also known as modifier) on all claims for Part D prescriptions that were filled with 340B drugs.

As discussed in detail in comments submitted by other members of the FQHC community, FQHCs' experience clearly indicates that requiring a 340B modifier on Part D drugs would:

a. Result in data that is highly unreliable.
b. Force FQHCs to shut down many of their contract pharmacy arrangements for Part D drugs, leading to an overall loss in 340B savings and subsequent reduction in services provided to underserved patients.

Instead of a modifier, we recommend that CMS implement a "clearinghouse" model for identifying 340B drugs covered by Part D. Compared to a modifier requirement, a clearinghouse would:

a. Produce much more reliable data.
b. Be significantly less labor-intensive.
c. Preserve the ability of FQHCs and other 340B providers to rely on contract pharmacies to dispense 340B drugs to Part D enrollees, thereby avoiding reductions in access.
d. Be scalable to include 340B drugs dispensed to Medicaid patients.

Thank you for considering our serious concerns about the modifier model and our proposed alternative. Please contact me if we can provide additional information or assistance.

Sincerely,

Darcy Shargo

Darcy Shargo, MFA
Chief Executive Officer
Maine Primary Care Association
dshargo@mepca.org

Model N

March 10, 2023

VIA ELECTRONIC FILING (email) – IRARebateandNegotiation@cms.hhs.gov

Dr. Meena Seshamani, M.D. Ph.D., CMS Deputy Administrator and Director of the Center for Medicare

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Subject: Medicare Part D Inflation Rebate Comments

Dear CMS:

Model N appreciates the opportunity to comment on the Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, dated February 9, 2023.

Model N provides a suite of Revenue Management applications for manufacturers of pharmaceutical and medical device products to align their business processes of pricing strategy and execution, contract development and management, contract performance compliance, and payment of trade settlements, such as rebates, chargebacks, and fees. In addition, to address aspects of life sciences regulatory compliance, Model N offers government pricing and Medicaid claims processing applications as a part of the suite. By aligning revenue transactions with Medicaid and other government drug-pricing policies, as well as with government best-price reporting requirements, the Model N regulatory applications eliminate the financial and brand name exposure to regulatory non-compliance.

As a part of Model N's continued support of the prescription drug manufacturing industry, we have created an internal team of subject matter experts and solicited feedback and comments from our customers and partners regarding implementation of the Medicare Part D Inflation Rebate given the details shared in the Initial Memorandum. The comments below represent a summary of our consolidated views. The comments are not legal advice and do not necessarily represent details on past, present, or future Model N products and solutions.

For the Medicare Part D Inflation Rebate guidance, Model N requests clarification on specific aspects of the regulation, as well as the initial guidance memorandum, and requests CMS to consider these points in the final regulation:

1. **Comments pertaining to Section 40 of the Initial Memorandum, Calculation of the Part D Drug Inflation Rebate Amount:**

   Section 40.2.2 – Calculation of Benchmark Period Manufacturer Price:

   In this section, the determination of the benchmark period for Part D inflation rebates is based on the 'approval date' of the drug. For example, for drugs approved on/before October 1st, 2021, the benchmark period is Q1-Q3 2021. The following are some clarifications that we request from CMS for determining the benchmark period for the drugs:

- Given that the FDA approval is for the NDA/BLA, is it reasonable to assume that the same approval date would be applicable for all products and package sizes within the same NDA/BLA? If not, what date should be used?
- Since Part D inflation rebates are based on volume weighted average annualized AMP (AnMP) (based on the average manufacturer price (AMP)), which is determined based on when the drug entered the market (and not necessarily the FDA approval date), what would the benchmark volume weighted average annualized AMP for such drugs be that were approved and do not have an AMP calculated for the determined benchmark period? For example, a drug was approved on September 1st, 2021, and has a market entry date in February 2022. The benchmark period for this drug, based on the current provisions is Q1-Q3 2021, but the drug would not have a calculated AMP for any of the quarters of the benchmark period. How should the manufacturer account for such a scenario?

Section 40.1.2 - Situations in Which Manufacturers Do Not Report Units:
In this section, the following statements seem to be contradictory, and we request CMS to clarify on how manufacturers must calculate the weighted AnMP and/or the benchmark period manufacturer price, in cases where there are no sales for the drug during the calendar quarters of an applicable period or the benchmark period:

"Given that no units would be reported, however, because of the lack of sales, that calendar quarter's data would not be used in calculating the AnMP or the benchmark period manufacturer price for the purposes of calculating Part D drug inflation rebates.".

The above statement contradicts the following:
"If there are no sales of the drug for the entire payment amount benchmark period, the manufacturer's reported price using reasonable assumptions would be averaged over the calendar quarters of the payment amount benchmark period in order to determine the benchmark period manufacturer price."

In scenarios where the drug has no sales during the calendar quarters of an applicable period or the benchmark period, should the manufacturer use the quarterly reported price using reasonable assumptions in calculating AnMP or the benchmark period manufacturer price, though there are no sales during those quarters?

We would appreciate any guidance that CMS can provide on how the terminated or expired drugs will be treated for the Medicare Part D Inflation Rebates:

- If a drug has expired, does the manufacturer still owe Part D inflation rebates for any period after the drug's termination date, like in Medicaid?
- Does CMS/the manufacturer continue to calculate the Part D inflation rebate penalty per unit past the drug's termination/expiration date?

Section 40.2.5 – Use of PDE Data to Determine Total Units Subject to Rebate and Crosswalk to AMP Units:

Model N encourages CMS to strongly consider the inclusion of a field on the PDE to collect how the amount reported in the PDE "quantity dispensed" field is measured, as stated in the

final paragraph in this sub-section. We feel there is ample time for implementation, and the positive impact to the data submitted to CMS will improve the overall accuracy of the derived Units used to report to manufacturers and used to calculate an accurate rebate amount, thus increasing the integrity of the Part D Drug Inflation Rebate Payments.

Section 40.2.7 – Exclusion of 340B Acquired Units from Part D Rebatable Drug Requirements:

In this section, the Initial Guidance contemplates whether requiring the 340B indicator on the PDE transactions is the most reliable way to enable the exclusion. First, we support process steps to operationalize this requirement and feel that requiring the 340B indicator alone is not likely the most reliable method to support this process for two primary reasons:

- The 340B indicator is not required to be submitted by the pharmacy as part of the related NCPDP transaction, thus the Part D Sponsor may not have this data readily available, and
- The identification of a prescription as 340B is often a retrospective identification that takes place in a variable duration of time after the prescription is dispensed, thus might often be after the PDE transaction has been submitted to CMS.

As a result, the 340B indicator alone, will not enable a reliable identification and exclusion of 340B units from the Inflation Rebate calculation. Other options may include an expansion of the indicator such that the Part D Sponsors must send an update when the prescription is identified as 340B, or a method to utilize data from the TPAs or Covered Entities that identify or assist in the identification of a prescription as 340B that can be compared against the PDE transactions received by CMS to exclude those that are 340B.

Section 40.5 – Reducing or Waiving the Rebate Amount for Part D Rebatable Drugs in Shortage and in Cases of Severe Supply Chain Disruptions:

In this section, a series of questions are asked related to waiving or reducing rebate amounts for drug shortages or severe supply chain disruptions. While we do not feel it is within our purview to comment on reasons for shortages and the impact to the Inflation Rebate calculation, we would like to make the following operational comments:

- When a manufacturer's Rebate Amount is impacted by a reduction or waiver, we would encourage the content shared by CMS with the manufacturer to uniformly include the original calculation details, as well as the calculation of the adjustment due to the reduction or waiver and any clarifying details depending upon whether the final approach includes variations to the waiver or reduction due to proration, reason, and time-based increases or decreases.
- We would recommend further clarification related to whether any reductions or waivers will be connected to the dates included on the shortage list for the affected product and the prescription Dates of Service (Fill Dates) as included on the PDE transactions so that the reduction is specific to the PDE transactions during the dates within which the product is listed on the shortage list.

2. Comments pertaining to Section 50 of the Initial Memorandum, Ensuring Integrity of Part D Drug Inflation Rebate Payments:

Section 50.1 – Timing of Rebate Reports and Payments:

We acknowledge the statement that "CMS expects to issue additional guidance regarding the form and manner in which Rebate Reports would be sent to manufacturers" and look forward to reviewing these details when they become available. In advance of this future guidance, we would like to provide the following statements on this subject:

- The initial guidance describes a series of reports including a Preliminary Rebate Report, a Rebate Report, and a True-Up Rebate Report. These report references seem to indicate that the reports and content within them are high-level details rather than data content. We would like to encourage CMS to consider providing a meaningful level and granularity of data to support the calculations of the rebates that are due by the manufacturer. Specifically, considering modern data structures (i.e., avoiding overpunch character formats) with content akin to the data provided to manufacturers as part of the Coverage Gap Discount Program (CGDP). The CGDP includes machine readable formats with many meaningful descriptive and numeric columns, as well as PDE-level data supporting the calculation. Furthermore, appropriate data background is paramount to manufacturers and enables them to support a wide range of operational, financial, and compliance requirements. Process and financial controls are embedded in all aspects of their work and providing data at an appropriate granularity that permits the continued implementation of these controls to avoid significant negative impacts to financial statements allows them to remain compliant with a wide range of federal regulations. We encourage CMS to consider these needs when designing the structure, formats, and delivery of the data and reports needed in support of the Inflation Rebate.

Section 50.2 – Restatements of PDE Units Reported and True-up Rebate Report:

Consistent with the previous comments on the design of the data and reports, we await further guidance on how this True-Up and Restatement process will work. The operational details are critical to understand how manufacturers will receive, evaluate, process, and pay based-on these activities, including how overpayments are to be handled.

This section further describes several use cases that could drive restatements, such as Unit changes and manufacturer re-calculation of the benchmark period price amount. We recommend additional clarification in this section in response to the 340B exclusion clarity as the retrospective updates to transaction identified as 340B will also be impactful to the basis for the Inflation Rebate calculation.

Section 50.3 – Manufacturer Suggestions of Calculation Errors in Preliminary Rebate Reports and Preliminary True Up Reports:

In response to the specific phrase in this section stating: "Section 1860D-14B(a)(3) expressly provides for a limitation of administrative or judicial review, specifically providing that there

shall be no such review of the determination of units under this program, the determination of whether a drug is a Part D rebatable drug, or the calculation of the rebate amount under this program", Model N encourages a reconsideration of this limitation. Again, referring to the CGDP, there is a dispute process included in this program and this program has strong similarities to this Inflation Rebate program. The limitation of data granularity and transparency to manufacturers interferes with their ability to support financial controls and compliance steps. Providing greater data granularity, as stated in the preceding section, and for a dispute process permits manufacturers to have ample time to review the transactional data and determine whether there are units that should not be subject to the Inflation Rebate.

3. Additional Clarifications:

Drug Divestitures and Acquisitions:

The memorandum does not talk about the Medicare Part D inflation rebates in case of drug divestitures and acquisitions. We would appreciate any guidance that CMS can provide on it:

- If a drug is divested, would the Part D inflation rebates, for PDE prior to the divestiture, lie with the old manufacturer and the Part D inflation rebates, for PDE post the divestiture, with the new manufacturer? Also, how does CMS plan to submit the inflation rebate reports to the respective manufacturers?

Model N appreciates the opportunity to engage with CMS and provide comments on the Initial Guidance and we feel that clarifications and expanded guidance to the points discussed here are critical for us to better understand how we will support pharmaceutical manufacturers in implementing key provisions within the IRA. We welcome the opportunity to collaborate with CMS and other key industry stakeholders to facilitate an efficient process in support of the Medicare Part D Inflation. We look forward to engaging further as this process evolves to deliver an efficient and effective outcome. Finally, we welcome any questions or additional information you may have and look forward to working with you to successfully implement this new rule.

Regards,

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NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

March 10, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Subject Line: Medicare Part D Inflation Rebate Comments
Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Submitted via email: IRARebateandNegotiation@cms.hhs.gov

Re: Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments

Dear Administrator Brooks-LaSure:

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to comment on CMS' Initial Memorandum Implementation of Section 1860D-14B of the Social Security Act regarding Medicare Part D Drug Inflation Rebates paid by manufacturers. On February 9, 2023, CMS issued proposed guidance to implement certain provisions of the Inflation Reduction Act (IRA) that require pharmaceutical manufacturers that increase their price for a covered Part D rebatable drug faster than the rate of inflation (based on a 2021 benchmark) to pay Part D drug inflation rebates to the Medicare Trust Fund for eligible Part D rebatable drugs.

The new law also requires CMS to use information submitted by manufacturers, states, and Part D plan sponsors, such as through Prescription Drug Event (PDE) records, to calculate the inflation rebate. The law excludes certain Part D drugs or biological products if the average annual total cost per individual is less than $100 and excludes 340B drugs (with the latter beginning in 2026).

Specifically, we would like to provide comments on Section 30.1, Exclusions of Application of Rebates to Part D Rebatable Drugs without a Manufacturer Drug Rebate Program (MDRP) agreement and that do not meet the definition of covered outpatient drug (COD); Section 30.2 Exclusion of Part D Rebatable Drugs Where Average Annual Total Cost of a Drug Under Part D Is Less than $100 Per Individual Using Such Drug per Year Adjusted by Changes in the Consumer Price Index for all Urban Consumers (CPI-U); Section 40.2.5, Use of PDE Data to Determine Total Units Subject to Rebate and Crosswalk to AMP Units; and most importantly Section 40.2.7, Exclusion of 340B Acquired Units from Part D Rebatable Drug Requirements. These four sections have the potential to impact community pharmacies' administrative capabilities and capacity, create new financial burdens and responsibilities, and significantly disrupt pharmacy workflow and continuity of care as pharmacies work to successfully implement other provisions of the IRA while delivering high-quality care to beneficiaries. As the voice of chain pharmacy, we would like to provide the

following comments to ensure integrity and a seamless transition in the development and implementation of the Part D Drug Inflation Rebate Program.

1. **Section 30.1: Exclusions of Application of Rebates to Part D Rebatable Drugs without an MDRP agreement and that do not meet the definition of covered outpatient drug (COD)-** The Part D drug inflation rebate calculation will use data that manufacturers submit under the MDRP, specifically the annual manufacturer price (AMP) data as defined in section 1927 for each COD dosage form and strength, and the total number of units of the dosage form and strength of said drug that are reported monthly that are used to calculate the monthly AMP. Since not every drug that may be deemed as a Part D rebatable drug is not marketed by a manufacturer under an MDRP agreement with the Secretary, all Part D rebatable drug information will not be available to CMS for the purposes of calculating the drug inflation rebate. Due to this operational limitation, CMS is searching for other alternatives to collect this information for their calculation. Furthermore, CMS shares another observation that Part D vaccines will be excluded from the Part D drug inflation rebate calculations at this time since vaccines are expressly excluded from the COD definition. Under these two exclusions, without necessary data reported from the manufacturer, no rebate amounts will be calculated or collected.

   NACDS' recommendation – We urge CMS to work with manufacturers to establish a path forward for identifying these outstanding Part D Rebatable drugs, including other drugs (in addition to vaccines) that may not be considered CODs, and ensure that these outstanding drugs, to the extent possible, are not increasing faster than the rate of inflation during this period of uncertainty which could have negative impacts on community pharmacies. We appreciate CMS' comment stating that they will monitor how these exclusions from the inflation rebates under Part D may impact manufacturers' behavior.

2. **30.2: Exclusion of Part D Rebatable Drugs Where Average Annual Total Cost of a Drug Under Part D Is Less than $100 Per Individual Using Such Drug per Year Adjusted by Changes in the CPI-U-** CMS intends to use available PDE data for applicable period October 1, 2022, through September 30, 2023 to determine drugs or biological products (at the NCD-9 level) with an average annual total cost under Part D less than $100 per individual. Drugs that meet this criterion will be excluded from the Part D rebatable drug calculation.

   NACDS' recommendation – We request that CMS clarify that the provisions related to the reporting of the PDE data neither imply nor would require additional reporting by community pharmacies for tracking and calculating drugs or biologicals below the $100 threshold per individual. Said differently, we want to ensure that the Part D inflation rebatable calculation is not implemented in any way that could impose new administrative burdens, stressors, or financial strains on community pharmacies. The burdens associated with compliance should be on the parties identified in the statute and should not be passed along to other parties such as community pharmacies.

3. **40.2.7: Exclusion of 340B Acquired Units from Part D Rebatable Drug Requirements-** CMS requires the total number of 340B acquired units to be excluded from the inflation rebate program, beginning January 2026. CMS intends to require a 340B indicator be included on the PDE file to identify discounted 340B drugs that were dispensed under Medicare Part D. Currently, the NCPDP telecommunication standard version D.0 for pharmacy claims does not require a pharmacy to indicate which drugs were dispensed and purchased under the 340B discount program. The 340B indicator in the NCPDP standard is an optional field that most trading partners do not utilize. Especially with the virtual replenishment model that most pharmacies and 340B covered entities utilize to provide timely care to 340B patients, there is no way for pharmacies to know at the point-of-sale which prescription drug claim is a 340B claim and which is not. Consequently, CMS should not require pharmacies to submit a 340B indicator on the prescription drug claim transaction. It would be impossible for pharmacies to comply with this requirement.

   Recognizing the impossibility of pharmacies submitting a 340B indicator on prescription drug claim transactions, in the draft guidance CMS suggests an alternative proposal of pharmacies utilizing the NCPDP "N1" transaction. However, CMS also recognizes that few, if any, pharmacies ever use this transaction.

   Except for a few pharmacies nationwide, the NCPDP "N1" transaction has not been implemented and is rarely utilized by community pharmacies because it is unworkable for numerous reasons. The "N1" transaction is retrospective and cannot be incorporated into pharmacy workflow without substantial disruption to current patient care processes, as well as deployment of additional and substantial time and resources, with the potential for negative impacts on pharmacies' abilities to continue to provide high quality patient care. Using a retrospective process such as the "N1" could create claim billing and 340B data timing discrepancies, as well as quantity unit discrepancies. For example, determination retrospectively that a claim is eligible for a 340B drug is an input to the replenishment process but not indicative that the replenishment process was successful. Also, a prescription for a 340B eligible patient could be partially filled with medication from the Section 340B inventory and partially with drugs from the non-340B Section inventory. In addition, utilization of the "N1" transaction could lead to pharmacies having to share proprietary information with pharmacy benefit managers (PBMs) and pharmaceutical manufacturers, to the detriment of the pharmacies. Finally, utilization of this transaction would likely lead to PBMs imposing new fees on pharmacies for receiving and processing the transactions as well as to forcing pharmacies to reverse and resubmit claims and then imposing on pharmacies new additional fees associated with doing so; and if the reversal and resubmission of claims fails, the pharmacy could potentially lose all of the reimbursement.

   Practically, if CMS required either the 340B indicator on the pharmacy prescription drug claim transaction or for pharmacies to retrospectively utilize the "N1" transaction, implementation of this requirement would take years to accomplish. The pharmacy software system changes would require system development, testing, and deployment across approximately 60,000 pharmacies nationwide, the development of policies, procedures, and training of pharmacy personnel, as well

as the hiring and training of new additional personnel, to comply with the new requirements. All of this would be required at a time when pharmacy reimbursements are lower than ever because of rampant and exponentially increasing direct and indirect remuneration (DIR) fees that CMS has yet to address, and for a provision of the IRA that does not even implicate community pharmacies.

CMS should abandon both proposals as unworkable and potentially devastating to pharmacies and continuity of care.

NACDS' recommendation – We recommend that CMS not implicate pharmacies in the 340B inflation rebate calculation requirements between CMS and manufacturers. CMS should not adopt or finalize the proposed guidance for pharmacies to use "N1" transactions (retrospective determinations) or for pharmacies to identify dispensed 340B drugs under Medicare Part D on the pharmacy claims for the inflation rebate calculation.

Instead, CMS should consider the establishment of a central clearinghouse to identify 340B transactions dispensed to Medicare Part D patients, similar to the model in Oregon. The Oregon model, which relies on covered entities to identify 340B Medicaid managed care claims, demonstrates that retrospective 340B claim identification is achievable without the use of the "N1" transaction and without the use of 340B identifiers on claims. The 340B clearinghouse would function as a claims verifier by reviewing transactions to determine if the claim is subject to the 340B price. This is a role that 340B TPAs (third party administrators) and split-billing vendors currently provide the market today. We believe the establishment of a 340B clearinghouse will be critical in the identification of 340B transactions. There is precedent for CMS using a clearinghouse in the Part D program, as CMS has contracted with a clearinghouse to serve as the TrOOP facilitation contractor since 2005.

We note, however, that the entity that operates the clearinghouse must be free from conflicts of interest. The contractor should have no incentive to minimize the use of 340B drugs for Part D beneficiaries and should be prohibited from using 340B claims information for purposes other than preventing duplicate discounts on Part D claims.

Alternatively, CMS should work directly with entities such as manufacturers impacted by the 340B pricing exclusion from the inflation rebate calculation to establish a financial reconciliation and extrapolation process and solution. For example, CMS could require a manufacturer to report the percentage of the manufacturer's sales that fall under 340B pricing via NDC and then CMS could determine the percentage of the manufacturer's 340B sales that apply to Medicare beneficiaries. Using the above percentages, CMS and manufacturers could determine the extrapolated 340B ratio by NDC to apply to the inflation rebate calculation. Since extrapolation is not prohibited in the statute, we see this as potentially a reliable and effective option if CMS and interested parties worked together. Additionally, to maintain the integrity and accuracy of the 340B ratio, we encourage CMS to consider re-evaluating and auditing the 340B ratio with manufacturers on an agreed upon timeframe.

4. **Sec 40.2.5: Use of PDE Data to Determine Total Units Subject to Rebate and Crosswalk to AMP Units -** From the PDE data, CMS plans to obtain the total number of Part D drug units from the field "Quantity Dispensed" for each dosage form and strength, and the drug's NDC from the "Product Service ID" field. The unit for each NDC is not reported on the PDE record, however this data is on FDA's Comprehensive NDC SPL Data Elements File (NSDE) in the "Billing Unit" field. Therefore, to identify the NCPDP billing unit for each NDC, CMS has proposed to crosswalk the data from the PDE record to FDA's NSDE file matching on the NDC. Units are reported differently under Medicare Part D because manufacturers report the AMP for their drugs in the Medicaid Drug Program (MDP) with ten different unit types (versus the limited unit types in the PDE). Due to the difference between how units are reported in the PDE and the MDP, for CMS to calculate Part D drug inflation rebates, CMS proposes to compare the Part D rebatable drug units in the PDE record to the units in MDP for the monthly AMP.

   Additionally, CMS is exploring the option of adding a new PDE file field to collect how the amount reported in the PDE "quantity dispensed" field is measured (e.g., each, milliliter, gram) to help facilitate the identification of the unit type for each NDC and quality assurance for CMS and manufacturers that the appropriate unit is used accurately calculate the inflationary rebates. Furthermore, CMS recognizes this would require additional work on the plans to report a unit type for each Part D rebatable drug on the PDE record and would still require a conversion to AMP units. CMS does not specify if this would require additional reporting requirements for pharmacy like the plans.

   NACDS' recommendation – We request that CMS clarify that the reporting of the PDE data does not imply or require additional reporting or any change to existing claim submission by community pharmacies for tracking and calculating Part D rebatable drugs. Moreover, we encourage CMS to ask FDA to consider working with NCPDP to address any discrepancies in the unit measurements should there any.

Thank you for your consideration of our comments on CMS' Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments. For questions or further discussion, please contact NACDS' Christie Boutte, Senior Vice President, Reimbursement, Innovation, and Advocacy, at CBoutte@NACDS.org or 703-837-4211.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

Submitted electronically via IRARebateandNegotiation@cms.hhs.gov

March 10, 2023

Dr. Meena Seshamani, M.D. Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Medicare Part D Inflation Rebate Comments

Dr. Seshamani,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide feedback on CMS' *Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments*.

NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a $78.5 billion healthcare marketplace, employ 240,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

40.2.7 Exclusion of 340B Acquired Units from Part D Rebatable Drug Requirements

CMS is soliciting comment on whether submission of the 340B identifier on the pharmacy claim is the preferred mechanism to identify 340B units dispensed in Part D, or if there is a better alternative. CMS is interested in determining the most reliable way to identify Part D claims filled with 340B units so these associated units can be excluded from the determination of units of Part D rebatable drugs beginning in 2026 in accordance with the statute.

Pharmacies submitting a 340B identifier involves high administrative burden and financial risk and should be considered a last resort. 340B Covered Entities may contract with retail pharmacies (e.g., national chains, regional chains, independents) to provide certain pharmacy services such as dispensing medications to patients who may be eligible to receive drugs covered under the 340B program. This "contract pharmacy" agreement is often administered by a Third-Party Administrator which coordinates data and financial obligations between the Covered Entity, contract pharmacy, and manufacturers.

Proactive Identification

As CMS stated in its solicitation of comments, the current NCPDP Telecommunications Standard Version D.0 for pharmacy claims does not require a pharmacy to identify which prescription claims were dispensed using drugs purchased at a discount under the 340B program. Although the standard does include a field where a 340B indicator could be provided, it is optional for pharmacies to use, based on trading partner agreements.

To proactively include a 340B identifier on a prescription claim, a pharmacy needs to know at the point of sale that the patient, their prescription and the parameters of their arrangement with the covered entity, qualify for the 340B program drug pricing. The indicator exists but there is a significant operational challenge to identifying when pharmacies should use it. Due to the multiple factors that go into determining that a drug dispensed is eligible for 340B pricing, it is not common for a pharmacy to know at the point of sale that a prescription could be dispensed with a 340B-priced drug. The model is also susceptible to pharmacy benefit managers reimbursing 340B claims at a lower rate, due to lower acquisition, thus capturing funds that are intended for the Covered Entity to provide care to un- or underinsured individuals. **For those reasons, NCPA opposes proactive identification of 340B units by pharmacies, and instead offers alternative proposals below.**

Retroactive Identification

NCPA opposes retroactive identification of 340B units by pharmacies, as it is unduly burdensome for pharmacies to be able to comprehensively make these identifications. NCPA instead offers alternative proposals below. This would be the case both for claims adjusted to 340B units, as well as claims that are adjusted from 340B identification. Pharmacies that use virtual inventory rely on third-party administrators to determine, after replenishment and potentially significant lag time, if a specific prescription was fulfilled using 340B inventory. Pharmacies using a virtual inventory are traditionally not determining 340B claim eligibility as they are wholly reliant on external entities, using completely separate, non-interfaced information systems, to determine missing data elements.

CMS recognizes that the NCPDP does allow use of an "N1" transaction to retrospectively identify drugs purchased under the 340B pricing, but CMS understands that few pharmacies use this transaction. **NCPA has found that the N1 transaction is not feasible as it is not adopted by pharmacy information systems**. Even if pharmacies did use the N1 transaction, they would still need to revisit every claim multiple times. NCPDP's guidance on N1s is extremely complex, and pharmacies would have to navigate the details of the 340B program as it relates to the relationship between the CE and the TPA.

Even if pharmacies could be able to retroactively identify claims, pharmacies would be saddled with administrative burden and financial risk to reprocess claims with a 340B indicator. Many pharmacy benefit managers (PBMs) have a specific timeframe for allowing claims to be reprocessed. Reprocessing outside this window in order to comply with this proposed rule could mean that the pharmacy would have to forfeit all third-party reimbursement for a prescription

that has already been dispensed to the patient. And, similarly to what was described above, PBMs may take advantage of knowing 340B pharmacy claims to pay the pharmacy less, leaving less to pass back to the Covered Entity. Disclosure of 340B pharmacy claims would likely result in a windfall to PBMs at the expense of Covered Entities.

For the reasons above, NCPA opposes CMS requiring pharmacies to retroactively identify 340B units, as this would result in a significant, unfunded administrative burden for pharmacies. NCPA suggests alternative proposals, below. On the other hand, pharmacies are reliant on the TPAs they use to navigate the intricacies of the 340B program, so TPAs would be a much better fit for being able to supply CMS with that information. Eligibility under the 340B program is also determined by a Covered Entity via a Third-Party Administrator (TPA) through a retrospective analysis.

PDE Record

CMS stated in its solicitation for comments that it believes that requiring that a 340B indicator be included on the PDE record is the most reliable way to identify drugs that are subject to a 340B discount that were dispensed under Medicare Part D. CMS also stated that this indicator would need to be included on all pharmacy claims where a drug subject to a 340B discount was dispensed to a Part D beneficiary so that units submitted on such claims can be excluded from the inflation rebate calculation. CMS has stated on a NCPDP WG9 Medicare FAQ call that CMS intends to expand the PDE layout of 1000 characters to accommodate new fields. Further, the new field in Version F.6 is Submission Type Code (D17-K8) with a value of "AA" for 340B. **NCPA opposes CMS requiring plans to require pharmacies to provide any of this information. As stated above, pharmacies are not the entity best suited to report this information. Instead, NCPA recommends that a TPA provide this information to CMS.**

Alternative Proposal #1: Third-Party Administrator (TPA) Provides the Data to CMS

NCPA supports an alternative solution where Third-Party Administrators provide 340B data to CMS. The most reliable entity that would have 340B data would be the Third-Party Administrator (TPA). NCPDP has also recommended that they compile such data, as they are the best situated and capable of doing so. TPAs already collect this type of data, so NCPA believes that it would not be difficult to provide this information to CMS as well. HRSA could also make the provision of this information a condition for Covered Entities to participate in the HRSA program.

Additionally, entrusting the TPAs and not the PBMs with this data would contribute less additional administrative burden in administrating the 340B program generally, and, as mentioned above, would reduce the likelihood that PBMs will use this information to give themselves more money at the expense of Covered Entities.

Alternative Proposal #2: Manufacturers Report to CMS Aggregate, Approximate 340B Units Dispensed

CMS may also be able to get manufacturers to use their own data to approximate the total 340B units dispensed in Medicare Part D**.** If manufacturers know the percentage of drugs sold at a 340B price, the amount of Part D rebates they receive, and what percentage of their drugs are Part D,

manufacturers may be able to extrapolate to get an approximate amount of 340B units dispensed in Part D. **NCPA is unsure of the viability of this option and recommends that CMS look into this proposal in more detail.**

Conclusion

NCPA thanks CMS for the opportunity to provide feedback, and we stand ready to work with CMS to offer possible solutions and ideas.

Should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

Steve Postal, JD
Director, Policy & Regulatory Affairs
National Community Pharmacists Association

Submitted March 10, 2023 electronically at: IRARebateandNegotiation@cms.hhs.gov

Dr. Meena Seshamani, M.D., Ph.D., CMS Deputy Administrator and Director of the Center for Medicare
Center for Medicare and Medicaid Services

RE: Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments

Dear Dr. Seshamani,

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit American National Standards Institute (ANSI) accredited Standards Developer (ASD) consisting of more than 1,500 members representing entities including, but not limited to, claims processors, data management and analysis vendors, federal and state government agencies, insurers, intermediaries, pharmaceutical manufacturers, pharmacies, pharmacy benefit managers, professional services organizations, software and system vendors and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop business solutions, including ANSI-accredited standards and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

For over 40 years, NCPDP has been committed to furthering the electronic exchange of information between healthcare stakeholders. The NCPDP Telecommunication Standard is the standard used for eligibility, claims processing, reporting and other functions in the pharmacy services industry as named in Health Insurance Portability and Accountability ACT (HIPAA). The NCPDP SCRIPT Standard and the Formulary and Benefit Standard are the standards in use in electronic prescribing as named in Medicare Modernization ACT (MMA).

NCPDP submits the following comments in response to *Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments*, released February 9, 2023.

Section 40.2.5 Use of PDE Data to Determine Total Units Subject to Rebate and Crosswalk To AMP Units
The statute defines "units" as the lowest dispensable amount (such as tablet or capsule, milligram of molecules, or grams) of the Part D rebatable drug, as reported under section 1927(b)(3). Part D PDE data would be used to determine the total number of units of the Part D rebatable drug dispensed under Part D during each 12-month applicable period for the inflation rebate calculation.

From the PDE data, CMS intends to obtain the total number of units of the Part D drug from the field "Quantity Dispensed" for each dosage form and strength, and the NDC of the drug from the field "Product Service ID" for each 12-month applicable period. Units reported in the Quantity Dispensed field on the PDE record are industry standard National Council for Prescription Drug Programs (NCPDP) defined values of each, milliliter, and grams. The unit for each NDC is not reported on the PDE record, but this information is available on FDA's Comprehensive NDC SPL Data Elements File (NSDE) in the "Billing Unit" field. In order to identify the NCPDP billing unit for each NDC, CMS intends to crosswalk the information from the PDE record to the NSDE file matching on the NDC.

In contrast to how units are reported under Medicare Part D, manufacturers can report the AMP for their drugs in the MDP with 10 different unit types (e.g., each, capsule, tablet, suppository, transdermal patch, injectable anti-hemophilic factor, millicurie, microcurie, gram, and milliliter). Given the difference between how units are reported between the two programs, in order to calculate Part D drug inflation rebates, CMS intends to compare the Part D rebatable drug units reported in the PDE record to the units reported in MDP for the monthly AMP. Based on initial analyses, CMS expects that the majority of units of the dosage forms and strength of each Part D rebatable drug reported in the PDE record will match the AMP units reported.

However, in the limited instances where the units do not match, CMS intends to convert the total units reported from the PDE to the AMP units that are reported by the manufacturer for the drug under section 1927. For example, if an NDC is reported as a unit of "each" in the PDE record, and as a unit of "grams" to Medicaid, CMS intends to multiply the unit of "each" times the total "grams" for each unit to convert the PDE units to AMP units. For example, if the product is dispensed in a 10-gram tube and the PDE record has this recorded as a unit of "1" for "each," this will be converted to "10" for the purposes of Part D drug inflation rebates to conform to the Medicaid units of "grams" for this product.

CMS is exploring the option of adding a field to the PDE file layout to collect how the amount reported in the PDE "quantity dispensed" field is measured (e.g., each, milliliter, gram). This additional data element would facilitate the identification of unit types for each NDC and add an additional level of assurance for CMS and manufacturers that the unit used to calculate inflationary rebates is accurate. CMS recognizes that requiring the plans to report a unit type for each Part D rebatable drug on the PDE record would create a new reporting burden, create possible opportunities for error, and would still require a conversion to the AMP units. CMS is soliciting comment on this option. As discussed in more detail below, beginning in calendar year 2026, the Part D rebatable drug units identified as having been filled with a 340B acquired drug would be removed from the total units of Part D rebatable drugs that will be subject to a rebate as provided under section 1860D-14B(b)(1)(B).

NCPDP Comment: NCPDP recommends CMS not make Unit of Measure (UOM) a required field on the PDE. If CMS makes UOM a required field for PDE reporting, it would require the pharmacy to submit the UOM on the claim billing at point of sale (POS). This could cause unnecessary hardship to beneficiaries if the claim is rejected due to a missing UOM, making the beneficiary unable to obtain their medication. The processors would need to retain the claim UOM and report it on the PDE, adding a large burden on processors and pharmacies. Additionally, pharmacies have various software systems that use data from different sources. In order for all of the pharmacies to submit the UOM identically, they would need to use the same data source.

The NCPDP Billing Unit Standard is in place so every pharmacy bills, processor adjudicates and compendia reports the prices of the product in the same way. When occasional discrepancies are found in the compendia there are existing processes to resolve these. Most processors/payers do a lookup on the submitted NDC to validate units and pricing. There is no need to add an additional field on the PDE for the UOM provided at POS if CMS will be completing their own similar check behind the scenes.

If the UOM is required to be included on the PDE, the UOM will be inaccurately reported on the PDE if it was inaccurate at POS.

NCPDP additionally recommends the Food and Drug Administration (FDA) and CMS request the NCPDP billing unit and billing quantity data from each manufacturer to create the complete crosswalk file suggested.

Section 40.2.7 Exclusion of 340B Acquired Units from Part D Rebatable Drug Requirements
Section 1860D-14B(b)(1)(B) requires that beginning with plan year 2026, CMS shall exclude from the total number of units for a dosage form and strength for a Part D rebatable drug, with respect to an applicable period, those units for which a manufacturer provides a discount under the 340B Drug Pricing Program. Because this requirement starts after the first quarter of the applicable period that begins in October 2025, CMS intends to exclude the 340B units starting in January 2026.

The current NCPDP Telecommunications Standard Version D.0 for pharmacy claims does not require a pharmacy to identify which drugs that were dispensed were purchased at a discount under the 340B program. Although the standard does include a field where a 340B indicator could be provided, it is optional for pharmacies to use, based on trading partner agreements. In addition, the standard specifies that the indicator can only be used prospectively, so a pharmacy that makes the retrospective determination that the drug was purchased at 340B pricing cannot apply the modifier retrospectively to the claim. The NCPDP does allow use of an "N1" transaction to retrospectively identify drugs purchased under the 340B pricing, but CMS understands that few pharmacies use this transaction. Consequently, CMS does not currently require or even accept a 340B indicator on the PDE record.

CMS believes that requiring that a 340B indicator be included on the PDE record is the most reliable way to identify drugs that are subject to a 340B discount that were dispensed under Medicare Part D. This indicator would need to be included on all pharmacy claims where a drug subject to a 340B discount was dispensed to a Part D beneficiary so that units submitted on such claims can be excluded from the inflation rebate calculation.

CMS is soliciting comment on whether submission of the 340B identifier on the pharmacy claim is the preferred mechanism to identify 340B units dispensed in Part D, or if there is a better alternative. In other words, CMS is interested in ascertaining the most reliable way to identify Part D claims filled with 340B units so these associated units can be excluded from the determination of units of Part D rebatable drugs beginning in 2026 in accordance with the statute.

NCPDP Comment: NCPDP reviewed this section of the memo and was unable to reach a consensus on a viable 340B option. NCPDP agrees 340B must be identified retrospectively and concurs with CMS' statement that the N1 is not widely implemented within the industry.

NCPDP thanks CMS for the opportunity to provide comments and for the consideration of our comments. NCPDP looks forward to continuing its work with CMS.

For direct inquiries or questions related to this letter, please contact:
Alaina Clark
NCPDP Standards Specialist

standards@ncpdp.org

Respectfully,

Lee Ann C. Stember
President & CEO
National Council for Prescription Drug Programs (NCPDP)

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March 9, 2023

Meena Seshamani, MD, PhD
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Concerns about modifier approach for identifying 340B drugs dispensed under Medicare Part D

Dear Dr. Sheshamani,

On behalf of the North Country HealthCare, Inc., thank you for the opportunity to provide input into CMS' plans for implementing the Medicare inflationary rebates established under the Inflation Reduction Act. North Country HealthCare ("NCHC") is a Federally Qualified Health Center ("FQHC") that received federal grant funds under Section 330 of the Public Health Service Act. NCHC has its historical roots in a free clinic model that transitioned to FQHC status upon community health center funding in 1996. The primary clinic site and administrative hub are located in Flagstaff, a population center with Medically Underserved Population (MUP) designation. NCHC operates 16 satellite clinics targeting the uninsured in Seligman, Winslow, Holbrook, Round Valley, Show Low, Williams, Grand Canyon, Dolan Springs/Kingman, Bullhead City, Lake Havasu City and Payson communities. All, excluding Lake Havasu City, are Medically Underserved Areas (MUA's) and Health Professional Shortage Areas (HPSA's). Other access points are specialty clinics providing primary care services at behavioral health centers and homeless shelters. Including NCHC's primary site in Flagstaff, NCHC now operated sixteen access points in twelve communities located in six rural or rural like counties across northern Arizona. The Center's scope of services includes: diagnosis, treatment and referral for all illness, management of chronic diseases, prenatal care/delivery, perinatal outreach, well woman checks, well child services/immunizations, pharmacy, laboratory and radiology services, preventive care/health education, oral health services and integrated behavioral health. Additional health services include significant health promotion/disease prevention and enabling programs.

As you know, FQHCs are the backbone of the health care safety net, providing high-quality, affordable care to over 30 million medically-underserved patients, regardless of whether they have insurance or their ability to pay. In Arizona during 2021, community health centers served 289,844 patients with incomes 100% the federal poverty level and 389,336 patients who were 200 percent below the federal poverty level. Finally, in 2021 community health centers served 130,636 patients who were uninsured.

FQHCs offer a broad range of services, including primary care, dental, behavioral health, and pharmaceuticals. Many of these services – and the sliding fee discounts that make them affordable for our patients -- are supported by savings generated through the 340B drug discount program. The first and most critical benefit provides access to affordable medications for low-income uninsured and underinsured patients. Without this program, our patients would not have access to life-saving medications in an atmosphere of dignity and respect regardless of their ability to pay. The 340B program allows NCHC to reach patients across our service area, regardless of having an in-house pharmacy within

that area. The 340B program allows NCHC to provide care to the homeless population with no-cost medications.

Proceeds from the 340B program also support our clinical pharmacy program. These are pharmacists that do not work in the pharmacy dispensing medications. They work in the clinics as members of interdisciplinary care teams to optimize medication regimens, promote adherence, generate medication alternatives and provide both group and individual patient education. The clinical pharmacists are critical on teams that provide chronic disease management, anticoagulation services and pain management. These pharmacists practice with collaborative practice agreements to expand patient access to care, improve patient outcomes, decrease workload on the medical providers and improve provider satisfaction. These efforts are not reimbursable by CMS or commercial insurance and without the 340B program, these roles would not be possible.

The revenue generated from the 340B contract pharmacy environment is used to support our clinics in the most rural locations. Without the subsidy of the contract pharmacy revenue source, the clinics in the most rural locations would not be sustainable. These clinics have lower patient volumes that would not support the extended hours of the clinics or the consistent appointment availability that North Country is able to provide by designating 340B savings to these locations. Without these monies, NCHC may be forced to close as many as six of our locations and lay off approximately 100 staff and providers. As a result, we welcome the opportunity to share our experiences, concerns, and ideas about this critical program.

Nationally, FQHCs rely on contract pharmacy arrangements to dispense roughly 50-60% of the 340B drugs provided to their patients – the highest percentage of any type of 340B provider. Thus, the 340B savings generated at contract pharmacies support many services that the FQHC would otherwise be unable to provide. Given the importance of 340B savings – including those generated by contract pharmacies – we were very concerned to hear that CMS is considering requiring an indicator (also known as modifier) on all claims for Part D prescriptions that were filled with 340B drugs.

As discussed in detail in comments submitted by other members of the FQHC community, FQHCs' experience clearly indicates that requiring a 340B indicator (also known as a modifier) on Part D drugs would:

a. Result in data that is highly unreliable.
b. Force FQHCs to shut down many of their contract pharmacy arrangements for Part D drugs, leading to an overall loss in 340B savings and subsequent reduction in services provided to underserved patients.

Instead of a modifier, we recommend that CMS implement a "clearinghouse" model for identifying 340B drugs covered by Part D. Compared to a modifier requirement, a clearinghouse would:

a. Produce much more reliable data.
b. Be significantly less labor-intensive.
c. Preserve the ability of FQHCs and other 340B providers to rely on contract pharmacies to dispense 340B drugs to Part D enrollees, thereby avoiding reductions in access.
d. Could be expanded to include 340B drugs dispensed to Medicaid patients.

Thank you for your consideration of our serious concerns about the modifier model, and our proposed alternative. If you have any questions about our comments, please contact:

- Kimberly Chen, Pharmacy Director at kchen@nchcaz.org or 928-522-9572
- Anne Newland, CEO at anewland@nchcaz.org or 928-522-9564

Sincerely,

Anne Newland, MD, MPH
Chief Executive Officer

March 6, 2023

Dr. Meena Seshamani, MD, PhD
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE:Concerns about modifier approach for identifying 340B drugs dispensed under Medicare Part D

Dear Dr. Sheshamani,

On behalf of the Ohio Association of Community Health Centers (OACHC) thank you for the opportunity to provide input into CMS' plans for implementing the Medicare inflationary rebates established under the Inflation Reduction Act.

OACHC supports Ohio's 57 Federally Qualified Health Centers and FQHC Look-Alikes (more commonly referred to as Community Health Centers or CHCs), providing care to nearly a million Ohioans across 485+ sites throughout 75 of the 88 counties. For 55+ years, CHCs have provided integrated whole person care, often providing medical, dental, behavioral health, pharmacy, vision, and other needed supplemental services under one roof.

Across the state, Community Health Centers use 340B to provide reduced prices on drugs making vital medications affordable and accessible for qualifying patients who otherwise would not be able afford it. In addition, Community Health Centers use remaining 340B savings to increase access by expanding hours of operation, locations, and providing services beyond medical care that it would not otherwise be able to. Ohio's Community Health Centers report the following services offered today, in part or completely supported by savings from the 340B Program:

- Dental including mobile dentistry
- Optometry
- MAT/Substance abuse disorder treatment services
- Behavioral Health/Psychiatry
- Language assistance/interpreter services
- Physical therapy
- Clinical pharmacy
- Chiropractic services
- Patient assistance including but not limited to food, clothing, shelter, insurance navigation
- Home visits
- School Based Health Care
- Vaccines
- Nutritional/Dietitian services
- OB/GYN services
- Diabetes education
- Transportation services to appointments

- Home delivery of medications
- Medication counseling
- PrEP counseling and access
- HIV and Hepatitis treatment and prevention services
- Chronic Care Management
- COVID-19 Testing and Care

The ability to reinvest 340B savings to support or expand primary care services ultimately increases patients' access to the care they need, when they need it and in the appropriate, most cost-effective setting, thus reducing costs elsewhere in the healthcare system.

Nationally, FQHCs rely on contract pharmacy arrangements to dispense roughly 50-60% of the 340B drugs provided to their patients – the highest percentage of any type of 340B provider. Thus, the 340B savings generated at contract pharmacies support many services that the FQHC would otherwise be unable to provide. Given the importance of 340B savings – including those generated by contract pharmacies – we were very concerned to hear that CMS is considering requiring an indicator (also known as modifier) on all claims for Part D prescriptions that were filled with 340B drugs.

As discussed in detail in comments submitted by other members of the FQHC community, FQHCs' experience clearly indicates that requiring a 340B indicator (also known as a modifier) on Part D drugs would:

- Result in data that is highly unreliable.
- Force FQHCs to shut down many of their contract pharmacy arrangements for Part D drugs, leading to an overall loss in 340B savings and subsequent reduction in services provided to underserved patients.

Instead of a modifier, we recommend that CMS implement a "clearinghouse" model for identifying 340B drugs covered by Part D. Compared to a modifier requirement, a clearinghouse would:

- Produce much more reliable data.
- Be significantly less labor-intensive.
- Preserve the ability of FQHCs and other 340B providers to rely on contract pharmacies to dispense 340B drugs to Part D enrollees, thereby avoiding reductions in access.
- Could be expanded to include 340B drugs dispensed to Medicaid patients.

Thank you for your consideration of our serious concerns about the modifier model, and our proposed alternative. We greatly appreciate the opportunity to provide comment on this proposed rule. Should you have any questions about our comments, please feel free to contact Julie DiRossi-King at jdirossi@ohiochc.org or (614) 884-3101.

Sincerely,

Randy Runyon
President & CEO

PATIENTS FOR AFFORDABLE DRUGS NOW™

Comments of

Patients For Affordable Drugs Now to

The Centers For Medicare & Medicaid Services on the

Implementation of the Medicare Prescription Drug Inflation Rebate Program under

The Inflation Reduction Act of 2022 9P.L. 1117-169

March 9, 2023

Patients For Affordable Drugs Now (P4ADNow) is pleased to offer these comments in support of effective, patient-centered implementation of the Medicare Prescription Drug Inflation Rebate Program guidance provided by the Centers for Medicare & Medicaid Services (CMS) as enacted in the Inflation Reduction Act of 2022.

P4ADNow is the only national patient advocacy organization exclusively focused on lowering prescription drug prices. P4ADNow is independent, nonpartisan, and does not accept funding from any organizations that profit from the development or distribution of prescription drugs.

P4ADNow applauds the timely and comprehensive work by CMS on implementation of the Medicare Prescription Drug Inflation Rebate program. According to the Congressional Budget Office (CBO), the benefits of this program will be far-reaching and will accrue to millions of patients, people on Medicare, and even to employers and employees in the commercial health care sector.

There are four areas that we will comment on specifically.

The Medicare Prescription Drug Inflation Rebate Program (MPDIRP) is monumental for patients on Medicare who will, for the first time, know the prices they pay will be limited to the rate of inflation. It reins in historically unrestrained price increases taken annually by drug companies at rates that far outpace inflation. Given that cost sharing in Medicare Parts B and D is typically based on list prices, this will directly reduce patients' out-of-pocket costs. According to the CBO, the MPDIRP literally bends the curve on pricing — in 2031, average net prices in Medicare will be two percent lower than they would have been without the new law. P4ADNow strongly supports CMS' swift implementation of this provision.

Medicare beneficiaries are protected from higher out-of-pocket costs even if the manufacturer chooses to raise the list price of a drug and to pay the penalty dictated by this provision. CMS' plan to base cost sharing on the inflation adjusted "list" price, notwithstanding behavior of the drugmaker, will provide meaningful savings to people on Medicare. It will insulate millions of older people and disabled people from annual price increases and provide predictability in their drug costs. CBO expects this provision will lead Medicare enrollees to increase their adherence to prescribed drugs, thereby improving health. The health benefits to people on Medicare are expected to lead to billions of dollars in savings in Medicare Parts A and B by preventing visits to doctors' offices and hospitalizations. In addition, starting on April 1, Part B beneficiaries will pay cost sharing based on inflation-adjusted prices instead of list prices, delivering an immediate benefit for many patients. Altogether, CBO says the MPDIRP program will save Part D enrollees about $5 billion dollars through 2031. Reduced prices, improved health, and prevention of hospitalizations will greatly enrich the health and well being of our patient community.

The method of measurement of list price increases for the MPDIRP is expected to attenuate list prices in the commercial sector, which will reduce prices and premiums for employers and employees. This is an enormous and — until now — largely unrecognized benefit of the inflation rebate provisions. According to CBO, "*Commercial drug prices, and therefore health insurance premiums, will be lower than they would have been absent the policy."* Lower premiums are expected to shift a portion of employees' compensation from health insurance to wages, putting more money in people's paychecks. Given that nearly 50 percent of people in the United States get health coverage through their employer, this effect will provide significant savings for employers and more money for consumers. We strongly support the proposed method of calculation of list price increases as iterated in the law and urge CMS to protect this method throughout implementation so that the provisions can positively impact prices outside Medicare.

The Medicare Prescription Drug Inflation Rebate Program (MPDIRP) — together with other provisions in the Inflation Reduction Act (IRA) — can decrease health disparities. Black and Latino adults, women, people with lower incomes, and people with chronic conditions are more likely to experience difficulty affording prescription drugs. Additionally, Black Americans are more likely to suffer from chronic pain, diabetes, high blood pressure, and other diseases that require expensive medications due to long-standing and pervasive systemic barriers. These realities underscore the importance of prompt, consumer-focused implementation of the Inflation Reduction Act in order to bring relief to communities disproportionately affected by high drug prices.

P4ADNow urges CMS to move forward with the MPDIRP program as proposed by its guidance and to ensure timely implementation that will benefit people in the U.S. who use prescription drugs.

March 10, 2023

Submitted electronically via email at IRARebateandNegotiation@cms.hhs.gov

Dr. Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director, Center for Medicare
U.S. Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments

Dear Dr. Seshamani:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments in response to the Centers for Medicare & Medicaid Services' (CMS) proposed Part B and Part D Inflation Rebate Guidance documents (Guidance) captioned above.

PCMA is the national association representing America's PBMs, which administer prescription drug plans and operate specialty pharmacies for more than 275 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and through the exchanges established by the Affordable Care Act. Our members work closely with plans and issuers to secure lower costs for prescription drugs and achieve better health outcomes.

Our comments begin from the premise that Congress imposed the obligation of paying Part B and D inflation rebates on manufacturers of Part B and D drugs; and therefore, CMS should implement the Part B and D inflation rebates in a way that ensures manufacturers are chiefly responsible for ensuring the integrity of the data that informs the Part B and D inflation rebates that they must pay. We offer specific commentary in the following areas:

- **Impact of Part D Inflation Rebates on Part D Plan Negotiations and Plan Premiums.** While PCMA understands that Congress elected to apply an inflation rebate scheme to the Part D program, we note that the specter of inflation rebates will adversely impact Part D plans' ability to negotiate rebates with manufacturers. Regardless of whether a manufacturer's pricing policies trigger the inflation rebates, the risk of inflation rebates will be factored by manufacturers in their pricing practices, including their negotiations with Part D plans. PCMA expects that manufacturers will launch with higher launch prices to reduce the need to adopt price increases in future years, and we expect that manufacturers will be less inclined to negotiate significant rebates with Part D plans as manufacturers will be limited in their ability to offset these price concessions with price increases. In short, Part D inflation rebates will be perceived as "price concessions" by manufacturers that they are unlikely to compound

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substantially further with additional price concessions to Part D plans. This may result in higher Part D plan premiums and beneficiary cost sharing.

- **Using Part D Manufacturer Discount Program Agreement To Ensure Data Reporting.** PCMA recognizes that not all manufacturers of Part D rebatable drugs may be required to report necessary pricing and utilization data to CMS because they may not have a signed Medicaid Drug Rebate Program (MDRP) agreement. To address these situations, CMS should consider incorporating the same reporting obligations into the Part D Manufacturer Discount Program Agreement (DPA). Since manufacturers of Part D drugs must sign the DPA anyways to access Part D coverage, it naturally follows that they should also report the necessary data to ensure CMS's ability to calculate applicable Part D rebates. Not only could this solve the reporting issue for non-signatories of the MDRP agreement, it could also facilitate Part D rebate calculations for Part D rebatable drugs that do not satisfy the definition of covered outpatient drugs (CODs) under the MDRP.
- **Using Medicaid Drug Program (MDP) Reporting to Identify Part D Drug Billing Units.** PCMA opposes requiring that the identification of Part D rebatable drug billing units be included in the Prescription Drug Event (PDE) file. Instead, CMS should require that any necessary drug billing units, including any applicable conversion factors for converting non-standardized National Drug Codes (NDCs) (e.g., kits) into billable units, be provided by the manufacturer via their MDP reports. Requiring that the PDE file layout be amended to accommodate this data inappropriately shifts the burden of implementing an obligation on manufacturers to Part D plans and fails to recognize the technical challenges associated with making changes to the PDE. PCMA believes that using the MDP reports is the optimal way for CMS to collect the necessary information for calculating Part D inflation rebates, and it places the primary responsibility of ensuring accurate data on manufacturers who are ultimately liable for Part D inflation rebates.
- **340B Covered Entities and Manufacturers.** Consistent with our view that changes to the PDE is technically challenging and that manufacturers should be primarily responsible for implementation of the Part D inflation rebates, PCMA recommends that CMS look to 340B covered entities and manufacturers to identify and exclude 340B units from the Part D inflation rebate calculation, rather than shift the burden to Part D plans and pharmacies.
- **Coordinating PDE File Layout Changes and Avoiding Duplication.** Should CMS proceed with any changes to the PDE file layout to accommodate Part D billing unit types and/or 340B units, CMS should align any such changes with the currently planned PDE changes for January 1, 2025 as outlined in CMS's November 1, 2022 memo. PDE changes are technically challenging, and it is not reasonable to expect stakeholders to pursue parallel tracks for certification of new PDE changes when all such changes could be consolidated into one system-wide change.
- **Audits and Liability In Case of Erroneous Information.** CMS should clarify that in cases where audits associated with the calculation of Part D inflation rebates reveal that Part D inflation rebates were incorrectly calculated due to erroneous information Part D plans will not be liable for any payments associated with Part D rebatable drugs, irrespective of whether manufacturer-reported data or the PDE is the vehicle for transmission of the erroneous data. While CMS may require Part D plans to cooperate in any audits, Part D inflation rebates represent a separate legal obligation imposed on manufacturers that do not implicate Part D plan sponsor obligations to CMS or any other

stakeholder, nor do they affect whether the claim in question was appropriately dispensed and paid under the Part D program.

- **Commissioning an Office of Inspector (OIG) Report on Part D Inflation Rebates.** CMS should commission the OIG of the Department of Health and Human Services (HHS) to issue a report that considers the various implementation options submitted to CMS by stakeholders, in addition to any others, and makes recommendations or flags any other considerations that could support CMS's implementation of the Part D inflation rebates, similar to what the OIG did with respect to the Part B inflation rebates.
- **Transparent Comment Submission.** CMS should provide public access to the comments that are submitted by interested stakeholders in response to the Guidance. While CMS is not obligated to publish comments as part of this solicitation process, an open and transparent process is generally more conducive to a robust and informed decision-making process. PCMA believes that transparency in this complicated area will promote smoother implementation.

We discuss our comments and recommendations in further detail below. PCMA welcomes the opportunity to provide further feedback to CMS on other issues that come to our attention as we continue to assess the impact of the Part B and D inflation rebates on the administration of the Part D program.

I. Part D Inflation Rebates Will Adversely Impact Part D Plan Negotiations and May Negatively Affect Beneficiaries.

While PCMA understands that Congress elected to apply an inflation rebate scheme to the Part D program, we note that the specter of inflation rebates will adversely impact Part D plans' ability to negotiate rebates with manufacturers. PCMA champions the private-market model on which the Part D program is based, and we highlight this dynamic only to ensure that CMS is informed in its policymaking across the Part D program.

As we have discussed in detail in our comments in response to the CY 2024 Part C and D Proposed Rule, and in particular regarding CMS's proposed definition of "gross covered prescription drug costs," the experience of our PBM and Part D plan stakeholders indicates that manufacturers are able to nimbly respond to mandatory price controls and mitigate any potential losses by passing on the costs to other stakeholders, such as Part D plans, through reduced price concessions. Manufacturer avoidance and gaming tactics are already being discussed by other experts in the field.[1] We anticipate that Part D inflation rebates will have a similar effect.

While, unlike Medicare negotiation, Part D inflation rebates are not price concessions that will apply in every circumstance, Part D inflation rebate liability still represents a potential "cost of doing business" for manufacturers that they will take into account when negotiating rebates with Medicare Part D plans. Since significant price increases could be penalized through inflation rebates, manufacturers are more likely to launch CODs with higher list prices to front-end revenue that they would have otherwise generated through incremental price increases over time.

[1] "Strengthening The Inflation Reduction Act By Predicting Drugmakers' Avoidance And Gaming", *Health Affairs Forefront*, March 2, 2023. DOI: 10.1377/forefront.20230228.520743.

Relatedly, manufacturers may be less incentivized to agree to the same level of rebates with Part D plans that they would otherwise agree to in the absence of Part D inflation rebates. Manufacturers typically frame price concessions as a percentage of their list prices. In a scenario where manufacturers are able to increase their prices over time without restriction, manufacturers are able to offset the cost of rebates over time. If, however, manufacturers are penalized for price increases over the rate of inflation, price concessions made to Part D plans will be more difficult to recoup by manufacturers, thereby incentivizing manufacturers to provide them more sparingly. In a market where manufacturers are frequently the sole source of the drugs in question, manufacturer perceptions of inflation rebate liability can significantly affect their willingness to negotiate on pricing at all. The issue is further compounded in cases where Part D plans must comply with coverage mandates, such as the six protected classes and two-drugs per-category/class rule.

We raise these concerns because reduced price concessions plus higher launch prices for Part D covered drugs will have two effects: premiums will increase, as plans cover a higher share of the drug's list price, and beneficiary cost sharing will increase since new brand drugs with resultant higher launch prices represent a significant share of Part D plan spending. We note that this stands in stark contrast to the Part B inflation rebates which involve a prospective adjustment to beneficiary coinsurance to account for prior-quarter inflation. While such a mechanism would be unworkable in the Part D context, CMS should simply acknowledge that Congress's intent will have unintended negative consequences for beneficiaries.[2]

***PCMA recommendation*: CMS should publicly acknowledge unintended consequences associated with Part D inflation rebates.**

II. CMS could ensure the availability of required price and drug product data to calculate Part D inflation rebates by incorporating such requirements into the Part D Manufacturer Discount Program.

Background: As outlined at § 30.1 of the Guidance, at least during the initial phases of implementation, CMS intends to rely on the price and drug product reporting obligations that manufacturers must comply with under the MDRP, including average manufacturer price (AMP) data for each dosage form and strength of a drug, and the total number of units of the dosage form and strength that are reported each month and used to calculate monthly AMP. However, CMS acknowledges that not every drug that may satisfy the definition of a "Part D rebatable drug" is marketed by a manufacturer that has an MDRP agreement in effect with the Secretary. Similarly, CMS notes that not all drugs meet the definition of CODs, and therefore manufacturers with MDRP agreements may not be required to submit price and drug product information for non-CODs. Accordingly, CMS solicits comments on how to address both of these situations.

Comment: PCMA agrees with CMS that relying solely on section 1927 of the Social Security Act, as implemented by the MDRP agreement, does not adequately meet the needs of the Part D inflation rebates for the reasons identified by CMS: not all manufacturers have signed MDRP agreements, and even for those that have, the definition of a COD in the Medicaid statute and subsequent regulations does not fully align with the definition of a Part D drug.

[2] We note that prospectively applying an adjusted coinsurance amount may require plans to use coinsurance and recalibrate coinsurance at the drug level, not formulary level.

PCMA recommends that instead of relying on the MDRP agreement to ensure the agency has the necessary data, CMS should consider using the existing Part D Coverage Gap Discount Agreement, and any successor Manufacturer Discount Program agreement (together referred to as the "Discount Program Agreement"), as the legal instrument to require manufacturers to provide all necessary pricing and drug product information to CMS for Part D rebatable drugs. Even in the absence of the Part D inflation rebates, manufacturers are required to sign the Discount Program Agreement (DPA) to ensure that their drugs can qualify for coverage under the Part D program. Given that the DPA already serves as the threshold agreement for manufacturer participation in the Part D program, it naturally follows that it could also be used to implement the Part D inflation rebates, which is a requirement with which all manufacturers must be prepared to comply.

Although manufacturers may protest that the statute must contemplate separate contracting authority for CMS to require manufacturers to sign an agreement, arguably such an argument invokes a meaningless distinction. Section 1860D-14B of the Social Security Act imposes on manufacturers an obligation to pay rebates for Part D rebatable drugs with price increases faster than the rate of inflation, irrespective of whether manufacturers sign an agreement to do so. Stated differently, section 1860D-14B is self-executing, and using the DPA to ensure the agency has access to the data necessary to operationalize the Part D inflation rebates is nothing more than an implementation mechanism.

PCMA also requests that CMS consider issuing guidance on the treatment of drugs that straddle the Part B and D benefits. In many cases Medicare Advantage (MA) plans that offer Part D (PD) coverage may cover a drug under one or both Parts B and D depending on how it is prescribed and dispensed. Relatedly, a Part D plan may cover a drug that is later determined to have been erroneously covered under Part D and should have been covered under Part B. In such situations, what, if any, obligation does the MA-PD or Part D plan have with respect to Part D inflation rebates?

***PCMA recommendation*: CMS should use the Discount Program Agreement as the legal instrument to ensure that it has the necessary pricing and drug product information to calculate Part D inflation rebates. CMS should also clarify a Part D plan's obligations, if any, in cases where a Part D rebatable drug is later determined to not be a Part D rebatable drug.**

III. CMS can require manufacturers to incorporate into their Discount Program submissions any necessary Part D drug billing unit information rather than implement burdensome PDE file layouts.

Background: The statute stipulates that "units" for purposes of the Part D inflation rebates means the "lowest dispensable amount (such as capsule or tablet, milligram of molecules, or grams) of the part D rebatable drug, as reported under section 1927."[3] However, in § 40.2.5 of the Guidance, CMS notes that how units are reported under Part D may differ when compared to how they are reported under the MDRP. Accordingly, CMS solicits comments on options to

[3] Social Security Act, § 1860D-14B(g)(2).

identify the Part D drug billing units on the prescription claim and PDE file to assure that manufacturers are being accurately billed for Part D drug inflation rebates.

Comment: PCMA opposes requiring that the identification of Part D rebatable drug billing units be included in the PDE file. Instead, CMS should require that any necessary drug billing units, including any applicable conversion factors for converting non-standardized NDCs (e.g., kits) into billable units, be provided by the manufacturer via their DPA reports. CMS already plans to rely on a reconciliation procedure using existing DPA reports at least up to CY 2026.

As CMS notes, the PDE uses industry standard units in the "Quantity Dispensed" field as defined by the National Council for Prescription Drug Programs (NCPDP). Presumably, any additions to the PDE would also need to be standardized via the policies and procedures of the NCPDP. Indeed, we would strongly oppose any addition to the PDE that is not standardized as the lack of standards regarding the use and interpretation of any values in the PDE is likely to contribute to entry and interpretation errors and lead to disputes. In the context of audits, these types of errors are administratively costly to *monitor*, investigate and rectify, and *lack of an industry-wide standard accompanied by official regulatory support* can potentially expose stakeholders to significant liability.

Using the MDP as the primary mechanism to appropriately identify drug product information and units is also optimal because it places the primary responsibility of ensuring data integrity for the Part D inflation rebates on the entity responsible for paying them: manufacturers. PCMA believes that manufacturers have visibility into the units that dispensing pharmacies and other drug supply chain stakeholders use in furnishing Part D drugs to a Part D enrollee; and therefore, manufacturers are best position, and incentivized, to provide any necessary data to CMS via the MDP infrastructure that already exists. Additionally, manufacturers could include any "conversion factors" that facilitate the conversion of Part D units into AMP units by CMS, like the North Dakota Medicaid Unit Conversion File.[4]

***PCMA recommendation*: CMS should not finalize any changes to the PDE file layout to accommodate a broader range of Part D drug billing units for purposes of implementing the Part D inflation rebates. CMS can require that the same information be submitted by manufacturers as part of their MDP submissions.**

IV. CMS can exclude 340B units from the Part D inflation rebates by requiring manufacturers to identify 340B utilization via an extrapolation methodology that is written and auditable.

Background: Section 1860D-14(b)(1)(B) requires that 340B units be excluded from calculation of the Part D inflation rebates beginning January 1, 2026. CMS notes at § 40.2.7 of the Guidance that while pharmacies may prospectively include a 340B indicator on the claim to identify when a drug is dispensed at a discount under the 340B program, the NCPDP Telecommunications Standard Version D.0 does not require the use of this indicator. To the extent 340B claims are identified retrospectively, pharmacies may use the "N1" indicator. CMS notes that neither indicator is widely used, and as such, CMS does not currently require or even

[4] "Medicaid Drug Rebate Program Dispute Resolution, (last updated March 02, 2023), https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/medicaid-drug-rebate-program-dispute-resolution/index.html.

accept a 340B indicator on the PDE record. CMS is soliciting comment on whether submission of the 340B identifier on the PDE record is the preferred mechanism to identify 340B units dispensed to Part D, or if there is a better alternative.

Comment: PCMA opposes requiring a 340B indicator in pharmacy claims and the PDE record for many of the same reasons why we oppose modifications to the PDE file layout to accommodate a broader range of unit types: imposing administrative requirements on entities that have no vested interest in the integrity of the data contributes to a greater likelihood of data entry and interpretation errors and disputes. The same quantity unit discrepancies and associated challenges as described above would also apply here. Moreover, it is unclear how requiring pharmacies and Part D plans to report 340B utilization may impact the prevailing 340B drug distribution model that is relied upon by many covered entities. CMS's proffered approach also shifts the burden of implementation on stakeholders that are not ultimately impacted by the Part D inflation rebates. As the case with Part D and AMP unit types, manufacturers have the most interest in ensuring that Part D inflation rebates are appropriately calculated by excluding 340B utilization.

***PCMA recommendation*: CMS should not require 340B indicators on pharmacy claims or the PDE record. CMS should look to manufacturers and 340B covered entities to appropriately identify and exclude 340B claims from the Part D inflation rebate program.**

V. If CMS proceeds with PDE file layout changes, CMS should incorporate such changes into the existing processes as announced in the November 1, 2022 HPMS memo.

As discussed above, PCMA is opposed to any changes to the PDE file layout to implement the Part D inflation rebates for many different reasons. However, to the extent CMS proceeds with such changes, PCMA requests that CMS align any PDE file layout changes with the timeline that the agency outlined in the HPMS memo entitled "New 2025 Prescription Drug Event (PDE) File Layouts (draft); Seeking Feedback" that was published on November 1, 2022. According to that HPMS memo, CMS is considering various changes to the PDE file size and layouts for implementation by January 1, 2025. CMS outlines in that HPMS memo that the file layout will be finalized by April, 2023, and that Part D sponsors will be required to submit certification (CERT) test files beginning on July 1, 2024.

Submitting for CERT is a very resource-intensive process that takes significant lead-time to successfully secure. PCMA believes that pursuing changes to the PDE on a separate track for purposes of the Part D inflation rebates would be administratively burdensome and unnecessarily duplicative. It is unreasonable to expect stakeholders to submit and secure CERT for one purpose and then have to go through the process again for a different set of requirements.

***PCMA recommendation*: If CMS proceeds with misguided changes to the PDE file layout, CMS should at the very least align such changes with other PDE file layout changes that Part D plans are currently undergoing per CMS's November 1, 2022 HPMS memo.**

VI. CMS should clarify that Part D plans do not bear any liability in cases where erroneous information is used to calculate Part D inflation rebate calculation.

While PCMA anticipates that Part D plans and their downstream contractors may need to cooperate in audits to verify data used to calculate the Part D inflation rebates, we request that CMS clarify that under no circumstances can Part D plans be held liable for any payments associated with Part D rebatable drugs. Section 1860D-14B of the Social Security Act is plainly an obligation imposed on manufacturers of Part D rebatable drugs and the statute does not suggest that Part D plans may bear any liability for payments associated with errors in the calculation of such inflation rebates. Accordingly, CMS should clarify that it is not the responsibility of the Part D plan to assess the accuracy of any Part D drug billing unit or 340B indicators supplied by pharmacies. Especially with respect to the variation and inconsistency in tracking 340B information by pharmacies, PCMA does not believe that Part D plans should be held responsible for potential external errors or omissions.

Unlike with other obligations imposed on manufacturers under the Part D program, such as the existing Coverage Gap Discount Agreement, the Part D inflation rebates do not affect whether the drug in question can appropriately be reimbursed as a "covered Part D drug" under section 1860D-2(e) of the Social Security Act. As such, we do not see any circumstance where an error in calculating the Part D inflation rebate can necessitate recoupment or any other payment adjustment on claims paid by Part D plans. This is true even if CMS pursues the PDE changes it is considering in the Guidance since nothing in the statute permits CMS to hold Part D plans or their contracted PBMs or pharmacies liable for good-faith errors in data entry and interpretation.

***PCMA recommendation*: CMS should clarify that under no circumstances can Part D plans be held liable for any payments associated with Part D rebatable drugs. CMS should also clarify that it is not the responsibility of the Part D plan to assess the accuracy of any Part D drug billing unit or 340B indicators supplied by pharmacies.**

VII. Other Recommendations

On February 07, 2023, the OIG of HHS published a "Technical Assistance Brief" regarding the implementation of the Part B inflation rebates.[5] The OIG identified several administrative issues and solutions to those issues that may improve CMS's ability to implement Part B inflation rebates. PCMA recommends that OIG perform the same assessment for Part D inflation rebates to support CMS's implementation of the Part D inflation rebates.
CMS should also provide public access to the comments that are submitted by interested stakeholders in response to the Guidance. While CMS is not obligated to publish comments as part of this solicitation process, an open and transparent process is generally more conducive to a robust and informed decision-making process. PCMA believes that transparency in this complicated area will promote smoother implementation.

***PCMA recommendation*: The Secretary should commission the OIG of HHS to review potential implementation options for Part D inflation rebates and identify important considerations and make recommendations. CMS should also publish comments submitted in response to the Part B and D inflation rebate guidance.**

[5] OEI-BL-23-00170 (Feb. 7, 2023), https://oig.hhs.gov/oei/reports/OEI-BL-23-00170.asp.

VIII. Conclusion

PCMA appreciates the opportunity to provide comments on the proposed Guidance. If you need additional information, please contact Tim Dube (tdube@pcmanet.org).

Sincerely,

Tim Dube

Tim Dube
Vice President, Regulatory Affairs

March 10, 2023

Dr. Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator, Director of the Center for Medicare
Centers for Medicare & Medicaid Services
200 Independence Avenue SW
Washington, DC 20201

Re: Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of the Social Security Act, and Solicitation of Comments

Dear Dr. Seshamani,

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to provide feedback to the Centers for Medicare & Medicaid Services (CMS, the Agency) on the implementation of the Medicare Part D drug inflation rebate.[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $1.1 trillion in the search for new treatments and cures, including $102.3 billion in 2021 alone.

In the sections below, PhRMA provides comments to the Agency on questions raised by CMS in its guidance, as well as additional topics.

As a threshold matter, PhRMA urges CMS to promptly issue final inflation rebate guidance after carefully considering and publicly issuing written responses to stakeholder comments. Clarifying how CMS intends to implement critical aspects of the inflation rebate program is necessary to provide manufacturers with fair notice of their compliance obligations. This bedrock constitutional principle takes on heightened importance given the risk of potentially significant financial penalties.

* * *

[1] PhRMA offers this technical input in an effort to improve implementation of the Inflation Reduction Act (IRA)-mandated inflation rebate process and to support program integrity; however, PhRMA continues to reserve its policy and legal concerns with the IRA more broadly.

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* * *

I. Exclusion of Application of Inflation Rebates to Part D Rebatable Drugs Marketed by Manufacturers Without a Section 1927 Agreement in Effect with the Secretary of HHS and that Do Not Meet the Definition of Covered Outpatient Drug (30.1)

Under section 1860D-14B(d)(1) of the Social Security Act (SSA, the Act), CMS must reference pricing information submitted by manufacturers under section 1927(b)(3). However, some medicines that would otherwise meet the definition of a "Part D rebatable drug" under section 1860D-14B do not have pricing information reported under section 1927(b)(3), namely medicines without a Medicaid Drug Rebate Program (MDRP) agreement and medicines that do not meet the definition of a covered outpatient drug (COD) under section 1927(k)(2) – (4). Given this, CMS is proposing to exclude medicines that fall into either category from the Part D inflation rebate at this time.

PhRMA supports the Agency's proposed approach. In response to the solicitation of comments on alternative approaches, PhRMA is not aware of statutory authority allowing CMS to collect the information necessary for an alternative approach. If the Agency believes there is such authority notwithstanding the unambiguous exclusions in section 1927, PhRMA urges CMS to undertake notice-and-comment rulemaking to clearly explain the basis for such a proposal and to ensure all stakeholders have an opportunity to comment.

II. Use of PDE Data to Determine Total Units Subject to Rebate and Crosswalk to AMP Units

Section 1860D-14B(g)(2) of the SSA defines "units" for purposes of the Part D inflation rebate as "the lowest dispensable amount (such as a capsule or tablet, milligram of molecules, or grams)… as reported under section 1927." CMS intends to determine the number of units dispensed using the "Quantity Dispensed" field in the Part D Prescription Drug Event (PDE) record. However, as the Agency notes, units reported on the PDE are industry standard National Council for Prescription Drug Programs (NCPDP) defined values, whereas manufacturers report the Average Manufacturer Price (AMP) for a drug under the MDRP using one of 10 different unit types, which may differ from NCPDP units.

CMS can crosswalk unit types by relying on the NCPDP defined unit of a drug as reported on the United States Food and Drug Administration's (FDA's) Comprehensive NDC SPL Data Elements File and adjusting this reported unit measure to align with AMP-reported units if necessary. But to facilitate the identification of unit types, CMS is exploring the option to add a field to the PDE to collect how the amount reported in the "Quantity Dispensed" field is measured.

PhRMA supports the Agency's proposed approach for identifying the total units subject to a Part D inflation rebate using units reported in the "Quantity Dispensed" field of the PDE record and, if necessary, converting those units to AMP units reported by the manufacturer for the drug under section 1927. Furthermore, PhRMA supports the Agency adding a field to the PDE file layout to collect how the amount reported in the "Quantity Dispensed" field is measured using the NCPDP defined values. PhRMA concurs that this additional data element is essential to help ensure accurate calculation of Part D drug inflation rebates.

III. Exclusion of 340B Acquired Units from Part D Rebatable Drug Requirements (40.2.7)

Beginning in Part D plan year 2026, section 1860D-14B(b)(1)(B) of the SSA requires CMS to exclude units of drugs dispensed to Part D enrollees that are subject to an agreement under section 340B of the Public Health Service Act. The current NCPDP Telecommunication Standard, the HIPAA compliant standard for Part D transactions, allows for, but does not require, the identification of units subject to a 340B agreement via a submission clarification code that can be populated and sent during claims adjudication. And while NCPDP does permit the retrospective identification of 340B units under the "N1" transaction, it is very rarely utilized. As such, CMS believes the most reliable way to identify drugs subject to a 340B discount that are dispensed under Part D is to require a 340B indicator be included on the PDE record and included on all pharmacy claims for such drugs and solicits comments on that approach.

PhRMA supports the Agency's proposed approach for identifying and excluding units subject to 340B agreements. PhRMA also urges CMS to add a second, "non-340B" indicator value such that the PDE is never silent on the 340B status of each claim. PDE submissions without either of the two indicator values should be rejected as incomplete. This approach would give CMS needed certainty that a 340B determination has been made for each claim. In addition, this would align with the approach taken by the Agency for the discarded drug refund modifier, where providers and suppliers submitting claims for single-dose container or single-use package drugs under Part B must use the "JW" modifier to indicate the amount of a medicine that was discarded, or, effective July 1, 2023, use the "JZ" modifier to attest that no amount of a medicine was discarded.[2]

Based on PhRMA's understanding, the vast majority of prescriptions subject to 340B agreements are identified as such within two weeks of the prescription being written. Thus, it seems reasonable to require the identification of claims subject to 340B agreements either at the pharmacy or within the window of adjudication between the Part D plan and the pharmacy (a period of time that typically spans two weeks).

Even with a set of mandatory claims indicators, however, PhRMA has significant concerns that all prescriptions subject to a 340B agreement may not be appropriately captured, as there currently does not appear to be a penalty contemplated for covered entities (CEs) that fail to comply with the required indicators, and manufacturers have no ability to pursue an audit or investigation for this type of CE non-compliance. A recent report by IQVIA found that only 61% of treatments for Part B separately payable drugs originating at rural referral centers and sole community hospitals used a relevant 340B modifier,[3] a highly concerning result given that CMS requires these entities to use the "JG" and "TB" modifiers on claims seeking Medicare payment for a 340B-acquired drug. While there are situations where it is appropriate for CEs to not use the relevant 340B claims modifiers,[4] a finding of 61% modifier usage seems outside the bounds of expected utilization. By comparison, IQVIA found that 89% of treatments for Part B separately payable drugs originating at disproportionate share hospitals (DSHs) used a

[2] CMS. Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy: Frequently Asked Questions. Available at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf.
[3] IQVIA. Can 340B Modifiers Avoid Duplicate Discounts in the IRA? Feb. 2023. Available at: https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2023/can-340b-modifiers-avoid-duplicate-discounts-in-the-ira.pdf.
[4] For example, if the CE is able to purchase the drug at a lower price than the 340B price, the CE would not claim the 340B discount and not utilize the relevant modifier on the Part B claim.

relevant modifier.[5] Since the requirement to use either the "JG" or "TB" modifiers applies equally to DSHs, rural referral centers, and sole community hospitals, PhRMA would have expected more similar modifier utilization.

PhRMA believes that the addition of a "non-340B" indicator and the rejection of PDE records that lack one of the two relevant indicators discussed above will help to improve appropriate reporting of units subject to 340B agreements. However, given the Agency's obligation to exclude 340B units under section 1860D-14B(b)(1)(B) of the SSA starting in 2026, PhRMA encourages CMS to establish a robust process to audit 340B CEs to confirm the appropriate identification of units subject to 340B agreements, with penalties for CEs found to be out of compliance and restatements for manufacturer inflation rebate obligations if warranted. Alternatively, CMS could establish a clearinghouse-type organization to identify 340B units dispensed or administered to Medicare enrollees. The 340B clearinghouse would act as a claims verifier, reviewing Part D PDE data as well as data submitted by 340B CEs (or entities acting on their behalf) to confirm whether a claim is subject to a 340B agreement, similar to the role played by 340B third-party administrators (TPAs) and split-billing vendors today.[6] Units marked as subject to 340B agreements on either the pharmacy claim or by the 340B clearinghouse would be excluded from calculation of the Part D inflation rebate.

PhRMA is aware of alternative methods for excluding 340B units that have been considered by other stakeholders. For example, one such method suggests CMS exclude 340B units based on the manufacturer-reported ratio of the manufacturer's 340B sales in relation to the manufacturer's Part D sales for a given National Drug Code (NDC). PhRMA does not support approaches that rely on this type of extrapolation; extrapolation would not comply with CMS's statutory obligation to accurately identify units subject to 340B agreements dispensed to Part D enrollees as required under section 1860D-14B(b)(1)(B) of the SSA.[7] Furthermore, extrapolating the number of 340B units to exclude from the inflation rebate is unnecessary because adding a claims indicator is an exact method available to the Agency that is feasible and not overly burdensome.

The statute's prohibition against duplicate 340B discounts and inflation rebates is absolute. But the Government Accountability Office (GAO) and the Department of Health and Human Services (HHS) Office of Inspector General (OIG) have both found continued risk of duplicate 340B discounts and Medicaid rebates despite a similar absolute prohibition.[8] By ensuring CE compliance with the required modifiers via a CMS audit process or a clearinghouse-type organization, the Agency can significantly improve the implementation of the statute. PhRMA also encourages CMS to coordinate with HRSA to prevent duplicate 340B discounts and inflation rebate obligations.

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[5] IQVIA. Can 340B Modifiers Avoid Duplicate Discounts in the IRA? Feb. 2023. Available at: https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2023/can-340b-modifiers-avoid-duplicate-discounts-in-the-ira.pdf.

[6] 340B TPAs and split-billing vendors assist 340B CEs in managing prescription 340B eligibility, ordering, and payment. These entities track electronic data feeds (such as inpatient or outpatient status, prescriber eligibility, clinic location, Medicaid payer status, drug identifier, and quantity dispensed) so 340B patient eligibility can be assessed.

[7] In addition, the share of units subject to 340B agreements can vary significantly by payer segment or site of care, making the extrapolation approach inaccurate. And such a ratio may be slow to capture underlying changes in the Part D or 340B programs over time. Furthermore, implementing this extrapolation approach would require the Agency to develop a new reporting process for manufacturers that goes beyond the statute and that is outside the Medicare program.

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

Finally, PhRMA also recommends that CMS make clear that the requirement for a 340B indicator preempts any state or local law or regulations that would conflict with or frustrate compliance with this requirement with respect to Part D prescription drug plans (PDPs), including state laws applicable to pharmacy benefit managers (PBMs) or other intermediaries. The SSA provides that the standards established under Part D shall "supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency)" with respect to PDPs which are offered by Part D sponsors.[9] Under this broad preemption authority, federal standards directly governing an entity's conduct with respect to PDPs supersede state laws.[10]

IV. Treatment of Subsequently Approved Drugs for Part D Inflation Rebate Purposes (40.3)

Under section 1860D-14B(b)(5)(A) of the SSA, the Agency must use a different payment amount benchmark period and a different benchmark period for the Consumer Price Index for all urban consumers (CPI-U) for drugs first approved or licensed after October 1, 2021. Specifically, the payment amount benchmark period for these drugs is defined as "the first calendar year beginning after the day on which the drug was first marketed," and the benchmark CPI-U period is defined as the "January of the first year beginning after the date on which the drug was first marketed." CMS is proposing to establish the first applicable period for subsequently approved drugs as the period running from January through October immediately following the end of the payment amount benchmark period. For example, if a drug was first approved and marketed in September 2024, the payment amount benchmark period would run from January 1, 2025 through December 31, 2025, and the first applicable period for the drug would run from January 1, 2026 through September 30, 2026.

PhRMA opposes the Agency's proposal for the first rebate period for subsequently approved drugs to run from January through September immediately following the end of the payment amount benchmark period. Under section 1860D-14B(g)(7) of the SSA, an applicable rebate period is defined as "a 12-month period beginning with October 1 of a year…." As such, for subsequently approved medicines, beginning the first applicable period on January 1 is contrary to a plain reading of the statute.

To follow the statute, which requires consistency in administration of the Part D inflation rebate with regard to applicable period start dates, CMS should recognize the first applicable period as the period beginning October 1 after the payment amount benchmark period, consistent with the statute. For the illustrative drug above with a payment amount benchmark period of January 1, 2025 through December 31, 2025, this would mean the first applicable period would begin October 1, 2026, not January 1, 2026.

V. Reducing or Waiving the Rebate Amount in the Case of a Part D Rebatable Drug Currently in Shortage on the FDA Shortage List (40.5.1)

Under section 1860D-14B(b)(1)(C) of the SSA, CMS must reduce or waive rebate amounts for Part D rebatable drugs for an applicable period when the drug is described as currently in shortage at any time

[9] SSA § 1860D-12(g) (incorporating SSA § 1856(b)(3)).

[10] *See e.g., Uhm v. Humana, Inc.*, 620 F.3d 1134 (9th Cir. 2010) (Part D preemption extends to parent organization of Part D sponsor); *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 971–72 (8th Cir. 2021) (Part D preemption should be considered "field" preemption; state laws are preempted as applied to Medicare Part D plans if they "(1) regulate the same subject matter as a federal Medicare Part D standard (in which case they are expressly preempted), or (2) otherwise frustrate the purpose of a federal Medicare Part D standard (in which case they are impliedly preempted).").

during the applicable period on the FDA shortage lists maintained pursuant to section 506E of the Federal Food, Drug, and Cosmetics Act (FDCA).[11] CMS intends to require at least one 11-digit NDC code (NDC-11) for a Part D rebatable drug to be on the FDA shortage lists in order for a drug to be eligible for a reduction or waiver. Further, a Part D rebatable drug would not be eligible for a reduction or waiver of the rebate amount if the drug is designated as "discontinued," "to be discontinued," or "resolved" on the shortage lists.

CMS is soliciting comments on the amount and duration of the reduction of the rebate amount for the applicable period when a Part D rebatable drug is on a shortage list, as well as for scenarios when a waiver could be considered. CMS is considering two specific options — a variable reduction in the rebate amount, which would be based on the length of time the drug was on the shortage list and would decrease over time, or a limited standard reduction in the rebate amount that would include a reporting process by which manufacturers could request an increased reduction or waiver for certain types of shortages.

In section 40.5.1 of the guidance, CMS additionally seeks comment on several specific topics related to reducing or waiving the rebate amount for Part D rebatable drug on a shortage list:

- *CMS asks how it should reduce or waive the rebate amount in the case of a Part D rebatable drug that is on the shortage list.* PhRMA requests that CMS waive the full rebate amount for the applicable period when a Part D rebatable drug is on a shortage list. Drugs listed as currently in shortage on the FDA shortage lists present significant access issues for providers and patients. In fully waiving any rebate amount, the Agency will not risk reducing access further, and the manufacturer can put resources towards addressing the shortage instead of the prospect of inflation rebate obligations. In addition, PhRMA recommends that CMS adopt a modified version of the second option that the Agency proposed — a limited standard waiver in the rebate amount that would include a reporting process by which manufacturers could request a longer waiver for certain types of shortages — as opposed to the first option of a variable reduction in the rebate amount.

- *CMS asks how it might adjust the rebate amount in cases where not all of the NDC-11s for the Part D rebatable drug are listed as "current" on the FDA shortage list.* PhRMA recommends that CMS waive the rebate amount for a drug for the applicable period regardless of whether all NDC-11s are listed as "current" on the FDA shortage lists, as a shortage for one NDC-11 can affect the availability of other NDC-11s. Furthermore, the uneven sales patterns for drugs in shortage can cause swings in AMP outside of a manufacturer's control. PhRMA urges the Agency to avoid penalizing manufacturers with inflation rebates in this situation.

- *CMS asks whether there are specific causes for or types of a shortage such that CMS might reduce or waive the rebate amount differently, such as for drugs that treat certain conditions or address critical needs, and how CMS would identify such drugs.* The factors that contribute to drug shortages are complex and multidimensional and can occur for various reasons and at different points throughout the drug supply chain. These disruptions can include shifts in clinical practice, changes in hospital and pharmacy contractual relationships with suppliers and wholesalers, the discontinuation of a competing product leading to unanticipated increased

[11] The FDA Center for Drug Evaluation and Research (CDER) and the FDA Center for Biologics Evaluation and Research (CBER) maintain separate lists for purposes of section 506E.

utilization, raw materials shortages, natural disasters, geopolitical disruptions, and public health emergencies. For example, recent hurricanes in major manufacturing hubs and the ongoing pandemic have resulted in major supply chain disruptions that have put tremendous burdens on manufacturers, particularly as they try to avoid shortages. Pharmaceutical manufacturers develop risk mitigation plans and invest in risk managements systems that focus on the continuity of global supply chains. In developing any exclusions for waiving the rebate amount for Part D rebatable drugs on the shortage list, PhRMA recommends that CMS consider adopting the same exclusions it has proposed for supply chain disruptions for biosimilars and generic part D rebatable drugs, such as an interruption in manufacturing due to routine maintenance or failure to comply with good manufacturing practices.

- *CMS asks what safeguards would be necessary to ensure that a reduction or waiver of the rebate amount did not give a manufacturer an incentive to intentionally maintain a Part D rebatable drug on the shortage list to avoid a rebate obligation.* PhRMA does not believe that safeguards would be necessary to ensure that manufacturers are not incentivized to intentionally maintain a Part D rebatable drug on the shortage list to avoid a rebate obligation. There are significant negative ramifications — including negative reputational, financial, and market ramifications — to a manufacturer if its drug experiences a shortage; as such, a manufacturer is unlikely to intentionally expose itself to those ramifications solely to avoid paying a rebate. In addition, when there is a shortage, FDA works with the manufacturer and other stakeholders to maintain treatment options and ensure continuity, including expediting the review of new suppliers or manufacturing sites as needed. PhRMA also notes that drug shortages more commonly have affected generic medications and the vast majority of generic medications are outside the scope of these inflation rebate provisions. Finally, it is the FDA — not manufacturers — that determines what drugs appear on its shortage lists. Since manufacturers are not in control of this designation, the safeguards that CMS is contemplating are not needed or warranted.

VI. Reducing or Waiving the Rebate Amount for a Biosimilar or Generic Part D Rebatable Drug for When There Is a Severe Supply Chain Disruption (40.5.2)

Under section 1860D-14B(b)(1)(C)(ii) of the SSA, CMS is required to reduce or waive the inflation rebate amount for an applicable period for a generic Part D rebatable drug or biosimilar Part D rebatable drug when there is a "severe supply chain disruption" during the applicable period, such as a disruption caused by a natural disaster or other "unique or unexpected event." CMS states that it will define a "severe supply chain disruption" as a change in production or distribution that causes a reduction in the U.S. supply by a manufacturer of a Part D rebatable drug and significantly affects the manufacturer's ability to fill orders or meet expected demand for its product for at least 90 days. Under CMS's proposal, a severe supply chain disruption will not include interruptions in manufacturing due to routine maintenance, failure to comply with good manufacturing practices, or insignificant changes in manufacturing about which the manufacturer expects to resume operations within 90 days.

CMS is soliciting comment on the amount and duration for which CMS might reduce or waive the rebate amount for a Part D rebatable generic or biosimilar drug when there is a "severe supply chain disruption" during the applicable period.

PhRMA strongly encourages CMS to waive the full rebate amount for the applicable period and also requests that CMS consider the severity of the event that caused the severe supply chain disruption

when determining the duration of the waiver. Supply chain disruptions can cause swings in AMP that are beyond a manufacturer's control. As a result, PhRMA urges the Agency to avoid penalizing manufacturers with inflation rebates in this situation.

VII. Timing of Rebate Reports and Payment and Manufacturer Suggestions of Calculation Errors in Preliminary Rebate Reports and Preliminary True Up Reports (50.1 and 50.3)

In sections 50.1 and 50.3 of the guidance, CMS notes its intention to send manufacturers a Preliminary Rebate Report no later than six months after the end of each applicable period.[12] Manufacturers would then have ten days to review the Preliminary Rebate Report for potential errors in the calculation of the rebate amount for the Part D rebatable drug for the applicable period or for a statutory exclusion that was not applied. CMS would have "discretion" to review a manufacturer's suggestions about the Preliminary Rebate Report. Following this process, CMS would send manufacturers a Rebate Report — an invoice that would identify the rebate amount due for Part D rebatable drugs.

CMS also notes its intention to take a similar approach for the True Up Rebate Reports. Approximately one year after CMS sends a Rebate Report to manufacturers and rebate amounts have been paid, CMS plans to conduct a one-time true-up of the rebate amounts, which would allow for changes in any price and/or unit restatements of AMP data reported by manufacturers or in the Part D units dispensed reported by Part D Plan Sponsors, corrected for calculation errors. CMS plans to provide a Preliminary True-Up Rebate Report and again provide ten days for manufacturers to review for calculation errors, which the Agency would consider at its discretion.

CMS is soliciting comment on this proposed approach.

While PhRMA appreciates the opportunity to review the Preliminary Rebate Report and Preliminary True-Up Rebate Report to suggest calculation errors to CMS, ten days is not a sufficient period of time to review these reports and document potential errors to CMS. PhRMA urges CMS to lengthen the period of review to at least 30 days. As a point of comparison, a 30-day review period would align with the period of time manufacturers have to calculate AMP and best price for reporting to the Agency under the MDRP.

In addition, PhRMA urges CMS to provide sufficient information in the rebate reports to allow manufacturers to independently verify the rebate calculation, and to allow manufacturers to provide comment back to the Agency on more than "calculation errors" or statutory exclusions not applied. In section 50 of the guidance, CMS states that the Preliminary Rebate Report and the Rebate Report will include only three pieces of information: 1) the total number of units for each dosage form and strength for the Part D rebatable drug for the applicable period; 2) the amount, if any, of the excess of the Annual Manufacturer Price (AnMP) for each dosage form and strength during the applicable period and 3) the rebate amount for each dosage form and strength of a Part D rebatable drug for the applicable period.[13]

[12] Under section 1860D-14B(a)(3) of the SSA, CMS may delay invoicing manufacturers until December 31, 2025 for applicable periods beginning October 1, 2022 and October 1, 2023.

[13] PhRMA notes that the guidance document inconsistently refers to the fields that would be included on manufacturer invoices. For example, in section 20 of the guidance, CMS refers to the invoice as only including the amount, if any, of the excess of the AnMP for each dosage form and strength and the total rebate amount for each dosage form and strength. In revised guidance, PhRMA urges CMS to clearly state the fields that will be made available to manufacturers on the invoices.

This is not enough information for a manufacturer to independently verify the correct calculation of any inflation rebate amount owed.

In contrast, under other statutory provisions under which manufacturers can incur financial obligations, the Agency (and TPAs acting on its behalf) provides highly detailed information that manufacturers can review to verify the correct calculation of their payment obligations. For example, under the Part D Coverage Gap Discount Program (CGDP), the CGDP TPA provides manufacturers with claims-level data files with which to verify the TPA's calculation of CGDP invoice amounts. At a minimum for the Part D inflation rebate, the Agency should broaden the information shared with manufacturers in the Preliminary Rebate Reports, Rebate Reports, Preliminary True Up Reports, True Up Reports, and any post-True Up Reports to include:

- The benchmark price calculated by the Agency for each dosage form and strength, as well as the quarterly AMP and AMP unit figures used in calculating the benchmark price;
- The AnMP calculated by the Agency for the applicable period for each dosage form and strength, as well as the quarterly AMP and AMP unit figures used in calculating the AnMP;
- The benchmark and applicable period CPI-U values used by the Agency;
- The billing unit reported on the FDA's Comprehensive NDC SPL Data Elements File; and
- Claims-level data at the NDC-11 level for the applicable period with:
    - The NDC;
    - The date of service (i.e., date filled);
    - Prescription ID number;
    - Part D Contract ID and Part D Plan Benefit Package ID;
    - De-identified Medicare beneficiary ID;
    - The National Provider Identifier (NPI) of the prescribing provider;
    - Pharmacy NPI;
    - The number of units dispensed;
    - Days supply;
    - Fill number;
    - Paid date (date the Part D plan paid the pharmacy);
    - Claims status (whether the claim was paid or reversed); and
    - An indicator for claims excluded due to being subject to 340B agreements (and any "non-340B" claim indicator the Agency may add) as of 2026.

PhRMA further urges the Agency to make clear that manufacturers may suggest errors in any of the information fields included on the Preliminary Rebate Report and Preliminary True Up Report.

Finally, PhRMA urges CMS to promptly notify manufacturers if a Part D rebatable drug will have its inflation rebate reduced or waived due to shortage or a severe supply chain disruption, or if the Agency has determined that a drug is not subject to the inflation rebate for an applicable period due to the low annual cost exemption.

VIII. Restatements of PDE Units Reported and True-up Rebate Report and CMS Identification of Errors (50.4)

Under section 1860D-14B(b)(6) of the SSA, CMS is required to establish a process for reconciling manufacturer rebate amounts in the case of revised information on units dispensed by a Part D plan

sponsor. In section 50.4 of the guidance, CMS states that the Agency "reserves the right to update or change the rebate amount and true-up amount due from manufacturers for applicable periods based on any calculation errors, or misreporting of manufacturer pricing or product data under section 1927(b)(3) that CMS identifies *at any point* after each applicable period ends. This process… could occur during the calculation error process, after Rebate Report and True Up Rebate Report invoices are submitted to manufacturers, or after the rebate amount or true-up rebate amount is paid to CMS" (emphasis added).

PhRMA opposes the Agency's broad intention to update manufacturer rebate liabilities at any time. CMS cites to no statutory authority to justify such an open-ended error correction process, nor does it articulate standards for limiting the Agency's ability to reopen, such as standards of materiality or intent that would lead the Agency to calculate a revised invoice amount adverse to a manufacturer. PhRMA also urges CMS to consider a minimum threshold for reopening to avoid inappropriate expenditures of resources for both the government and the manufacturers paying the inflation rebate assessments. Manufacturers should be able to expect some finality to the invoices transmitted by the Agency, without being subject to error correction *ad infinitum* and without any articulated standards or statute of limitations. In other contexts, the law typically provides three to four years for reopening or restatements, with reopening "at any time" at the behest of the Agency only in cases of fraud or similar fault.[14] At the same time, reciprocity and fairness demand that manufacturers shall also be able to reopen for the full three years during which AMP restatements may occur,[15] and certainly should be permitted to seek corrections to inflation rebate amounts within the same timeframe available to the government.[16]

IX. Enforcement of Rebate Payments by Manufacturers: Civil Monetary Penalties (60)

In section 60 of the guidance, CMS very briefly describes certain aspects of the procedures the Agency proposes to follow for purposes of imposing civil monetary penalties (CMPs) against manufacturers in accordance with section 1128A of the SSA. PhRMA would have significant concerns if CMS intends to rely only on this scant guidance and not further articulate Part D CMP procedures through notice-and-comment rulemaking before seeking to impose CMPs on manufacturers. As we describe below, addressing the Part D CMP process as part of the Part B CMP rulemaking would minimize duplication and promote efficient use of government resources while potentially avoiding these legal concerns. We look forward to providing comments on a CMP proposed rule but also highlight here some key CMP principles.

CMS Should Implement the Part B and Part D CMP Processes Through the Same Rulemaking

[14] *See e.g.,* 42 C.F.R. § 405.980(b); Reopening of a Medicare contractor's Part A or Part B determination:
(1) Within 1 year from the date of the initial determination or redetermination for any reason.
(2) Within 4 years from the date of the initial determination or redetermination for good cause as defined in § 405.986.
(3) At any time if there exists reliable evidence as defined in § 405.902 that the initial determination was procured by fraud or similar fault as defined in § 405.902.
(4) At any time if the initial determination is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting a clerical error on which that determination was based.

[15] Under 42 C.F.R. § 447.510, manufacturers may report revisions to average manufacturer price, best price, customary prompt pay discounts, or nominal prices for up to 12 quarters or 36 months, except in specified circumstances where a longer restatement period applies.

[16] Allowing manufacturers to note errors in CMS's calculations would not violate the limitation on administrative review, as it would be a reconsideration, and nothing in the IRA would authorize CMS to cite to limits on administrative or judicial review as a justification to violate the statute.

Given the significant overlap between the CMP provisions in Section 1847A(i)(7) (governing Part B rebatable drugs) and Section 1860D-14B(e) (governing Part D rebatable drugs), PhRMA urges CMS to develop the Part D CMP process in the same notice-and-comment rulemaking as the Part B CMP process.[17] Proceeding through notice-and-comment rulemaking for the Part D CMP process would be consistent with CMS's obligation to issue regulations before establishing a substantive legal standard under Section 1871(a) of the SSA.[18] Further, as a general matter, agencies are permitted to afford regulated parties *more* procedural protections than a statute requires.[19]

Addressing both the Part B and Part D inflation rebate CMPs in the same rulemaking would also minimize duplication and promote efficient use of government resources. Because no appreciable differences exist between the CMP processes applied under the Part B and Part D inflation rebate programs, PhRMA encourages CMS to develop both CMP processes through the same rulemaking. PhRMA looks forward to commenting on the determination of the CMP amount as part of such rulemaking. In any event, manufacturers should not be subject to any inflation rebate CMPs until final CMP regulations are in place and effective.

CMS Should Model the CMP Process After Well-Established Agency Procedures

In developing processes to govern the imposition and appeals of CMPs under the inflation rebates, CMS should use well-established agency procedures as a model. Examples include the CMP procedures for Medicare Advantage organizations (MAOs) and Part D prescription drug plan sponsors (PDPs),[20] and the CMP procedures issued by the HHS OIG.[21] All of these examples establish clear notice, procedures, and timeframes for regulated parties to, among other things, respond to CMP notices, request hearings before an administrative law judge (ALJ), and appeal ALJ decisions to the HHS Departmental Appeals Board before seeking review in the U.S. Court of Appeals.[22]

In addition, the CMP procedures should provide an opportunity for manufacturers to confer with the Agency prior to the imposition of CMPs. Even when the regulations do not require it, it is customary for government agencies to issue pre-enforcement notification letters or pursue other informal means to give regulated parties an opportunity to respond before the agency initiates formal proceedings.[23] PhRMA believes engaging in pre-enforcement discussions with manufacturers would be beneficial to

[17] To clarify, CMS should codify separate regulatory provisions to address the circumstances under which a manufacturer could be subject to a CMP under: (1) the Part B inflation rebate program, and (2) the Part D inflation rebate program. These separate regulatory provisions should cross-reference a single CMP appeals procedure that applies to all inflation rebate program CMPs.
[18] As discussed in Section X(e) of our comments.
[19] *See, e.g., New Life Evangelistic Ctr., Inc. v. Sebelius*, 753 F. Supp. 2d 103, 121 (D.D.C. 2010) ("Agencies are, of course, free to adopt additional procedures as they see fit.").
[20] 42 C.F.R. Part 422, Subparts O and T (CMP imposition and appeals procedures for MAOs); 42 C.F.R. Part 423, Subparts O and T (parallel procedures for PDPs).
[21] 42 C.F.R. Parts 1003 and 1005.
[22] We note that the limitation on administrative and judicial review set forth in section 1860D-14B(f) of the SSA does not limit a manufacturer's right under section 1128A(e) of the SSA to seek judicial review of a determination by the Secretary to impose a CMP pursuant to section 1860D-14B(e).
[23] *See, e.g*., OIG. Revisions to the OIG's Exclusion Authorities. 82 Fed. Reg. 4100, 4109 (Jan. 12, 2017) ("In practice, OIG also contacts potential subjects of section 1128(b)(7) exclusions, often through 'pre-demand letters' or other means to give defendants the opportunity to respond to OIG before formal proceedings are initiated."); 42 C.F.R. §§ 422.756, 423.756 (setting forth CMS's procedure for imposing intermediate sanctions on MAOs and PDPs, respectively, which provides for a written notice to the plan of CMS's proposed intermediate sanction and an opportunity for the plan to provide a written rebuttal within 10 days of receipt of CMS's notice).

both manufacturers and CMS. This is particularly true because the Part B and Part D inflation rebate programs are new and are still being implemented. Both manufacturers and CMS will likely be working through implementation challenges, often fact-specific, for the first few years of the program. Because CMS is proposing a very limited opportunity for manufacturers to engage with CMS on calculation errors and similar issues, and the potential for large CMP amounts, it is critical that CMS implement a process to informally engage with manufacturers through pre-enforcement communications before initiating formal CMP proceedings.

CMS Should Exercise Enforcement Discretion When Deciding Whether to Seek or Impose CMPs on Manufacturers

The inflation rebates are a new obligation on manufacturers under Medicare and, as such, may require time for both the Agency and manufacturers to address programmatic questions and develop new rules. Accordingly, CMS should clearly state in its CMP regulations that it will consider exercising enforcement discretion when deciding whether to seek or impose CMPs on manufacturers in certain circumstances.[24] Specifically, CMS should clarify that it will consider exercising enforcement discretion and not impose CMPs (or, alternatively, impose a reduced CMP) on a manufacturer that does not fully satisfy its obligations under Section 1847A(i)(1)(B) or Section 1860D-14B(a)(2) due to: (i) a good faith payment mistake (*e.g.*, payment of the incorrect amount); (ii) a *bona fide* disagreement with CMS's calculations; (iii) a payment discrepancy resulting from unclear guidance on a manufacturer- or drug-specific issue; or (iv) other similar situations in which a manufacturer did not knowingly or intentionally violate the inflation rebate statute.

CMS has clear statutory authority to exercise such discretion. Specifically, Sections 1847A(i)(7) and 1860D-14B(e) each provide that a manufacturer shall be "subject to" a CMP, meaning that CMS may use its judgment to pursue — or not pursue — a CMP. Moreover, both provisions reference SSA 1128A, which requires that, in determining the amount of any CMP, agencies must take into account "the nature of claims and the circumstances under which they were presented,… the degree of culpability,… [and] such other matters as justice may require," and authorizes agencies to "compromise" CMPs imposed on regulated parties.[25]

The Statute Does Not Permit CMS to Impose CMPs on True-Up Amounts

CMS's guidance would require a manufacturer to pay the "true-up" amount described in Section 60 within 30 days of receipt to avoid a CMP. PhRMA does not support CMS's proposal to impose CMPs in this scenario, as CMS lacks authority under Section 1860D-14B(e) to impose CMPs in any circumstance other than the manufacturer's failure to pay the *initial* invoice for an applicable period on time.

Specifically, Section 1860D-14B(e) permits CMS to impose a CMP on a manufacturer if the manufacturer "fail[s] to comply with the requirement under subsection (a)(2)…." Subsection (a)(2), in turn, requires a

[24] We note that OIG proposed adopting a similar policy of enforcement discretion in its 2020 proposed rule on CMPs related to information blocking. *See* 85 Fed. Reg. 22979, 22985 (Apr. 24, 2020) ("We appreciate that information blocking is newly regulated conduct. We also understand the significant negative effect that information blocking can have on patient safety, care coordination in the healthcare system, and the ability of patients and providers to have information to make informed, appropriate decisions about important healthcare decisions. The goal in exercising our enforcement discretion is to provide individuals and entities that are taking necessary steps to comply with the ONC Final Rule with time to do so while putting the industry on notice that penalties will apply to information blocking conduct within a reasonable time.").
[25] SSA § 1128A(d), (f).

manufacturer to provide to CMS "*a rebate*" within "30 days after the date of receipt from the Secretary of the information described in paragraph (1)…." (emphasis added). Paragraph (1), in turn, requires CMS to report to a manufacturer "*[n]ot later than 9 months* after the end of each applicable period," certain information about the amount (if any) of the excess AMP increase for such drug and period, and the rebate amount for such drug and period (emphasis added).

No provision in the statute permits CMS to impose CMPs in any circumstance other than a manufacturer's failure to pay a rebate on its Part D rebatable drug within 30 days after receiving the invoice that CMS is required to send within 9 months after the end of the applicable period (or by December 31, 2025 under the transition rule at Section 1860D-14B(a)(3)). While Section 1860D-14B(b)(6) provides for reconciliation in the case of a Part D plan revising the number of units of a rebatable covered Part D drug dispensed, there is no provision in Section 1860D-14B(e) or elsewhere in this section to suggest CMPs can be imposed on manufacturers for "true-up" or other similar invoices provided to manufacturers after the 9-month period specified in Section 1860D-14B(a)(1). CMS should not finalize this policy in its final Part D inflation rebate guidance.

X. Other Issues

a. Clarity on Timing of Invoices

Under Section 1860D-14B(a)(3) of the SSA, CMS may elect to delay Rebate Reports for rebate periods beginning October 1, 2022 and October 1, 2023 until December 31, 2025. However, manufacturers could have begun accruing liability effective October 1, 2022, which carries requirements for manufacturers' financial reporting and tax filings.

PhRMA encourages the Agency to provide clarity on its intended timeline for release of the Preliminary Rebate Reports and Rebate Reports for the rebate periods beginning October 1, 2022 and October 1, 2023. For example, CMS could provide a 30-day notice prior to sending the first Preliminary Rebate Reports, or the Agency could publish an anticipated schedule of release dates. This information would provide needed clarity to manufacturers on when they may need to revise estimated inflation rebate liabilities in their financial reporting and tax filings.

b. Manufacturer Point of Contact

The implementation of the Part D inflation rebate program will be a novel payment obligation for manufacturers in the Medicare program. PhRMA requests that CMS provide manufacturers with a contact at the Agency who can serve as a single point of contact for manufacturer questions, similar to how manufacturers are provided with a dedicated contact person and email address for questions related to the MDRP.

c. CMS Administration of Rebate Program

PhRMA urges CMS to administer the Part D inflation rebate program directly as opposed to contracting with a third party to administer the program. PhRMA believes that CMS administration will best ensure that the inflation rebate program is implemented as intended under Section 1860D-14B and avoid inconsistent procedures or interpretations by third parties.

d. Reasonable Assumptions in Price Reporting

The Part D inflation rebate is based on AMP, a pricing metric that manufacturers calculate and report to CMS. Particularly given the complexities of the pharmaceutical marketplace, CMS regulations and guidance do not always address how particular sales should be treated in calculating AMP. In the absence of guidance, CMS permits manufacturers to rely on reasonable assumptions that are consistent with the requirements and intent of federal laws and regulations.[26]

Under the Part D inflation rebate regime, these assumptions used in Medicaid price reporting will have a more significant impact than they have had in the past, as they will affect inflation rebates. With this newly-expanded role of AMP, it may be more important than ever for CMS to be responsive to manufacturer requests for technical assistance on price reporting questions that arise.

e. CMS Procedures

In section 10 of the guidance, CMS states that it is "voluntarily" seeking comments, and that the Agency may make "changes to any policies… including policies on which CMS has not expressly solicited comment, based on the agency's further consideration of the relevant issue."

While PhRMA appreciates HHS providing a period of comment on its guidance, PhRMA strongly urges CMS to offer at least a 60-day comment period, and to respond to all such comments received. Doing so would help to ensure compliance with section 1871 of the SSA, as well as with the Supreme Court's decision in *Azar v. Allina Health Services*,[27] holding that under SSA 1871, when CMS promulgates substantive legal standards — including through guidance — it must comply with the notice and comment requirements of section 1871.

HHS's Office of the General Counsel has explained that a "substantive legal standard" is a standard that: "1) defines, in part or in whole, or otherwise announces binding parameters governing, 2) any legal right or obligation relating to the scope of Medicare benefits, payment by Medicare for services, or eligibility of individuals, entities, or organizations to furnish or receive Medicare services or benefits, and 3) sets forth a requirement not otherwise mandated by statute or regulation."[28] The Agency's inflation rebate guidance clearly creates substantive legal standards. Among other issues, the guidance addresses: rebate calculation for line extensions; reopening invoiced rebate amounts; procedures for imposing and challenging CMPs; and reduced or waived rebates in the case of shortages or severe supply chain disruptions.

Based on the timelines laid out in statute, CMS has sufficient time to comply with section 1871. As CMS acknowledges, section 1860D-14B(a)(3) of the SSA provides a transition period for invoicing manufacturers for the first two applicable periods (beginning October 1, 2022 and October 1, 2023) until not later than December 31, 2025. By offering only 30 days for comment, forecasting that it may unilaterally adopt new substantive legal standards without subjecting them first to comment, and failing

[26] *See, e.g.*, 85 Fed. Reg. 87000, 87010 (Dec. 31, 2020) ("manufacturers are permitted to make reasonable assumptions in the absence of applicable statute, regulation or guidance regarding how to treat [particular arrangements]").
[27] 139 S. Ct. 1804, 1813 (2019).
[28] OGC Advisory Opinion 20-05 on Implementing *Allina*. Dec. 3, 2020. Available at: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2101111604-mh-advisory-opinion-20-05-on-implementing-allina_12.03.2020_signed.pdf.

to commit to responding in any manner to the comments received, CMS short-changes the stakeholder community, undermines due process, and runs afoul of section 1871.

To the extent CMS determines that it will adopt substantive legal standards without following the process of section 1871, PhRMA urges CMS to acknowledge that such a noncompliant process may not be used to fill in the gaps of the statute or promulgate binding or enforceable standards.

* * *

On behalf of PhRMA and our member companies, thank you for consideration of our comments. Should you have any questions, please feel free to reach out to us at the email addresses below.

Sincerely,

/s/ Kristen Bernie
_____
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/s/ Judy Haron
_____
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03/09/2023

Dr. Meena Seshamani, MD, PhD
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Concerns about modifier approach for identifying 340B drugs dispensed under Medicare Part D

Dear Dr. Sheshamani,

On behalf of Rocking Horse Community Health Center, thank you for the opportunity to provide input into CMS' plans for implementing the Medicare inflationary rebates established under the Inflation Reduction Act. We are a local FQHC in Springfield, OH serving about 14,000 underserved patients. We have multiple services we provide to patients including pediatric care, family practice, behavioral health, chiropractic, dental, pharmacy (clinical and retail), and patient advocacy services. We provide all these services to any patient that comes to our clinic, regardless of insurance status. We serve a large Hispanic and Haitian-creole populations as well with translation services available at all locations.

As you know, FQHCs are the backbone of the health care safety net, providing high-quality, affordable care to over 30 million medically-underserved patients, regardless of whether they have insurance or their ability to pay. Give an overview of your patients – e.g., In our state/ CHC, 70% of CHC patients have incomes below 100%/ 200% FPL, 10% are uninsured, etc.

FQHCs offer a broad range of services, including primary care, dental, behavioral health, and pharmaceuticals. Many of these services – and the sliding fee discounts that make them affordable for our patients -- are supported by savings generated through the 340B drug discount program. Some services specifically are largely funded by 340B savings and include chiropractic, dental, patient advocacy, medication copay assistance for uninsured patients, and our clinical pharmacy services (diabetes management, smoking cessation, etc.)

Nationally, FQHCs rely on contract pharmacy arrangements to dispense roughly 50-60% of the 340B drugs provided to their patients – the highest percentage of any type of 340B provider. Thus, the 340B savings generated at contract pharmacies support many services that the FQHC would otherwise be unable to provide. Given the importance of 340B savings – including those generated by contract pharmacies – we were very concerned to hear that CMS is considering requiring an indicator (also known as modifier) on all claims for Part D prescriptions that were filled with 340B drugs.

As discussed in detail in comments submitted by other members of the FQHC community, FQHCs' experience clearly indicates that requiring a 340B indicator (also known as a modifier) on Part D drugs would:

a. Result in data that is highly unreliable.
b. Force FQHCs to shut down many of their contract pharmacy arrangements for Part D drugs, leading to an overall loss in 340B savings and subsequent reduction in services provided to underserved patients.

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Instead of a modifier, we recommend that CMS implement a "clearinghouse" model for identifying 340B drugs covered by Part D. Compared to a modifier requirement, a clearinghouse would:

a. Produce much more reliable data.
b. Be significantly less labor-intensive.
c. Preserve the ability of FQHCs and other 340B providers to rely on contract pharmacies to dispense 340B drugs to Part D enrollees, thereby avoiding reductions in access.
d. Could be expanded to include 340B drugs dispensed to Medicaid patients.

Thank you for your consideration of our serious concerns about the modifier model, and our proposed alternative. If you have any questions about our comments, please contact Erin Hanson, Pharmacy Director, ehanson@rockinghorsecenter.org

Sincerely,

Erin Hanson, PharmD
Pharmacy Director
937-324-1111 ext. 237
ehanson@rockinghorsecenter.org

Ryan White Clinics
340B for 340B Access

March 11, 2023

Dr. Meena Seshamani, M.D. Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
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VIA EMAIL to: IRARebateandNegotiation@cms.hhs.gov

Re: Medicare Part D Drug Inflation Rebate Comments

Dear Dr. Seshamani:

RWC-340B appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the guidance memorandum entitled "Medicare Part D Drug Inflation Rebates Paid Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments" ("Memorandum"). Our comments concern Section 40.2.7 of the Memorandum: "Exclusion of 340B Acquired Units from Part D Rebatable Drug Requirements."

As background, RWC-340B is a national association of HIV/AIDS health care clinics and service providers receiving support under the Ryan White Comprehensive AIDS Resources Emergency ("CARE") Act. Ryan White clinics are dedicated to caring for low-income and vulnerable patients living with HIV/AIDS and are serving on the frontlines of both the AIDS epidemic and the COVID pandemic, supporting high risk clients and communities. RWC-340B members provide primary care, case management, and other support services for persons living with HIV/AIDS. For many of these services, Ryan White clinics receive little to no compensation and, for that reason, are highly dependent on the 340B drug pricing program ("340B Program") to underwrite the cost of providing comprehensive care to their patients. The ADR process is a critical component of the 340B Program that ensures that Ryan White clinics and other 340B covered entities have access to accurate 340B ceiling prices.

RWC-340B supports CMS's objective to identify 340B drugs billed to Medicare Part D through the best and most effective means possible. We understand that CMS must develop a means to identify Part D 340B drug claims in order to exclude those claims in its calculation of rebates owed by drug manufacturers under the Inflation Reduction Act (IRA) of 2022.

In the Memorandum, CMS stated it believes that a modifier requirement is the most reliable way to identify Medicare Part D claims for 340B drugs. RWC-340B is are concerned, however, about both the burden and ineffectiveness of requiring a modifier to identify 340B drugs. We also write to propose a practical solution

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that is less burdensome, accurate, and effective in identifying 340B drug claims and more likely to allow covered entities to continue to use contract pharmacy arrangements to dispense 340B drugs. If that solution is unacceptable, we offer an alternative option that is a hybrid of CMS's proposal and ours.

CMS's Proposal

In the Memorandum, CMS describes the National Council for Prescription Drug Programs (NCPDP) standards for identifying 340B drugs at the point of sale (POS) or retroactively through an N1 transaction. CMS acknowledges that the current NCPDP Standard Version D.0 does not require an indicator to identify 340B drugs, but allows for an optional identifier by using code "20" in the submission clarification code (420-DK) field.[1] CMS also acknowledges that the NCPDP allows an "N1" transaction to identify 340B drug claims retrospectively.

The Memorandum states that, "CMS believes that requiring that a 340B indicator be included on the PDE [prescription drug event] record is the most reliable way to identify drugs that are subject to a 340B discount that were dispensed under Medicare Part D." CMS states that it is "soliciting comment on whether submission of the 340B identifier on the pharmacy claim is the preferred mechanism to identify 340B units dispensed in Part D, or if there is a better alternative." CMS also states that it is "interested in ascertaining the most reliable way to identify Part D claims filled with 340B units."

The undersigned urge CMS not to adopt a 340B claims identifier requirement at the POS or the N1 transaction. Either of these alternatives, or giving covered entities the option to use either methodology, would create significant administrative and financial burdens for covered entities and pharmacies that dispense 340B drugs on behalf of covered entities. Moreover, these methodologies are not the most reliable method to identify 340B drugs. Instead, RWC-340B urges CMS to adopt a 340B claims identification process modeled on the one used in the state of Oregon to identify 340B claims to Medicaid managed care organizations.

Known Deficiencies with Claims Identification at POS and the N1 Transaction

As noted above, CMS states in the Memorandum that it is considering requiring pharmacies to include a modifier on the Part D claims to identify 340B drugs. The principal problem with CMS' proposal is that the modifier would have to be reported at the POS. For most contract pharmacies and some entity-owed pharmacies, identifying 340B drug claims at the POS is impractical because the pharmacy cannot determine whether a patient is eligible to receive 340B drugs at the POS. Imposing a 340B identifier requirement at the POS, therefore, would have significant consequences for 340B covered entities.

The determination of whether an individual is eligible to receive 340B drugs from a particular covered entity is complicated and can be time-consuming. A pharmacy often has to fill a prescription quickly to respond to patient needs without the requisite time to verify patient eligibility by the POS. For example, an individual

[1] CMS, Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments at 18 n.19 (Feb. 9, 2023) ("A pharmacy would use the "20" submission clarification code (420-DK) to indicate use of a 340B drug at the time of the adjudication or dispensing of the claim.").

who presents a prescription to a pharmacy that resulted from an outpatient visit at a covered entity likely meets the patient definition guidelines established by the Health Resources and Services Administration (HRSA) to allow the prescription to be filled with 340B drugs.[2] But, making a definitive determination requires review of whether the covered entity maintains medical records for the individual and whether the individual received health care services from a professional who is employed by, under contract with, or has another similar arrangement with, the covered entity. Covered entities and pharmacies typically use software systems that are coupled with a virtual inventory system to allow patient determinations and 340B drug purchases to be made with great accuracy because those determinations are made retrospectively.[3]

Requiring pharmacies to make the patient eligibility determination at the POS would potentially lead to several significant problems for 340B covered entities. First, requiring a POS modifier could lead to inaccurate claims submissions and potentially increase the risk that 340B drugs are dispensed to individuals who do not qualify as patients of the covered entity. Second, it may cause certain pharmacies to refrain from acting as contract pharmacies in the 340B program because they cannot comply with the modifier requirement without a significant risk of submitting inaccurate claims. Third, if pharmacies do continue to dispense 340B drugs, they will incur increased costs due to the significant administrative burden of adding a 340B modifier and will likely pass along that cost to 340B covered entities as increased dispensing fees. Fourth, requiring a modifier may result in pharmacies moving from a virtual inventory system to a physical inventory system, which takes more space and is more costly to administer. Fifth, requiring a POS modifier could lead to certain hospital in-house pharmacies purchasing all drugs at wholesale acquisition cost, even for eligible patients, in order to avoid the prohibition against purchasing covered outpatient drugs through a group purchasing organization.[4] (Some RWC-340B members are affiliated with 340B hospitals that are subject to the GPO prohibition.) Any added cost or administrative burden to a pharmacy will likely be passed onto the 340B covered entity as increased dispensing fees. These increased dispensing fees detracts from the purpose of the 340B program, which is to allow covered entities "to stretch scarce federal resources to reach more eligible patients and provide more comprehensive services."[5] Lastly, we are concerned that a POS modifier would result in discriminatory payment practices for 340B drugs by Medicare Part D plans because the modifier would allow the Part D plan to differentiate between claims for drugs that were purchased with 340B discounts and those that were not. For all of these reasons, RWC-340B urges CMS not to adopt a POS modifier.

CMS describes a method for retrospectively identifying 340B drug claims in the Memorandum; specifically, the NCPDP N1 transaction. Although CMS does not propose to require pharmacies to use the N1 transaction, we think it is important to identify the drawbacks of the N1 transaction because we otherwise support a retrospective methodology to identify 340B drugs. Like a POS modifier, the N1 transaction is administratively and financially burdensome. The N1 transaction essentially requires the resubmission of

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[2] *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992, Patient and Entity Eligibility. 61 Fed. Reg. 55,156-01 (October 24, 1996).
[3] In a survey conducted by 340B Health in May 2015, 88.43% (84/95) of respondent hospitals reported that each their contract pharmacies use a virtual 340B inventory.
[4] 42 U.S.C. §§ 256b(a)(L), (M), (N), (O).
[5] H.R. Rep. No. 102-384, pt. II (Sept. 22, 1992); *Drug Discount Program: Status of Agency Efforts to Improve 340B Program Oversight,* GAO (May 15, 2018).

each claim.[6] Submission of a second transaction to identify 340B drugs dispensed to Part D beneficiaries would be time consuming and a strain on pharmacy resources. A contract pharmacy's staff would be required to devote significant time to submission of the N1 transaction. As with a POS modifier, pharmacies may choose not to dispense 340B drugs rather than assume these significant administrative responsibilities. Alternatively, the pharmacy could pass along the costs of the increased administrative burden to covered entities in the form of an increased dispensing fee. As with a POS modifier, Part D plans would have the ability to develop discriminatory payment rates for 340B drugs if claims for 340B drugs are identified through the N1 transaction. Therefore, RWC-340B urges CMS not to adopt use of an N1 transaction as a means to identify 340B drugs on Medicare Part D claims.

Proposed Solution

To provide greater reliability and accuracy for identifying 340B drug claims, some states have implemented methods of identifying 340B Medicaid claims that do not require the identification of 340B eligible patients at the POS and are less burdensome than the N1 transaction process. Specifically, the Oregon Medicaid agency has developed a system that allows covered entities to identify 340B Medicaid MCO claims on a quarterly basis through a retrospective clearinghouse model.[7] Considering the inaccuracy and administrative burden imposed by POS modifiers and the N1 transaction, and the fact that either of those options could lead to discriminatory payments for 340B drugs by Part D plans, RWC-340B believes that a better alternative – and the "most reliable way to identify Part D claims filled with 340B" – would be to use a system similar to the one adopted in Oregon.

Oregon pioneered a simple and accurate method for identifying 340B drugs billed to Medicaid managed care organizations.[8] Covered entities and contract pharmacies submit 340B claims data periodically (e.g., monthly, quarterly) to a state vendor. The data file contains the information necessary to determine whether the state Medicaid agency should submit a rebate request to the manufacturer: Medicaid identifier, the dispense date, the NDC, the prescription number, the NPI of the pharmacy, and the NPI of the prescriber.

We urge CMS to adopt a similar methodology that requires pharmacies that submit 340B claims to Medicare Part D to provide a data file that would allow CMS to exclude those claims from its calculation of the rebate amount that manufacturers owe under the IRA. This solution has several significant benefits:

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[6] The NCPDP 340B Information Exchange, Reference Guide, Ver. 2, describes the N1 Transaction process as follows: "[t]he pharmacy will submit two transactions to the payer/processor at different times. At the point of service, in the normal course of business, a claim transaction is submitted with no Section 340B information. At a subsequent time, a 340B-N1 is submitted with the Section 340B Submission Clarification Code (420-DK) included.

[7] Policy Notification—Oregon Medicaid 340B Drug Claims File (Feb. 13, 2015), http://www.oregon.gov/oha/healthplan/tools/Policy%20Notification%20-%20Oregon%20Medicaid%20340B%20Drug%20Claim%20File.pdf. The State of Hawaii has developed a similar retrospective approach that requires submission of data on 340B drugs claims retrospectively. *See* https://medquest.hawaii.gov/content/medquest/en/archive/PDFs/Provider%20Memos/ACSMEMO2013/ACS%20M13-03.PDF.

[8] This Medicaid managed care claims identification model is one of the few "best practices" recognized by CMS. CMS, *Best Practices for Avoiding 340B Duplicate Discounts in Medicaid* at 6 (Jan. 8, 2020) ("Some states have chosen to provide their claims level data via a secured web portal managed by the state's invoicing vendor and/or an independent third-party data company. If claims level data is provided, this may reduce the state's administrative burden and expense of researching manufacturer dispute issues"), https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib010820.pdf.

Legal—Consistent with the 340B statute and implementing guidance by HRSA, the Oregon model preserves the covered entity's right to use 340B drugs when billing Medicare. According to HRSA, "[i]f the covered entities were not able to access resources freed up by the drug discounts . . . and bill private health insurance, their programs would receive no assistance from the enactment of section 340B and there would be no incentive for them to become covered entities."[9] Use of an Oregon-type model for purpose of the IRA does not present the same sort of administrative hurdles that use of a claims modifier or the N1 transaction involve, thereby allowing covered entities to continue to use contract pharmacy arrangements and realize the benefits of the 340B program.

Accurate—Use of an Oregon-type model would allow CMS to formulate accurately its Medicare rebate requests to manufacturers under the IRA. A retrospective 340B patient identification model provides covered entities, along with the pharmacies that dispense 340B drugs on their behalf, more time to verify the 340B patient-entity relationship, which is not feasible with real-time patient eligibility determinations. The IRA allows CMS nine months from the "applicable [twelve month] period" to submit its rebate request to manufacturers.[10] Under a model similar to the Oregon model, pharmacies that dispense 340B drugs will be able to submit the data needed for CMS to calculate manufacturer rebates well ahead of the nine month deadline, thereby giving CMS adequate time to calculate its rebate requests to manufacturer.

Administrative Ease—As noted above, most contract pharmacy arrangements and many in-house retail pharmacies rely on virtual inventory systems in which identification of 340B eligible claims is performed after the drugs are dispensed and billed. The Oregon model accommodates identification of claims used in 340B virtual inventory systems with significantly less administrative burden than a POS modifier or use of the N1 transaction.

Supports Safety Net Providers and Their Patients—Use of an Oregon-type approach would allow covered entities to maintain as much 340B program savings as possible and use it for patient care and the health of their communities. Grantees are required to report 340B program revenue and use it to further their grant objectives. Hospitals use the savings to fund essential services needed in the community and to support their programs for low income and underserved populations. In addition, this model avoids the possibility of discriminatory payment practices by Part D plans because the data is submitted directly to CMS or its vendor, rather than to the Part D plan.

Alternative Solution

[9] HRSA, Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act, Part I, Section G.
[10] 42 U.S.C. § 1395w-114b(a)(1).

Although the Oregon model is the preferred solution for covered entities, a possible alternative is to develop a hybrid arrangement that combines elements of CMS's claims-level identification proposal with the retroactive batched-claims approach used by the Oregon Medicaid program. Like the Oregon model, covered entities would download and submit a file of all 340B claims submitted by the covered entity and its contract pharmacies for a specified period of time (monthly or quarterly, etc.) to CMS or a vendor (thus avoiding the possibility of discriminatory payment practices by the Part D plan). The deadline for submitting the file would give covered entities sufficient time to retrospectively identify claims for 340B drugs and CMS sufficient time to calculate and submit its rebate requests to manufacturers. Like the CMS proposal, each of the claims would bear the code "20" in the submission clarification code (420-DK) field. The only difference is that, rather than submitting each 340B-identified claim individually with the Medicare Part D plan – whether at the POS or retrospectively as an N1 transaction – the claims would be batched and submitted directly to CMS and/or its designated contractor. CMS, in turn, would use the claims file to identify and remove 340B claims from the rebate requests that CMS is expected to send to drug manufacturers in accordance with the IRA.

It is our understanding that covered entities, with the assistance of their 340B administrators, can download 340B claims into a common data file relatively easily, regardless of whether the claims are submitted by an in-house or contract pharmacy. Application of the code "20" to each of the claims within the data file would require some level of software support, but the necessary technology, we are told, has already been developed and made available by some 340B vendors. Hence, RWC-340B believes this alternative is feasible if CMS chooses not to pursue the Oregon model.

Applicability to Single Source Drugs and Biologics Only

The IRA Part D rebate requirements apply only to single source drugs and biologics. No matter what requirement CMS adopts, we urge CMS to apply the requirement only to the drugs and biologics that could potentially be subject to a rebate (i.e., not to generic drugs) purchased under the 340B program.

* * *

RWC-340B appreciates the opportunity to provide input on this important issue. Thank you for your consideration of our comments. If you have any questions, please feel free to reach out to me at ceo@cempa.org.
Sincerely,

Shannon Stephenson

Shannon Stephenson
President, RWC-340B

SALINA FAMILY
HEALTHCARE CENTER

Medical 785-825-7251 | Dental 785-826-9017 | Pharmacy 785-452-3900 | Main Office 785-825-7251

March 7, 2023

Dr. Meena Seshamani, MD, PhD
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Concerns about modifier approach for identifying 340B drugs dispensed under Medicare Part D

Dear Dr. Sheshamani,

Salina Health Education Foundation, Inc. dba Salina Family Healthcare Center (SFHC) appreciates the opportunity to provide input on CMS' plans for implementing the Medicare inflationary rebates established under the Inflation Reduction Act. SFHC is a Federally Qualified Health Center (FQHC) that was formed in 2004 to serve Saline County, Kansas and the surrounding area with no other safety-net clinic within 40 miles. As you know, FQHCs are the backbone of the health care safety net, providing high-quality, affordable care to over 30 million medically-underserved patients, regardless of whether they have insurance or their ability to pay. Over 10,500 patients receive full scope primary medical, dental, vision, and behavioral health care services annually at SFHC. Among those patients, over 62% are at or below 200% of the federal poverty level. SFHC also owns a pharmacy, Salina Family Healthcare Pharmacy, where it saved 937 eligible 340B patients $2.6 million on the cost of their prescriptions compared to the cash price in fiscal year 2022.

Many of the services, and the sliding fee discounts that make them affordable for our patients, are supported by savings generated through the 340B drug discount program. Examples of 340B-supported services available at SFHC that are either poorly paid for or not paid for at all include free medication delivery, enhanced clinical pharmacy services including chronic care management, an eye care center, community outreach services that extends the reach of our FQHC outside our walls, in-house behavioral health and substance abuse disorder therapists, a MedSafe collection unit open to our community for the safe disposal of unused medications, and a team of care coordinators that assist with the overall needs of our patients from affording food to paying for prescription drugs.

SFHC contracts with eight local contract pharmacies and several specialty contract pharmacies. Nationally, FQHCs rely on contract pharmacy arrangements to dispense roughly 50-60% of the 340B drugs provided to their patients – the highest percentage of any type of 340B provider. Thus, the 340B savings generated at contract pharmacies support many services that FQHCs would otherwise be unable to provide. Given the importance of 340B savings – including those generated by contract pharmacies – SFHC was very concerned to hear that CMS is considering requiring an indicator (also known as a modifier) on all claims for Part D prescriptions that were filled with 340B drugs.

651 E. PRESCOTT RD, SALINA, KS 67401 | SalinaHealth.org

SALINA FAMILY
HEALTHCARE CENTER

As discussed in detail in comments submitted by other members of the FQHC community, FQHCs' experience clearly indicates that requiring a 340B indicator (also known as a modifier) on Part D drugs would:

a. Result in data that is highly unreliable.
b. Force FQHCs to shut down many of their contract pharmacy arrangements for Part D drugs, leading to an overall loss in 340B savings and subsequent reduction in services provided to underserved patients.

Instead of a modifier, SFHC strongly recommends that CMS implement a "clearinghouse" model for identifying 340B drugs covered by Part D. Compared to a modifier requirement, a clearinghouse would:

a. Produce much more reliable data.
b. Be significantly less labor-intensive.
c. Preserve the ability of FQHCs and other 340B providers to rely on contract pharmacies to dispense 340B drugs to Part D enrollees, thereby avoiding reductions in access.
d. Could be expanded to include 340B drugs dispensed to Medicaid patients.

Thank you for considering the serious concerns SFHC has about the modifier model, and the proposed clearinghouse alternative. If you have any questions about these comments, please contact Derek Pihl via the contact information below.

Sincerely,

Derek Pihl, PharmD, 340B ACE
Executive Director of Pharmacy Services
(785) 825-7251 x240
dpihl@salinahealth.org

Siouxland Community Health
an iowahealth center

March 6, 2023

Via Email: IRARebateandNegotiation@cms.hhs.gov

Dr. Meena Seshamani, MD, PhD
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Concerns about modifier approach for identifying 340B drugs dispensed under Medicare Part D

Dear Dr. Seshamani:

On behalf of the Siouxland Community Health Center (SCHC), thank you for the opportunity to provide input into CMS' plans for implementing the Medicare inflationary rebates established under the Inflation Reduction Act. Siouxland Community Health Center serves 34,776 patients in a tri-state area that includes northwest Iowa, northeast Nebraska, and southeast South Dakota. Because of the many meat processing plants in the area, our SCHC staff of 350+ employees serves a significant number of Hispanic, Black/African American, and Asian patients.

As you know, FQHCs are the backbone of the health care safety net, providing high-quality, affordable care to over 30 million medically underserved patients, regardless of whether they have insurance or their ability to pay. Over 41% of our patients at Siouxland Community Health Center are at or below 100% of the Federal Poverty Level, with 45% of our total patients on Medicaid and 18% are self-pay or on the sliding fee scale.

FQHCs offer a broad range of services, including primary care, dental, behavioral health, and pharmaceuticals. Many of these services – and the sliding fee discounts that make them affordable for our patients – are supported by savings generated through the 340B drug discount program. Many of our patients live with chronic conditions, such as diabetes, hypertension, obesity, that require ongoing medications. Our HIV/AIDS team serves 211 patients who require expensive, life-saving medicines.

Nationally, FQHCs rely on contract pharmacy arrangements to dispense roughly 50-60% of the 340B drugs provided to their patients – the highest percentage of any type of 340B provider. Thus, the 340B savings generated at contract pharmacies support many services that the FQHC would otherwise be unable to provide. Given the importance of 340B savings – including those generated by contract pharmacies – we were very concerned to hear that CMS is considering requiring an indicator (also known as modifier) on all claims for Part D prescriptions that were filled with 340B drugs.

1021 Nebraska Street – Sioux City, IA 51105
712-252-2477 or 888-371-1965
www.slandchc.com

As discussed in detail in comments submitted by other members of the FQHC community, FQHCs' experience clearly indicates that requiring a 340B indicator (also known as a modifier) on Part D drugs would:

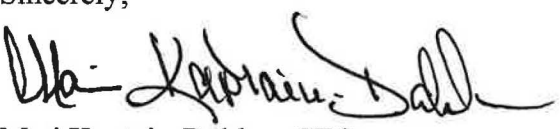
a. Result in data that is highly unreliable.
b. Force FQHCs to shut down many of their contract pharmacy arrangements for Part D drugs, leading to an overall loss in 340B savings and subsequent reduction in services provided to underserved patients.

Instead of a modifier, we recommend that CMS implement a "clearinghouse" model for identifying 340B drugs covered by Part D. Compared to a modifier requirement, a clearinghouse would:

a. Produce much more reliable data.
b. Be significantly less labor-intensive.
c. Preserve the ability of FQHCs and other 340B providers to rely on contract pharmacies to dispense 340B drugs to Part D enrollees, thereby avoiding reductions in access.
d. Could be expanded to include 340B drugs dispensed to Medicaid patients.

Thank you for your consideration of our serious concerns about the modifier model, and our proposed alternative. If you have any questions about our comments, please contact me through the contact information provided below.

Sincerely,



Mari Kaptain-Dahlen, CEO
1021 Nebraska Street
Sioux City, IA 51105
Office Phone: 712-226-9010
mkaptaindahlen@slandchc.com

Southeast Healthcare Inc. dba Apothecare

03/10/2023

Dr. Meena Seshamani, MD, PhD
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: **Concerns about modifier approach for identifying 340B drugs dispensed under Medicare Part D**

Dear Dr. Sheshamani,

On behalf of Southeast Healthcare, thank you for the opportunity to provide input into CMS' plans for implementing the Medicare inflationary rebates established under the Inflation Reduction Act. We are a Mental Health facility located in eight different counties in Ohio. Each one of these facilities is an FQHC which provides Behavioral Health Care, Primary care and Dentistry. We own the Homeless shelter in Columbus, Oh.

As you know, FQHCs are the backbone of the health care safety net, providing high-quality, affordable care to over 30 million medically underserved patients, regardless of whether they have insurance or their ability to pay. *50% of our patients are homeless, which makes it even more challenging. Without an address to send insurance information to, many lose their insurance benefits and fall through the cracks. The 340b program allows us to provide medication to these individuals until we can get them back on insurance.*

FQHCs offer a broad range of services, including primary care, dental, behavioral health, and pharmaceuticals. Many of these services – and the sliding fee discounts that make them affordable for our patients -- are supported by savings generated through the 340B drug discount program. As stated earlier we offer Behavioral Health care, Primary care and Dentistry. We have a PATH van that drives out into the community to service patients who are homeless and will not come in for treatment. We have a MAT program to treat addiction. We actually work with the Franklin County court system, the Police and EMS to help people in crisis. We will meet them in the emergency room to offer our programs regardless of insurance. This is all possible with 340b revenue resources.

Nationally, FQHCs rely on contract pharmacy arrangements to dispense roughly 50-60% of the 340B drugs provided to their patients – the highest percentage of any type of 340B provider. Thus, the 340B savings generated at contract pharmacies support many services that the FQHC would otherwise be unable to provide. Given the importance of 340B savings – including those generated by contract pharmacies – we were very concerned to hear that CMS is considering requiring an indicator (also known as modifier) on all claims for Part D prescriptions that were filled with 340B drugs.

As discussed in detail in comments submitted by other members of the FQHC community, FQHCs' experience clearly indicates that requiring a 340B indicator (also known as a modifier) on Part D drugs would:

a. Result in data that is highly <u>un</u>reliable.

b. Force FQHCs to shut down many of their contract pharmacy arrangements for Part D drugs, leading to an overall loss in 340B savings and subsequent reduction in services provided to underserved patients.

Instead of a modifier, we recommend that CMS implement a "clearinghouse" model for identifying 340B drugs covered by Part D. Compared to a modifier requirement, a clearinghouse would:

a. Produce much more reliable data.
b. Be significantly less labor-intensive.
c. Preserve the ability of FQHCs and other 340B providers to rely on contract pharmacies to dispense 340B drugs to Part D enrollees, thereby avoiding reductions in access.
d. Could be expanded to include 340B drugs dispensed to Medicaid patients.

Thank you for your consideration of our serious concerns about the modifier model, and our proposed alternative. If you have any questions about our comments, please contact Joan Wissinger at Apothecare Pharmacy. I would love to talk to you about all the wonderful things we are able to do. 614-228-4476

Sincerely,

Joan Wissinger

March 11, 2023

Dr. Meena Seshamani, M.D. Ph.D.
CMS Deputy Administrator
Director of the Center for Medicare

Re: Medicare Part B and Part D Inflation Rebate Comments

Dear Dr. Seshamani,

I appreciate the opportunity to respond to CMS's request for comments on Medicare Part B and Medicare Part D inflation rebates. More specifically, I would like to submit comments on the drug shortage provisions included in the inflation rebate section of the IRA.

As Congressional leaders and President Biden have suggested, inflation rebates are meant to curb the almost clockwork increases in prices for many drugs. Nonetheless, Congress recognized that sometimes price increases can be a result of supply shocks – the same supply shocks that may lead to shortages.

In its concern of the impact of inflation rebates on drug shortages, Congress responded in two ways. First, it exempted most drugs at risk of shortage by limiting inflation rebates to single source drugs. Second, it granted CMS the ability to reduce inflation rebates for brands and single source Part D generics.

However, in recognition of perverse incentives that tying shortages to rebates might yield, Congress also granted CMS flexibility in determining appropriate reductions.

CMS would be wise to leverage this flexibility in focusing on low margin products – the relatively rare single source generics and brands with no IP protection – to the extent they are in shortage or at risk of shortage. But CMS must also structure any reductions in a way not to prolong shortages.

In a recently published article, I describe a set of considerations for setting rebate reductions, designed to support the spirit of the inflation rebates while also minimizing the risk of exacerbating shortages:

- Default to minimal reductions
- Distinguish between low margin and high margin products
- Distinguish between current period increases versus pre-existing price increases
- Minimize potential gaming of shortage end date
- Consult with FDA's Drug Shortage Staff

The article, which I also attach to this letter, elaborates on the rationale for each of these recommendations.

Thank you for the opportunity to comment on CMS's implementation of the inflation rebate provisions.

Sincerely,

Marta E Wosińska, PhD
Visiting Fellow
The Brookings Institution

Encl.
Drug shortages and IRA inflation rebates: Considerations for CMS (brookings.edu)

Published at *www.brookings.edu* on February 9, 2023

Author: Marta E. Wosińska, PhD

Editor's Note: *This analysis is part of the USC-Brookings Schaeffer Initiative for Health Policy, which is a partnership between the Economic Studies Program at Brookings and the USC Schaeffer Center for Health Policy & Economics. The Initiative aims to inform the national health care debate with rigorous, evidence-based analysis leading to practical recommendations using the collaborative strengths of USC and Brookings. We gratefully acknowledge financial support from Arnold Ventures.*

Drug shortages of essential medicines such as amoxicillin, saline and epinephrine occur with troubling frequency – in the last few years, the Food and Drug Administration (FDA) has reported around 30 to 50 new drug shortages per year, many lasting months if not years. Due to economic, clinical, and technological factors, shortage drugs tend to be low-cost sterile injectable generics. In contrast, on-patent branded drugs have more resilient supply chains – they are less likely to end up in shortage and they recover faster when a shortage does occur.

In its concern about drug shortages and price spikes that sometimes occur with supply interruptions, Congress put forward provisions in the Inflation Reduction Act (IRA) directing the Centers for Medicare & Medicaid Services (CMS), as an agent of the Secretary, to reduce the newly required Medicare inflation rebates for drugs in shortage.

One concern Congress wanted to address in relation to shortages appears when a low margin producer experiences an input cost increase due to a severe supply disruption. If unable to pass such an increase forward, a low margin producer may choose to exit the market. On the flipside, tying shortage status to inflation rebates creates financial incentives to keep drugs in shortage.

In recognition of the tension between the potential to prevent shortages and exacerbate them, Congress gave CMS flexibility in implementing the drug shortage provision – CMS can waive or reduce inflation rebates, with no direction on the magnitude of the reduction.

In this essay, I propose a set of considerations for setting rebate reductions so that they balance Congressional intent for inflation rebates with the potential impact of waivers and reductions on shortages. To motivate these recommendations, I describe the IRA drug shortage provisions and provide background on how FDA determines whether a shortage exists or has ended. To illustrate how the IRA drug shortage provisions work with different types of drugs, I review the current drug shortage list, before concluding with recommendations to CMS.

As I describe below, by focusing inflation rebates on single source drugs, Congress addresses inflation rebates for majority of drugs in shortage – generics. What is left for consideration under shortage provisions heavily skews towards brands, which already have strong incentives to resolve shortages. For this reason, CMS should focus its analysis on low margin drugs – the relatively rare single source Part D generics and brands with no IP protection – to the extent they are in shortage or at risk of shortage. But CMS must assess the reason for shortage to make sure it meets Congressional intent behind inflation rebates – unsubstantiated price increases. It must also structure any reductions in a way not to prolong shortages.

IRA drug shortage provisions

IRA Sections 11101(a) and 11102(a) directs manufacturers of single source drugs to pay Medicare inflation rebates if prices for those drugs increase faster than the consumer price index. For Part B, the law defines single source drugs as biologics and drugs marketed and distributed under new drug applications (NDAs). For Part D, the law defines single source drugs as biologics, NDAs, and single source generics not subject to "first applicant" FDA programs such as 180-day exclusivity or competitive generic therapy. Under the new law, inflation rebate requirements only apply to single source drugs for which average Medicare annual charges per patient are more than $100.

Rebates paid in a given year are structured to account for both past price increases and decreases. The rebate amount is equal to the total number of units sold in Medicare multiplied by the amount by which a drug's price in a given year exceeds the inflation-adjusted price. The base year for measuring cumulative price changes relative to inflation is 2021.

For single source drugs that do pay rebates – biologics, NDAs, and Part D single source generics – IRA Sections 11101(a) and 11102(a) direct CMS to reduce or waive inflation rebates if those drugs are listed by FDA in shortage during the applicable period.

The IRA also directs CMS to reduce or waive inflation rebates for Part B biosimilars and single source Part D generics that experience "a severe supply chain disruption during the applicable period, such as that caused by a natural disaster or other unique or unexpected event." In general, severe disruptions will cause shortages, but this language directs CMS to also account for situations where no shortage exists in the applicable period. Should CMS determine that such a disruption will likely lead to a *future* shortage of a *generic*, CMS is directed to waive or reduce the generic's *current* inflation rebate.

The law does not provide guidance as to how CMS should determine what level of reduction to provide.

FDA's Drug Shortage List

Because the law specifically ties eligibility for waivers and reductions to FDA's Drug Shortage list, it is important to understand how FDA determines whether a shortage exists.

First, it is important to understand what brings about shortages – situations where supply of a drug falls short of quantity demanded arise. Such a shortfall can happen when there is a sufficiently large supply disruption, or a demand increase, to which the supply chain cannot adjust. The shock can be exogenous (an input price increase or a hurricane that damages a facility) or endogenous (when a company does not follow good manufacturing practices causing batches of the product to be thrown away).

Whether the supply chain can withstand a shock depends on the size of the shock relative to factors such as fungibility of the manufacturing process, the level of spare capacity, and the level of inventory in the system. It also depends on availability of close substitutes and whether the shock affects a bottleneck in the system, such as closure of a single manufacturing plant for a critical product like contrast media.

To determine whether a market-wide shortage exists, FDA defines the relevant market. To do so, FDA considers the clinical implications of the supply disruption in question, for example whether a different dosage level or a different formulation could be used. Typically, the market ends up being defined on the ingredient-route level (injectable doxycycline). This is in contrast to ASHP, another prominent list of drug shortages, which defines shortages at the national drug code (NDC) level.

FDA determines whether a market-wide shortage exists using a variety of data sources. Companies must notify FDA "of a permanent discontinuance or an interruption in manufacturing of the product that is likely to lead to a meaningful disruption in supply." The resulting lead time on potential shortages allows FDA to assess the shortfall using third party data on market share and typical use rates. It also assesses the existing potential for closing that shortfall using manufacturer-provided data on inventories, as well as the ability of the affected and competing manufacturers to restore or ramp up production.

FDA uses a range of tools to prevent impending shortages or mitigate the impact of those that do occur. FDA will expedite the review of any company proposals to resolve the shortage, including qualifying manufacturing changes or qualifying new suppliers. Where appropriate, FDA will use regulatory flexibility, letting companies sidestep FDA requirements if doing so can mitigate a shortage without undue safety risks. For example, FDA may determine that a drug is safe to use past its expiration date or that the product can be dispensed with a filter to remove impurities in the product. FDA also allows compounding of drugs in shortage.

FDA will determine whether to delist a shortage using some of the same inputs it used to determine whether there is a shortage: historical utilization rate for the drug, ordering patterns, and existing levels of inventory.

However, FDA's resolution of shortages is complicated by behavioral responses to shortages. Even in situations where there is a supply disruption, a shortage tends to increase demand for the product as customers try to build up a safety stock. This demand increase exacerbates the shortage and makes it not only longer to resolve but also more difficult to assess because FDA no longer can simply rely on historical use patterns to determine the level of shortfall. Instead, it must rely on company-provided data on demand, in addition to company-supplied data on output and inventory levels.

Drugs currently in shortage

To motivate how CMS should consider implementing the IRA drug shortage provisions, it is instructive to explore drugs currently in shortage. As of January 20, 2023, FDA listed 124 such drugs.

For this discussion, I categorize these drugs in shortage as either multiple source generics, single source generics, "505(b)(2) generics," or branded products. These categories are useful for illustrating drug shortage vulnerability, incentives faced by manufacturers in shortage, and how CMS actions might affect shortages of those drugs.

Multiple source generics

A review of the current list suggests that 75% of these drugs have more than one manufacturer listed – an indication that they are multi-source drugs. This includes drugs like cytarabine for pediatric cancers, amoxicillin oral suspension for treatment of bacterial infections in those unable to take oral dose formulations, and something as basic as sterile water for injection.

Single source generics

Single source generics are just that – one generic drug on the market and no other direct competitors, whether branded or generic. These drugs are older drugs that experience significant exit of generic competitors, leaving just one in the market. This often happens as the market becomes unattractive because of increased availability of other therapeutic substitutes, which not only shrinks the market but also takes away pricing power as better substitutes abound. In some cases, substantive exit is a sign of a drug becoming obsolete. In other cases, this means that the use cases for the drug get narrower.

Unlike in Part B, Part D single source generics are subject to inflation rebates. Based on an analysis of FDA's current shortage list, the Part D Drug Spending Dashboard, and Drugs@FDA, there appear three such drugs currently in shortage: amoxapine tablets, chlorothiazide oral suspension, and methyldopa tables. These kinds of drugs will require attention from CMS.

Single source drugs will also require attention from CMS for another reason – the legislation specifies that single source Part D generics not on the shortage list may be subject to shortage rebate reductions if the manufacturer experienced a severe supply disruption and the disruption has not yet resulted in a shortage but may do so in a future period. An example of a disruption outside of the control of the manufacturer – the kind that the law describes through examples – would be a significant increase in the cost of an input. If margins are sufficiently small, which they might be if the drug faces competition from other molecules, then the manufacturer would need to pass on the cost increases to stay on the market.

505(b)(2) generics

505(b)(2) generics is not a formal term, but an apt description of drugs that that have the same dosage form and active ingredient as the reference brand but could not pursue the standard generic Abbreviated New Drug Application (ANDA) pathway because of differences in inactive ingredients. Generic manufacturers may need to use different inactive ingredients to get around patents. In these situations, FDA recommends a manufacturer files a type of an NDA called 505(b)(2).

From CMS's perspective, the defining feature of a multiple source drug is not whether a drug is approved under an ANDA but whether it has a therapeutic equivalence code listed in FDA's Orange Book. CMS recently issued guidance stating that 505(b)(2) drugs without therapeutic equivalence codes are single source drugs and therefore will be issued separate HCPCS codes. Notably, the drugs listed in that guidance are the low-margin sterile injectable generics that are prone to shortages. Many of those drugs have been or are currently in shortage.

Reviewing the list of drugs currently in shortage, five include 505(b)(2) generics among the set of same-molecule competitors: calcium gluconate injection, chloroprocaine hydrochloride injection, epinephrine injection, midazolam injection, and morphine sulfate injection. Review of the CMS Part B dashboard reveals that all five had average spending per beneficiary below $100. However, there is no assurance that other 505(b)(2) drugs will not cross the $100 threshold, thereby rising to CMS's attention.

Yet unlike with single source generics, this group of drugs may not need to be a concern to CMS but rather to FDA. Qualified drugs can obtain therapeutic equivalent codes if they request them through citizen petitions to the FDA. Currently FDA has a backlog of these petitions but is now required to resolve those petitions within 180 days. FDA may need to dedicate extra resources to resolving the backlog, which might increase if having a therapeutic equivalence code absolves the 505(b)(2) generic from inflation requirements.

Branded products

The current drug shortage list includes 23 drugs marketed under an NDA or BLA, in addition to the five 505(b)(2) generics described above. All 23 brands would appear subject to inflation rebates and therefore eligible for rebate reductions. In contrast, only three generics currently in shortage, all single source Part D generics, would be subject to rebates and therefore potentially eligible for rebate reductions.

In general, brands have more resilient supply chains because high margins earned by their products provide a countervailing incentive to prevent production disruptions. Brands have a greater incentive to

invest in systems that minimize production disruption, to have alternate supply sources, and to maintain spare capacity in case production unexpectedly has to be shut down. When production disruptions occur, they tend to be resolved faster.

But not all brands may have the margins and sales that incentivize fast recovery from shortages. Just as with single-source generics, some brands may not face generic competition because they are unattractive through a combination of size, relative efficacy and safety to other drugs, and sometimes formulation challenges. Of the 23 brands in the current shortage list, 14 appear to have no more IP protection. An analysis of 2020 CMS suggests significant variation of per unit costs for these drugs.

To the extent these old brands provide important benefits to special populations and have low margins, they warrant similar consideration to single source Part D generics. For both groups, the law allows such rebate reductions while the drugs are in shortage but not if the branded drug, even if low margin and low volume, might experience a shortage in a future period.

Recommendations for implementing drug shortage provisions

In considering how CMS should apply its authority to adjust rebate reduction levels according to market conditions, it is important to assess the purpose of giving CMS the ability to waive inflation rebates. One clear rationale is that Congress was seeking to minimize unintended consequences of inflation rebates as they relate to shortages and, in appreciation for the possible unintended consequences, afforded CMS with flexibility on how to deploy the adjustments.

A key unintended consequence of inflation rebates in relation to shortages appears when a low margin producer experiences an input cost increase. To maintain positive margins, the manufacturer would need to pass on those cost increases, but then those cost increases would then have to be rebated back to Medicare. Depending on the level of needed passthrough and share of the drug's sales in Medicare, the manufacturer may not find it feasible to continue marketing the product.

This scenario would not, however, occur with high margin products, whose prices are less tied to marginal cost of production and more to the demand for the product.

On the flipside, attaching potentially sizable dollars to shortages may have unintended consequences.

First, shortages often occur for reasons that are in control of the manufacturer—be it not following good manufacturing practices (GMPs) or not vetting suppliers properly. Providing extra relief in the short term is undoubtedly beneficial but it sends the wrong signal to the manufacturer.

Second, and perhaps more concerning, drug manufacturers control capacity and have superior access to information on market conditions. Sizable rebate reductions would incentivize high margin manufacturers to ramp up production just short of what FDA would consider necessary to close the supply-demand gap.

With these considerations in mind, I propose the following set of recommendations.

Default to minimal reductions

CMS should default to minimal reductions and then ask companies to provide information supporting their request for a greater reduction. This has an additional benefit as such a default can unlock access to FDA information, much of which is proprietary. To obtain higher reductions, companies can authorize FDA to release relevant data to CMS for the sole purpose of determining inflation rebate reductions.

Distinguish between low margin and high margin products

As discussed above, inflation rebates do not adversely affect the high margin manufacturers' ability to stay in the market and they do not lower the incentives of the single-source manufacturer to resolve a shortage. On the other hand, low margin manufacturers closer to a cost-plus pricing structure may be adversely affected by inflation rebates. For this reason, CMS should consider market size, spending per claim, and manufacturing complexity when assessing whether the manufacturer should have inflation rebates significantly reduced.

Consider the reason behind the price increase

Drug supply shocks can cause increases in the cost of goods sold. If a manufacturer is closer to a cost-plus pricing model, it may need to pass through such increases to keep the drug on the market. On the other hand, exercising market power as in the case of the IP-expired brand Daraprim appears as to be exactly the kind of price increases targeted by Congress. Similarly, the clockwork January price increases by many brands are also for what Congress intended inflation rebates. To help assess the role of supply shocks, CMS should distinguish between current period increases versus pre-existing price increases.

Minimize potential gaming of shortage end date

Should CMS decide to offer reductions, it should be wary of tying the reduction to a discrete end of shortage. As described above, manufacturers control the output level and have superior information about demand. If CMS were to abruptly turn off reductions, it could incentivize companies to increase production to just under the level that would close off a shortage. Such an adverse incentive could be mitigated, to some extent, by reducing the rebate reduction as the gap between supply and demand shrinks. Doing so would necessarily require a lot more coordination with the FDA and access to proprietary data. Because much of the data would be company-provided, CMS would have to set up audit processes to verify the veracity of provided information, as needed.

Consult with FDA's Drug Shortage Staff

The FDA Drug Shortage team has intimate knowledge of the relevant drug markets. FDA also does assessments of medical necessity and close substitutes. All these data may be useful in determining when and how CMS should engage.

Conclusion

In its concern of the impact of inflation rebates on drug shortages, Congress responded in two ways. First, it exempted the majority of drugs at risk of shortage by limiting inflation rebates to single source drugs. Second, it granted CMS the ability to reduce inflation rebates for brands and single source Part D generics. However, in recognition of perverse incentives that tying shortages to rebates might yield, Congress also granted CMS flexibility in determining appropriate reductions. CMS would be wise to leverage this flexibility in focusing on low margin products and assessing their reason for price increases.

Acknowledgements: I would like to thank Erin Fox, Richard Frank and Rena Conti for providing useful comments. I would also like to thank Erin Fox, Robin King and Amalis Cordova-Mustafa for their help in characterizing drugs currently in shortage.