This file contains 36 Part B comments received on the 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. As noted in the Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Revised Guidance, Implementation of Section 1847A(i) 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.

March 11, 2023

Dr. Meena Seshamani, M.D. Ph.D
Deputy Administrator and Director of the Center for Medicare
U.S. Department of Health and Human Services
Centers for Medicare and Medicaid Services
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Submitted via IRARebateandNegotation@cms.hhs.gov

RE: 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 B 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 30.1 Identification of Part B Rebatable Drugs</u> - CMS will have to work directly with the FDA to expand the resources utilized to evaluate if a biosimilar qualifies for exclusion as a rebatable product**

In addition to brand drugs and biologics, the statute narrows the scope of part B rebatable drugs to single source drugs or biological products including a biosimilar biological product, but excluding a qualifying biosimilar biological product (as defined in section 1847(b)(8)(B)(iii)). To evaluate if an approved drug meets these criteria, the memorandum notes that CMS intends to use information available at FDA.gov, including approval information (such as labeling and approval letters), therapeutic equivalents as determined by FDA (i.e., those listed in FDA's Orange Book), and available products shown in drug pricing compendia. However, these resources can be dated or can include inaccurate information. FDA's Drugs@FDA database and FDA's Electronic "Orange Book", while valuable, are not always a source for reliable information.

Additionally, in order for a manufacturer to best predict how a rebatable drug might be determined is dependent on when updated information is available through the FDA. The guidance outlines CMS' intent to provide all manufacturers of Part B rebatable drugs with a Preliminary Rebate Report within 6 months of the end of each applicable period, however, it does not indicate how CMS will determine the specific date on which the agency will solicit data from the FDA. Also, because this market fluctuates regularly, eligible single source drugs in Part B could become multiple source drugs at the start of and/or during a calendar quarter. This makes it difficult for manufacturers to accurately predicts if and when the entrance of a competitor's product will nullify the inclusion of their drug in the inflation rebate program.

To mitigate this, 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. In doing so, <u>we recommend CMS identify a specific date on which they will evaluate public FDA resources to make their determinations and use an approach for Part B rebatable drugs, similar to that for Part B drugs, that identifies if a product is single source using the date of first sale and prorates the timeline for the inflation penalty accordingly.</u> Manufacturers would then be provided an opportunity to share confirmatory or contradictory details on the status and nature of their products.

- **<u>50.8.1 Removal of 340B Units</u> - CMS should ensure that providers include a 340B indicator on claim forms.**

We commend CMS for their effort to ensure that rebates are not paid for products purchased by 340B entities. Avoiding this type of double-penalty is critical to program integrity. The proposed requirement that providers 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 eliminate units acquired by the 340B program from the total number of rebatable units assessed, determine a process for which manufacturers have a basis to submit disputes and to implement this process as soon as possible.

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

- **60.2 Manufacturer Suggestions of Calculation Errors in Preliminary Rebate Reports and Preliminary True-Up Reports – CMS should provide clarity for manufacturers on which products will be considered rebatable and the anticipated rebate amount to allow for manufacturers to appropriately forecast their financial obligations.**

The memorandum discusses the transition period that allows CMS to delay invoices 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.

- **60.1 Timing of Reports and Payment – 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 from 500 to 1000 SKUs. Because program participants will not be aware of which NDCs are considered rebatable until their initial Rebate Report is produced, it would be challenging for a manufacturer's pricing 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 both manufacturers and CMS.

- **Section 60.3 Restatements and True-Up 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 the AMP data for any error or change (other than lagged price concessions ratio) within a 3-year window. While 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 wouldn't 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 to once per 3-year period, 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 some discretion in determining when a drug is in shortage and may be excluded from inflation penalty rebates. Congress provided the Secretary with this discretion in order to avoid compounding the supply challenges associated with drug shortages while balancing incentives against price increases. Some of the more common causes of drug shortages include delays in receiving raw materials and components from suppliers, and discontinuations in product manufacturing. Unpredictable, onerous penalties on often low-margin medicines create significant risk for manufacturers that would consider entering these markets and generate challenging circumstances for manufacturers to continue participating in those markets, ultimately resulting in negative impacts on patient access. As the agency continues to develop this policy, we strongly recommend that CMS use an expanded definition of what constitutes a shortage to avoid unnecessary penalties and protect beneficiary access.

- **50.10 Reduction or Waiver of the Rebate Amount for Part B Rebatable Drugs in Shortage and in Cases of Severe Supply Chain Disruptions - CMS should structure this policy in manner that prioritizes the reduction of drug shortages**

The Inflation Reduction Act grants the Secretary discretion to waive or reduce inflation penalty rebates when a drug is in shortage. Congress intended this provision to prevent price increases exceeding inflation without compounding the challenge of drug shortages, including the ability of a drug manufacturer to exit or avoid a potential shortage. We are therefore concerned by portions of the memorandum that seem more concerned with avoiding "incentives for misuse" than with preventing 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 Federal Food, Drug and Cosmetics Act (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.[2] The industry reports shortages, supply

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

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. In order 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.

- **50.11 Reducing or Waiving the Rebate Amount in the Case of a Part B Rebatable Drug on the Shortage List Recommendation - CMS should waive rebates for drugs in shortage unless unique extenuating circumstances apply.**

Section 50.11 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 B 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 B rebatable drug are "current" on the shortage list?
3. Are there specific types of Part B rebatable drugs where CMS might reduce or waive the rebate amount differently, and why would such an approach be necessary?
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 B 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 B rebatable drug on the shortage list so as to avoid a rebate obligation?

AAM strongly believes that the default approach for Part B 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 is most in alignment with 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 noted above, 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.
    c. In the generic market, 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 it first started.
3. That said, shortages are not limited to generic drugs. If CMS is concerned about abuse and instances where it should take a different approach, it may wish to consider varying approaches tailored to the unique differences between brand and generic market dynamics.

- **<u>Section 50.12 Reducing or Waiving the Rebate Amount for a Severe Supply Chain Disruption for a Part B Rebatable Biosimilar Biological Product -</u> CMS should lengthen the time period for a manufacturer to request a reduction or waiver in a severe supply chain disruption**

Section 50.12 requires CMS to 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". CMS should lengthen the time period for manufacturers to submit a request to 90 or 120 days.

In addition, CMS should interpret this authority 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.

Finally, CMS solicits comment on the amount and duration to reduce or waive the rebate amount in this scenario. 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.

Overall, we appreciate CMS providing advance 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 B 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 B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the Social Security Act, and Solicitation of Comments* (referred to below as the Part B 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 B 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

[1] Implementing section 1847A(i) of the Social Security Act (the SSA), as amended by section 11101 of the Inflation Reduction Act (Codified at 42 U.S.C. § 1395w-3a(i)).
[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.").

forth below are intended to enhance the safeguards needed to achieve greater program integrity as 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:

- **Removal of Excluded Units (Section 50.8):**
    - Medicare Advantage units are not subject to the Part B inflation rebate, per the IRA.
    - In addition to flagging 340B units using the JG and TB modifiers, CMS should require a claims modifier to identify non-340B units, to determine statutorily excluded units more accurately.
    - CMS should create an enforcement mechanism to ensure that 340B covered entities and their contract pharmacies, if applicable, accurately and consistently use such claims modifiers.
- **Rebate Calculation, Where Multiple NDCs Share HCPCS Code (Section 50.13):**
    - As CMS has confirmed, multiple source drugs—including those within the same billing and payment code as of October 1, 2003, must be treated as multiple source drugs and are not Part B Rebatable Drugs. For other drugs that do not meet this statutorily required exclusion, CMS should revise the methodology for allocating financial responsibility for rebate responsibility where multiple NDCs share the same HCPCS code to contribute to the average sales price (ASP) dollars, and not merely the converted billing units, associated with those NDCs.
- **Rebate Reports (Section 60):**
    - CMS should provide additional time, for manufacturers to comment on such reports and should provide manufacturers a date certain in each rebate cycle when all 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 for 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 ASP and other data more adequately.

abbvie

REQUESTS, OBJECTIONS, AND RECOMMENDATIONS

I. REMOVAL OF EXCLUDED UNITS (SECTION 50.8)

A. Medicare Advantage units are not subject to the Part B inflation rebate.

Per the IRA, "Part B rebatable drug" is defined as "a single source drug or biological . . . , including a biosimilar biological product . . . but excluding a qualifying biosimilar biological product . . . *for which payment is made under this part* . . . ."[3] "This part" refers to Part B of Title 18 of the Social Security Act. Payments by MA plans are made under Medicare *Part C*, not Part B.[4]

For reasons that are unclear and unspecified, CMS proposes to include MA units in the Part B inflation rebate utilization. However, CMS does not articulate *why* it believes that MA units are or may be subject to the Part B inflation rebate; it nonetheless seeks input on the operational considerations for implementing the rebate with respect to MA units.[5] Operationalizing such an expansion in rebate liability would violate the statute. The only units subject to the Part B inflation rebate are those for which payment is made under Medicare Part B. Moreover, as a practical matter, there does not appear to be an accurate or meaningful way to ensure that 340B utilization reimbursed by MA plans is excluded from the rebate calculation as required by the statute: Manufacturers do not have access to MA utilization data, and CMS does not require 340B modifiers in the MA program.

B. CMS should require a claims modifier to identify <u>non</u>-340B units, in addition to the JG and TB modifiers to identify 340B units.

By statute, units with respect to which a manufacturer provides a 340B discount or rebate (referred to below as 340B units) are excluded from Part B inflation rebate utilization.[6] In the Part B Rebate Guidance, CMS states that it will identify and exclude from Part B inflation rebate utilization separately payable units in claim lines billed with an applicable "JG" or "TB" modifier.[7] AbbVie appreciates this approach and agrees that this is one important way to adhere to the dictates of the statute and minimize duplicate discounting across the programs. Using "JG" and "TB" modifiers is particularly apt given that many 340B covered entities that are reimbursed under the Medicare Part B outpatient prospective payment system are already billing using these modifiers, and others will be required to do so beginning in 2024.[8] In addition, CMS has stated that, for 2023, it will remove certain institutional units, which we support as a necessary interim measure pending universal required use of a "JG" or "TB" modifier starting in 2024.[9]

Both of the approaches CMS discussed in the Part B Rebate Guidance should work together to help ensure that 340B units are not also invoiced for Part B inflation rebates. However, additional steps are necessary to ensure that the statutory restriction on billing for Part B inflation

[3] Social Security Act (SSA)§1847A(i)(2)(A) (emphasis added).
[4] *See Id.* § 1852(a).
[5] Part B Rebate Guidance § 50.8.5 (Feb. 9, 2023).
[6] SSA § 1847A(i)(3)(B)(ii)(I).
[7] Part B Rebate Guidance § 50.8.1.
[8] *Id.*
[9] *Id*.

rebates on 340B units is implemented appropriately. Specifically, CMS should require all 340B covered entities or contract pharmacies that submit claims to Medicare Part B to identify, through claims modifiers, where *either* 340B units *or* *non*-340B units are dispensed/administered, in order for a claim to be considered complete and payable.

Existing modifiers "JG" and "TB" are useful insofar as each designates a drug or biological acquired under the 340B drug pricing program at the time of billing. Without a corollary *non*-340B modifier, however, providers may selectively evaluate sites of care or categories of drugs for 340B status in applying these modifiers, missing the identification of 340B units across their larger portfolio of care. The addition of a modifier for non-340B status ensures that providers and suppliers will evaluate and affirmatively designate the 340B status of the entire universe of drugs billed to Part B, and thereby enhance the integrity of the Part B inflation rebate process.

C. CMS should ensure that 340B covered entities accurately and consistently use the new 340B claims modifiers.

AbbVie urges CMS to implement enforcement mechanisms designed to ensure compliance with appropriate claims modifier requirements. *For instance, CMS should consider instructing MACs to reject claims if the applicable modifier is not utilized.* Enforcing the use of 340B claims modifiers is critical to the integrity of the Medicare Part B rebating process, as studies have shown that 340B covered entities are otherwise unlikely to accurately and consistently use such modifiers.[10] A recently published study by health information technology firm IQVIA found: "[340B 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. 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."[11]

We are aware that some states have contravening laws prohibiting certain entities from using 340B claims modifiers. CMS should recognize that Medicare billing requirements preempt any such state laws to the extent providers are billing Medicare (whether primary or secondary).[12]

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[10] *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.

[11] *Id.* at 10.

[12] *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.").

II. REBATE CALCULATION WHERE MULTIPLE NDCS SHARE THE SAME HCPCS CODE (SECTION 50.13)

A. CMS should revise the proposed methodology for allocating financial responsibility for rebate responsibility where multiple NDCs share the same HCPCS code to account for the ASP dollars, and not merely the converted billing units, associated with those NDCs.

As CMS has confirmed, multiple source drugs described in SSA section 1847A(c)(6)(C) are excluded from the definition of Part B Rebatable Drugs.[13] Accordingly, drugs that are within the same billing and payment code as of October 1, 2003, must be treated as multiple source drugs and are not Part B Rebatable Drugs.[14]

For other drugs that do not meet this statutorily required exclusion, drugs marketed by more than one producer or distributor can be "single source drugs" for purposes of the Part B inflation rebate, and such products have distinct NDCs. CMS acknowledges in the Part B Rebate Guidance that "NDCs for all such manufacturers would, in most instances, be assigned to the same HCPCS code(s) and each manufacturer (including repackagers and relabelers) would be responsible for reporting ASP data to CMS, which includes sales volume."[15] The payment amount for the shared HCPCS code is generally determined after CMS calculates a single, weighted average ASP across all the NDCs in the code.

The Part B Rebate Guidance indicates that CMS will allocate rebate liability across the manufacturers of the different single source NDCs in a HCPCS code, should the code become subject to a Part B inflation rebate. The proposed allocation methodology would apportion the rebate liability based on each manufacturer's reported unit-based volume of the NDC within the HCPCS code. That means that a manufacturer that reports more unit volume (as converted from ASP units to billing units) would be liable for proportionally more of the rebate liability than a manufacturer that reports proportionally less unit volume.

This proposed apportionment methodology does not take into account the amount by which a given NDC has contributed to the overall ASP increase over time for a given HCPCS code, such that one of those manufacturers may contribute disproportionally to the calculation of the per-unit rebate amount based on its individual pricing decisions and without regard to unit volume alone. We appreciate that CMS recognizes the need to allocate inflation rebate liability across the NDCs of the distinct manufacturers in such a scenario, but the units-based methodology described in the Part B Rebate Guidance should be revised to account for each NDC's reported ASP value as well. That will ensure that the allocation of rebate liability is "apples to apples," such that a manufacturer's contribution to the amount of a Part B inflation rebate depends, appropriately, on both the number of reported billing units as well as the rate of increase of its NDC's ASP. The methodology described in the Part B Rebate Guidance for allocating rebate responsibility addresses only the first but not the second of those two variables.

[13] Part B Rebate Guidance § 30.
[14] SSA section 1847A(c)(6)(C)(ii).
[15] Part B Rebate Guidance § 50.13.

III. REBATE REPORTS (SECTION 60)

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 B inflation rebates within 30 days after receiving an invoice from the Secretary.[16] The Part B 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.[17] The Part B Rebate Guidance proposes that manufacturers will have only 10 calendar days to review any 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 inadequate process for this critical obligation that is imposed upon manufacturers, given the significant dollar amounts anticipated to be paid in Part B 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 time frame.

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 Report for such cycle will be transmitted to manufacturers. Given the importance of the review process and 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

[16] SSA § 1847A(i)(1)(B).
[17] Part B Rebate Guidance § 60.

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: "the total number of units of the billing and payment code(s) for each Part B rebatable drug for the calendar quarter; the amount (if any) of excess average sales price increase for the Part B rebatable drug for the given quarter; and the rebate amount for the Part B rebatable drug for the given quarter."[18] The Part B Rebate Guidance does not specify what information will 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 manufacturer to analyze and identify unit discrepancies. Such data are equally critical to provide in connection with the Part B 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.[19]

There is no required process by which to restate ASP data. In order to better align with the analogous restatement timeframe 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). That would better ensure that restatements of ASP (as well as other data) are accounted for, and thereby enhance the accuracy of any true ups.

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[18] *Id.* § 60.1.
[19] *Id.*

abbvie

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AbbVie appreciates this opportunity to provide input on the Part B Rebate Guidance. We appreciate that CMS has been tasked with implementing a major IRA-imposed undertaking in a short time frame, 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 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.

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March 11, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: Medicare Part B Inflation Rebate Comments

Dear Administrator Brooks-LaSure:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) initial guidance regarding certain Inflation Reduction Act (IRA) requirements. Specifically, CMS has issued guidance on establishing an inflation rebate for certain single source drugs and biosimilar biological products covered by Medicare Part B when drug companies raise the prices of these drugs faster than the rate of inflation.

The AHA supports the agency's guidance, which will help rein in the high and rising price of drugs through the implementation of inflationary rebates that apply to the Medicare Part B programs. Pharmacy-related expenses represent the fast-growing and, oftentimes, most unpredictable portion of a hospital's budget. High launch prices and continued price increases throughout the year for products already on the market make the current drug pricing environment unsustainable. Similarly, the high cost of drugs for Medicare beneficiaries can force individuals to make difficult decisions about their health care while also obligating the federal government with excessive cost. Inflationary rebates represent one mechanism that can help manage these challenges. Such policies have already demonstrated success through their use in the Medicaid program, which consistently achieves better pricing on drugs than Medicare. The implementation of a similar inflation cap on the price of drugs under the Medicare program should demonstrate similar success. Once established, this policy, in addition to generating savings, will protect the program and beneficiaries from dramatic price increases for drugs, such as the recent 533% for Miacalcin (used for treating bone

disease), 638% increase for Neostigmine (used in anesthesia) and staggering 1,261% increase for Vasopressin (used to treat diabetes and bleeding in critical care).

In order to make CMS's guidance on implementing the IRA Medicare Part B program inflationary rebates even more effective, we urge the agency to make two changes, discussed further below. Specifically, we urge the agency to:

- Mitigate the risk of incentivizing drug companies to artificially extend the duration of shortages of drugs to receive reductions in the IRA's inflation rebate.

- Not require the use of "JG" and "TB" modifiers for drugs purchased under the 340B program in implementing the IRA's inflation rebate.

MITIGATE THE RISK OF INCENTIVIZING DRUG COMPANIES TO ARTIFICIALLY EXTEND SHORTAGES IN ORDER TO RECEIVE REDUCTIONS IN THE INFLATION REBATE AMOUNT

Drug shortages have many causes, ranging from raw material sourcing, to manufacturing problems (quality control and compliance issues), to drug company consolidation and business decisions that result in drugs being discontinued. Hospitals and health systems have long been concerned about chronic and increasing drug shortages which have serious consequences for patient safety, quality of care and access to therapies. Addressing drug shortages is complex and costly to hospitals and health systems in terms of staff time and other resources required to manage the shortages, as well as the increased cost of buying alternative drugs "off contract."

The IRA includes provisions that require CMS to reduce or waive the rebate amount for a Part B rebatable drug when the drug is described as currently in shortage on the Food and Drug Administration's (FDA) drug shortage list. It also requires the same for a biosimilar biological product when the Secretary determines there is a severe supply chain disruption, such as that caused by a natural disaster or other unique or unexpected event.

In its initial guidance, CMS requests comments on how it can carry out this mandate in a way that does not create incentives for drug companies to misuse the drug shortage reporting process by intentionally maintaining their drug or biological is in shortage for the purpose of avoiding an obligation to pay a rebate. It notes that it is considering two options for implementing this policy. The first option is applying a variable reduction in the rebate amount that decreases with the length of time that a rebatable drug is on FDA's shortage list. The second option is applying a limited standard reduction in the rebate amount for a rebatable drug on the FDA's list with a reporting process under which drug companies may request a higher reduction or waiver for certain types of shortages.

The AHA recommends that CMS adopt the second option. This has the advantage of encouraging close coordination between CMS and FDA in order to validate drug company claims that increased relief from the rebate is needed. To obtain higher reductions, drug companies would have to participate in a reporting process under which they could request a higher reduction or waiver for certain types of shortages. In this process they would need to permit FDA to release relevant and likely proprietary data to CMS for the sole purpose of determining inflation rebate reductions. Such a process would provide guardrails against drug companies exaggerating or falsifying claims for extended or higher financial relief from paying the full rebate amount.

In assessing whether the drug company should have rebates significantly reduced or waived, the AHA recommends that CMS consider market size, spending per claim and manufacturing complexity. Specifically, according to a report from the Brookings Institution,[1] inflation rebates are less likely to adversely affect the ability of drug manufacturers producing high margin drugs to stay in the market because their prices are less tied to the marginal cost of production and more tied to the demand for the product. On the other hand, drug companies producing low margin drugs may be adversely affected by inflation rebates. A possible unintended consequence of inflation rebates for low margin drugs in shortage occurs when an input cost increases. According to the Brookings report, to maintain positive margins, the drug company would need to pass on those cost increases, but those cost increases would then have to be rebated back to Medicare. Depending on the level of needed pass through and share of the drug's sales in Medicare, the drug company may not find it feasible to continue marketing the product.

Finally, the AHA encourages CMS to work together with the FDA in determining whether to offer financial relief to drug companies with drugs on the FDA's drug shortage list and biosimilar biological products experiencing a severe supply chain disruption. The FDA drug shortage team has intimate knowledge of the drug markets, including assessing the medical necessity of drugs and therapeutic substitutes in the event of shortages. It determines whether a particular drug shortage is posted as active and when it has been resolved. FDA tracks industry data such as sales over time and can request drug company and wholesaler inventory data as well. All these data may be useful in determining when and how CMS should apply its authority.

DO NOT REQUIRE THE USE OF "JG" AND "TB" MODIFIERS FOR DRUGS PURCHASED UNDER THE 340B PROGRAM IN IMPLEMENTING THE REBATE

The IRA specifically excludes units of drugs that were purchased under the 340B program from being subject to the inflation rebate. In this initial guidance, CMS states that effective implementation of the Part B inflation rebate requires identifying units of

[1] "Drug shortages and IRA inflation rebates: Considerations for CMS", Brookings Institution, https://www.brookings.edu/essay/drug-shortages-and-rebates/ accessed on March 2, 2023.

drugs acquired through the 340B program for purposes of determining the Part B inflation rebate. Therefore, the guidance instructs all 340B covered entities to use the "JG" and "TB" modifiers (depending on the type of 340B hospital) for all Medicare Part B claims as soon as possible, but beginning no later than Jan. 1, 2024.

These claim modifiers were first introduced in the calendar year 2018 Outpatient Prospective Payment System (OPPS) rule as part of a policy to cut Part B reimbursement to certain hospitals participating in the 340B program. However, this policy was found to be unlawful by the U.S. Supreme Court in its unanimous ruling in *American Hospital Association v. Becerra* and is no longer in place. Despite this fact, CMS has chosen to continue to require certain 340B hospitals to use these claims modifiers to identify 340B drugs within the OPPS. CMS' IRA guidance would now require ***all*** 340B hospitals to use them going forward, even those that were previously not required to use these modifiers for 340B claims. In this case, CMS does have other viable alternatives that would be less burdensome on hospitals. For example, the agency could exclude all units of separately-payable outpatient drugs identified using the claim status indicator "K" that are billed by hospitals that participate in 340B. CMS also has the ability to identify which hospitals are currently participating in 340B, since that list is public and available through the Health Services and Resources Administration (HRSA) website. Under this alternative, the agency could use a far less burdensome approach, while still adhering to the IRA provision.

As many hospitals have reported, the use and implementation of modifiers adds significant administrative burden since it requires considerable investment in systems and staff time to ensure that the modifiers are appropriately appended to the claims. Forcing all 340B hospitals to undertake this cost and staff burden directly contravenes CMS' longstanding policy to reduce provider burden, especially when less burdensome alternatives exist. This is especially true at a time when many hospitals around the country are resource-strapped as they continue to deal with the aftereffects of the COVID-19 pandemic and the rapid growth in expenses and inflation.

The AHA urges the agency not to require the use of these modifiers for separately-payable drug claims purchased under the 340B program for implementation of the Medicare Part B inflation rebate. These modifiers are no longer used for Medicare Part B payment purposes, and while we recognize the value the inflation rebate offers in constraining the growth of high drug prices, its implementation should not come at the expense of 340B hospitals. Instead, AHA recommends that CMS consider alternatives that are less burdensome for 340B hospitals as we outline above.

We appreciate your consideration of these issues. Please contact me if you have questions or feel free to have a member of your team contact Roslyne Schulman, AHA's director for policy, at rschulman@aha.org.

Sincerely,

/s/

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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
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Washington D.C. 20201

Re: Medicare Part B Inflation Rebate Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the 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 B Inflation Rebate Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the 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 issues raised by CMS in the Initial Memorandum are summarized as follows:

I. RECOMMENDATIONS REGARDING THE DEFINITION OF PART B REBATABLE DRUG AND UNITS SUBJECT TO THE REBATE CALCULATION

A. Under the plain language of the statute, Medicare Advantage (MA) units are not subject to a Medicare Part B inflation rebate.

B. We support the universal requirement to use a 340B claims modifier starting in 2024 (and the interim approach to excluding 340B units in 2023), but CMS should require use of *either* a 340B *or* a non-340B claims modifier, as applicable, for each unit billed under Medicare Part B and specify that such a modifier is necessary for a claim to be considered complete and eligible for reimbursement.
C. We commend CMS for excluding units that are packaged into the payment amount for an item or service and are not separately payable (i.e., bundled units) from the calculation of the Medicare Part B inflation rebate.
D. CMS should exclude units subject to a discarded drug refund from the units subject to a Part B inflation rebate

II. RECOMMENDATIONS REGARDING APPORTIONMENT OF REBATE LIABILITY WHERE AVERAGE SALES PRICES (ASPS) OF MULTIPLE MANUFACTURERS' NATIONAL DRUG CODES (NDCS) ARE USED TO CALCULATE A PAYMENT AMOUNT

A. The allocation methodology should account for each NDC's ASP and its respective contribution, if any, to the amount by which the payment amount for the rebate quarter exceeds the inflation-adjusted payment amount for the benchmark quarter.
B. ASP-reported units that do not qualify as Part B rebatable drugs should not be used to allocate rebate liability.

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. 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 ASP.

We discuss these comments below.

I. RECOMMENDATIONS REGARDING THE DEFINITION OF PART B REBATABLE DRUG, AND UNITS SUBJECT TO THE REBATE CALCULATION

A. Under the Plain Language of the Statute, MA Units Are Not Subject to a Medicare Part B Inflation Rebate

CMS may not include units furnished to Medicare beneficiaries who are enrolled in MA in the calculation of the Part B inflation rebate as doing so would be contrary to the plain language of the statute.

Under the Inflation Reduction Act (IRA), manufacturers must pay a rebate for Part B rebatable drugs calculated as "the product of [] the total number of units . . . for the billing and payment code of such drug; and [] the amount (if any) by which [the Part B payment amount] exceeds [] the inflation-adjusted payment amount . . . for such part B rebatable drug during the calendar quarter."[1] "Part B rebatable drug" is defined as "a single source drug or biological . . . , including a biosimilar biological product . . . but excluding a qualifying biosimilar biological product . . . ***for which payment is made under this part*** . . . ."[2] "This part" refers to Part B of title 18 of the SSA—in short, a Part B rebatable drug is defined as a drug for which payment is made under Medicare Part B (and not under MA).

Moreover, the statute expressly provides for the exclusion of certain units from the Part B inflation rebate calculation, including "the number of units for such billing and payment 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***."[3] CMS finances MA benefits through a capitated payment on a per member per month basis for all items and services, and thus CMS does not make separate payments for MA units of a drug.[4]

Despite the clarity of the statute, CMS, in its initial guidance on the Part B inflation rebate, signals an intent to include MA units in the Part B inflation rebate calculation. In doing so, CMS does not identify any authority for doing this; it instead skips over this critical threshold consideration and solicits comment on how to operationalize the rebate with respect to MA units.[5] The "significant operational complexities" associated with the removal of these units only reinforces that these units are not intended to be included in the Part B inflation rebate calculation in the first place.[6]

For example, MA plans submit utilization data to CMS well after the time frame in which they are needed to calculate Part B inflation rebates. CMS has reported that 90 percent of fee-for-service data are submitted within three months, 96 to 99 percent within six months, and nearly 100

[1] SSA § 1847A(i)(3)(A).
[2] *Id.* §1847A(i)(2)(A).
[3] *Id.* § 1847A(i)(3)(B).
[4] *Id.* § 1853(c).
[5] CMS, Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the SSA, and Solicitation of Comments, § 50.8.5 (Feb. 9, 2023) (hereinafter Part B Inflation Rebate Guidance).
[6] *Id*.

percent within twelve months.[7] In contrast, CMS has reported that MA plans submit between 61 and 72 percent of their encounter data to CMS within three months, 80 to 86 percent within six months, and 92 to 95 percent within twelve months.[8] If Congress had intended CMS to include MA units in the Part B inflation rebate, it would have addressed this discrepancy by giving CMS more time to issue Part B inflation rebate invoices so as to account for MA units, i.e., within one year of the end of a rebate quarter, as opposed to six months.[9] Given this statutory deadline, CMS would have to lean heavily on true-ups of Part B inflation rebates if it were to proceed to assess Part B inflation rebates on MA units, a process that, though welcome, is not provided for by statute, further indicating that Congress did not intend to include MA units in the Part B inflation rebate calculation. Including such units in the calculation, thus, would create a substantial amount of uncertainty about rebate liability for manufacturers while CMS tries to collect and process the MA unit data through the true-up process.

As another example of the operational complexities posed by including MA units in the rebate calculation, the Medicare Payment Advisory Commission (MedPAC) has found a lack of accuracy and completeness in MA encounter data reporting.[10] Inaccurate and incomplete data could only exacerbate the challenges CMS is already facing with respect to the proper removal of excluded units from Part B inflation rebates.

Again, only units for which payment is made under Medicare Part B may be subjected to a Part B inflation rebate. Thus, CMS may not include MA units in the calculation of the Part B inflation rebate, by the plain terms of the statute.

B. CMS Should Require the Use of Either a 340B or a Non-340B Claims Modifier, as Applicable, for Each Unit Billed Under Medicare Part B and Specify That Such a Modifier Is Necessary for a Claim to Be Considered Complete and Eligible for Reimbursement

Part B inflation rebates may not be invoiced on units on which a manufacturer has provided a 340B discount or rebate (referred to herein as 340B units).[11] In the initial guidance, CMS provides that it will identify and exclude separately payable units in claim lines billed with an applicable JG or TB claims modifier.[12] CMS created these modifiers in 2018 to support the identification of 340B units for Medicare billing purposes; the JG modifier was described as identifying a "[d]rug or biological acquired with 340B drug pricing program discount," and the TB modifier was described as identifying a "[d]rug or biological acquired with 340B drug pricing program discount, reported

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[7] CMS Preliminary COVID-19 Data Snapshot Overview, at 3 https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-services-through-2021-08-21.pdf (last accessed Mar. 7, 2023) (discussing the lagged MA encounter data and their impact on the accuracy of COVID-19 claims data).
[8] *Id*.
[9] *See* SSA § 1847A(i)(1)(A).
[10] *See generally* MedPAC, Ensuring the Accuracy and Completeness of Medicare Encounter Data (Jun. 2019).
[11] SSA § 1847A(i)(3)(B)(ii)(I).
[12] Part B Inflation Rebate Guidance, § 50.8.1.

for informational purposes."[13] Certain 340B covered entities reimbursed under the outpatient prospective payment system thus are already billing using these modifiers.[14]

Starting in 2024, CMS will require all other 340B covered entities to include the JG or TB modifier on claim lines for units acquired under the 340B program to enable their exclusion from Part B inflation rebates.[15] Notably, that means the TB modifier will begin to be used for more than merely informational purposes. In the interim (i.e., in 2023), CMS will exclude all units of such 340B covered entities, in light of the lag in their obligation to use a 340B claims modifier.[16] Amgen supports CMS's decision to require use of 340B modifiers to ensure that 340B units are properly excluded when calculating the inflation rebate in accordance with the statute, as well as CMS's interim solution for 2023.

Amgen urges CMS to take additional steps to ensure that 340B units are appropriately identified at the time a unit is billed and thus can be properly excluded from the Part B inflation rebate calculation. Providers and suppliers must agree to "submit claims that are accurate, complete, and truthful" when they participate in Medicare.[17] CMS should build on this requirement and require providers and suppliers to identify each unit as *either* 340B *or* non-340B as a condition of receiving payment for a "complete" claim. Specifically, CMS should:

- Require use of a claims modifier to identify *non*-340B units, in addition to the JG or TB claims modifier to identify 340B units, as applicable; and
- Specify that accurate use of the JG or TB claims modifier, or the non-340B claims modifier, as applicable, is not only required but also necessary for a claim to be considered complete and eligible for reimbursement.

Without a non-340B claims modifier, providers and suppliers may only selectively evaluate units across its portfolio of care for 340B status, and thereby miss the identification of 340B units. The addition of a claims modifier for non-340B status will require providers and suppliers to affirmatively designate the 340B status of each and every unit billed to Part B and thereby better ensure the integrity of the Part B inflation rebate process.

Adopting a requirement that accurate use of either a 340B or a non-340B claims modifier is necessary for a claim to be considered complete and payable will further enhance the integrity of the process. It will establish a meaningful mechanism for incentivizing compliance and penalizing non-compliance because, as noted above, covered entities will be required to consider whether

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[13] At the time these modifiers were created, the JG modifier was used to identify 340B drugs billed under Medicare Part B that were to be reimbursed at a reduced rate—ASP less 22.5 percent. CMS, Medicare-FFS Program: Billing 340B Modifiers Under the Hospital Outpatient Prospective Payment System, https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/billing-340b-modifiers-under-hospital-opps.pdf (Apr. 2, 2018). The TB modifier was created to identify 340B units for informational purposes, and thus its use did not impact the reimbursement rate. *Id*. Subsequently, the Supreme Court invalidated the reduced reimbursement for 340B units. *Am. Hosp. Ass'n v. Becerra*, 142 S. Ct. 1896 (Jun. 15, 2022).

[14] Part B Inflation Rebate Guidance, § 50.8.1.

[15] *Id.*

[16] *Id*.

[17] CMS, Medicare Claims Processing Manual, ch. 24, § 30.2 (Feb. 19, 2019).

each and every unit billed is 340B eligible and will not be paid if they do not identify each and every unit as one or the other.

C. We Commend CMS for Excluding Units That Are Packaged into the Payment Amount for an Item or Service and Are Not Separately Payable (i.e., Bundled Units) from the Calculation of the Medicare Part B Inflation Rebate

The IRA provides that the total number of units for purposes of calculating the Part B inflation rebate does not include, among other types of units, units that "are packaged into the payment amount for an item or service and are not separately payable," i.e., bundled units.[18] In its guidance, CMS confirms that it will exclude bundled units from its inflation rebate calculations, as it will include units "for separately payable claim lines for Part B rebatable drugs only" when counting units for purposes of the Part B inflation rebate calculation.[19] We thank CMS for confirming that it will follow the clear directive of the statute by excluding bundled units from the calculation.

D. CMS Should Exclude Units Subject to a Discarded Drug Refund from the Units Subject to a Part B Inflation Rebate

By statute, manufacturers must pay a refund for a single-dose container or single-use package of a single source drug or biological reimbursed under Medicare Part B under specified circumstances.[20] The refund is calculated as the amount by which the payment rate for the drug for the quarter multiplied by the total number of units of the billing and payment code for the drug for such quarter exceeds ten percent of the total allowed charges for the drug.[21] Since January 1, 2017, Medicare Part B has required providers to bill discarded units of a "single use vial or other single use package" using the JW modifier; this modifier is now used to implement the discarded drug refund.[22] For a unit of a discarded drug subject to a refund, Medicare Part B effectively does not pay for such unit.[23]

CMS should exclude units subject to a discarded drug refund from the calculation of units on which a Part B inflation rebate is due. As explained above, as a result of discarded drug refund, Medicare Part B effectively does not pay for a unit of a discarded unit drug subject to a refund. As such, if such units were subject to Part B inflation rebates, manufacturers would perversely be paying rebates on units that Medicare Part B is not paying for. The purpose of the Part B inflation rebate statute—ensuring that Medicare Part B is not paying for price increases that outpace inflation—is simply not implicated where Medicare Part B is not paying at all.[24]

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[18] SSA § 1847A(i)(3)(B).

[19] Part B Inflation Rebate Guidance, § 50.8.3.

[20] SSA § 1847A(h)(2), (8).

[21] *Id.* § 1847A(h)(3), (4).

[22] Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule, 87 Fed. Reg. 69,404, 69,718 (Nov. 18, 2022); Medicare Claims Processing Manual, ch. 17 § 40 (Jan. 3, 2017). Units administered to a beneficiary are to be billed using the JZ modifier. 87 Fed. Reg. at 69,718.

[23] *Id.* at 69,726.

[24] CMS has already recognized that Part B inflation rebates and discarded drug refunds have a significant relationship, stating "implementation of the Parts B and D rebates mandated under the IRA should be considered together with the operational implications of [the] discarded drug refund . . . because the refunds

Notably, the statutory Part B inflation rebate calculation specifies the units on which a rebate may be invoiced. Specifically, the statute provides in relevant part: "[T]he total number of units for the billing and payment code with respect to a part B rebatable drug ***furnished*** during a calendar quarter . . . is equal to . . . the number of units for the billing and payment code of such drug ***furnished*** during such calendar quarter . . . ."[25] A unit of a discarded drug subject to a refund cannot be said to have been "furnished" to a beneficiary and thus should not be included in the units subject to the Part B inflation rebate calculation.[26]

We urge CMS to exclude units subject to the discarded drug refund from the Part B inflation rebate calculation.

II. RECOMMENDATIONS REGARDING APPORTIONMENT OF REBATE LIABILITY WHERE ASPS OF MULTIPLE MANUFACTURER NDCS ARE USED TO CALCULATE A PAYMENT AMOUNT

A. The Allocation Methodology Should Account for Each NDC's ASP and Its Respective Contribution, If Any, to the Amount by Which the Payment Amount for the Rebate Quarter Exceeds the Inflation-Adjusted Payment Amount for the Benchmark Quarter

Under the ASP statute, a single source drug or biological is defined as:

> (i) a biological; or
> (ii) a drug which is not a multiple source drug and which is produced or distributed under a new drug application approved by the Food and Drug Administration, ***including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application***.[27]

Thus, single source drugs or biologicals for purposes of the Part B inflation rebate include drugs or biologicals marketed by multiple producers or distributors (i.e., manufacturers), typically with their own NDCs and under a single NDA or BLA. As CMS notes in the initial guidance, "NDCs for all such manufacturers would, in most instances, be assigned to the same [Healthcare Common Procedure Coding System (HCPCS)] code(s) and each manufacturer (including repackagers and relabelers) would be responsible for reporting ASP data to CMS, which includes

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and rebates both require CMS to accept payments from drug manufacturers to the Federal Supplementary Medical Insurance (SMI) Trust Fund." *Id.* at 69,711.

[25] SSA § 1847A(i)(3)(B).

[26] *Id*.

[27] SSA § 1847A(c)(6)(D) (emphasis added).

sales volume."[28] A single, weighted average ASP is then calculated across all these NDCs to set the payment amount for the HCPCS code.[29]

Where such a shared HCPCS code becomes subject to a Part B inflation rebate, CMS proposes to allocate rebate liability across the manufacturers of the NDCs in proportion to the sales volume of each NDC within the HCPCS code.[30] Effectively, if 100 billing units are reported for a billing and payment code across the manufacturer NDCs in that code in a rebate quarter, with 60 billing units reported for one manufacturer's NDC and 40 billing units reported for the other manufacturer's NDC, 60 percent of the inflation rebate due would be assessed against the first manufacturer and 40 percent would be assessed against the second.

We appreciate CMS's recognition of the need to allocate inflation rebate liability across the NDCs of the manufacturers in such a scenario, but the proposed units-based methodology should be revised to account for each NDC's ASP as well. Simply put, a manufacturer's contribution toward a Part B inflation rebate should be based on both the number of reported ASP units as well as the rate of increase in each NDC's ASP; the methodology for allocating rebate responsibility should address both considerations, and not simply the first.

The proposed methodology assumes that each NDC is equally responsible for driving an increase in the payment amount for the rebate period that exceeds the inflation-adjusted payment amount for the benchmark period. The methodology therefore has the potential to assign rebate liability to the NDC of a manufacturer whose ASP increased at or below the rate of inflation. Such a result raises fundamental concerns of fairness. It is entirely possible that a HCPCS code could be subject to a Part B inflation rebate, and 60 of the ASP-reported units for the code are of one NDC and manufacturer, and 40 of the ASP-reported units are of another NDC and manufacturer, but only the first manufacturer's NDC has an ASP that increased faster than the pace of inflation.

Under these circumstances, the manufacturer of the NDC with the ASP that did not increase faster than the pace of inflation should not be liable for a rebate just because it shares the same HCPCS code. The Part B inflation rebate statute is intended to discourage manufacturers from raising their prices faster than the pace of inflation by clawing back price increases that are above adjustments for inflation. For the rebate liability to be assigned to a

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[28] Part B Inflation Rebate Guidance, § 50.13. Where single source drugs or biologicals, and thus multiple NDCs, were in a shared HCPCS code before October 1, 2003, those products are treated as a multiple source drug and thus not are subject to a rebate. SSA § 1847A(c)(6)(C)(ii); Part B Inflation Rebate Guidance, § 30.1.

[29] SSA § 1847A(b)(3)-(4). As CMS knows, there are also certain circumstances involving single source drug and biologicals in which separate HCPCS codes are assigned to NDCs marketed under a single application, with the ASPs for those NDCs used to calculate a single payment rate applicable to the distinct HCPCS codes. *See* CMS, Update to Information Regarding Medicare Payment and Coding for Drugs & Biologics, (May 18, 2007), *available at* https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_annoucement.pdf.

[30] Manufacturers typically report ASP units at the NDC-11 package level; thus, CMS would convert these manufacturer-reported ASP units to HCPCS code billing units to allocate rebate liability. Part B Inflation Rebate Guidance, § 50.13.

manufacturer that has not increased its price would penalize that manufacturer merely for having an NDC in the same HCPCS code as another manufacturer—which cannot have been Congress's intent in enacting the Part B inflation rebate statute.

Where the NDCs of both manufacturers have contributed to the triggering of the inflation rebate, ***CMS should apportion liability based on their respective ASPs***. Manufacturers should be assessed rebate liability only in proportion to the degree by which their NDC drove the payment amount for the rebate quarter to exceed the inflation-adjusted payment amount for the benchmark quarter. CMS should develop a methodology for ensuring that rebate liability will be assessed against each manufacturer only in proportion to its actual responsibility for the triggering of the inflation rebate.

B. ASP-Reported Units That Do Not Qualify as Part B Rebatable Drugs Should Not Be Used to Allocate Rebate Liability

The above comment, in Section II(A), regarding the allocation of rebate liability with respect to HCPCS codes containing NDCs of multiple manufacturers, advocates for the allocation of rebate liability based on each NDC's unit volume *as well as* its ASP, as opposed to each NDC's unit volume alone. That comment, and CMS's proposed methodology, presume that the ASP-reported units for a particular NDC qualify as Part B rebatable drugs, such that the relative volumes of ASP units per NDC is a reasonable proxy for each NDC's respective share of the overall Part B rebatable utilization for the code.

That assumption may be reasonable in most situations, but Amgen has identified at least one circumstance where that assumption is not reasonable and urges CMS to qualify its allocation methodology accordingly. Specifically, where the ASP units for an NDC in a shared HCPCS code are primarily *non*-Part B rebatable drugs, CMS should adjust the ASP units attributed to that NDC in the allocation of rebate liability for the code.

By way of example, there are currently two HCPCS codes with respect to epoetin alfa, namely:

- J0885, Injection, epoetin alfa, (for non-esrd use), 1000 units; and
- Q4081, Injection, epoetin alfa, 100 units (for esrd on dialysis).

Under the current ASP crosswalk, the ASPs of NDCs of multiple manufacturers are used to calculate a single unit-based payment amount across both codes.[31] Amgen markets its epoetin alfa NDCs for use in the dialysis setting and to be billed using the Q code, which is used only in the ESRD setting and thus signals payment as part of a bundled payment.[32] Because that utilization is not be subject to a Part B inflation rebate, the units that sourced that utilization should not be used to apportion rebate liability. Amgen urges CMS to adapt its allocation methodology to exclude those NDC ASP-reported units that are subject to bundled payment.

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[31] The current ASP crosswalk is available here: https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2023-asp-drug-pricing-files.

[32] *See* SSA § 1881(b)(1).

In sum, in the case of a shared HCPCS code where the Part B inflation rebate is allocated across the NDCs of multiple manufacturers, CMS should develop an allocation methodology that is based on:

- Each NDC's ASP and its contribution to the degree by which the payment amount for the rebate quarter exceeded the inflation-adjusted payment amount for the benchmark quarter; and
- Each NDC's ASP-reported units, *reduced by the amount of such units reasonably identifiable as not constituting Part B rebatable drugs*.

This adjustment to any allocation methodology is needed to ensure CMS complies with the statutory definition of a Part B rebatable drug and its explicit exclusion of units subject to bundled payment.

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 B inflation rebate statute, manufacturers must pay inflation rebates on Part B rebatable drugs within thirty days of receipt of an invoice from the Secretary, which CMS's guidance denominates a Rebate Report.[33] The statute directs CMS to furnish the Rebate Report to the manufacturer within six months of the end of the rebate quarter.[34] The Rebate Report is to include (1) the total number of units of the billing and payment code for the Part B rebatable drug for the rebate quarter; (2) the amount by which the payment amount for the rebate quarter exceeds the inflation-adjusted payment amount for the benchmark quarter; and (3) the total rebate amount.[35]

In its guidance on the Part B inflation rebate, CMS indicates that it will provide a Preliminary Rebate Report to the manufacturer five months after the end of the rebate quarter, 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

[33] SSA § 1847A(i)(1)(B); Part B Inflation Rebate Guidance, § 60.1.
[34] SSA § 1847A(i)(1)(A); *see also* § 1847A(i)(1)(C) (permitting CMS to delay the time frame of rebate reports for calendar quarters beginning in 2023 and 2024 until not later than September 30, 2025).
[35] *Id*.

review.[36] Manufacturers will be given ten calendar days to review the Preliminary Rebate Report and provide feedback to CMS.[37]

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 B 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, Medicaid Drug Rebate Program (MDRP) units, bundled units, any units of drugs determined to be in shortage or biosimilars in cases of severe supply chain disruptions, and units of drugs that are no longer a Part B rebatable drug; 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. Accordingly, CMS should issue the Preliminary Rebate Report no later than four months after the end of the rebate quarter in order to give the manufacturer at least thirty days to review and respond to its contents, which would still allow CMS sufficient time to review and respond to the feedback before issuing the final Rebate Report by the six-month post-quarter statutory deadline.

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 fourth 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 number of units subject

[36] Part B Inflation Rebate Guidance, § 60.1.
[37] *Id*.

to the rebate and 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 percent increase in inflation calculated by CMS 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 III(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 ASP

The Part B inflation rebate statute does not mandate any adjustment or reconciliation process on the basis of restatements of ASP or other data.

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 proposed to send approximately one year after the Preliminary Rebate Report is sent.[38] The True-Up Rebate Report "will . . . capture any potential changes related to revised [ASP] data submitted by a manufacturer, CMS revision of payment limits, revisions to the CPI-U, and any updates to claims data that occurred after the rebate amounts were calculated."[39] 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.[40]

CMS should extend the true-up period from one to three years, because one year is insufficient to appropriately capture restatements of ASP. The Medicare Part B ASP User Manual allows manufacturers to restate ASP but does not specify a time frame in which manufacturers must do so.[41] Manufacturer submission of ASP restatements often is triggered by items identified through

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[38] Part B Inflation Rebate Guidance, § 60.3.
[39] *Id.*
[40] *Id*. § 60.1.
[41] Medicare Part B ASP User Manual, § 11 (Apr. 15, 2019), *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Downloads/Medicare-Part-B-ASP-Data-Collection-User-Guide.pdf.

the manufacturer's restatement of average manufacturer price and best price under MDRP, where restatements are required within 12 quarters (three years) of when such data were originally due.[42] Given these time frames 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 ASP data are accounted for, and thereby significantly enhance the accuracy of any true-ups.

* * * * *

We appreciate your consideration of our comments as you develop Part B inflation rebate policy. We look forward to continuing to work with CMS to ensure the Part B inflation rebates are implemented appropriately. Please contact Andy Swire by telephone at (202) 585-9660 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

[42] 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

March 11, 2023

Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: 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.

ASHP is pleased to submit our comments on the Centers for Medicare & Medicaid Services' (CMS) initial guidance regarding the implementation of Medicare Part B Drug Inflation Rebates. ASHP is the collective voice of pharmacists who serve as patient care providers in hospitals, health systems, ambulatory clinics, and other healthcare settings spanning the full spectrum of medication use. The organization's more than 60,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 80 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

ASHP appreciates the opportunity to comment on the initial guidance and we look forward to providing additional feedback as the agency further refines the inflation rebate framework. As a general matter, we urge the agency to implement a rebate framework that does not create new administrative burdens for pharmacy departments or interfere with established workflows. Our specific feedback on the proposed structure for the rebates is as follows:

- **50.8.1 – Removal of 340B Units**: ASHP has consistently objected to the use of the JG and TB modifiers. With the discontinuation of the CMS policy of differential payment under Part B for 340B drugs, there is no longer a basis for requiring these modifiers. Retaining these modifiers merely for the purposes of identifying drugs to exclude from rebate calculations unnecessarily increases the administrative burdens on pharmacy departments at a time when they are already stretched thin.

- **50.10 – Reduction or Waiver of the Rebate Amount for Part B Rebatable Drugs in Shortage and in Cases of Severe Supply Chain Disruptions; and 50.11 – Reducing or Waiving the Rebate Amount in the Case of a Part B Rebatable Drug on the Shortage List:** ASHP supports CMS's proposal to create a rebates framework that does not create any incentive for manufacturers to artificially limit the supply of drugs subject to rebates. As CMS is aware, drug shortages continue to pose a significant threat to patient care in our nation, resulting in delayed treatment, increased risk of adverse reactions and medication errors, and additional unnecessary healthcare costs. Drug shortages strain hospital operations and force clinicians to spend time locating medications instead of providing patient care.

  It is imperative that the inflation rebates framework is crafted to minimize any potential incentives for manufacturers to create shortages. Specifically, if a drug remains in shortage for multiple quarters, particularly for manufacturing quality issues, which are the cause of most drug shortages, the waiver amount should be reduced over time to remove any incentive to keep a drug in shortage.

  Regarding a "severe supply chain disruption" that results in a shortage, a waiver may be appropriate initially, but should be reduced over time to ensure that manufacturers move expeditiously to address

underlying causes. The proposed reporting requirements for a "severe supply chain disruption" seem reasonable, be we question creating a structure where CMS, rather than the U.S. Food and Drug Administration (FDA), determines whether a drug is in shortage or short supply due to "severe supply chain disruption." Tasking multiple agencies with making shortage determinations seems likely to result in confusion and unnecessary duplication of effort. In all situations regarding identifying and addressing drug shortages, CMS should coordinate with FDA to create consistent reporting requirements and definitions. Given the complicated nature of shortage determinations and their implications, we urge CMS to either extend the comment period on this section of the initial guidance or to seek additional stakeholder feedback on this issue prior to finalizing the guidance.

Thank you for your consideration of our comments. We continue to support CMS's efforts to create a workable inflation rebates framework, and we stand ready to assist the agency in any way possible. Please do not hesitate to contact me at 301-664-8698 or jschulte@ashp.org if ASHP can provide any further information or assist the agency in any way.

Sincerely,

Jillanne Schulte Wall

Jillanne Schulte Wall, J.D.
Senior Director, Health & Regulatory Policy

VIA ELECTRONIC FILING — *http://www.regulations.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
Attention: CMS–4201-P
Baltimore, MD 21244-1850

Re: 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 Dr. Seshamani:

Introduction

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of diseases in three therapy areas – Oncology, Cardiovascular, Renal & Metabolism and Respiratory & Immunology. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. We appreciate the opportunity to comment on the initial guidance document entitled *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* (initial guidance).

30.3 Exclusions for Certain Vaccines

In accordance with section 1847A(i)(2)(A)(ii) of the Social Security Act, CMS will exclude vaccines described in section 1861(s)(10) of the Act. This provision excludes influenza, pneumococcal, hepatitis B, and COVID-19 vaccines from the Part B inflation rebate.

With respect to COVID-19 monoclonal antibodies that are covered and paid for under the Medicare Part B preventive vaccine benefit, the initial guidance provides that these products would be excluded from the definition of Part B rebatable drug for applicable calendar quarters until the end of the calendar year in which the March 27, 2020 Emergency Use Authorization Declaration for Drugs and Biological Products under section 564 of the FD&C Act ends.

In the *Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies* final rule (87 Fed. Reg. 69404, 69986-92), with respect to monoclonal antibody therapies used to treat COVID-19, CMS finalized their policy to transition coverage of these biologicals to coverage and payment under section 1847A of the Social Security Act. Per the PFS rule, effective January 1 of the year following the year in which the EUA declaration for drugs and biological products ends, CMS will pay for covered COVID-19 monoclonal antibody products used for the treatment or for post-exposure prophylaxis of COVID-19 as biological products paid under section 1847A

of the Act. In this regard, the position provided in section 30.3 of this initial guidance document is consistent with CMS coverage policy.

However in the same 2023 PFS Rule noted above, CMS separately finalized a policy to provide coverage and payment for monoclonal antibodies indicated for pre-exposure prophylaxis against COVID-19 under the Part B vaccine benefit at section 1861(s)(10)(A) of the Act, even after the EUA declaration for such products ends, as long as the products receive market authorization. In finalizing this coverage policy, CMS recognized the importance of continued access to pre-exposure prophylactic products for immunocompromised patients who cannot receive effective protection against COVID-19 from conventional vaccines. On this point, the initial guidance is not consistent with CMS policy to provide coverage and payment for monoclonal antibody products used for pre-exposure prophylaxis against COVID-19 under section 1861(s)(10).

We therefore request that CMS update section 30.3 of the initial guidance to clarify that monoclonal antibodies indicated for pre-exposure prophylaxis against COVID-19, which will continue to be covered and paid for under the Part B vaccine benefit even after the March 27, 2020 EUA declaration for drugs and biological products is terminated, are also excluded from the Part B inflation rebate.

50.13 Financial Responsibility for Part B Inflation Rebate Amount

While the Part B inflation rebate program is administered at the HCPCS level, there are instances where NDCs attributable to single-source drugs from more than one manufacturer are included under the same HCPCS code. In the event the average cost represented by the HCPCS code increases by more than the allowable amount, CMS proposes to allocate financial responsibility for any rebate amount owed in proportion to each manufacturer's share of billing units sold during the rebate quarter as reported in ASP data submissions.

AstraZeneca is opposed to CMS's intended approach, as it could result in a manufacturer owing an inflation rebate even when the growth in ASP for the manufacturer's own NDCs has been below inflation or flat as measured from the benchmark quarter. Section 1847A(i)(1)(B) requires a "manufacturer of a part B rebatable drug" to "provide to the Secretary a rebate that is equal to the amount specified… for such drug for such calendar quarter." There is no basis for requiring a manufacturer to provide a rebate based on the growth in ASP of another manufacturer's Part B rebatable drug.

When or if CMS must impose an inflation rebate on a HCPCS code comprised of NDCs from multiple manufacturers, the agency should calculate inflation rebate liability at the NDC-11 level. In order to properly facilitate this approach, CMS should require reporting of NDC-11s on the CMS-1500 and 837P claims forms.

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

In sections 60.1 and 60.2 of the guidance, CMS notes its intention to send manufacturers a Preliminary Rebate Report no later than five months after the end of each calendar quarter.[1] 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 B 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

[1] 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.

Rebate Report. Following this process, CMS would send manufacturers a Rebate Report – an invoice that would identify the rebate amount due for Part B rebatable drugs.

Ten days is not a sufficient period of time to review these reports and document potential errors to CMS. A ten-day turnaround time for disputes does not allow opportunity for manufacturers to perform root cause analysis if the CMS data does not align to our expectations. From experience with Medicaid disputes, we attempt to reproduce the logic that caused the error in the government invoice in order to resolve the error and cross-walk the correction to an updated invoice amount. This process can be time consuming and challenging given limited data in the invoice itself.

Furthermore, ten days is significantly shorter than the dispute timeframe provided for similar rebate programs:

- The Medicare Coverage Gap Discount Program (CGDP) requires manufacturers to submit disputes within 60 days of receipt of an invoice
- When implementing manufacturer refunds for discarded amounts of refundable single-dose container or single-use package drugs in the CY 2023 PFS, CMS final policy allows manufacturers to contest a refund calculation during the 30-day period following the issuance of a refund report
- Across the Medicaid Drug Rebate Program (MDRP), rebate invoices must be placed in dispute or paid by the manufacturer within 37 calendar days after the postmarked date on the original invoice

CMS should also provide additional time for payment beyond 30 days, at least for the first round of invoices. CMS should anticipate the potential for manufacturer system issues during the first round of rebate invoices, which can take several weeks to resolve in partnership with outside IT support. Invoices such as those for inflation rebates will likely run through three different IT systems to be (1) validated, (2) processed, and (3) paid. Extending payment time on the first invoice would be helpful to ensure manufacturers' systems are configured properly.

The MDRP and CGDP contracts and payments have been extensively tested and provide longer timelines for dispute and payment. We suggest that CMS update the initial guidance to better align error submission and payment timelines to existing programs.

***

AstraZeneca greatly appreciates the opportunity to provide these comments. We look forward to continued engagement with CMS and other stakeholders on this topic. If you have any questions or would like additional information on these or any other related topics, please contact me at 202-779-1917 or via e-mail at thad.flood@astrazeneca.com.

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 B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the Social Security Act, and Solicitation of Comments

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March 10, 2023

Brian Nagle
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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 B 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 also 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. Removal of 340B Units (50.8.1)

As described by CMS in section 50.8, Part B rebatable drugs will be identified by HCPCS code using final action claims in the CMS Medicare fee-for-service claims repository. CMS would then identify claim lines for such HCPCS code for dates of service in the calendar quarter, remove units in claim lines as required by the IRA and the sums of the remaining units will be used as the basis for the rebate payment. Rebates are owed starting on January 1, 2023.

Regarding products for which discounts are provided under section 340B of the Public Health Services Act, as noted under section 1847A(i)(3)(B)(ii)(I), CMS is required to exclude these units from the rebate calculation. For 2023, only 340B covered entities that are paid under the Outpatient Prospective Payment System (OPPS) are required to report claims modifiers (i.e., "JG" or "TB") from identified final claims for rebatable drugs indicating a related 340B prescription has been dispensed. However, expansion of the requirement for covered entities not paid under the OPPS does not go into effect until 2024. Thus, a discrepancy would presumably exist in reporting that would allow these 340B units to remain in the rebate request amount.

We note that CMS encourages non-OPPS providers to start using the appropriate modifier as soon as possible, but no later than January 1, 2024. In the meantime, CMS indicates its intent to begin removing all institutional claims with the "JG" or "TB" modifier, and all other units in institutional claims submitted by critical access hospitals, Maryland waiver hospitals, and non-excepted off-campus provider-based departments. CMS also intends to remove all units in claims for Medicare suppliers listed by the Health Resources and Services Administration (HRSA) as participating in the 340B Drug Pricing Program.

Bayer supports the expanded requirement for 340B modifiers beginning in 2024, as well as its proposed approach to exclude units during 2023 that might have otherwise been inappropriately captured under this rebate program. However, we believe further safeguards are needed to ensure appropriate removal of 340B units from the rebate program.

With the use of a single claims modifier, the potential exists for the claim to be left open without a definitive indication of a 340B status for 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.

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

[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: Can 340B Modifiers Avoid Duplicate Discounts in the IRA? - IQVIA

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, we encourage CMS 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 administered to Part B 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.

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

Once Part B drugs are identified, as previously described, CMS must also remove drugs for which a rebate is paid under section 1927 of the Social Security Act. Regarding products for which these rebates are paid, as noted under section 1847A(i)(3)(B)(ii)(I), CMS states that it intends to remove units in claim lines for dates of service during a quarter when the beneficiary has Medicaid coverage. To accomplish this task, CMS would identify the dates a beneficiary has Medicaid coverage during the time the rebate is being calculated for a calendar quarter.

Bayer supports the approach proposed by CMS. As part of its approach, CMS should also make sure it accounts for rebates among the Medicaid managed care population for which rebates are paid. As noted by the Medicaid and CHIP Payment and Access Commission (MACPAC), "…over one-third (36.5 percent) of enrollees age 65 and older were enrolled in comprehensive managed care in FY 2020…"[2]

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

CMS is seeking input on how to remove the excluded drugs from units from Medicare Advantage plans. However, the IRA, under section 1847A(i)(2), defining a Part B rebatable drug reads as follows:

> (2) PART B REBATABLE DRUG DEFINED.—
>
> (A) IN GENERAL.—In this subsection, the term 'part B rebatable drug' means a single source drug or biological (as defined in subparagraph (D) of subsection (c)(6)), including a biosimilar biological product (as defined in subparagraph (H) of such subsection) but excluding a qualifying biosimilar biological product (as defined in subsection (b)(8)(B)(iii)), **for which payment is made under**

[2] Medicare and CHIP Payment and Access Commission. *MACStats: Medicaid and CHIP Data Book.* December 2022. Accessed February 28, 2023 at: MACStats: Medicaid and CHIP Data Book 2022 (macpac.gov)

> **this part**, except such term shall not include such a drug or biological—[emphasis added]
>
> (i) if, as determined by the Secretary, the average total allowed charges for such drug or biological under this part for a year per individual that uses such a drug or biological are less than, subject to subparagraph (B), $100; or
>
> (ii) that is a vaccine described in subparagraph (A) or (B) of section 1861(s)(10).

In addition, section 1847A(i)(3)(B)(ii)(II) states that CMS should exclude from the number of units for the billing and payment code drugs provided during the quarter "…that are packaged into the payment for an item or service and are not separately payable."

Based on our review of the IRA, we believe the CPI rebate provisions pertain just to Medicare Part B. Thus, we believe Medicare Advantage, which is Medicare Part C, does not qualify for the Part B rebate program and we request that CMS revise this section of the guidance.

IV. Timing of Reports and Payment (60.1)

As stated in the initial memorandum, CMS plans to issue a Preliminary Rebate Report to manufacturers within 5 months of the end of each calendar quarter. 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 60.2 of the memorandum. Information in the report, as proposed, would include the total number of the billing and payment code(s) for each Part B rebatable drug for the calendar quarter; the amount (if any) of excess average sales price (ASP) increase for the Part B rebatable drug for a given quarter; and the rebate amount for the Part B rebatable drug for the given quarter. We also understand that additional guidance will be issued pertaining to how the Rebate Report will be sent to manufacturers.

For each calendar quarter, CMS plans to conduct a one-time true-up recalculation to allow for updated ASP data submitted by a manufacturer, CMS revision of payment limits, revisions to the CPI-U, and any updates to claims data that occurred after the rebate amounts were calculated on the number of units and ASP. It is expected that the true-up will occur one year after CMS sends its Rebate Report to manufacturers.

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 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 data that would help with the error assessment includes information used by CMS to develop its invoices, such as the benchmark price, applicable payment amount for the quarter, values for the benchmark and rebate quarter CPI-U, and claims-level data for the billing and payment code. Information on the number of 340B and Medicaid claims units removed from the 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.

V. Manufacturer Suggestions of Calculation Errors in Preliminary Rebate Reports and Preliminary True Up Reports (60.2) and CMS Identification of Errors (60.4)

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.

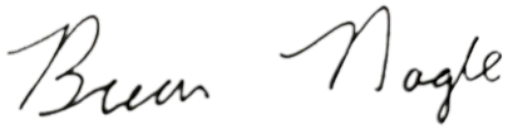
Conversely, CMS notes that it "…reserves the right to update or change the rebate amount and true-up amount due from manufacturers for the calendar quarter based on any calculation errors, or misreporting of manufacturer pricing or product data that CMS identifies at any point, after each quarter ends." Clearly, this is different from the process being 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. 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 quarter 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 B 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.

Timeframe for Identifying Rebatable Drugs

- BCBSA appreciates CMS identifying Part B rebatable drugs two months before the start of a calendar quarter as MA plans require sufficient lead time to operationalize the beneficiary coinsurance percentages. We ask CMS to work with plans during the quarter (April 1, 2023) when the adjusted coinsurance percentages first apply to address any implementation challenges and mitigate any member confusion or abrasion.

Excluded Units

- BCBSA appreciates CMS identifying excluded units for Part B rebatable drugs using existing sources of data, including: (1) units in claim lines that were billed with the "JG" or "TB" modifiers for units where manufacturers applied a 340B discount and (2) units in claim lines for dates of service during which the Medicare beneficiary has Medicaid coverage.
    - We recommend CMS add as an acceptable 340B identifier the "UD" modifier. While this often is used for Medicaid claims, providers may just choose one regardless of line of business.

  We believe CMS can use these existing data sources to identify such units.
- We further recommend that CMS provide model language (for both member communication and provider communication) describing coinsurance adjustments due to Part B inflation rebates for communication alignment about this benefit across health plans.

Treatment of MA Enrollees' Part B Drugs

- CMS is requesting guidance on the best source of information to "determine the number of units of a drug furnished to MA enrollees and how to remove units" in accordance with the IRA. CMS should use existing data sources to the extent practicable to identify drugs administered to MA enrollees such as encounter data. The contents of encounter data files for Part B outpatient services may be sufficient for CMS to calculate the number of units of Part B drugs administered to MA enrollees. Encounter data that MA plans routinely submit to CMS contains the HCPCS codes for each provider visit such that this may be the best source of data to identify such units for Part B rebate calculation.

Removal of Units Not Separately Payable – Application to MA

- BCBSA requests further clarification on the application to MA claims regarding CMS' guidance that it will only identify units for separately payable claim lines for Part B rebatable drugs. MA plans commonly utilize a variety of payment methodologies to reimburse providers for Part B drugs when the unit is not paid separately. Some providers take full risk from MA plan sponsors, receive capitated payments, and generate encounter data without submitting claims to MA plan sponsors. Other contracted MA providers receive bundled payments or other forms of value-based reimbursement that do not include a line-item amount for the Part B medication. In some MA plan sponsor relationships with providers, there is not even a claim with pricing submitted by the provider.
- For these reasons, we recommend CMS clarify in guidance that only when MA plans are paying providers under a fee-for-service (FFS) arrangement, where the cost of a Part B rebatable drug is evident and on a separately payable claim line (i.e., paid separately under their own unique HCPCS code), will such units be included in the Part B rebatable calculation. This is consistent with CMS' interpretation for FFS claims and aligned with the IRA requirement to exclude units "that are packaged into the payment amount for an item or service and are not separately payable."

Rebatable Drug Coinsurance Adjustment

- BCBSA requests guidance on the applicability of the coinsurance adjustment (0 - 20%) for Part B rebatable drugs towards out-of-network claims.

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 B Inflation Rebate Guidance Comments

Dear Administrator Brooks-LaSure:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Initial Medicare Part B Inflation Rebate Guidance issued by the Center for Medicare & Medicaid Services (CMS) 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).*

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 appreciate 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). In addition, we note our strong disagreement with CMS's assumption that Part B inflation rebates may be invoiced on units of drugs furnished to Medicare Advantage (MA) beneficiaries – such an assumption is in direct conflict with the plain language of the statute. Finally, when CMS issues revised guidance on Part B 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.

Section 30 – Determination of Part B Rebatable Drugs

CMS outlines its approach for identification of Part B rebatable drugs, including its approach for identifying drugs where allowed charges are less than $100 per individual and for excluding vaccines.

In section 30.1, CMS states that "multiple source drugs (described in section 1847A(c)(6)(C) of the Act) and qualifying biosimilar biological products (as defined in section 1847A(b)(8)(B)(iii) of the Act) will be excluded" from Part B rebatable drugs.

> ***BIO Comment:*** BIO encourages CMS to clarify that all drugs defined as "multiple source drugs" under section 1847A(c)(6)(C) of the Social Security Act are excluded from Part B inflation rebates. This includes certain single source drugs that section 1847A(c)(6)(C)(ii) requires CMS to treat as multiple source drugs because they "are within the same billing and payment code as of October 1, 2003." Because the statute requires CMS to treat these drugs as if they are multiple source, it would not be permissible for CMS to apply Part B inflation rebates to these drugs, as the inflation rebate applies only to single-source drugs. We encourage CMS to include this clarification in its revised guidance.

In this initial guidance, CMS does not address the interface of Part B inflation rebates and discarded drug refunds. By way of background, CMS noted in its November 4, 2022, Final Physician Fee Schedule Rule: "We believe implementation of the Parts B and D rebates mandated under the IRA should be considered together with the operational implications of discarded drug refund discussed in this final rule, because the refunds and rebates both require CMS to accept payments from drug manufacturers to the Federal Supplementary Medical Insurance (SMI) Trust Fund. In order to align the operation of these programs and minimize burden, we are declining to finalize some aspects for collection of discarded drug refunds. … We intend to address these aspects in future rulemaking."

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BIO Comment: As soon as possible, CMS should provide stakeholders with operational clarity regarding how inflation rebates under the IRA will interact with refunds for discarded amounts of drugs covered under Medicare Part B, packaged in a single-dose container or single-use package, as enacted in the Infrastructure Law. Most critically, CMS should clarify that discarded drug refund units are excluded from the units used to calculate Part B inflation rebates. Refunded units of discarded amounts of drugs net out as non-paid for the manufacturer. It would therefore be inappropriate to extract a penalty on an amount of product that is ultimately accounted for as unsold by the manufacturer. In addition, the statute provides that the total number of units for purposes of the rebate calculation is based on the number of units for the billing and payment code that were "furnished" during the applicable quarter. Of course, by definition, a discarded drug refund unit was not in fact furnished. For all of these reasons, we urge the Agency to clarify that discarded drug refund units are excluded from the Part B inflation rebate.

Section 40 – Computation of Beneficiary Coinsurance

CMS outlines its approach for ensuring that the 20% beneficiary coinsurance under Medicare Part B is based on the inflation-adjusted payment amount.

BIO comment: BIO supports CMS's approach and the goal of ensuring that Medicare beneficiaries benefit from lower out-of-pocket costs for Part B drugs and biologics when inflation rebates are paid under the program. To meet this goal, we encourage CMS to take the necessary steps to ensure that Medicare providers and beneficiaries are well-educated about and fully understand the impact that rebates will have on beneficiary coinsurance.

Section 50.8.1 – Removal of 340B Units

For claims with dates of service during 2023, CMS intends to exclude units in all institutional claim lines that were billed with the "JG" or "TB" modifier and all other units in institutional claims submitted by critical access hospitals, Maryland waiver hospitals, and non-excepted off-campus provider-based departments (PBDs). For professional claims with dates of service during 2023, CMS intends to exclude all units in claims of Medicare suppliers that are listed by the Health Resources and Services Administration (HRSA) as participating in the 340B Drug Pricing Program, by using employer identification numbers to identify these suppliers' Medicare Identification Numbers and the claims submitted with such identifiers. For claims with dates of service thereafter, by which point all 340B covered entities will be required to use the "JG" or "TB" modifier, CMS intends to exclude units by reference to such modifier.

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BIO Comment: We agree with and support CMS's proposed approach. In addition, CMS should (1) establish a *non*-340B claims modifier (such that either a 340B claims modifier or a non-340B claims modifier is included in each claim), and (2) specify that, where a claim fails to accurately include either modifier, it will be deemed incomplete and unpayable.

Further, and as we have noted in previous correspondence with the agency, CMS should require that 340B covered entities share claims level data with CMS and biopharmaceutical manufacturers, as this is the best way to avoid statutorily prohibited duplicate discounts. This is noted in CMS's own guidance to States, "Best Practices for Avoiding 340B Duplicate Discounts in Medicaid" (January 2020). CMS should also take additional steps to 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 CMS, and penalties for inaccurate use of the modifiers.

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 modifier preempts any such state law.

Section 50.8.2 Removal of Units with a Rebate Under Section 1927

CMS states that it intends to exclude units in claim lines for dates of service during a quarter when the Medicare beneficiary has Medicaid coverage. CMS intends to identify the dates on which a beneficiary has Medicaid coverage using available information at the time the rebate amount is being calculated for a quarter. CMS seeks comment on the exclusion of all units on the dates of service during a quarter when an individual has dual coverage under Medicare and Medicaid and on state data sources that would facilitate identification of units for which a state received a Medicaid drug rebate for a dual eligible individual.

BIO Comment: We agree with and support CMS's goal, and one step in the right direction would be for CMS to require states to take steps to help CMS achieve this goal.

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

CMS states that the calculation of units of drugs that are furnished to Medicare beneficiaries who are enrolled in MA plans poses significant operational complexities and seeks comment on the best source

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of information to determine the number of units of a drug furnished to MA enrollees and how to remove units in accordance with section 1847A(i)(3)(B)(ii) of the Act.

> ***BIO Comment:*** We strongly disagree with implicit predicate that a Part B inflation rebate may be invoiced on units of drugs furnished to MA beneficiaries since the statute expressly defines a Part B rebatable drug as a drug "for which payment is made under **this part** [emphasis added]," i.e., Medicare Part B – not Medicare Part C.
>
> Specifically, Section 1847A(i)(2)(A) defines a "Part B rebatable drug" to mean a "single source drug or biological product […] for which payment is made under this part"—referring to Part B. CMS's Guidance similarly defines a "Part B rebatable drug" as "a single source drug or biological product […] for which payment is made under Part B […]." However, Section 50.8.5 of CMS' Guidance appears to include MA units under Part C of Title XVIII of the SSA in Part B inflation rebate calculations. The inclusion of drugs furnished to MA enrollees under Part C exceeds the scope of the Part B inflation rebates set forth in SSA § 1847A(i). Those rebates are limited to drugs for which payment is made "under this part," which refers to Part B. No payment is made under Medicare Part B for units of drugs reimbursed by MA plans.

<u>50.11 Reducing or Waiving the Rebate Amount in the Case of a Part B Rebatable Drug on the Shortage List; 50.12 Reducing or Waiving the Rebate Amount for a Severe Supply Chain Disruption for a Part B Rebatable Biosimilar Biological Product</u>

To determine when a Part B rebatable drug is described as currently in shortage at any point during the quarter, CMS states that it intends to use the Food and Drug Administration 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 intends to define a severe supply chain disruption to mean a change in production or distribution that leads to a reduction in the United States supply of a Part B rebatable drug that significantly affects the ability of the manufacturer to fill orders or meet expected demand for its product in the United States for at least 90 days. CMS would also require the submission of specific information and supporting documentation to qualify.

> ***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.

50.13 Financial Responsibility for Part B Inflation Rebate Amount

CMS describes instances where a single source Part B rebatable drug could have more than one manufacturer. When calculating the rebate amount owed by manufacturers in such situation, CMS states that it intends to apportion financial responsibility for the rebate amount among the manufacturers by dividing the sum of the individual manufacturer's billing units sold during the rebate quarter for all NDCs of the manufacturer assigned to the HCPCS code (as reported in the ASP data submissions) by the sum of all of the manufacturers' billing units sold during the rebate quarter for all NDCs assigned to the HCPCS code (as reported in the ASP data submissions).

***BIO Comment**:* We oppose CMS apportioning rebate liability among manufacturers based on manufacturer's billing units sold. We recommend that CMS assess rebate liability based on which manufacturer's ASP triggered the rebate liability. It is our understanding that CMS has the data to make such a determination and encourage CMS to put forth such an approach for manufacturer input. Specifically, CMS should calculate inflation rebate liability at the NDC-11 level if it imposes an inflation penalty on a HCPCS code comprised of NDCs from multiple manufacturers. In such a case, CMS should develop a process to require reporting of NDC-11s on the claims forms and reject forms without specified NDC-11s as incomplete.

60. Ensuring Integrity of Part B Inflation Rebates; 60.1 Timing of Reports and Payment; 60.2 Manufacturer Suggestions of Calculation Errors in Preliminary Rebate Reports and Preliminary True-Up Reports; 60.3 Restatements and True-Up Report; 60.4 CMS Identification of Errors

CMS states that it intends to provide all manufacturers of Part B rebatable drugs with a Preliminary Rebate Report no later than 5 months after the end of each calendar quarter (noting that reports for CY 2023 and CY 2024 may be delayed until September 30, 2025, per IRA). Manufacturers would have 10 calendar days to review the Preliminary Rebate Report for potential calculation errors. In addition, CMS would perform a single reconciliation or "true-up" approximately one year after sending the final Rebate Report to the manufacturer.

BIO Comments: With respect to CMS's reference to the IRA provision that allows rebate reports for 2023 and 2024 to be delayed until September 30, 2025, we note that, in CMS's February 9, 2023, press release, the agency states it intends to send the first invoices to companies in 2025, but no specific date is provided. We urge the agency to provide clarity regarding its expected

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date of initial Part B inflation rebate invoicing, including whether invoicing will be delayed until September 30, 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 a number of reasons. Manufacturers will first have to run data and otherwise take steps to confirm that the drug is a Part B 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 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's 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, restatements of pricing data do not occur

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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. 60.4 (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.

70. Enforcement of Rebate Payments by Manufacturers: Civil Monetary Penalties (CMPs)
CMS notes that under the IRA, manufacturers that do not pay the Medicare Part B inflation rebate amount owed for a calendar quarter for a Part B rebatable drug within 30 calendar days of receiving an invoice will be subject to a CMP of at least 125 percent of the rebate amount for such drug for such quarter. CMS states it will establish a process for the Part B inflation rebate CMPs pursuant to regulations.

> ***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 Part D prescription drug plan sponsors and CMP procedures issued by OIG.

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Other Issues

We request that CMS provide guidance to manufacturers on situations where there are no sales during the entirety of the benchmark period. CMS's guidance is silent in that regard. At a minimum, it would be helpful for CMS to confirm that manufacturers may use reasonable assumptions in such situations.

We also recommend that CMS monitor ASP fluctuations and impacts on patient access. ASP 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, ASP 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 ASP 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

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

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

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[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 B 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

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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.

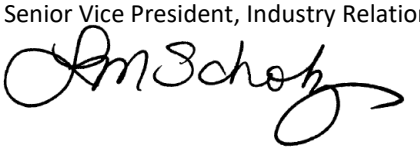
Thank you for the opportunity to provide comments on behalf of The Craneware Group and for your time to consider our recommendations. We welcome providing our insights into the IRA process to support covered entities manage the complexity of 340B in the current environment with a look to the future to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



CSL Behring 1020 First Avenue, King of Prussia, PA 19406 CSL.com CSLBehring.com

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 B Inflation Rebate Comments

Dear Dr. Seshamani:

CSL Behring is pleased to submit comments to the Centers for Medicare & Medicaid Services (CMS) concerning its initial guidance regarding manufacturer payment of inflation rebates on Part B rebatable drugs under Social Security Act (SSA) 1847A(i).[1]

CSL Behring is a global biotherapeutics leader with expertise across plasma, recombinant, monoclonal antibody, and cell and gene therapy platforms. Our areas of therapeutic focus include rare diseases such as primary immune deficiencies, peripheral neuropathies, hemophilia, hereditary angioedema and the form of genetic emphysema called alpha-1 antitrypsin deficiency, as well as cardiovascular disease, transplantation, and sickle cell disease, among others. Our comments concern the need for waiving inflation rebates on plasma-derived therapies in shortage. We begin below with background information on these critically important therapies.

1. BACKGROUND INFORMATION ON PLASMA-DERIVED THERAPIES

   a. Human Blood Plasma is Unique but a Fragile and Much Needed Life-Saving Ingredient

Human blood plasma is the critical ingredient necessary to produce essential life-saving treatments for serious diseases that affect more than 125,000 Americans, including primary and secondary immune deficiencies, respiratory diseases, neurological disorders, and hemophilia and other blood disorders.[2] CSL Behring also continues to study and invest in new plasma therapies, including the use of plasma in transplant, cardiac, and other therapeutic areas. In addition, CSL Behring operates one the world's largest and most sophisticated plasma collection networks. The plasma collected at these centers are used by CSL Behring for the sole purpose of manufacturing and delivering life-saving therapies to people in the U.S. and around the world.

In certain conditions treated with plasma-derived proteins, such as immune deficiencies, no other substance currently is available to substitute for human blood plasma.

[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 B Rebatable Drugs and Other Interested Parties (Feb. 9, 2023), https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf (the Guidance).

[2] Plasma-derived therapies are also used in cardiac surgery, burn treatment, and to prevent hemolytic disease of the newborn.

Many therapies are so plasma-intensive that patients require vast quantities of plasma each year. For instance, the U.S. Department of Health and Human Services highlights the following four statistics on its "Giving=Living" website explaining why giving plasma is so critical for so many patients:[3]

- *130* plasma donations will treat 1 person with primary immunodeficiency for 1 year;
- *465* plasma donations will treat someone with chronic inflammatory demyelinating polyneuropathy treatment for 1 year;
- *900* donations will treat 1 person with alpha-1 antitrypsin deficiency for 1 year; and
- *1,200* plasma donations will treat someone with hemophilia for 1 year.

These realities translate to millions of plasma donations needed every year to treat thousands and thousands of patients in the United States.

b. Sourcing and Manufacturing Considerations Unique to Plasma-Derived Therapies

The manufacturing of plasma-derived therapies requires high, steady volumes of plasma donations. The starting material for plasma-derived therapies is donated plasma. The process by which plasma is donated is similar to, but more complicated than, blood donations. Although we continue to invest in new technologies for collecting plasma that could make the donor experience considerably better, the current process can take up to two hours per donation.

Despite the large and growing need for plasma, the United States suffered a 20% industry-wide drop in plasma donations due to COVID-19.[4] And because it takes an average of seven to nine months after plasma collection to produce plasma protein therapies, due to the complex manufacturing process,[5] the effects of the pandemic continue to limit the availability and development of plasma-based therapies.

Plasma donors are compensated for their time and inconvenience, and plasma donation centers must raise compensation to incentivize necessary donations when the number of plasma donations drops. Increased donor compensation results in higher production costs for plasma-based therapies. One study showed that between 2016 and 2021

[3] *See* Dep't of Health and Hum'n Services, *Why Giving Plasma is So Critical*, https://www.hhs.gov/givingequalsliving/giveplasma/why-give (citing Liebe, R. (2020, January 23). See also Plasma. Plasma Protein Therapeutics Association (PPTA) and Lewis, R. A. (2020, November). *Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)*. Grifols Plasma. Retrieved July 20, 2022) (emphasis added).

[4] *See* Plasma Protein Therapeutics Ass'n, *Plasma donations remain disappointingly low through ongoing pandemic, risking patients' lives*, https://www.pptaglobal.org/media-and-information/157-media-and-information/ppta-statements/1119-plasma-donations-remain-disappointingly-low-through-ongoing-pandemic-risking-patients-lives.

[5] *See* Plasma Protein Therapeutics Ass'n, *10 Facts About Plasma Donation*, https://www.pptaglobal.org/images/Fact_Sheets/Redone/PPTA_Fact_Sheet_10Facts_FINAL_rev2.pdf.

there was an unprecedented *339%* increase in introductory plasma donor compensation.[6] This dramatic increase in plasma donor compensation followed large declines in the number of plasma donations per center, which fell from 64,342 in 2019, to 46,740 in 2020, to 42,075 in 2021.[7] And, unlike traditional pharmaceuticals, plasma-derived therapies have production costs that are highly volatile, unpredictable, and represent a substantial portion of the cost of goods sold. Increased donor compensation necessarily results in higher production costs. According to an economic analysis by Vital Transformation, before COVID-19, the cost to acquire plasma represented *49%* of cost of goods sold for plasma-derived therapies[8]—a percentage that is substantially higher today. Plasma therapy costs have also risen due to increased demand, as an ever-increasing number of patients rely on plasma-derived therapies for more conditions, while manufacturers (inside and outside the United States) compete for plasma donors in the United States.

c. CMS Should Ensure that its Guidance Does Not Inadvertently and Disproportionately Impact Plasma-Derived Therapies

In light of the sourcing and manufacturing considerations unique to plasma-derived therapies, we are concerned that inflation rebates could cause and then exacerbate shortages of plasma-derived therapies. Prior to the IRA's inflation penalties – which began to accrue in January 2023, for Part B drugs -- plasma manufacturers had some flexibility to raise prices in response to periods of higher input costs resulting from reduced plasma donations. However, that freedom will be limited by the IRA's inflation rebates. Further, while the CMS inflation rebate guidance provides for reducing or waiving inflation rebates for products on the FDA shortage list, plasma-derived products may not appear on FDA shortage lists until a year or more after a plasma shortage is observed–thus restricting manufacturers' ability to mitigate potential impacts on patients and cascading supply chain disruptions.

The government has often recognized the heightened risks of shortage associated with plasma products, and the need for government policies to take into account those heightened risks. For example, in 2022, HHS launched a campaign to raise awareness of the importance of plasma donations and encourage Americans to donate regularly[9]; the same year, HHS held a cash-prize challenge to solicit strategies to increase plasma donations.[10] In 2020, CMS exempted plasma-derived immune globulin products from its MFN interim final rule. Noting that a commenter "suggested that CMS exclude plasma-derived products and stated that such products have potential unique sourcing and distribution, and past supply shortages," CMS concluded that "After considering this concern, we are excluding intravenous immune globulin products from the MFN Model, because these products are at higher risk of shortage

[6] *See* Vital Transformation, *The Impact of International Pricing Index / Negotiated Pricing on the Plasma Sector* at p. 5 (Dec. 10, 2021), https://vitaltransformation.com/wp-content/uploads/2021/12/Vital-Transformation-Presentation-12-10-2021-4886-4096-9222-v.1.pdf.

[7] *See* Plasma Protein Therapeutics Ass'n, *Plasma FAQs*, https://www.pptaglobal.org/resource-center/plasma-faqs.

[8] *See* Vital Transformation, *The Impact of International Pricing Index / Negotiated Pricing on the Plasma Sector* at p. 8 (Dec. 10, 2021), https://vitaltransformation.com/wp-content/uploads/2021/12/Vital-Transformation-Presentation-12-10-2021-4886-4096-9222-v.1.pdf.

[9] *See* hhs.gov/givingequalsliving/.

[10] *See* https://www.challenge.gov/?challenge=givingequalsliving-blood-and-plasma-innovation-challenge.

based on their complex sourcing and production, and we are aware of the ongoing exploration of the potential benefit of plasma in the treatment of patients with COVID-19."[11]

2. GIVEN THE HEIGHTENED SHORTAGE RISKS INHERENT TO PLASMA-DERIVED THERAPIES, CMS MUST USE ITS FULL WAIVER POWERS TO HELP MITIGATE SHORTAGES AND SUPPORT PATIENT ACCESS TO THESE THERAPIES

Under SSA section 1847A(i)(3)(G)(i), CMS must reduce or waive the inflation rebate amount for a Part B rebatable drug for a calendar quarter in the event of shortages.[12] In Section 50.11 of the Guidance, CMS solicits comments on the amount and duration of such a rebate reduction, as well the scenarios in which the inflation rebate should be fully waived, for a Part B rebatable drug that is on the FDA shortage list at any point during a calendar quarter. CMS seeks comment on several specific issues, including cases where not all of the NDC-11s for the Part B rebatable drug are "current" on the shortage list[13]; specific types of Part B rebatable drugs where CMS might reduce or waive the rebate amount differently; 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 whether there are certain scenarios (e.g., certain market factors) where a greater reduction, or waiver, would be appropriate.

Because all plasma-derived therapies—regardless of the specific therapy, or the conditions it treats—rely on donations of plasma, shortages affecting any single plasma-based therapy may quickly affect the entire class of treatments. And because all such therapies involve complex manufacturing considerations that result in an average lag of seven to nine months between plasma collection and production of plasma protein therapies, the full impact of shortages in plasma and other supplies on related and similar therapies may not be felt until months or years after one product appears on a shortage list.

Given these circumstances, and the other circumstances unique to plasma therapies discussed above, it is critically important – to reduce well-known heightened risks of shortage for plasma therapies, and to support continued access to these therapies for vulnerable Medicare patients who rely on them – that CMS use its statutory waiver authority to its fullest extent. The circumstances surrounding these treatments call out for CMS to use the waiver powers Congress granted in SSA 1847A(i)(3)(G)(i) to help patients who need these products receive ongoing treatment. Accordingly, we urge CMS to take the following steps:

- In connection with any plasma-derived therapies, CMS should fully waive inflation rebates for all NDC-11s in a HCPCS code if any of the NDC-11s that fall within the code (or that fall under the same NDA or BLA as an NDC-11 within the code) appears on a shortage list under section 506E of the Federal Food, Drug, and Cosmetic Act (FD&C

[11] 85 Fed. Reg. 76180, 76191 (Nov. 27, 2020) (emphasis added).

[12] In the case of biosimilar biological products, CMS must also reduce or waive the rebate due to severe supply chain disruptions. SSA 1847A(i)(3)(G)(ii).

[13] The CMS guidance states that to be eligible for a reduction or waiver of the inflation rebate, a Part B rebatable drug "must have a shortage status described as 'current' on a FDA shortage list at any point during the calendar quarter, and not designated as 'discontinued,' 'to be discontinued,' or 'resolved.'" Guidance, section 50.11.

Act) at any point during the calendar quarter, and should keep the waiver in place throughout the quarter (and throughout any future quarters in which an NDC-11 falling within the HCPCS code or within the same FDA approval appears on a shortage list); and

- CMS should analyze whether there are any other measures authorized under SSA 1847A(i)(3)(G)(i), or under other pertinent statutes, that could improve CMS' ability to avert supply chain disruptions affecting plasma therapies or otherwise to mitigate shortages of these therapies and help Medicare beneficiaries who need them maintain access. CMS should adopt any such measure it identifies.

    - ❖ In particular, we ask that CMS explore the possibility of providing a waiver for plasma-based therapies under the same circumstances described in SSA 1860D-14B(b)(1)(C)(iii), which requires reducing or waiving the Part D inflation rebate for a generic Part D rebatable drug when "the Secretary determines that without such reduction or waiver , the drug is likely to be described as in shortage on such [FDA] shortage list during a subsequent applicable period" (emphasis added).

    - ❖ Further, CMS should also consider whether it may provide a waiver for plasma-based therapies under the same circumstances described in SSA 1847A(i)(3)(G)(ii), which requires reducing or waiving the Part B rebate for a biosimilar when "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."

We hope that CMS will give serious consideration to these recommendations when finalizing the inflation rebate Guidance, and in all other aspects of the IRA's implementation. Given the lag between plasma shortages and the appearance of any plasma-based drug on FDA's shortage list, we are concerned that the existing remedies may prove inadequate to address the combined impact of inflation rebates and plasma-specific market and technical factors on access to plasma therapies. But while additional tools to address the unique constraints posed by the manufacturing of plasma-derived therapies may be needed, CMS must use every tool within its current statutory arsenal to maintain and improve access to these essential life-saving treatments for serious diseases that affect an increasing number of Americans. Full use of CMS' power to waive inflation rebates will be critical to that effort.

3. CMS MUST TREAT SINGLE SOURCE DRUGS AND BIOLOGICALS THAT WERE WITHIN THE SAME HCPCS CODE AS OF OCTOBER 1, 2003 AS MULTI-SOURCE DRUGS FOR INFLATION REBATE PURPOSES.

Consistent with SSA 1847A(i)(2), Section 30.1 of the Guidance explains that "multiple source drugs . . . and qualifying biosimilar biological products . . . will be excluded" from Part B inflation rebates. SSA § 1847A(c)(6)(D) defines a "single source drug or biological" as "a biological" or "a drug which is not a multiple source drug . . . ." Importantly, SSA 1847A(c)(6)(C)(ii) requires that, with respect to "single source drugs or biologicals that are within the same billing and payment code as of October 1, 2003, the Secretary *shall treat* such single source drugs or biologicals *as if the single source drugs or biologicals were multiple source drugs*" (emphasis added). Accordingly, all such drugs and biologicals that shared a HCPCS code with other products at that time must be treated as multiple source for Part B inflation rebate purposes, and therefore not subject to Part B inflation rebates. We ask that CMS confirm in the final Guidance that it will treat all drugs

and biologicals that fall within SSA 1847A(c)(6)(C)(ii) as multi-source drugs or biologics for inflation rebate purposes.

* * *

Thank you for your consideration of these comments. If you have any questions, please do not hesitate to contact me at 202-841-4686, mary-lacey.reuther@cslbehring.com.

Sincerely,

Mary-Lacey Reuther
Head, North America Policy, Advocacy & Government Affairs
CSL Behring

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.

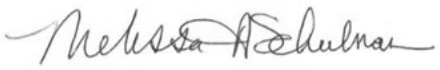
[1] CMS, Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the Social Security Act, and Solicitation of Comments; Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B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

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

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

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

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 10, 2023

VIA ELECTRONIC DELIVERY

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 B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the 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 B rebatable drugs (Part B inflation rebates) pursuant to Section 11101 of 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 B 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 emphasize

[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 B Rebatable Drugs and Other Interested Parties (Feb. 9, 2023), https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.

certain suggestions included in PhRMA's and BIO's comments. Together, we believe that our suggestions will help promote efficiency, accuracy, and reliability in Part B inflation rebate calculations and help ensure that the law is implemented consistent with Congress' intent.

Our specific comments on the Guidance can be summarized as follows:

- Gilead urges CMS not to include Part B drugs furnished to Medicare Advantage (MA) enrollees in the Part B inflation rebate calculation. Not only does the statutory language make clear that CMS does not have the authority to collect such rebates, but doing so would also impose significant operational hurdles, as CMS would need to obtain claim-level data from each MA plan on an expedited timeline with sufficient identifiers to exclude 340B and Medicaid claims.

- Gilead supports CMS' methodology for excluding 340B units from the Part B inflation rebate calculation, and we recommend that CMS also create a mechanism for identifying non-340B units to ensure that all 340B units are appropriately identified and providers do not inadvertently fail to populate the modifier field. Gilead also recommends that CMS establish a mechanism for manufacturers to identify 340B units in their Preliminary Rebate Report and Preliminary True-Up Rebate Report.

- Gilead supports CMS' mechanism for excluding Part B units subject to rebates under the Medicaid Drug Rebate Program (MDRP), by removing units in claim lines for dates of service during a quarter for Medicare beneficiaries that have Medicaid coverage in such quarter. We encourage CMS to ensure that Medicaid Managed Care Organizations (MCOs) report information for their dual-eligible enrollees in the State Medicare Modernization Act File, so that CMS can accurately identify and exclude Part B claims for drugs furnished to MA beneficiaries from Part B inflation rebates.

We encourage CMS to adopt these suggestions when developing the revised guidance.

I. Including Part B Drugs Furnished to Medicare Advantage Enrollees in Part B Inflation Rebate Calculations Raises Significant Legal and Operational Concerns

Section 1847A(i)(2)(A) of the Social Security Act ("SSA"), as amended by Section 11101 of the IRA, defines a "Part B rebatable drug" to mean a "single source drug or biological product […] for which payment is made under *this part*"—referring to Part B. CMS's Guidance similarly defines a "Part B rebatable drug" as "a single source drug or biological product […] for which payment is made under *Part B* […]."[2] In contradiction to this definition, however, Section 50.8.5 of CMS' Guidance seemingly includes Medicare Advantage (MA) units under Part C of Title XVIII of the Social Security Act in Part B inflation rebate calculations. CMS acknowledges that

[2] *See* Initial Memorandum at 1, n. 1 (emphasis added).

"[t]he inclusion in this calculation of units of drugs that are furnished to Medicare beneficiaries who are enrolled in Medicare Advantage (MA) plans poses significant operational complexities."[3]

As an initial matter and as discussed in more detail in comments provided by PhRMA [and BIO], Gilead notes that the inclusion of drugs furnished to MA enrollees under Medicare Part C exceeds the scope of the Part B inflation rebates set forth in SSA § 1847A(i). Those rebates are limited to drugs for which payment is made "under *this part*," which refers to Part B. No payment is made under Medicare Part B for units of drugs reimbursed by MA plans. Moreover, while CMS generally pays for Part B drugs on a unit by unit basis, drugs furnished to MA enrollees are *not* paid for separately by CMS. Instead, MA plans are compensated through capitated payments on a per member per month (PMPM) basis. SSA § 1847A(i)(3)(B)(ii)(II) makes clear that Part B inflation rebates are not owed on units that are not separately payable:

> The total number of units of the billing and payment code of a refundable single-dose container or single-use package drug of a manufacturer furnished during a calendar quarter for purposes of subparagraph (A)(i), and the determination of the estimated total allowed charges for the drug in the quarter for purposes of paragraph (3)(A)(ii), shall not include such units that are packaged into the payment amount for an item or service and are not separately payable.

Accordingly, the inclusion of payments for Part C drugs—which are not separately payable or reimbursable by CMS—into the Part B rebate calculation would be inconsistent with the IRA statutory language.

In addition, the significant operational challenges posed by including MA units in Part B inflation rebate calculations also suggests that Congress did not intend for Part B inflation rebates to be collected on these units. Providers submit claims for drugs furnished to MA enrollees to the applicable MA plan, which is in turn compensated on a capitated basis—a model which does not require the submission of timely claims data to CMS. The existing data files that MA plans submit to CMS do not appear to contain all the data necessary to calculate Part B inflation rebates (including the identification all of 340B and Medicaid claims).[4] Even assuming these data contained sufficient data to complete the Part B inflation rebate calculation, because MA Plans "typically have 13 months after the end of a service year to submit encounter data to CMS . . . ,"[5] this data would not necessarily be available for inflation rebate calculation purposes including within the "true-up" period that is intended to "capture any potential changes related to … any updates to claims data."[6] CMS would need to obtain claim-level data from each MA plan for each Part B drug on an expedited timeline with sufficient identifiers to exclude 340B and Medicaid claims—a significant burden that Congress did not contemplate in the statute.

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[3] Guidance § 50.8.5.

[4] CMS's Medicare Encounter Data User Guide's explains that "CMS uses MA encounter data for risk adjustment purposes," and that "CMS does not use MA encounter data as the basis for direct payments to providers." Medicare Encounter Data User Guide 17 (Jan. 2023, Version 2.8).

[5] *Id.*

[6] Guidance § 60.3.

II. Gilead Supports CMS' Methodology for Excluding 340B Acquired Units from Part B Inflation Rebates

Gilead supports the methodology described in the Guidance to exclude 340B units from the Part B inflation rebate calculation, but we recommend that CMS also create a mechanism for providers to identify non-340B units. As outlined in Section 50.8.1 of the Guidance, CMS issued program guidance in 2022 that requires all 340B covered entities to include the "JG" or "TB" modifier, as applicable, on separately payable claim lines for drugs acquired through the 340B program with dates of service beginning no later than January 1, 2024. While not yet implemented, Gilead believes that these modifiers will serve as an accurate and straightforward way to identify 340B units and will not be overly burdensome for 340B covered entities to implement into their billing systems.[7]

While including the "JG" or "TB" modifier is a key step towards accurately identifying 340B utilization, it may not be sufficient to ensure that all 340B acquired units are excluded from Part B rebate calculations. Gilead further urges CMS to employ similar practices to ensure accuracy in identifying *non*-340B units. Specifically, Gilead asks that CMS also require the use of a 340B claims modifier as well as a non-340B claims modifier on every Part B drug claim to ensure that all excludable 340B units are appropriately and clearly identified. Requiring that every Part B drug claim use a 340B claims modifier also will help ensure that providers do not inadvertently fail to populate the modifier field.

In November 2022, CMS took a similar approach when it finalized the requirements for the use of the JW modifier for reporting discarded amounts of drugs, and the JZ modifier for attesting that there were *no* discarded amounts in the Calendar Year (CY) 2023 Medicare Physician Fee Schedule Final Rule. CMS added "the JZ modifier requirement" to "improve the completeness of the discarded drug data to effectively implement" the Infrastructure Investment and Jobs Act.[8] CMS explained that "providers who use the [JW] modifier do not do so consistently, and they vary in their reporting from one drug to another, and across claims for the same patient and drug," producing incomplete data.[9] As a result, "even though reporting the JW modifier has been required since 2017," the "current data for discarded drug amounts are underestimates due to omission of the JW modifier when it should be used."[10] Because "providers are the only party that can obtain complete and accurate information on used and discarded amounts of variably dosed drugs" and "the absence of the modifier cannot be relied upon to signify that there is no amount of discarded drug," CMS implemented the JZ modifier requirement.[11] CMS further explained that "using the JZ modifier does not add additional burden beyond the existing

[7] As CMS has recognized, the modifiers "provide an existing mechanism to identify drugs acquired through the 340B Program that is familiar to most 340B covered entities paid under the" Outpatient Prospective Payment System. CMS, Part B Inflation Rebate Guidance: Use of the 340B Modifiers (Dec. 20, 2022), https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf.

[8] 87 Fed. Reg. 69404, 69715 (Nov. 18, 2022).

[9] *Id.* at 69716.

[10] *Id.*

[11] *Id.*

requirement of measuring discarded amounts by use of the JW modifier" and that "[if] a provider is already required to determine whether there are discarded amounts from single-dose packages, then they are already assessing and documenting what is needed for the JZ modifier."[12] CMS should take a similar approach with respect to 340B modifiers because the absence of a 340B modifier cannot be relied upon to signify that the claim is not a 340B claim. Moreover, providers already must assess whether a Part B drug claim is a 340B claim, so the only additional action needed would be to add a modifier on every non-340B Part B drug claim.

The Guidance provides that "Manufacturers of Part B rebatable drugs that owe an inflation rebate can submit a suggestion of a calculation error if they identify . . . an exclusion specified in statute that was not applied in their Preliminary Rebate Report and Preliminary True-Up Rebate Report."[13] As part of this process, CMS should establish a mechanism for manufacturers to identify drug units that were not correctly identified as subject to a 340B discount. For example, CMS could provide an opportunity like the process that manufacturers currently use to dispute 340B units in 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.

Importantly, if a manufacturer identifies 340B units that should have been, but were not, excluded from Part B 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 the statutory requirement that such units be excluded from Part B inflation rebate liability.[14]

III. Gilead Supports CMS' Methodology for Excluding Part B Units Subject to Rebates Under the MDRP, Which Would Extend to Both Medicaid Fee-For-Service and Medicaid MCO Enrollees

Finally, Gilead supports the mechanism described in the Guidance for excluding Part B units subject to rebates under the MDRP, which we understand would exclude utilization by both Medicaid fee-for-service and MCO enrollees. As CMS recognizes, the IRA requires that units on which a Medicaid rebate is paid must not be subject to duplicate Part B inflation rebates.[15] In the Guidance, CMS states that it intends to address this statutory requirement by removing units in claim lines for dates of service during a quarter for Medicare beneficiaries that have Medicaid coverage in such quarter (*i.e.*, dual-eligible beneficiaries).[16] Gilead believes this approach is appropriate, given that Medicaid rebates typically would be owed on a single source drug or biological product that is dispensed to a dual eligible beneficiary and is separately payable under Medicare Part B.

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[12] *Id.*

[13] Guidance § 60.2.

[14] *See* SSA § 1847A(i)(3)(A)(i), (B)(ii)(I).

[15] SSA § 1847A(i)(3)(A)(i), (B)(ii)(I).

[16] Guidance § 50.8.2.

As contemplated in the Guidance, CMS will identify claim lines for dual eligible beneficiaries using available information, including the State Medicare Modernization Act File.[17] Based on CMS' guidance regarding *Reporting Expectations for Dual-Eligible Beneficiaries, Updated*, we understand that this file should include data for dual eligible beneficiaries enrolled in MCOs, although we are not sure how consistently MCOs report such data.[18] MCO utilization is subject to Medicaid rebates pursuant to the terms of the Medicaid rebate statute,[19] and therefore must be excluded from Part B inflation rebates. Therefore, we encourage CMS to ensure that MCOs report information for their dual-eligible enrollees in the State Medicare Modernization Act File so that that Part B claims for drugs furnished to these beneficiaries are accurately excluded from Part B inflation rebate calculations.

* * *

Thank you for the opportunity to provide feedback on the initial Guidance regarding Part B inflation rebates. If you have any questions, please do not hesitate to contact Laura Okpala at laura.okpala@gilead.com.

Sincerely,

Rekha Ramesh
Gilead Sciences, Inc.
Vice President, Policy, Government Affairs and Policy

[17] Guidance § 50.8.2

[18] CMS, Guidance: Reporting Expectations for Dual-Eligible Beneficiaries, Updated, https://www.medicaid.gov/medicaid/data-and-systems/macbis/tmsis/tmsis-blog/entry/51064 ("If a dual-eligible beneficiary is in Medicaid managed care or Medicare-Medicaid integrated care including PACE, D-SNPs, and Medicare-Medicaid Plans (MMPs), states should report the following data elements in the Managed-Care-Participation segment (MANAGED-CARE-PARTICIPATION-ELG00014) in the Eligible File….").

[19] SSA § 1927(b)(1)(A).

HARROW

Your patients. **Our purpose.**

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

March 10, 2023

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

RE: Medicare Part B Inflation Rebate Comments

Dear Deputy Administrator Seshamani,

Harrow Health, Inc. (Harrow) appreciates the opportunity to comment on the Initial Medicare Part B Inflation Rebate Guidance issued by the Centers for Medicare & Medicaid Services 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).[1]

Harrow is an eyecare pharmaceutical company focused on the development, production, sale, and distribution of innovative ophthalmic prescription medications that are accessible and affordable to Medicare beneficiaries.

In January of 2023, Harrow acquired five (5) ophthalmic products from Novartis including TRIESENCE® ("Triesence," triamcinolone acetonide injectable suspension) 40 mg/ml, a steroid injection for the treatment of certain ophthalmic diseases and for visualization during vitrectomy. Harrow has long understood the clinical and economic value that Triesence has provided to U.S. eyecare professionals and their patients and sought to acquire it from Novartis to ensure its accessibility. Indeed, since its launch on February 1, 2008, Medicare beneficiaries have come to rely on Triesence's ability, as an affordable and accessible intravitreal injection, to efficaciously treat inflammation of the eye caused by disease, injury, or its unique properties as an injectable visualization media used during certain eye procedures. For certain of its uses (e.g., visualization during vitrectomy), Triesence is the only FDA-approved product indicated for such use.

Despite its unique value, Triesence has been on the drug shortage list for the past four (4) years due to manufacturing issues. Harrow, through its acquisition of Triesence, has committed to restore access to Triesence by making additional financial investments to resolve the manufacturing issues that have kept Triesence continually on the drug shortage list. In doing so, Harrow intends for Triesence to be made

1 https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwigzt3i9MX9AhUoMVkFHQyRCaUQFnoECBAQAQ&url=https%3A%2F%2Fwww.cms.gov%2Ffiles%2Fdocument%2Fmedicare-part-b-inflation-rebate-program-initial-guidance.pdf&usg=AOvVaw0ajaUVZADpH7Qkcftd0-Kh

available and hence taken off the drug shortage list by late Q4 2023. Given this, Harrow has a particular interest in CMS' implementation of the statutory provision[2] authorizing CMS to reduce or waive the rebate amount in the case of a Part B Rebatable Drug on the shortage list.

50.11 Reducing or Waiving the Rebate Amount in the Case of a Part B Rebatable Drug on the Shortage List

Harrow supports CMS' general approach as outlined here and encourages CMS to consider flexible parameters in implementing these provisions. Below please find our specific answers to the Agency's questions on this important matter of relevance to Harrow:

- ***How should CMS reduce or waive the rebate amount in the case of a Part B rebatable drug that is on the shortage list?***

Harrow requests that CMS waive the full rebate amount for the calendar quarter when a Part B 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 invest the necessary financial resources towards addressing the shortage instead of the prospect of inflation rebate obligations.

In addition, for the benefit of Medicare beneficiaries, under certain circumstances, CMS should consider the economic commitments made by the manufacturer to remove a drug from the shortage to determine if this timeframe should be extended or waived altogether. This could indeed be the incentive needed to manufacturers that helps enable the drug to get off the FDA's drug shortage list.

- ***Are there specific types of Part B rebatable drugs where CMS might reduce or waive the rebate amount differently, and why would such an approach be necessary?***

Harrow believes that Part B rebatable drugs such as Triesence that are used for serious medical conditions such as the potential for the loss of sight or more generally for a life-threatening condition, should be provided a full waiver of the rebate, with additional consideration provided to products that do not have readily available therapeutic substitutes. Single-source drugs with a unique indication on the shortage list, for example, should also receive a full waiver of the rebate.

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, and the discontinuation of a competing product leading to unanticipated increased utilization. In developing any exclusions for waiving the rebate amount for Part B rebatable drugs on the shortage list, Harrow recommends that CMS consider adopting the same exclusions it has proposed for waivers for supply chain disruptions for rebatable biosimilars, such as an interruption in manufacturing due to routine maintenance and failure to comply with good manufacturing practices.

[2] Social Security Act (SSA) §1847A(i)(3)(G).

- ***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 need, and how CMS would identify such drugs?***

Harrow respectfully asks that CMS should define a severe supply chain disruption to mean a change in production or distribution that leads to a reduction in the U.S. supply of a Part B rebatable drug and significantly affects the ability of the manufacturer to fill orders or meet expected demand for the product. Under such circumstances, CMS should waive the rebate amount and develop policies to favor a slow removal of a product from shortage while resetting base date to a reasonable level to offset the financial burden by the manufacturer to restore the supply of the product. Harrow advocates this approach to avoid creating a perverse incentive for the manufacturer to maintain the product on the drug shortage list.

- ***Are there certain scenarios where a greater reduction, or a waiver, would be appropriate (e.g., due to the Part B rebatable drug's level of price increases over time, impact on manufacturer's solvency, or certain market factors)?***

CMS should respectfully consider the duration and frequency of a drug that has been on shortage including the manufacturer's plans to resolve the shortage. A product that has been on the drug shortage list for durations longer than 90 days due to supply chain disruption or production issues should be granted greater economic flexibility through a full waiver by CMS. As important, CMS should consider historical price increases of the drug, as well as pricing of other like or similar drugs (e.g., in the case of Triesence, similar steroid ocular injections and implants) to assess the reasonableness of any price increase and ensure it is in-line with, or in the case of Triesence – far below – the current market demands and rates for other category-related products.

- ***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 B rebatable drug on the shortage list so as to avoid a rebate obligation?***

Harrow agrees with CMS that it must avoid creating a policy that provides a perverse incentive for manufacturers of the product to conveniently keep it on the drug shortage list. As referenced above in response to the previous question, this policy criteria should include the duration and frequency a product has been on shortage as well as the actions the manufacturer plans (and has done) to resolve the shortage (e.g., investments in supply chain, an open and active technical transfer engagement, etc.). A product that has been frequently on/off drug shortage for more than six months over the last year (or longer) or that has a history of extended or frequent shortages, should be allowed greater economic flexibility by CMS to encourage the manufacturer to invest in the accessibility of the product and hence keep the product off the shortage list.

Conclusion

Overall, and given our situation with Triesence, we commend CMS for its efforts to ensure inflation rebates will be waived or, at a minimum, reduced during a product shortage situation. Harrow supports CMS's intentions to use the FDA's drug shortage lists to determine when a Part B rebatable drug is described as currently in shortage at any point during the calendar quarter. At the same time, if a shortage persists, rebate reductions (or waivers) should be maintained and not reduced.

To this end, Harrow welcomes the opportunity to partner with CMS to carefully strike the balance of removing drugs from this list while creating the incentive for manufacturers to remove them from the list. As important, Harrow is receptive to working with CMS to find innovative approaches to reintroduce drugs and therapies that have served the interests of eye care professionals and the Medicare Program.

If you have additional questions regarding the comments in this letter, please contact Andrew Thorrens, Vice President, Head of Market Access, and Health Policy at (773) 368-0091 or athorrens@harrow.com.

Sincerely,

MARK L. BAUM
Founder and Chief Executive Officer,
Harrow Health, Inc.

_____

ANDREW THORRENS
Vice President, Head of Market Access,
Harrow Health, Inc.

_____

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 B Inflation Rebate Comments

Haystack Project appreciates the opportunity to submit its comments in response to the Centers for Medicare & Medicaid Services' (CMS') Medicare Part B 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 B. 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 B 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 B rebatable drug for an applicable calendar quarter in two cases: (1) when a Part B 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 ASP Fluctuations Are Outside their Control.

Haystack Project expects that ASP 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 can have a significant impact on the ASP – 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 and other payers in reducing payment for new accelerated approval treatments. Haystack Project has voiced its objection to this policy and will continue to do so. If, however, Medicare and other 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.

Computation of Beneficiary Coinsurance

CMS' guidance ensures that the 20% beneficiary coinsurance for Part B drugs is based on the inflation-adjusted payment amount calculated each quarter. Haystack Project appreciates that CMS seeks to enable lower out-of-pocket costs for Medicare beneficiaries. We urge CMS to engage the provider and patient communities with educational outreach and resources to enable a full understanding of the rebates and their impact on beneficiary coinsurance.

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 consultant, M Kay Scanlan, JD at 410-504-2324.

Very truly yours,

Chevese Turner
CEO
Haystack Project
chevese.turner@haystackproject.org

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]

Dear Dr. Meena Seshamani,

I write to respectfully submit a comment on the approach for allocating financial responsibility for the Part B inflation rebate amount for a calendar quarter when there is more than one manufacturer assigned the same HCPCS code. Please note that my comments do not represent the thoughts or opinions of my organization and are mine alone.

Seeing as the intent of the rebate is to curb price inflation for drugs reimbursed under the Part B program, I believe the rebate formula needs to include some recognition of the prices of the products in the HCPCS code, and not just the units. With that overarching principle in mind, I submit three (3) potential options for CMS's consideration, along with some of the pros and cons I see for each option.

1. Option 1: Calculate share of financial responsibility based on each product's ASP relative to the inflation-adjusted benchmark payment rate. The ratio applicable to each manufacturer's product would be calculated based on the percentage by which *each product's ASP is greater than the inflation-adjusted benchmark payment rate*.
    a. Pro: This calculation formula is relatively simple and allocates the greatest share of the financial responsibility to manufacturers that have priced their products in a manner that has bolstered the Part B payment rate.
    b. Cons: This approach is arguably unfair because it fails to account for each product's relative market share (i.e., sales units). This approach is also unfair because it fails to account for the *price increase* taken by each manufacturer – which is the driver of the per unit rebate amount.

2. Option 2: Calculate share of financial responsibility based on the *rate by which each product's ASP has increased greater than inflation* relative to the benchmark period.
    a. Pro: This approach is arguably fairer as compared to Option 1 because it considers the underlying cause for the Part B payment rate increasing at a rate greater than inflation.
    b. Con: As with Option 1, this approach is arguably unfair because it fails to account for each product's relative market share.

3. Option 3: Calculate share of financial responsibility that is weighted 50/50 based on: 1) the rate by which each product's ASP has increased greater than inflation relative to the benchmark period AND 2) each product's relative market share.
    a. Pro: This approach is arguably fairer than both Options 1 and 2 because it considers *both* the underlying cause for the Part B payment rate increasing at a rate greater than inflation and the units
    b. Cons: This calculation formula adds greater operational complexity as compared to a formula that considers just units or just dollars. Arguably, there could also be considerable debate as to how much weight to assign to the price vs. the units component of the equation.

Please let me know if your team is interested in further exploring any of the above-described options and/or if numerical examples would be useful. I would be happy to provide additional context or help in any way to support CMS's efforts that are going into implementing the program.

Sincerely,

[redacted]

March 10, 2023

VIA ELECTRONIC SUBMISSION

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

IRARebateandNegotiation@cms.hhs.gov

Re: Medicare Part B Inflation Rebate Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the Social Security Act (SSA), and Solicitation of Comments

Dear Administrator Brooks-LaSure:

On behalf of Integra LifeSciences Corporation (Integra LifeSciences), I am writing to provide comments on the Medicare Part B Inflation Rebate Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the SSA, and Solicitation of Comments posted on the Centers for Medicare & Medicaid Services (CMS) website on February 9, 2023.[1] While Integra appreciates the statement in Section 30.1 of the Part B Inflation Rebate Guidance that skin substitute products will not be counted for purposes of identifying Part B rebatable drugs for a calendar quarter during 2023, we ask that CMS clearly confirm in revised guidance that the agency does not have the discretion to include skin substitute products that are not approved by the Food and Drug Administration (FDA) as biologicals in the Part B inflation rebate calculation in any calendar quarter in any year.

BACKGROUND

Currently, skin substitute products are regulated by the FDA in a number of ways. The typical ways are as devices cleared by the FDA through the 510(k) clearance process, as devices approved through the premarket approval process, as devices for which a de novo classification request is granted, or as

[1] This guidance document (hereinafter "Part B Inflation Rebate Guidance") is available at https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.

products regulated as human cells, tissues, and cellular and tissue-based products (HCT/Ps). While a skin substitute product could be approved for marketing as a biological through the biologics license application (BLA) process, no skin substitute products are currently approved for marketing through this process.

Section 30.1 of the Part B Inflation Rebate Guidance addresses skin substitute products and, in doing so, includes the following statement:

> While CMS considers making changes to the Medicare Part B payment policies for such products, HCPCS codes that describe products currently referred to as skin substitutes will not be counted for purposes of identifying Part B rebatable drugs for a calendar quarter during 2023 and, as such, will not be subject to the coinsurance adjustment described in section 40 of this memorandum.

By indicating that skin substitute products will not be counted as Part B rebatable drugs for calendar quarters in 2023, CMS is strongly suggesting that it has the authority to so count skin substitute products in the future. With one exception that is not applicable today, this suggestion is contrary to the statutory definition of Part B rebatable drugs.

CMS'S PART B INFLATION REBATE GUIDANCE MUST ACKNOWLEDGE THAT SKIN SUBSTITUTES THAT ARE NOT FDA APPROVED AS BIOLOGICALS CANNOT, BY LAW, BE PART B REBATABLE DRUGS

Section 1847A(i)(1)(A) of the Social Security Act (SSA) specifies that only a "part B rebatable drug" is subject to the rebate program. Such term is defined in SSA § 1847A(i)(2) as "a single source drug or biological (as defined in subsection (c)(6)(D)) or a biosimilar biological product (as defined in subsection (c)(6)(H)) for which payment is made under this part and that is furnished from a single-dose container or single-use package." Under the law, then, a product falls within the definition of Part B rebatable drug only if it is (i) a single source drug, (ii) a biological, or (iii) a biosimilar biological product. No existing skin substitute product fits within any of these categories, and, thus, as a whole, skin substitute products today are not Part B rebatable drugs.

As noted above, currently, there no skin substitute products that are marketed as biologicals, and, thus, skin substitute products today are neither biologicals under SSA § 1847A(c)(6)(I) nor biosimilars under SSA § 1847A(c)(6)(H). As such, the only remaining way for a current skin substitute product to be a Part B rebatable drug is if such a product falls within the definition of "single source drug" under SSA § 1847A(c)(6)(D)(ii). Under that provision, to be a "single source drug," a product must be produced or distributed under a new drug application, which skin substitutes are not. Therefore, under the law, skin substitute products today are not (i) single source drugs, (ii) biologicals, or (iii) biosimilar biological

products, as those terms are defined in pertinent parts of SSA § 1847A(c)(6), and thus are not Part B rebatable drugs under the letter of the law.

Given the clear bounds of the law, we urge CMS to revise the Part B Inflation Rebate Guidance to state clearly that skin substitute products are not Part B rebatable drugs unless they are approved by the FDA as biologicals through the BLA process.

CONCLUSION

Thank you for considering Integra LifeSciences's comments. The law is clear that skin substitutes that are not FDA approved as biologicals, which constitutes the full set of currently marketed skin substitute products, cannot be Part B rebatable drugs. But the guidance that CMS released suggests otherwise, so it is important that revised guidance include a clear statement of the law as applied to skin substitute products. If you have any questions, do not hesitate to call Donna Cartwright at (609) 529-2741 or email her at donna.cartwright@integralife.com at your convenience.

Sincerely,

Kristen V. Hedstrom

Kristen V. Hedstrom, MPH
Vice President, Market Access & Professional Education

White Paper

Can 340B Modifiers Avoid Duplicate Discounts in the IRA?

Authors:
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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.

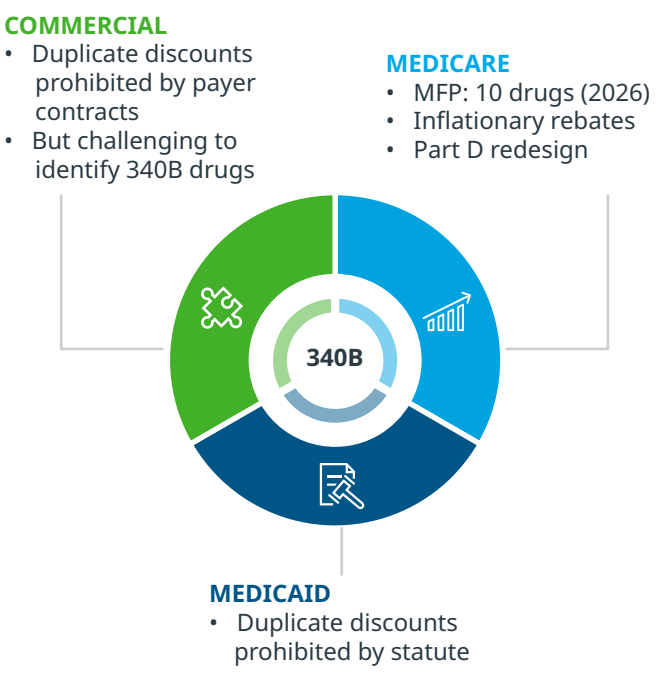
Medicare Part D represents 40.1% of business for 340B-eligible, branded drugs while Medicare Part B is 36.3%, meaning that $34.0B to $37.5B of sales at wholesale acquisition cost (WAC) pricing may be at risk for IRA/340B duplicate discounts. These findings suggest that 340B modifiers provide visibility 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.

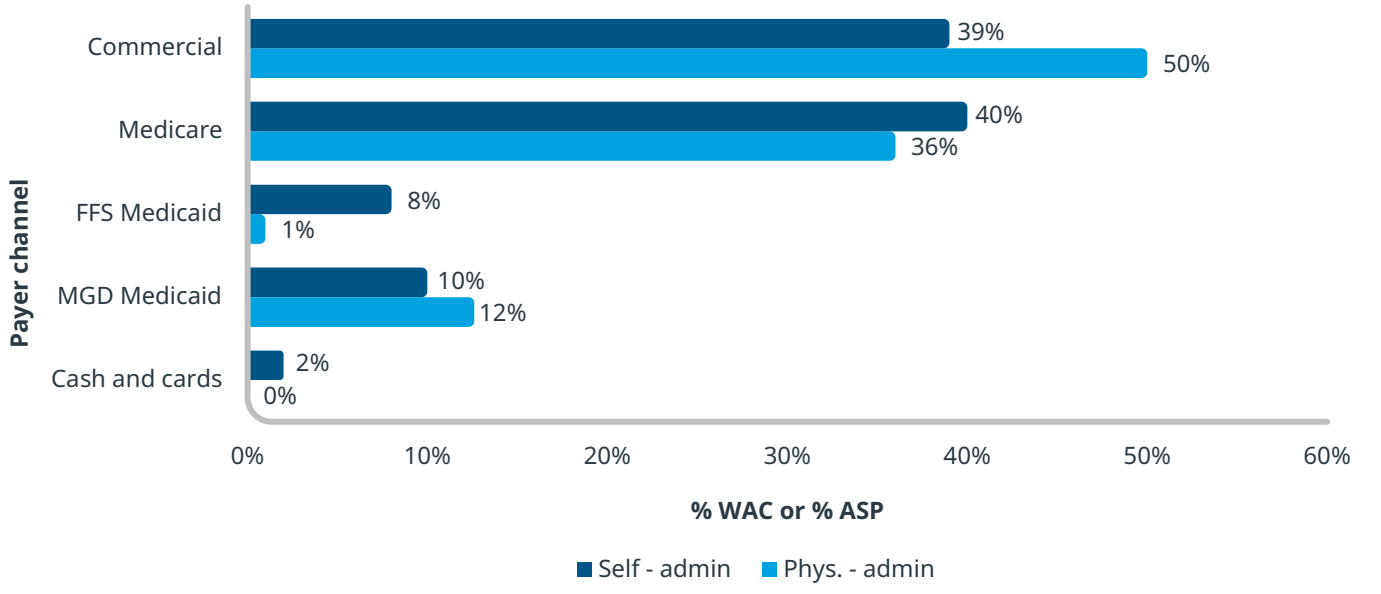


Figure 3: Modifier frequency for drug treatments by payer channel and entity type for pass-through and separately payable drugs

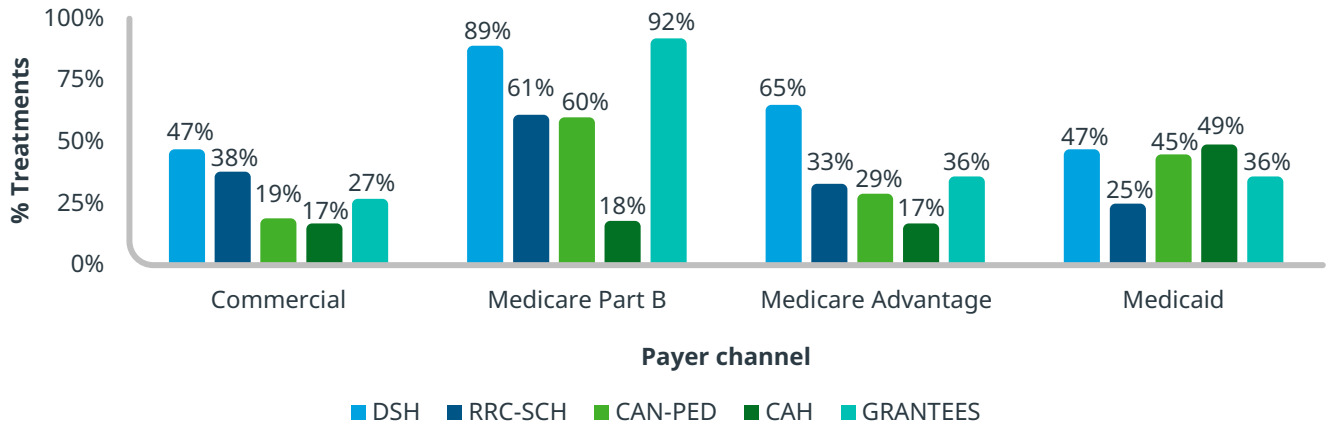
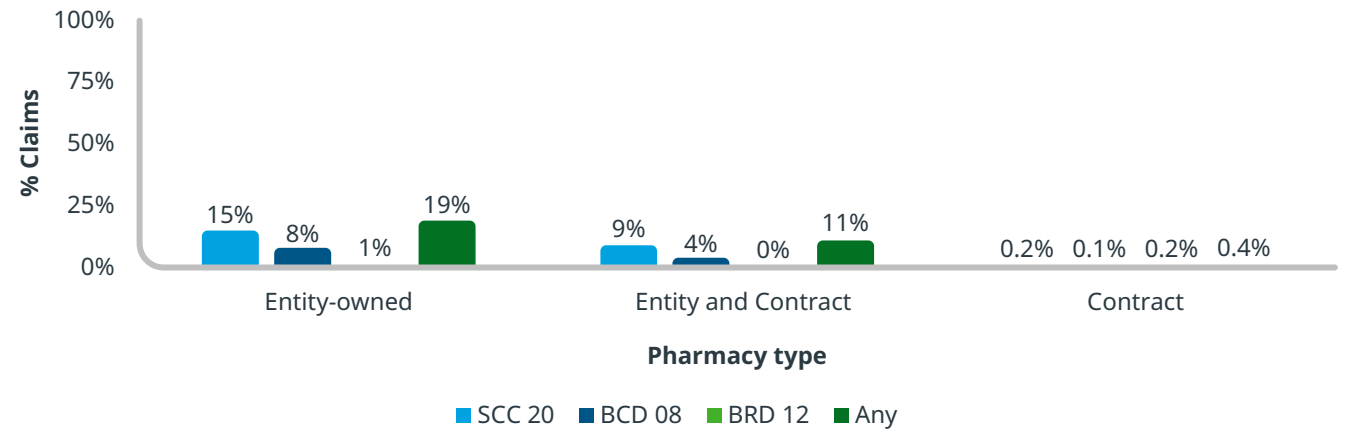


Table 3: 340B modifier frequency by entity type and drug type for Medicare Part B physician-administered drugs. Mandatory reporting for Part B is indicated by a bold font, while modifier rates are shown using shading. There were no reporting requirements for federal grantees during the period of the 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.

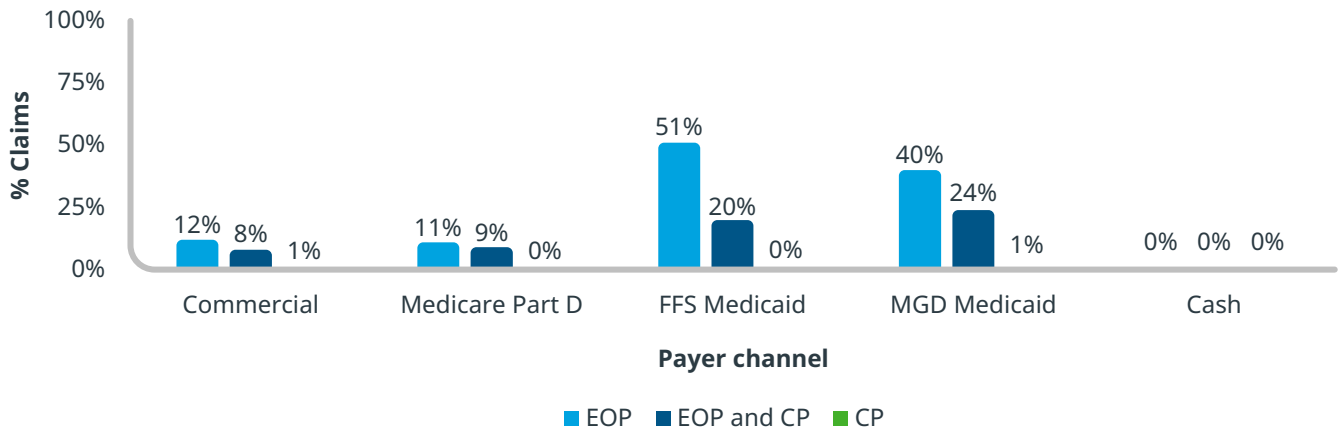
SELF-ADMINISTERED DRUGS

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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Harish applies data science techniques to draw insights from large data sets, and implements inovative methods to aid Gross to Net efforts at IQVIA. He has a background in scientific research and publications.

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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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Johnson & Johnson

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 B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) 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 B 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.

J&J thanks CMS for the opportunity to continue our ongoing dialogue with the agency on the implementation of the IRA and appreciate CMS' consideration of these comments. Of note, we would like to underscore two key issues that are critically important in the implementation of the Part B inflation rebates.

1. **Transparency is fundamental in ensuring program integrity**. The economic impact of the inflation rebate program is substantial – estimated at $9 billion in 2031 by CBO[1]. Adequate financial controls must be in place to ensure the accurate implementation of this significant program. At a minimum, this includes 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.

2. **CMS Does not Have the Statutory Authority to Include Units Furnished to Medicare Advantage (MA) Enrollees in Part B Inflationary Rebates.** The statutory language states that inflation penalties apply to Part B rebatable drugs, not drugs furnished under Medicare Advantage (MA), or Part C. CMS does not have the required information to reliably include Part C units in the Part B rebate calculation. As CMS makes capitated per member, per month (PMPM) payments to the MA plans, and the plans pay providers for Part C items and services furnished to enrollees, we interpret the language of the statute, as well as Congressional intent and practical application of the legislative provisions, as withholding authority from CMS to include Part C units in the calculation of Part B rebates.

[1] https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf

Section 30: Determination of Part B Rebatable Drugs
In this section CMS notes that it does not intend to count drugs and biological products that are billed using a HCPCS code that represent an "unclassified," "unspecified," or "not otherwise classified" drug or biological product or claims for such drugs and biological products when no other HCPCS code is applicable. J&J supports this approach, and for clarity asks CMS to stipulate in final guidance that new Part B drugs are not subject to the inflation penalty until a HCPCS code is assigned.

Section 50: Calculation of the Medicare Part B Inflation Rebate Amount

50.4: Identification of the Payment Amount in the Payment Amount Benchmark Quarter
J&J asks CMS for clarification for new Part B drugs for which the HCPCS payment amount has not yet been established. For these products, CMS pays WAC + 3%; however, manufacturers also perform the calculation and submit "specified" ASP at the NCD11 level. We ask CMS to clarify that for establishing the benchmark quarter, it will use data *reported by manufacturers* for each HCPCS code at the NDC11 level and provide visibility to manufacturers as to the detailed methodology for the calculation.

50.8: Determination of the Total Number of Units:
In this section CMS outlines its approach for determining the total number of units for each Part B rebatable drug by HCPCS code. We appreciate the initial guidance for this process but note that manufacturers will need transparency into the methodology, calculation and ultimately the determination of the total number of units, including visibility to the claims-level data for the included / excluded units in order to confirm and validate CMS' determinations.

50.8.1: Removal of 340B Units
J&J supports CMS' proposed approach to exclude 340B units from the rebate calculations prior to 2024 by excluding all units captured on claims by CAHs, MD waiver hospitals, and non-excepted off-campus provider-based departments, as well as all professional claims for Medicare suppliers listed by HRSA as participating in the 340B program. Beginning in 2024, CMS outlines its approach to exclude units identified through use of the JG and TB modifiers. While J&J supports the exclusion of such units, we recommend CMS implement a non-340B modifier to ensure 340B claims are consistently and correctly identified. To enforce use, we recommend CMS reject claims submitted without a340B or non-340B modifier. Compliance with these required modifiers is critical to enabling CMS to comply with statutory requirements to 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. In the case where improper identifiers are attached, we suggest CMS impose appropriate penalties including all subsequent claims from the entity should be assumed to be miscoded until demonstrated otherwise, via an audit or other demonstration of due diligence. 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. J&J reiterates that we are aligned, and support PhRMA's comments related to this section.

50.8.2: Removal of Units with a Rebate Under Section 1927 of the Social Security Act
CMS states its intent to remove units in claim lines for dates of service during a quarter when the Medicare beneficiary has Medicaid coverage by identifying the dates for which a beneficiary has Medicaid coverage at the time the rebate amount is being calculated for a calendar quarter. J&J supports this policy, and notes that Medicaid claims submissions often lag by 2+ quarters. We ask CMS to clarify the process for accounting for units included on claims submitted after the calculation period for Medicare beneficiaries that have Medicaid coverage. We encourage CMS to ensure they are appropriately removed. We also ask CMS to clarify in final guidance its process for identifying and excluding claims for Medicaid MCO enrollees in addition to Medicaid FFS enrollees.

50.8.5: Operational Considerations Related to the Inclusion of Units Furnished to Beneficiaries Who are Enrolled in Medicare Advantage Plans
J&J disagrees with CMS' interpretation that Medicare Advantage units are included in the statutory definition of Part B rebatable drug. For beneficiaries enrolled in Medicare Advantage, payment for physician administered drugs is made under Part C. The statutory language states that inflation penalties apply to Part B rebatable drugs, not Part C. Moreover, we point out that the statutory language describes applying the penalty amounts to reduce cost sharing for FFS beneficiaries but does not make the same mention of Medicare Advantage beneficiaries. In addition, we are

concerned that the inclusion of Medicare Advantage units could introduce program integrity issues, as the agency itself noted the significant operational complexities posed by the inclusion of these units.

The statute limits the definition of rebatable Part B drugs to drugs "for which payment is made under this part". Because section 1847A of the SSA is codified under Part B of Title XVIII, "this part" refers to Part B. Additionally, we note that the statute 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" from the Part B rebate calculation."[2] CMS makes capitated payments to MA plans on a PMPM basis to cover MA plan costs of reimbursement for the full range of inpatient, outpatient, and provider-based services covered under Part C, and therefore units furnished under Medicare Advantage are not separately payable and should be excluded. Based on a plain reading of the statute, inflation penalties apply to Part B rebatable drugs, and not drugs furnished under Medicare Advantage.

For these reasons, we strongly encourage CMS to exclude MA units from the calculation of rebatable units. J&J is aligned with and strongly supports the comments submitted by PhRMA related to this section.

Section 50.13: Financial Responsibility for Part B Inflation Rebate Amount

In cases where a single source drug has multiple manufacturers, we recommend that CMS determine financial responsibility for the inflation rebate using the manufacturer "specified" or reported ASP data at the NDC11 level. It is important that CMS identify rebate liability based on each manufacturer's Part B rebatable drug and avoid assessing penalties to manufacturers whose growth in ASP have been below inflation. Rebate liabilities should be calculated separately for each manufacturer using reported ASP data at the NDC11 level. As an example, blending ASP data would unfairly burden "Manufacturer A", who does not have any NDC-11s with a rebate period ASP exceeding the inflation-adjusted ASP when the associated HCPCS code includes additional NCD-11s belonging to "Manufacturer B" that did exceed the inflation-adjusted ASP. It would be incorrect to assess penalty liability to Manufacturer A in this scenario. We further ask CMS to require providers to report the associated product NDC11 on claim forms. To enforce reporting, claims submitted without this information should be rejected. Assessing rebate liabilities for each manufacture using reported ASP data at the NDC 11 level will also eliminate the risk, or incentives, for a manufacture to raise prices above inflation while knowing that their rebate liability may be distributed across other manufacturers who did not take the same price increase actions.

Section 60: Ensuring Integrity of Part B Inflation Rebates

60.0: Ensuring Integrity of Part B Inflation Rebates

J&J appreciates CMS creating a process for manufacturers to review preliminary rebate reports and identify errors to CMS. However, to allow for meaningful and informed reviews, J&J asks that CMS provide all data necessary to assess the accuracy of the calculated amount and rebate. For example, we ask CMS to provide manufacturers visibility to the benchmark payment amount for the billing and payment codes, applicable payment amount for the calendar quarter for the billing and payment code, benchmark and rebate quarter CPI-U values, claims level data for the billing and payment code with number of units administered during the calendar quarter, indicators for units excluded due to being subject to 340B agreements, indicators for units excluded due to a Medicaid rebate; dosage for the billing and payment code, and the date on which a Part B rebatable drug has become a multiple source drug.

Moreover, we ask CMS to establish a process for receiving and resolving disputes related to incorrect invoices. This is important to program integrity and accurate implementation of the law.

60.1: Timing of Reports and Payment

We are concerned that 10 days for review of these preliminary rebate and true up 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 our fiduciary duties, 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, ASP, 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

[2] SSA § 1847A(i)(3)(B)(ii)(II)

ensure appropriate levels of review. As noted above, we underscore that manufacturers will need visibility to all 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 strongly recommends and requests a computer readable file format within a modern spreadsheet application, such as ASCII delimited for fixed file format.

60.2 and 60.4: Restatements and True-Up Report and 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 time of three to four years in which it may true up rebate amounts based on CMS identification of errors.

70. Enforcement of Rebate Payments by Manufacturers: Civil Monetary Penalties (CMPs)
Consistent with the statute, CMS notes its intent to establish a process for Part B inflation rebate CMPs pursuant to regulations. J&J urges CMS not to subject manufacturers to inflation rebate penalties until final regulations are established through notice and comment rulemaking 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 the Medicare Advantage organizations, Part D prescription drug plan sponsors, and CMP procedures issued by the Office of the Inspector General (OIG).

Other Topics:

Discarded Units of Certain Part B Single-Dose Container Drugs
J&J asks CMS to clarify that refunded units of discarded single-dose container Part B drugs will not be included in calculation of the inflation drug rebate penalties. Beginning in 2023, CMS will bill manufacturers for refunds on discarded units of these drugs. Because these units are refunded by manufacturers, payment is not made under Part B for the units. Therefore, under the statute, they should not be included in the Part B inflation rebates. The methodology we propose is the removal of the discarded units rebate obligations from the inflationary rebate calculations quarterly by drug (also accounting for the remove of all other required units, such as 340B etc.).

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 B 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 1847(A)(i) of the Social Security Act concerning Medicare Part B Drug Inflation Rebates Paid by Manufacturers (hereinafter, "Part B Initial Guidance" or "Guidance"). Kalderos has also submitted corresponding comments on 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.

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 B 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 B 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 B Initial Guidance frames the dispute process as a "suggestion" that an error may exist, which is not sufficient to ensure that Part B 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 B 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.

- Claims Data With PHI: Unlike claims data related to drugs covered under Medicare Part D, physician-administered drugs covered by Medicare Part B often do not include information needed for a manufacturer to a) compare a Part B rebate against MDRP claims data, and b) work effectively with 340B Covered Entities to verify if a 340B duplicate discount happened. Without claims data containing the appropriate identifiers that can be used to compare a Part B inflation rebate against MDRP rebate claims data, it will be impossible for manufacturers to ensure they are not paying a duplicate MDRP rebate and Part B Inflation Rebate on the same unit sold.

- Identification of 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 B Inflation Rebate. Specifically, we are concerned that the proposed method of identifying such products—using a modifier—will be insufficient to properly identify claims. As a result, duplicate discounts 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 channel partners to identify 340B claims and facilitates 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 B Inflation Rebates. The Part B Initial Guidance merely provides:

> Manufacturers of Part B rebatable drugs may provide suggestions of calculation errors in their Preliminary Rebate Report and Preliminary True-up Rebate Report (as described in section 60.3 below) to CMS, for its discretionary consideration, 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 B rebatable drugs that owe an inflation rebate can submit a suggestion of a calculation error if they identify a mathematical error in the calculation by CMS or an exclusion 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. … CMS reserves discretion to review or consider these suggestions as appropriate.[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

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[1] *See* CMS, "Medicare Part B Drug Inflation Rebated Paid By Manufacturers: Initial Memorandum, Implementation of Section 1847(A)(i) of the Social Security Act, and Solicitation of Comments" at 30 (Feb. 9, 2023), https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.

[2] *See* 42 U.S.C. 1395w-3a(a)(i)(8).

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 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 B 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 B Inflation Rebates. We urge CMS to implement a dispute resolution process for Part B Inflation Rebates. As a starting point, CMS should consider drawing from the dispute resolution process provided under the MDRP. Kalderos supports a Part B 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

[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.

process, in which they are required to respond to data inquiries and to confirm the accuracy of claims. Revised guidance should clarify that providers, pharmacies, and states to the extent MDRP claims are not appropriately excluded for dual eligible individuals, must assist in reviewing and validating claims data.

3. **Require CMS to review all reports of inaccurate data**: The Part B Initial Guidance currently allows CMS discretion to review 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 B 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.[6] 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."[7] The best practices guidance goes on to state that "manufacturers likely need claims level data for true invoice validation purposes."[8] 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] 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.
[7] *Id*.
[8] *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**.[9]

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."[10] 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."[11] 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.[12] 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 B 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 must provide claims data to manufacturers in the Preliminary Reports for validation purposes. Without manufacturers receiving claims data and using the claims data identify and report inaccurate or duplicate claims to CMS, accurately calculating Part B Inflation Rebates owed by manufacturers will be impossible.

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[9] 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).
[10] 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.
[11] CMS, Hot Topics and Best Practices (Aug. 2020), available at https://www.medicaid.gov/sites/default/files/2020-09/drp-hottopics-bestpractices.pdf.
[12] OIG, Medicaid Drug Rebate Dispute Resolution Could be Improved (Aug. 2014), available at https://oig.hhs.gov/oei/reports/oei-05-11-00580.pdf.

Additionally, the provision of claims data is an important element in preventing duplicate discounts under the 340B Program for individuals that are dually eligible for Medicaid and Medicare Part B. Under the Part B Initial Guidance, CMS states:

> CMS intends to remove units in claim lines for dates of service during a quarter when the Medicare beneficiary has Medicaid coverage. CMS intends to identify the dates for which a beneficiary has Medicaid coverage using available information (for example the State Medicare Modernization Act File ("MMA file") of dual eligible beneficiaries) at the time the rebate amount is being calculated for a calendar quarter.[13]

We support CMS' intention to remove dual eligible claims, however, we note that CMS' method of removing these claims – by using dates of coverage – will lead to inaccurate calculations. Medicaid enrollment often takes several months between when a beneficiary applies for Medicaid and when the beneficiary is added to the Medicaid database. Given this delay, it is common for claims for new Medicaid beneficiaries to be processed after the patient was enrolled in Medicaid, but before they may be properly identified as a Medicaid beneficiary. To prevent duplicate discounts, it is important that CMS provide claims data, including the claims data discussed in Section IV.

IV. CMS Must Include Claim Identifying Information as Part of Claims Data Sharing

We urge CMS to require that Part B Inflation Rebate claims and MDRP claims include identifying information to assist in the prevention of duplicate discounts. Specifically, we urge CMS to include the following identifying information in the claims data provided to manufacturers with the Inflation Rebate amounts: (1) medical record number; (2) patient date of birth; (3) National Provider Identifier (NPI) of the provider associated with medical billing; and (4) the internal control number (ICN).[14] This information is critical to correctly match Part B Inflation Rebate claims and MDRP claims to identify duplicate discounts. Absent this data, manufacturers will have no ability to identify duplicate discounts.

We understand that the hesitance in providing unique identifiers under the MDRP may be due to concerns that the sharing of such data would implicate data privacy and security provisions under the Health Insurance Portability and Accountability Act (HIPAA) and related data privacy laws. However, as the government has recognized, because rebate amounts are based on "drug utilization by individual enrollees, such disclosures are permitted" in the context of validating claims.[15] Accordingly, CMS should require that these data points be included in Part B Inflation Rebate claims and MDRP claims so that stakeholders can validate claims and identify duplicate discounts.

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[13] *See* CMS, Part B Initial Guidance at pg 19.

[14] We note that for Part D claims, the RxID can be used to identify claims across systems; no single identifier exists for Part B claims.

[15] *See* Department of Health and Human Services, HIPAA FAQ, (June 5, 2003), available at https://www.hhs.gov/hipaa/for-professionals/faq/456/does-hipaa-permit-state-medicaid-agencies-to-disclose-information-to-pharmaceutical-manufacturers/index.html

V. Claim Modifiers 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 B 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.[16] 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,"[17] 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."[18]

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, claims modifiers, such as the "UD" modifier used by many states, 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

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[16] *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.").

[17] 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.

[18] *Id.*

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.

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.

VI. Covered Entity Participation

We are concerned that the Part B 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 B 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
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RE: Medicare Part B Inflation Rebate Comments

Dear Deputy Administrator Seshamani:

Eli Lilly and Company (Lilly) is pleased to respond to the Initial Guidance on Medicare Part B 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 B Rebates on Eligible Units of Part B 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

[1] CMS, Center for Medicare, "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." (Feb. 9, 2023)

refunds. This view disregards statutory mandates and is shortsighted, as manufacturers will 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 and 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 back end for resolving these.

To avoid and minimize erroneous claims, **Lilly urges CMS, as a threshold matter, to provide Part B invoice documentation that makes available claim-level details to support Part B rebate invoices. Specifically, we request CMS provide the following data elements in their invoice reports:**

- Date of Service
- Prescription ID Number
- De-identified Beneficiary ID Number
- National Prescriber Identified (NPI)
- Pharmacy NPI
- National Drug Code
- HCPCS Code
- Days Supply (if applicable)
- Quantity Dispensed
- Fill Number

As Lilly has reviewed this draft Part B Inflation Guidance, we have identified several foreseeable examples where manufacturers are likely to seek resolution of fact-specific requests to correct or amend Part B rebate invoices. Specifically:

- Errors Attributable to Blended HCPCS Codes: Manufacturers who do not raise prices at all might share a HCPCS code with a manufacturer of a product who does increase prices. Because of the "quirks" in the HCPCPS coding system, the manufacturer who took no action to change prices (or discounts) offered in the market could have to pay "inflation rebates" based entirely on the actions of another manufacturer. This result is contrary to Section 1847A(i)(1)(B), which requires "the manufacturer of a Part B rebatable drug" to "provide to the Secretary a rebate that is equal to the amount specified… for ***such drug*** for such calendar quarter". Nowhere in section 1847A(i) is a manufacturer of a Part B rebatable drug required to provide a rebate to the Secretary for its Part B rebatable drug based on the growth in ASP of another manufacturer's Part B rebatable drug. What recourse do manufacturers have to addresses these erroneous rebate requests?

- Errors Identified in Preliminary Rebate Reports: In sections 60.1 and 60.2 of the Guidance, CMS notes its intention to send manufacturers a Preliminary Rebate Report no later than five (5) months after the end of each calendar quarter. 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 B 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 turnaround 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 ASP data by manufacturers, CMS revision of payment limits, 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 Associated with Changes to "Single Source" Status: In section 50.8.4 of the Guidance, CMS acknowledges that a single source drug that is a Part B rebatable drug could become a multiple source drug—and therefore no longer meet the "Part B rebatable drug" definition—either at the start of or during a calendar quarter. CMS intends to identify the date of first sale of a drug product that is rated as therapeutically equivalent to that drug under FDA's Orange Book. Again, manufacturers often monitor these developments closely and will know when a product's status changes. This also applies to drugs that are "treated" as multiple source drugs under section 1847A(c)(6)(C)(ii) of the Social Security Act because those drugs share a billing and payment code (*i.e.*, a HCPCS code) with another single source drug or biological as of October 1, 2003. To the extent there are discrepancies between CMS's timing or determination that a drug is no longer "single source" and a manufacturer's view, there should be a forum for resolving such disagreements.

- Errors Related to Ineligible Duplicate Discounts: Section 1847(i)(B)(ii)(II) prohibits duplicate discounts on units subject to Medicaid rebates or 340B discounts. 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 statutory commands are heeded.

- Discrepancies on Units Associated with Part B Wastage Refunds: Under section 1847A(h) of the SSA, titled "[r]efund for certain discarded single-dose container or single-use package drugs," a manufacturer must pay refunds to CMS for certain units of the manufacturer's drugs for which a provider receives Part B payment but that are discarded by the provider. Manufacturer refunds to Medicare on discarded units of these drugs (known as refundable

single-dose container or single-use package drugs) are calculated and billed to manufacturers by CMS and accrue on a quarterly basis starting in the first quarter of 2023.[2]

Discarded drug refunds paid by a manufacturer to CMS are not mentioned in the Guidance but are relevant to the calculation of Part B inflation rebates. As noted above, Part B inflation rebates are limited to certain drugs "for which payment is made under this part [Part B]."[3] Drugs on which manufacturers pay discarded drug refunds fall outside this category. While these drugs are initially paid by Part B (to the provider that administers the drug to the Medicare beneficiary), starting in 2023, the manufacturer refunds the Part B payment to Medicare via the 1847A(h) discarded drug refund. Accordingly, units of Part B drugs for which CMS receives a discarded drug refund should not generate Part B inflation rebates, because *"payment is [not] made under this part."*[4] Lilly believes it would be contrary to the statute to seek a Part B inflation rebate on a wastage units of drug that a manufacturer must effectively "buy back" from the government. While it is possible for CMS to net these units against a Part B rebate, one could envision discrepancies in these data and the need for a dialog with CMS as to the appropriate assessment of the Part B rebate calculation.

- Errors Based on Changes to the Maximum Allowable Cost or Average Sales Price (ASP): Outside of the routine restatement process, CMS should allow for non-routine restatements based on changes in the determination of a maximum allowable cost, which may be set with reference to ASP or, in some cases, the Average Manufacturer Price (AMP) or a "widely available market price" (WAMP). Manufacturers can, and do, continuously review their calculation methodologies and the transaction-level data that feed into them to ensure compliance with these price reporting obligations. Given the risk of Civil Monetary Penalties (CMPs) associated with erroneous reporting, including in connection with the Part B inflation rebate program, manufacturers should be able to contact CMS to work with the agency to correct erroneous pricing anytime it is necessary to avoid penalties.

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 to State Medicaid Programs Regarding the Collection and Availability of Claim Level Detail (CLD) to Manufacturers

Under section 1847A(i)(3)(B)(ii)(I) of the SSA, CMS is required to exclude units for which a manufacturer paid a Medicaid rebate under section 1927 of the SSA from the calculation of Medicare Part B inflation rebates. CMS is proposing to identity and exclude these units by removing claims for dates of service during a rebate quarter when a Medicare beneficiary also has coverage under Medicaid.

Lilly supports CMS's proposed approach for presumptively excluding units where a Medicaid rebate is paid, but we believe this should be accompanied by a mandate for state Medicaid agencies to provide manufacturers with claim-level detail (preferably in a standardized format) so that

[2] SSA § 1847A(h)(2).
[3] SSA § 1847A(h)(8)(A).
[4] *Id*. (emphasis added).

manufacturers can assist CMS in their efforts to identify and exclude ineligible Part B rebate requests. Assuming Medicare provides claim-level detail to manufacturers as supportive documentation for Part B invoices, manufacturers can compare these two datasets against one another to confirm that all the ineligible Part B rebate units have been properly excluded. This is even more important because enrollment data used for identifying Medicare beneficiaries dually enrolled in Medicaid covers enrollment in both Medicaid fee for service (FFS) plans and Medicaid managed care organizations (MCOs) may be imperfect. As of fiscal year 2020, 36.5% of Medicaid beneficiaries over the age of 65 were enrolled in MCO plans.[5] This is a significant share of enrollees that CMS needs to identify, but it may be more efficient for CMS to enlist manufacturer support in ensuring that this statutory requirement is met.

III. CMS Needs to Provide Additional Guidance Related to Penalties for Covered Entities That Fail to Include 340B Claims Modifiers

Under section 1847A(i)(3)(B)(ii)(I), the SSA requires CMS to exclude units subject to an agreement under section 340B of the Public Health Service (PHS) Act from the calculation of Medicare Part B inflation rebates. Similarly, in the context of Part D inflation rebates, section 1860D-14B(b)(1)(B) of the SSA also prohibits duplicate rebates in that context. Lilly appreciates that CMS issued guidance in December 2022 instructing covered entities to use the "JG" and "TB" modifier starting in 2024.[6]

While we appreciate this incremental approach, there are no clear consequences for covered entities that do not comply with this requirement. In fact, we are not even certain covered entities will agree that CMS's "subregulatory" guidance is legally binding on them.

We believe that CMS and its sister agency the Health Resources and Services Administration (HRSA) should work together to undertake a holistic review of all of the statutory prohibitions against duplicate discounts on 340B units. These non-duplication requirements extent to Part B rebate units, Part D rebate units, Medicaid rebate units (fee-for-service and managed care), and Maximum Fair Price (MFP) units. And these prohibitions are absolute – meaning zero instances of duplication should be countenanced. At Lilly, we have documented widespread noncompliance with the prohibition on Medicaid duplicate discounts, even after 30 years of waiting for HRSA to perfect their nonduplication procedures and guidances.

In the meantime, Lilly supports CMS's proposed approach for excluding units subject to a 340B agreement for rebate quarters in 2023 as a partial measure. We also support the proposed approach for excluding units subject to 340B discounts for rebate quarters in 2024 and future years. However, we strongly encourage CMS, through future guidance or rulemaking, to add a required "non-340B" modifier value and for the Medicare Administrative Contractors (MACs) to reject claims as incomplete if they do not contain one of the relevant 340B or non-340B modifier values. 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 CMS for the Part B 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

[5] MACPAC. MACStats: Medicaid and CHIP Data Book. December 2022. Available at: https://www.macpac.gov/wp-content/uploads/2022/12/MACSTATS_Dec2022_WEB-508.pdf

[6] CMS. Part B Inflation Rebate Guidance: Use of 340B Modifiers. December 20, 2022. Available at: https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf

discarded, or, effective July 1, 2023, use the "JZ" modifier to attest that no amount of drug was discarded.[7]

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 played by 340B third-party administrators (TPAs) and split-billing vendors today.[8] Units marked as subject to 340B agreements on either the claim or by the 340B clearinghouse would be excluded from calculation of the Part B inflation rebate.

Additionally, in the revised guidance, CMS should make clear that the requirement for covered entities to use claims modifiers to identify drugs acquired under the 340B program preempts any conflicting state or local laws or regulations. Both the Medicare program and the 340B program are federal programs, and states do not have the authority to enact laws that conflict with or otherwise interfere with fulfilling the requirements or objectives of those programs. Therefore, CMS should make clear that state laws are preempted by federal law to the extent they would otherwise conflict or interfere in any way with claims modifier requirements imposed by CMS under the Calendar Year 2023 Outpatient Prospective Payment System final rule,[9] CMS's December 20, 2022, guidance,[10] or otherwise.

IV. CMS Cannot Collect Part B Inflation Rebates on Product Furnished and Paid for Under Part C of the Medicare Statute

In section 50.8.5. of the Guidance, CMS suggests that section 1847A(i) of the SSA requires or permits the inclusion of units of drugs furnished to Medicare Advantage (MA) enrollees under Part C in the calculation of manufacturer rebate amounts and seeks comment on the best sources of information to capture these units, as well as on how to remove units CMS must exclude from the calculation of rebate obligations under section 1847A(i)(3)(B)(ii) of the SSA.

Lilly believes this is an incorrect reading of the statute because CMS does not have the authority to include units furnished to MA enrollees, covered under Part C, in the calculation of Part B rebates. Lilly recommends that CMS clarify in revised guidance that the Part B inflation rebate calculation only includes units of drugs furnished to Part B enrollees and does not include units of drugs furnished to MA (Part C) enrollees.

Under section 1847A(i)(2), the statutory definition of a "Part B rebatable drug" is expressly limited

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[7] 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

[8] 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.

[9] 87 Fed. Reg. 71748 (Nov. 23, 2022).

[10] CMS, Part B Inflation Rebate Guidance: Use of 340B Modifiers (Dec. 20, 2022), *available at* https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf.

to certain drugs "for which payment is made under this part" (emphasis added). Because section 1847A of the SSA is codified under Part B of Title XVIII, "this part" refers to Part B of the Medicare statute. MA is codified under Part C, and nothing in the statute suggests that CMS may extend the Part B inflation rebate to drugs furnished under Part C.

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). MA units are not separately payable by CMS, because CMS does not separately pay for drugs under MA. Rather, CMS makes capitated payments to MA plans on a per member per month basis to cover MA plan costs of reimbursement for the full range of inpatient, outpatient, and provider-based services covered under Part C. Therefore, MA units should be excluded from the total units considered in the inflation rebate calculation.

In the Guidance, CMS does not explain why the Agency believes the statute could be interpreted to extend to Part C utilization, stating only that the Part B inflation rebate "generally speaking, is calculated on the basis of the total number of units that were furnished in a calendar quarter"—omitting to mention that the units must be those "for which payment is made under this part." The Guidance then states that "the inclusion in this calculation of units of drugs that are furnished to Medicare beneficiaries who are enrolled in MA plans poses significant operational complexities," and asks for public comment on how to address these complexities. But there is no need to address these complexities, because CMS does not have the authority to include MA units in the Part B inflation rebate calculation.

CMS and the MACs do not receive or pay claims for items and services furnished to Part C enrollees. Instead, as noted above, CMS makes capitated per-member, per-month payments to MA plans, and the plans pay providers for Part C items and services furnished to their enrollees. Had Congress wanted Part C utilization to trigger Part B inflation rebates, it would have required that MA plans report their enrollees' utilization of provider-administered drugs to CMS (and to do so each quarter, such that the Part C utilization could be included in CMS's invoices for the inflation rebate). CMS would need accurate quarterly utilization data from MA plans — data that exclude 340B and dual eligible utilization — to include Part C utilization in the Part B rebate calculation. But Congress did not require this reporting.

CMS itself has noted that including MA utilization would pose "significant operational complexities" and did not identify a possible source of information to determine MA units. The potential sources of information for this data do not seem reliable for Part B inflation rebate calculation purposes. For example, CMS has not required the use of the "JG" and "TB" 340B claims modifiers under Part C. In addition, the MA encounter data may not be available during the timeframe in which CMS is required to calculate and assess the Part B inflation rebate.

Given that collection of rebates on Part C units is neither feasible nor legally permissible, Lilly requests that CMS abandon further efforts to expand the scope of the Part B Inflation Rebate Program.

V. CMS Should Extend Its Timeframes for Manufacturer Review and Payment of Part B Rebate Invoices and True-Up Reports

In sections 60.1 and 60.2 of the Guidance, CMS notes its intention to send manufacturers a Preliminary Rebate Report no later than five (5) months after the end of each calendar quarter.

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 B 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.

Furthermore, we request additional guidance on when and how manufacturers should restate ASP to CMS. For example, in 2019, CMS implemented an electronic ASP reporting system called the FFSDCS (ASP) Application. Pages 57 through 61 of the "Medicare Part B Drug Average Sales Price (ASP) User Manual v. 2.0" (User Manual) for that system describes the "Edit Restate Financial Data" field. Per the User Manual, "[i]f errors in either the ASP data or the payment limit calculation occur, revised drug pricing files may be implemented." And CMS purports that this "provides drug manufacturers the ability to restate Medicaid Part B financial data to CMS."[11] However, in 2020, when Lilly sought to implement a restatement via the FFSDCS (ASP) Application, we encountered an operational challenge and reached out to the ASP help desk. We were informed by CMS officials that Lilly should actually not endeavor to update ASPs via that field, leaving us confused. We encourage CMS to resolve this restatements issue prior to implementing the Part B Inflation Rebate Program and issue updated guidance to industry.

VI. CMS Should Wait to Implement the Part B Inflation Rebate Program Until It Has Addressed ASP Calculation Issues Recently Identified by the Office of the Inspector General

In December 2022, the HHS Office of the Inspector General (HHS OIG) issued a report titled "Manufacturers May Need Additional Guidance To Ensure Consistent Calculations of Average Sales Prices."[12] That report highlighted the limited guidance as relates to the calculation and submission of ASP and the primacy of manufacturer reasonable assumptions to making the ASP statute work as intended.[13] As the HHS OIG reported, there are some inconsistencies in manufacturer practices related to calculating ASP (i.e., TRICARE related drug sales and aspects of the bona fide service fee test). Manufacturers also reportedly sought guidance on several additional topics (i.e., value-based contracting, bundled sales arrangements, re-filing and restatements, negative ASPs, and whether or how to use the NCD-HCPCS Crosswalk table as a source of authority for reporting).

CMS concurred in HHS OIG's conclusions and recommendations and suggested that additional guidance would be forthcoming. And while Lilly appreciates CMS's efforts to provide guidance in two areas identified in the report (the treatment of sales in the territories and of rebates for wastage associated with single-use vials), CMS needs to complete any additional guidance updates before it implements Part B rebates because manufacturers who change practices in response to this new guidance might observe changes in ASP, and thus Part B payment amounts, that CMS could

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[11] See, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Downloads/Medicare-Part-B-ASP-Data-Collection-User-Guide.pdf

[12] HHS, Office of the Inspector General, "Manufacturers May Need Additional Guidance To Ensure Consistent Calculation of Average Sales Prices." OEI-BL-21-00330 (Dec. 2022). https://oig.hhs.gov/oei/reports/OEI-BL-21-00330.pdf

[13] *Id.*, *passim*, referencing reasonable assumptions sixteen times.

mistakenly consider a price increase, when, in reality, the "price change" merely reflects new guidance from CMS.

CMS should also implement the findings of HHS OIG's companion report, also issued in December 2022, titled "CMS Should Bolster Its Oversight of Manufacturer-Submitted Average Sales Price Data To Ensure Accurate Part B Drug Payments." [14] That report included several practical recommendations that could have unexpected operational implications for manufacturers that would, similarly, create the illusion of price change where the real cause for the difference is a change to CMS-mandated reporting practices. Again, we urge CMS to implement any of OIG's recommendations that it thinks are valid and actionable prior to implementing Part B rebates.

VII. CMS Needs to Provide Additional Guidance Related to HCPCS Coding and Assignment

Lilly appreciates that the statute requires Part B rebates to be assessed based on the "billing and payment code" (i.e., the HCPCS code) for a Part B drug. What the statute fails to anticipate, however, is the situation where more than one single-source drug is included in that HCPCS code. Under this scenario, a manufacturer of one product in the code could change their price or discounting strategy in a way that causes the overall Medicare payment amount to increase by more than CPI-U. This could leave the other manufacturer(s) with products included in the code "holding the bag" for Part B inflation rebates even though their prices or discounts did not change. This would run afoul of the statute's command to assess Part B inflation rebates on "such drugs" that increase prices in excess of CPI-U.

CMS could address this challenge in a few ways. One option, as PhRMA advances, is calculation and assessment of Part B inflation rebates based on the NDC-11 identifier for a product. Another is for CMS to reform their HCPCS coding practices to ensure that no single-source drugs share a single HCPCS code. Lilly prefers the latter option.

VIII. CMS Should Advocate for a More Equitable and Straightforward Metric for Assessing Inflation for Purposes of Assessing Part B Inflation Rebates

Lilly unsuccessfully advocated that any Medicare Part B inflation rebate program should be based on changes to the wholesale acquisition cost (WAC, also sometimes call the "list price") rather than the Part B payment amount for several reason. First, WAC and changes to WAC are fixed, definite, and easy to determine. Second, WAC is completely controlled by the manufacturer, whereas ASPs or AMPs are dictated by varying purchase and discount patterns controlled by ASP or AMP eligible customers, not the manufacturer. Third, the blending of different products (and non-Part B covered products) in a Part B payment HCPCS code makes administration of a rebate program unreliable. Finally, the most commonly used basis for Part B payment limits is ASP, a metric for which CMS guidance and clarity is limited and subject to revision.

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. In the meantime, since price changes are not measured with reference to WAC, but rather to the Part B payment amount, there are numerous steps CMS must take to update the Part B regulatory regime prior to imposing any new rebate obligations.

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[14] See, https://oig.hhs.gov/oei/reports/OEI-03-21-00390.asp (Dec. 2022).

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Lilly is grateful for the opportunity to comment on the Part B 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

MEDICARE RIGHTS CENTER
Getting Medicare right

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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 the Medicare population 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

[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/.

households spend 20% 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] As a result, 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, reining in the industry practice of sky-high annual price adjustments.[7] This deterrent will directly impact beneficiary finances. Drug price increases usually translate into higher out-of-pocket consumer costs, especially for people who pay coinsurance, as do most Medicare enrollees. Higher prices 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 B inflation-based rebates until 2025, the first quarterly period for which drug companies will be required to pay those rebates began January 1. Companies may have already adjusted their pricing behaviors in preparation.

Beneficiaries could also see other effects of the program this year. Beginning April 1, coinsurance amounts for inflation-busting Part B drugs will be based on what Medicare *would have paid* had the drug's price growth not outpaced inflation. This inflation-adjusted payment will protect beneficiaries from unnecessary costs and undue stress.

Importantly, the Rebate Program's changes will have a cumulative impact. The nonpartisan Congressional Budget Office (CBO) estimates it will save billions of dollars for beneficiaries, taxpayers, and Medicare. And it will do so while bolstering health outcomes and program solvency: lower drug costs will increase medication adherence, improving beneficiary health and reducing the need for—and Medicare spending on—more costly care.[9]

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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] 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.

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

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 B Inflation Rebate Comments

Dear CMS:

Model N appreciates the opportunity to comment on the 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, 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 pharmaceutical 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 B 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 B Inflation Rebate guidance, Model N requests clarification on specific aspects of the regulation and requests CMS to consider these points in the final regulation:

1. Comments pertaining to Section 50 of the Initial Memorandum, Calculation of the Medicare Part B Drug Inflation Rebate Amount:

Section 50.3 - Identification of the Payment Amount Benchmark Quarter:
In this section, the determination of the benchmark quarter for Part B inflation rebates is based on when the drug was first approved or licensed by the FDA. For drugs approved on/before December 1st, 2020, the benchmark quarter is Q3 2021. The following are some clarifications that we request for determining the benchmark quarter 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, which date should be used?

- Since, Part B inflation rebates are based on Average Sales Price (ASP), which is determined based on when the drug entered the market (and not necessarily the FDA approval date), what would the benchmark ASP be for such drugs that were approved and do not have an ASP calculated for the determined benchmark quarter? For example, a drug was approved on October 1st, 2020, with a market entry date in February 2022. The benchmark quarter for this drug based on the current provisions is Q3 2021, but the drug would not have a calculated ASP for this period. How should the manufacturer account for such a scenario?

Section 50.4 - Identification of the Payment Amount in the Payment Amount Benchmark Quarter:

In this section, it is mentioned that CMS intends to use the payment limit (as updated if applicable) for the applicable payment amount benchmark quarter determined in accordance with section 1847A of the Act. We request CMS to clarify the following:

- Is the "payment limit" based on the ASP of the drug that a manufacturer submits to CMS (which equals 106% of the ASP submitted) or is it based on the volume-weighted ASP of all drugs in any given HCPCS code, and potentially across multiple manufacturers?
- For the above comment, if the response is to use the volume-weighted ASP of all drugs in any given HCPCS code, would this apply to the calculation of the "specified amount" determination listed in section 50.1 of the memorandum as well?

2. Comments pertaining to Section 60 of the Initial Memorandum, Ensuring Integrity of Part B Inflation Rebates:

Section 60.1 – Timing of Reports and Payments:

We acknowledge the statement that "CMS expects to issue additional guidance regarding the form and manner in which Rebate Reports will 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, including the example of submitting 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 60.2 – 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 1847A(i)(8) of the Act precludes administrative or judicial review on the determination of units, whether a drug is a Part B rebatable drug, and the calculation of the rebate amount. No disputes on these topics will be considered.", 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.

Section 60.3 – Restatements and True-Up 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 revised ASP data by the manufacturers, CMS revision of payment limits, revisions to the CPI-U, and any updates to claims data that occurred after the rebate amounts were calculated. We recommend additional clarification in this section in response to the 340B exclusion clarity as the retrospective updates to transactions identified as 340B will also be impactful to the basis for the Part B Inflation Rebate calculation.

3. Additional Clarifications:

Part B Inflation rebates for terminated/expired drugs:

The memorandum does not talk about the Medicare Part B inflation rebates for terminated or expired drugs. We would appreciate any guidance that CMS can provide on how terminated or expired drugs will be treated for the Medicare Part B Inflation Rebates?

- If a drug has expired, does the manufacturer still owe Part B inflation rebates for quarters after the drug's termination date, similar to Medicaid?
- Does CMS/the manufacturer continue to calculate the Part B inflation rebate penalty per unit past the drug's termination/expiration date?

Model N

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 B Inflation Rebates. 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,

Michael Grosberg
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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.

950 F STREET NW, SUITE 300, WASHINGTON, DC 20004 • PHRMA.ORG

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 B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) 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 B 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 issue final inflation rebate guidance promptly 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.

Contents

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I. Removal of 340B Units (50.8.1)

Under section 1847A(i)(3)(B)(ii)(I) of the Social Security Act (SSA), the Agency is required to exclude units subject to an agreement under section 340B of the Public Health Service Act from the calculation of Medicare Part B inflation rebates. However, for 2023, only 340B-participating health care entities (known as covered entities, or CEs) paid under the Outpatient Prospective Payment System (OPPS) are required to use the "JG" and "TB" modifiers to identify units of separately payable medicines subject to 340B agreements.[2] The requirement for 340B CEs paid under Part B but not paid under OPPS to use the "JG" and "TB" modifiers, an expansion that PhRMA applauds, will not begin until 2024.[3]

To exclude units subject to 340B agreements in 2023, in section 50.8.1 of the guidance, the Agency is thus proposing to exclude all units captured in institutional claims submitted by critical access hospitals, Maryland waiver hospitals, and non-excepted off-campus provider-based departments. Furthermore, the Agency is proposing to exclude all units captured in professional claims submitted for Medicare suppliers that are listed by the Health Resources and Services Administration (HRSA) as participating in the 340B Drug Pricing Program. For rebate quarters in 2024 and future years, CMS is proposing to exclude units identified as subject to a 340B agreement solely through the use of the "JG" and "TB" modifiers.

PhRMA supports the Agency's proposed approach for excluding units subject to a 340B agreement for rebate quarters in 2023.

PhRMA also supports the Agency's proposed approach for excluding units subject to 340B discounts for rebate quarters in 2024 and future years. However, PhRMA strongly encourages CMS, through future guidance or rulemaking, to add a required "non-340B" modifier value and for the Medicare Administrative Contractors (MACs) to reject claims as incomplete if they do not contain one of the relevant 340B or non-340B modifier values. This approach would give CMS needed certainty that a 340B determination has been made for each claim. In addition, this would align with the Agency's approach for the Part B 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.[4]

PhRMA believes that the addition of a required "non-340B" modifier value and the rejection of claims without a relevant 340B or non-340B modifier value will help improve identification of 340B units. However, PhRMA remains concerned about 340B CEs' compliance with the required modifiers, as there currently does not appear to be a penalty for CEs that fail to comply with the required modifiers, 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,[5] a highly concerning result given that CMS requires these entities to use the "JG" and "TB" modifiers on claims

[2] 87 Fed Reg. 71974; CMS. Part B Inflation Rebate Guidance: Use of 340B Modifiers. Dec. 20, 2022. Available at: https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf.
[3] Ibid.
[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.
[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.

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,[6] 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 relevant modifier.[7] 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.

Given this, PhRMA urges 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 administered to Medicare enrollees. The 340B clearinghouse would act as a claims verifier, reviewing CMS-1500 and 837P claims 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.[8] Units marked as subject to 340B agreements on either the claim or by the 340B clearinghouse would be excluded from calculation of the Part B inflation rebate.

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.[9] 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.

Finally, in the revised guidance, CMS should make clear that the requirement for covered entities to use claims modifiers to identify drugs acquired under the 340B program preempts any conflicting state or local laws or regulations. Both the Medicare program and the 340B program are federal programs, and states do not have the authority to enact laws that conflict with or otherwise interfere with fulfilling the requirements or objectives of those programs. Therefore, CMS should make clear that state laws are preempted by federal law to the extent they would otherwise conflict or interfere in any way with claims modifier requirements imposed by CMS under the Calendar Year 2023 Outpatient Prospective Payment System final rule,[10] CMS's December 20, 2022 guidance,[11] or otherwise.

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[6] 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.

[7] 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.

[8] 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 and to virtually separate inventory dispensed to 340B CE patients from inventory dispensed to individuals who are not CE patients.

[9] 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.

[10] 87 Fed. Reg. 71748 (Nov. 23, 2022).

[11] CMS. Part B Inflation Rebate Guidance: Use of 340B Modifiers. Dec. 20, 2022. Available at: https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf.

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

Under section 1847A(i)(3)(B)(ii)(I) of the SSA, the Agency is required to exclude from the calculation of Medicare Part B inflation rebates units for which a manufacturer paid a Medicaid rebate under section 1927 of the SSA. Currently, CMS is proposing to identify and exclude these units by removing claims for dates of service during a rebate quarter when a Medicare beneficiary also has coverage under Medicaid.

PhRMA supports the Agency's proposed approach for excluding units where a Medicaid rebate is paid. However, PhRMA urges CMS to confirm that the enrollment data used for identifying Medicare beneficiaries dually enrolled in Medicaid covers enrollment in both Medicaid fee for service (FFS) and Medicaid managed care organizations (MCOs). As of fiscal year 2020, 36.5% of Medicaid beneficiaries over the age of 65 were enrolled in MCO plans.[12] This is a significant share of enrollees that CMS needs to be sure to capture.

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

In section 50.8.5 of the guidance, CMS seems to suggest that section 1847A(i) of the SSA requires the inclusion of units of drugs furnished to Medicare Advantage (MA) enrollees under Part C in the calculation of manufacturer rebate amounts. The Agency seeks comment on the best sources of information to capture these units, as well as on how to remove units CMS must exclude from the calculation of rebate obligations under section 1847A(i)(3)(B)(ii) of the SSA.

CMS Does Not Have Statutory Authority to Include Units Furnished to MA Enrollees in Inflation Rebates

PhRMA strongly opposes the Agency's interpretation of section 1847A(i). Because CMS does not have the authority to include units furnished to MA enrollees in the calculation of Part B rebates, PhRMA requests that CMS clarify in revised guidance that the Part B inflation rebate calculation only includes units of drugs furnished to Part B fee-for-service beneficiaries and does not include units of drugs furnished to MA enrollees.

Under section 1847A(i)(2), 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). Because section 1847A of the SSA is codified under Part B of Title XVIII, "this part" refers to Part B of the Medicare statute. MA is codified under Part C of the Medicare statute, and nothing in the statute suggests that CMS may extend the Part B inflation rebate to drugs furnished under Part C.

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*."[13] MA units are not separately payable by CMS, because CMS does not separately pay for drugs under MA. Rather, CMS makes capitated payments to MA plans on a per member per month basis to cover MA plan costs of reimbursement for the full range of inpatient, outpatient, and provider-based services covered under

[12] MACPAC. MACStats: Medicaid and CHIP Data Book. Dec. 2022. Available at: https://www.macpac.gov/wp-content/uploads/2022/12/MACSTATS_Dec2022_WEB-508.pdf.
[13] SSA § 1847A(i)(3)(B)(ii)(II) (emphasis added).

Part C. Therefore, MA units should be excluded from the total units considered in the inflation rebate calculation.

In the guidance, CMS does not explain how the Agency believes the statute could be interpreted to extend to Part C utilization, stating only that the Part B inflation rebate "generally speaking, is calculated on the basis of the total number of units that were furnished in a calendar quarter" — omitting to mention that the units must be those "for which payment is made under this part."[14] The guidance then states that "the inclusion in this calculation of units of drugs that are furnished to Medicare beneficiaries who are enrolled in MA plans poses significant operational complexities," and asks for public comment on how to address these complexities.[15] CMS does not have statutory authority to include MA units in the Part B inflation rebate calculation and even if there were such statutory authority, it acknowledges this poses operational complexities as described below.

Available MA Utilization Data is Not Sufficiently Reliable for Inflation Rebate Calculation Purposes

CMS and the MACs do not receive or pay claims for items and services furnished to Part C enrollees. Instead, as noted above, CMS makes capitated per-member, per-month payments to MA plans, and the plans pay providers for Part C items and services furnished to their enrollees. Had Congress wanted Part C utilization to trigger Part B inflation rebates, it would have required that MA plans report their enrollees' utilization of provider-administered drugs to CMS (and to do so each quarter, such that the Part C utilization could be included in CMS's invoices for the inflation rebate). CMS would need accurate quarterly utilization data from MA plans — data that exclude 340B and dual eligible utilization — to include Part C utilization in the Part B rebate calculation. But Congress did not require this reporting.

CMS itself has noted that including MA utilization would pose "significant operational complexities" and did not identify a possible source of information to determine MA units. The potential sources of information for this data do not seem reliable for Part B inflation rebate calculation purposes. For example, CMS has not required the use of the "JG" and "TB" 340B claims modifiers under Part C. In addition, the MA encounter data may not be available during the timeframe in which CMS is required to calculate and assess the Part B inflation rebate. CMS's Medicare Encounter Data User Guide[16] explains that:

> CMS uses MA encounter data for risk adjustment purposes. The timeline for this business need creates a time lag between the provision of the services and the time the CCW team can deliver encounter [Research Identifiable Files (RIFs)] to researchers. MAOs [Medicare Advantage Organizations] will typically have *13 months* after the end of a service year to submit encounter data to CMS that will be eligible for risk adjustment payment. After the CMS risk adjustment deadline has passed for a given service year, the CCW receives annual encounter files from the CMS Integrated Data Repository—starting with 2015. Typically, the time lag between the risk adjustment deadline and encounter RIF creation means that encounter data included in the RIF were not available when CMS calculated

[14] Part B Guidance, section 50.8.5.
[15] Part B Guidance, section 50.8.5.
[16] CMS. Chronic Conditions Warehouse Medicare Encounter Data File User Guide Version 2.8. Jan. 2023. Available at: https://www2.ccwdata.org/web/guest/user-documentation (hereinafter, Medicare Encounter Data User Guide).

> risk scored from the encounter data. Similarly, MAOs updated some encounter records after the CCW created the RIFs and therefore does not include them in those files.[17]

Our concern with use of MA encounter data for inflation rebate purposes was underscored in a recent report from the HHS OIG, which found that CMS may not currently be able to definitively identify denied claims in MA encounter data. Specifically, OIG found that certain "adjustment codes" present in existing data "are not a definitive method for identifying denied claims in the MA encounter data."[18] According to OIG, "[w]ithout a definitive method for identifying denied claims, the full scope of payment denials in the data is unclear."[19]

CMS's Proposed Interpretation is Inconsistent with the Agency's Interpretation of Analogous Statutory Provisions

Additionally, existing provisions throughout the Medicare statute make clear that, when Congress refers to payment "under this part" when discussing Part B, it means payment under the Part B benefit alone and not "payment under Part B or Part C." For example, section 1847A(a)(1) of the SSA states that the Average Sales Price (ASP)-based methodology in section 1847A applies to drugs described in section 1842(o)(1)(C), which in turn applies to specified types of drugs furnished after 2004 "for which payment may be made *under this part*." (emphasis added). CMS has interpreted 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 drugs furnished to plan enrollees. In addition, the language in section 1851(a)(1) of the SSA makes clear that Part B does not include Part C beneficiaries by clearly distinguishing Part B from the Medicare Advantage (previously called Medicare+Choice) Program. This provision — the first provision in Part C of SSA title XVIII — states that "each Medicare+Choice [MA] eligible individual… is entitled to receive benefits… under this title—(A) through the original [M]edicare fee-for-service program *under parts A and B, or* (B) through enrollment in a [MA] plan *under this part [Part C]*." (emphasis added).

Another example of what Congress means by "this part" in the Part B context is section 1842 of the SSA. This provision – the first provision under "Provisions Relating to the Administration of Part B" — states in 1842(a) that "[t]he administration of this part shall be conducted through contracts with Medicare administrative contractors [MACs] under section 1847A" — and MACs do not adjudicate requests for payment under Part C or otherwise administer Part C benefits.

ASP is Not the Required Basis for Provider Reimbursement in MA

Finally, the Part B inflation rebate measures price growth exceeding inflation under the ASP-based payment methodology. But as noted above, MA plans are not required to utilize ASP for provider reimbursement under Part C. In fact, as of 2016 — the most recent year for which public data is available — for physician office-based care, 38% of MA lives were reimbursed on a basis other than ASP.[20] For care received in hospital outpatient departments, over 50% of MA lives were reimbursed on

[17] Medicare Encounter Data User Guide at 17 (emphasis added).
[18] OIG. The Inability to Identify Denied Claims in Medicare Advantage Hinders Fraud Oversight. Feb. 2023. Available at: https://oig.hhs.gov/oei/reports/OEI-03-21-00380.asp.
[19] Ibid.
[20] Magellan. Magellan Rx Medical Pharmacy Trend Report. 2016. Available at: https://www1.magellanrx.com/documents/2019/03/medical-pharmacy-trend-report_2016.pdf/.

a basis other than ASP.[21] An inflation rebate that measures excess price growth in ASP is not logically suited for a program where ASP is not even the required basis of reimbursement.

IV. Reducing or Waiving the Rebate Amount in the Case of a Part B Rebatable Drug on the Shortage List (50.11)

Under section 1847A(i)(3)(G) of the SSA, CMS must reduce or waive rebate amounts for Part B rebatable drugs for a calendar quarter when the drug is described as currently in shortage at any time during the calendar quarter on the United States Food and Drug Administration (FDA) shortage lists maintained pursuant to section 506E of the Federal Food, Drug, and Cosmetics Act (FDCA).[22] A Part B 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 comment on the amount and duration of the reduction of the rebate amount for the calendar quarter when a Part B 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 50.11 of the guidance, CMS additionally seeks comment on several specific topics related to reducing or waiving the rebate amount for Part B rebatable drug on a shortage list:

- *CMS asks how it should reduce or waive the rebate amount in the case of a Part B rebatable drug that is on the shortage list.* PhRMA requests that CMS waive the full rebate amount for the calendar quarter when a Part B 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 eleven-digit National Drug Codes (NDC-11s) for the Part B rebatable drug are listed as "current" on the FDA shortage list.* PhRMA recommends that CMS waive the rebate amount for a drug for the calendar quarter 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 ASP outside of a

[21] Ibid.

[22] 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.

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 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 management systems that focus on the continuity of global supply chains. In developing any exclusions for waiving the rebate amount for Part B rebatable drugs on the shortage list, PhRMA recommends that CMS consider adopting the same exclusions it has proposed for waivers for supply chain disruptions for rebatable biosimilars, 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 B 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 B 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 generics medications, which are outside the scope of the Part B inflation rebate. 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.

V. Reducing or Waiving the Rebate Amount for a Severe Supply Chain Disruption for a Part B Rebatable Biosimilar Biological Product (50.12)

Under section 1847A(i)(3)(G) of the SSA, CMS must reduce or waive rebate amounts for Part B rebatable biosimilar biological products when the Secretary determines there is a severe supply chain disruption during the calendar quarter, 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 of a rebatable biosimilar product and significantly affects the manufacturer's ability to fill orders or meet expected U.S. 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 B rebatable biosimilar biological product when there is a "severe supply chain disruption" during the calendar quarter.

PhRMA strongly encourages CMS to waive the full rebate amount for the calendar quarter 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 ASP that are beyond a manufacturer's control. PhRMA urges the Agency to avoid penalizing manufacturers with inflation rebates in this situation.

VI. Financial Responsibility for Part B Inflation Rebate Amount (50.13)

Under section 1847(i) of the SSA, the Part B inflation rebate program is administered at the Healthcare Common Procedure Coding System (HCPCS) level. However, NDCs attributable to more than one manufacturer can be included under the same HCPCS code even for single source medicines in certain limited cases. In these situations, CMS proposes in section 50.13 to allocate financial responsibility for any rebate amount owed in proportion to each manufacturer's share of billing units sold during the rebate quarter as reported in ASP data submissions.

PhRMA opposes the Agency's intended approach, as it can result in a manufacturer owing an inflation rebate even when the growth in ASP for the manufacturer's own NDCs has been below inflation as measured since the benchmark quarter. An approach that yields this result is contrary to the plain language of the statute. Specifically, section 1847A(i)(1)(B) requires the "manufacturer of a part B rebatable drug" to "provide to the Secretary a rebate that is equal to the amount specified… *for such drug* for such calendar quarter" (emphasis added). Nowhere in section 1847A(i) is a manufacturer of a Part B rebatable drug required to provide a rebate to the Secretary for its Part B rebatable drug based on the growth in ASP of *another manufacturer's* Part B rebatable drug.

As an example, consider the following illustrative scenario. A given HCPCS code for a single source Part B rebatable drug is made up of six NDC-11s, with three NDC-11s belonging to Manufacturer A and three NDC-11s belonging to a repackager, Manufacturer B. The NDCs and associated ASP-based benchmark payment amounts, specified amounts, and inflation-adjusted payment amounts are shown in Appendix A.

With an assumed 12.5% growth in the consumer price index for all urban consumers (CPI-U) between the benchmark period and rebate period, none of the NDC-11s belonging to Manufacturer A have a rebate period ASP+6% that exceeds the inflation-adjusted ASP+6%. But all of the NDC-11s belonging to Manufacturer B exceed the inflation-adjusted ASP+6%.

At the HCPCS level, an inflation rebate of $0.90 per unit would be owed. Under CMS's proposed methodology, 49.6% of the liability for this rebate would be attributable to Manufacturer A (with the remaining 50.4% attributable to Manufacturer B) even though price increases by Manufacturer B are solely responsible for the inflation rebate liability.

Given this potential outcome, PhRMA urges CMS to calculate inflation rebate liability at the NDC-11 level if it imposes an inflation rebate on a HCPCS code comprised of NDCs from multiple manufacturers. In this scenario, the plain language of section 1847A(i) would require CMS to implement a process that precisely identifies rebate liability based on each manufacturer's Part B rebatable drug. In such a case, CMS should develop a process to require reporting of NDC-11s on the CMS-1500 and 837P claims forms and reject forms without specified NDC-11s as incomplete.

Note, however, that in many cases a HCPCS code containing single source drugs of multiple manufacturers will involve drugs that must be treated as multiple source under section 1847A(c)(6)(C)(ii) of the SSA. In such cases, these drugs should also be treated as multiple source drugs for inflation rebate purposes (and, therefore, should not be subject to inflation rebates). We discuss this issue in section X(e) of this letter.

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

In sections 60.1 and 60.2 of the guidance, CMS notes its intention to send manufacturers a Preliminary Rebate Report no later than five months after the end of each calendar quarter.[23] 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 B 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. Following this process, CMS would send manufacturers a Rebate Report — an invoice that would identify the rebate amount due for Part B 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, CMS plans to conduct a one-time true-up of the rebate amounts, which would allow for updated ASP data by manufacturers, CMS revision of payment limits, 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 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 ASP for reporting to the Agency.

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 60 of the guidance, CMS states that the Preliminary Rebate Report and the Rebate Report will

[23] 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.

include only three pieces of information: 1) the total number of units of the billing and payment code(s) for each Part B rebatable drug for the calendar quarter; 2) the amount, if any, by which the ASP increase exceeds the inflation-adjusted payment amount for a calendar quarter; and 3) the rebate amount. 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 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 B 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 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;
- Claims-level data for the billing and payment code during the calendar quarter with:
    - The HCPCS Code (J-Code/Q-Code);
    - Claim number;
    - The dosage for the billing and payment code;
    - Medicare provider number or National Prescriber Identifier (NPI);
    - De-identified Medicare beneficiary ID;
    - The number of units administered;
    - The date of administration or service;
    - The date of adjudication;
    - Place of service code;
    - 340B claims modifier field ("JG" and "TB" modifiers plus any "non-340B" modifier value the Agency may add);
    - Vial wastage modifier field ("JW" and "JZ" modifiers);
    - The "UD" modifier field; and
    - An indicator for units excluded due to a Medicaid rebate being paid under section 1927 of the SSA;
- The date on which a Part B rebatable drug has become a multiple source drug, as determined by CMS (see section X(d) of this comment letter for further discussion).

Should CMS require reporting of NDCs to address manufacturer inflation rebate liability under multi-manufacturer HCPCS codes (as recommended by PhRMA in section VI of this comment letter), the above claims-level data should be provided to manufacturers at the NDC-11 level. Whether at the billing and payment code or NDC-11 level, this claims-level data should be provided to manufacturers in an easily readable format (such as a .csv file).

PhRMA further urges the Agency to make clear that manufacturers may suggest errors in any of the information fields included in the Preliminary Rebate Report and Preliminary True Up Report.

Finally, PhRMA urges CMS to promptly notify manufacturers if a Part B 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 a calendar quarter due to the low annual cost exemption.

VIII. Restatements and True-Up Report and CMS Identification of Errors (60.2 and 60.4)

In section 60.4 of the guidance, CMS states that the Agency "reserves the right to update or change the rebate amount and the true-up amount due from manufacturers for the calendar quarter based on any calculation errors, or misreporting of manufacturer pricing or product data, that CMS identifies *at any point*, after each calendar quarter ends. This could occur during the calculation error dispute process, after invoices are reported to manufacturers, or after rebate or true-up invoices are 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 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, with reopening "at any time" at the behest of the agency only in cases of fraud or similar fault.[24] At the same time, reciprocity and fairness demand that, as is the case with other reopening rules, manufacturers should also be permitted to seek corrections to inflation rebate amounts within the same timeframe available to the government.[25]

IX. Enforcement of Rebate Payments by Manufacturers: Civil Monetary Penalties (70)

Consistent with section 1847A(i)(7) of the SSA, the guidance states that CMS "will establish a process for Part B inflation rebate CMPs pursuant to regulations." 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

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

[24] *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.

[25] 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.

develop the Part D CMP process in the same notice-and-comment rulemaking as the Part B CMP process.[26] 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.[27] Further, as a general matter, agencies are permitted to afford regulated parties *more* procedural protections than a statute requires.[28]

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),[29] and the CMP procedures issued by the HHS OIG.[30] 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.[31]

In addition, the CMP procedures should also 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.[32] PhRMA believes engaging in pre-enforcement discussions with manufacturers would be beneficial to 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

[26] 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.

[27] As discussed in Section X(e) of our comments on CMS's Part D inflation rebate guidance.

[28] *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.").

[29] 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).

[30] 42 C.F.R. Parts 1003 and 1005.

[31] We note that the limitation on administrative and judicial review set forth in section 1847A(i)(8) 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 1847A(i)(7).

[32] *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).

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.[33] 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 section 1128A of the SSA, 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.[34]

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 60.3 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 1847A(i)(7) 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 1847A(i)(7) permits CMS to impose a CMP on a manufacturer if the manufacturer "fail[s] to comply with the requirements under paragraph (1)(B)…." Paragraph (1)(B), in turn, requires a manufacturer to provide to CMS "*a* rebate" within "30 days after the date of receipt from the Secretary of the information described in subparagraph (A)…." (emphasis added). Subparagraph (A), in turn, requires CMS to report to a manufacturer "*[n]ot later than 6 months* after the end of each calendar

[33] 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.").

[34] SSA § 1128A(d), (f).

quarter," certain information about the total number of units of the Part B rebatable drug, the amount (if any) of the excess ASP increase for such drug and calendar quarter, and the rebate amount for such drug and calendar quarter (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 B rebatable drug within 30 days after receiving the invoice that CMS is required to send within 6 months after the end of the applicable calendar quarter (or by September 30, 2025 under the transition rule at section 1847A(i)(1)(C)). Simply put, section 1847A(i)(7) does not permit CMS to impose CMPs on "true-up" or other similar invoices provided to manufacturers after the initial invoice for an applicable calendar quarter. CMS should not finalize this policy in its final Part B inflation rebate guidance.

X. Other Issues

a. Clarity on Timing of Invoices

Under section 1847A(i)(1) of the SSA, CMS may elect to delay Rebate Reports for rebate quarters in 2023 and 2024 until September 30, 2025. However, manufacturers could have begun accruing liability effective in the first quarter of 2023, 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 rebate quarters in 2023 and 2024. 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 B 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 Medicaid Drug Rebate Program (MDRP).

c. CMS Administration of Rebate Program

PhRMA urges CMS to administer the Part B 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 1847A(i) and avoid inconsistent procedures or interpretations by third parties.

d. Removal of Units When a Drug is No Longer a Part B Rebatable Drug

In section 50.8.4 of the guidance, CMS states that a single source drug that is a Part B rebatable drug could become a multiple source drug — and therefore no longer meet the "Part B rebatable drug" definition — either at the start of or during a calendar quarter. CMS intends to identify the date of first sale of a drug product that is rated as therapeutically equivalent to that drug under FDA's Orange Book.

PhRMA requests that, in order for manufacturers of Part B rebatable drugs to have sufficient information to assess their potential inflation rebate obligations, CMS promptly notify the Part B rebatable drug manufacturer of the first sale date of a drug that is rated as therapeutically equivalent to the Part B rebatable drug after CMS learns the first sale from the generic manufacturer's ASP submission.

e. Clarity on Drugs Treated as Multiple Source Drugs

Under section 1847A(i)(2) of the SSA, the Part B inflation rebate is limited to single source drugs and biologicals and certain biosimilars.[35] In turn, the Part B statute defines a "single source drug" as "a drug that is *not a multiple source drug*…."[36] Section 30.1 of the Part B inflation rebate guidance acknowledges this exclusion, stating that "multiple source drugs (*described in section 1847A(c)(6)(C) of the Act*)… will be excluded" from the "Part B rebatable drug" definition.[37]

In the revised guidance, PhRMA urges CMS to make clear that the exclusion for "multiple source drugs" applies to *all* drugs defined under section 1847A(c)(6)(C) of the SSA, including drugs that the statute requires CMS to "treat" as multiple source drugs under clause (ii) of that section. Specifically, section 1847A(c)(6)(C)(ii) states that CMS "shall treat" certain single source drugs as multiple source drugs because they share a billing and payment code (*i.e.*, a HCPCS code) with another single source drug or biological as of October 1, 2003.[38] Because CMS must "treat" these single source drugs as multiple source drugs, CMS does not have the statutory authority to apply the Part B inflation rebate to these drugs, given that the inflation rebate is limited to single source drugs. Therefore, PhRMA requests that the revised guidance make clear that drugs that CMS "shall treat" as multiple source drugs are not subject to the Part B inflation rebate.

f. Discarded Units of Certain Part B Single-Dose Container Drugs

Under section 1847A(h) of the SSA, titled "[r]efund for certain discarded single-dose container or single-use package drugs," a manufacturer must pay refunds to CMS for certain units of the manufacturer's drugs for which a provider receives Part B payment but that are discarded by the provider (as denoted by the "JW" modifier on the provider's claim). Manufacturer refunds to Medicare on discarded units of these drugs (known as refundable single-dose container or single-use package drugs) are calculated and billed to manufacturers by CMS and accrue on a quarterly basis starting in the first quarter of 2023.[39]

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[35] SSA § 1847A(i)(2) (defines a "part B rebatable drug" as a "single source drug or biological . . ., including [certain] biosimilar biological product[s]….").
[36] SSA § 1847A(c)(6)(D)(ii) (emphasis added).
[37] Part B Guidance at 7 (emphasis added).
[38] "With respect to single source drugs or biologicals that are within the same billing and payment code as of October 1, 2003, the Secretary shall treat such single source drugs or biologicals as if the single source drugs or biologicals were multiple source drugs." SSA § 1847A(c)(6)(C)(ii).
[39] SSA § 1847A(h)(2).

Discarded drug refunds paid by a manufacturer to CMS are not mentioned in the inflation rebate guidance but are relevant to the calculation of Part B inflation rebates. As noted above, Part B inflation rebates are limited to certain drugs "for which payment is made under this part [Part B]."[40] Drugs on which manufacturers pay discarded drug refunds fall outside this category. While these drugs are initially paid by Part B (to the provider that administers the drug to the Medicare beneficiary), starting in 2023, the manufacturer refunds the Part B payment to Medicare via the 1847A(h) discarded drug refund. Accordingly, units of Part B drugs for which CMS receives a discarded drug refund should not generate Part B inflation rebates, because *"payment is [not] made under this part."*[41] PhRMA urges CMS to recognize and address this issue in its revised Part B inflation rebate guidance.

PhRMA has considered various methods for CMS to net out units for which CMS receives discarded drug refunds from Part B inflation rebate payments. Both of these metrics accrue and are calculated on a quarterly basis beginning in the first quarter of 2023, and both are calculated for HCPCS units. We believe one method for netting out discarded drug refund units would be for CMS to subtract the discarded drug refund amount for a certain quarter from the inflation rebate amount on the same drug for the same quarter, as shown below:

Net Part B Rebate Amount = (Part B Inflation Rebate Amount – Part B Discarded Drug Refund Amount)

PhRMA recognizes that CMS has not yet decided when it will invoice manufacturers for the refunds due for units of a drug that were discarded during a given quarter, and the statute does not specify the billing interval CMS must select for the discarded drug refund. The Agency's remarks in the preamble to the CY 2023 Physician Fee Schedule final rule suggest that CMS did not finalize its initial proposal (which was to bill discarded drug refunds annually, on October 1 of each year starting in 2023) and instead held off on a final decision to give more thought to coordinating the discarded drug refunds and the Part B inflation rebates. Specifically, CMS stated that:

> Due to the enactment of the Inflation Reduction Act…, and our efforts to efficiently implement two statutory provisions that require reporting and deposit mechanisms, we are not finalizing our proposal on the timing of the refund reports, which was to send the first report to manufacturers no later than October 1, 2023, and subsequent reports no later than October 1 of each year following. As previously mentioned, the discarded drug refunds are to be deposited into the Federal SMI Trust Fund. Similarly, the Part B and Part D rebates described in the [IRA] also are to be deposited into the Federal SMI Trust Fund. We aim to coordinate the collection of these funds in order to minimize the administrative burden on both manufacturers and CMS. This requires an alternative timeline for sending reports to manufacturers and different dates on which funds would be due and, therefore, we decline to finalize our proposal that the initial reports under the discarded drug refund provision to be sent no later than October 1, 2023. In addition, since the date that the initial report is sent will impact the number of quarters with mature claims data available, we also decline to finalize the policy regarding the inclusion of additional lagged data in [discarded drug refund] reports in this final rule. We will

[40] SSA § 1847A(h)(8)(A).
[41] Ibid. (emphasis added).

revisit the date of the initial report and the inclusion of lagged discarded drug data in future rulemaking.[42]

PhRMA believes that an effort to synchronize payment of discarded drug refunds and Part B inflation rebates is also important because, as noted above, the units on which manufacturers pay discarded drug refunds are not units "for which payment is made under this part [B]," given that Part B is refunded for discarded units and therefore an inflation rebate is not payable on them. We are happy to discuss this issue and the mechanics of subtracting discarded drug refunds for a certain drug and quarter from Part B inflation rebates with CMS.

g. Reasonable Assumptions in Price Reporting

The Part B inflation rebate is based on ASP, 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 ASP. In the absence of guidance, CMS permits manufacturers to rely on reasonable assumptions that are consistent with the requirements and intent of the SSA and regulations.[43]

Under the Part B inflation rebate regime, these assumptions 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 ASP, it may be more important than ever for CMS to be responsive to manufacturer requests for technical assistance on price reporting questions that arise.

h. CMS Procedures

CMS states in section 10 of the guidance that it may "in revised guidance, make changes to any policies in this memorandum, including policies on which CMS has not expressly solicited comment, based on the agency's further consideration of the relevant issue." CMS does not state that it will respond to comment, nor seek to provide the ordinary 60 days of comment typically required under section 1871 of the SSA. While PhRMA recognizes that section 1847A(c)(5)(C) provides permissive authority for CMS to implement provisions through program instruction, notwithstanding any other provision of law, we urge CMS to engage in notice-and-comment rulemaking wherever possible. CMS acknowledges that it has ample time to allow for a robust notice-and-comment process, given the transition period ending September 30, 2025 for the first two years of the program. Forecasting that CMS will unilaterally impose rules and regulations, without a period of comment, and without responding to such comment, short-changes the stakeholder community and undermines due process.

* * *

[42] 87 Fed. Reg. at 69726.
[43] 71 Fed. Reg. 69624, 69669 (Dec. 1, 2006).

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,

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Appendix A

Illustrative Example of Inflation Rebate Liability for a Multi-Manufacturer HCPCS Code

NDC	Benchmark ASP+6% per Unit	Rebate Quarter ASP+6% per Unit	Inflation-Adjusted ASP+6% per Unit*	Rebate Amount per Unit	Billing Units Sold**
Manufacturer A					
NDC XXXXX-XXXX-01	$60.00	$65.00	$67.50	$0.00	5,000
NDC XXXXX-XXXX-02	$60.00	$65.00	$67.50	$0.00	7,500
NDC XXXXX-XXXX-03	$60.00	$65.00	$67.50	$0.00	1,000
Manufacturer B					
NDC YYYYY-YYYY-01	$62.00	$74.00	$69.75	$4.25	4,800
NDC YYYYY-YYYY-02	$62.00	$74.00	$69.75	$4.25	8,000
NDC YYYYY-YYYY-03	$62.00	$74.00	$69.75	$4.25	900
HCPCS Code	$61.01	$69.53	$68.63	$0.90	27,200

* CPI-U is assumed to have grown 12.5% between the benchmark quarter and rebate quarter.
** Number of units sold as reported to CMS in ASP data submissions multiplied by the number of HCPCS code billing units.

PORTAL
Program On Regulation, Therapeutics, And Law

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March 10, 2023

Via Electronic Submission

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RE: Comments on CMS' Medicare Part B Inflation Rebate Program Initial Guidance

We are members of the Program On Regulation, Therapeutics, And Law (PORTAL) research center at Brigham and Women's Hospital in Boston. We applaud CMS' initial guidance to implement Part B inflation rebates, which will insulate Medicare from excessive price increases by manufacturers and lead to substantial savings. In a research letter published earlier this year in JAMA, we found that had the policy been in effect from 2018-2020, Part B drug spending would have been reduced by approximately 3%. The guidance also clearly lays out how the policy will contain growth in out-of-pocket costs for Medicare beneficiaries by limiting the coinsurance rate to 20% of the inflation-adjusted payment amount. This is essential because high out-of-pocket costs are a major contributor to medication non-adherence and consequently worse patient health outcomes.

We urge CMS to take precautions so its approach for establishing the payment benchmark quarter for newly approved drugs is not vulnerable to industry gaming. Section 50.3 of the draft guidance states that CMS will use manufacturer reported quarterly ASP data to determine the date when a drug is first marketed, with the benchmark quarter being the "third full calendar quarter" after this date. Section 50.4 states that the payment limit in this quarter will serve as the benchmark for determining inflationary rebates in future quarters. This leaves open the possibility of gaming by manufacturers to delay ASP reporting for the first full quarter of sales such that the payment limit in the benchmark quarter is based on WAC instead of ASP. This is problematic,

because manufacturers could artificially inflate WAC for new drugs while offering offsetting rebates to avoid future inflationary rebates, which are based on ASP. Thus, it is critical that the benchmark payment amount is based on ASP, not WAC.

Furthermore, the draft guidance assumes that new drugs will have a dedicated HCPCS code during the benchmark quarter. In fact, section 30.1 of the draft guidance states that "*CMS does not intend to count drugs and biological products that are billed using a HCPCS code that represents an "unclassified," "unspecified," or "not otherwise classified" drug or biological product or claims for such drugs and biological products when no other HCPCS code is applicable.*" This could be problematic, because some newly marketed drugs are not assigned dedicated HCPCS codes by the third full quarter after marketing. During data extraction for our JAMA study, we found that 13 (62%) of 21 newly or "subsequently approved Part B rebated drugs" (i.e., equivalent to those drugs approved or licensed by FDA after December 1, 2020), did not have an HCPCS code available by the expected payment amount benchmark quarter (i.e., the third full calendar quarter after the drug was first marketed). Many of these drugs did not have an available HCPCS code until more than 1 year after they were first marketed. If CMS intends to use HCPCS codes in determining the rebate amounts, it is important the agency takes measures to ensure HCPCS codes are available by the payment amount benchmark quarter and establish a plan for handling cases when HCPCS codes are not yet available during this quarter.

Finally, we would like to comment on section 50.8 of the draft guidance (Determination of the Total Number of Units). We strongly encourage CMS to include units of drugs reimbursed for beneficiaries in both fee-for-service and Medicare Advantage plans. In 2022, nearly half of Medicare beneficiaries were enrolled in Medicare Advantage plans; failure to include units administered to this population would substantially reduce the impact of these rebates. Section 50.8.5 of the guidance notes that including the Medicare Advantage units poses "significant operational complexities." We do not know of any existing data that can be used for this

purpose, but we believe that this is important enough that CMS should create a system for Medicare Advantage plans to report quarterly unit data by HCPCS code, such that these data can be used to inform the rebates.

In summary, this guidance document demonstrates the important opportunities for savings to patients and the federal government due to the new Part B inflationary rebates in the Inflation Reduction Act. To ensure maximal benefits, these must be implemented in a manner that minimizes opportunities for gaming by industry. We appreciate the opportunity to comment.

Sincerely,

Benjamin N. Rome, MD, MPH

Alexander C. Egilman, BA

Aaron S. Kesselheim, MD, JD, MPH

From the Program On Regulation, Therapeutics, And Law (PORTAL) in the Division of Pharmacoepidemiology and Pharmacoeconomics in the Department of Medicine at Brigham and Women's Hospital and Harvard Medical School

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
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
Independence Avenue, SW
Washington, DC 20201
VIA EMAIL to: IRARebateandNegotiation@cms.hhs.gov

Re: Medicare Part B 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 B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the Social Security Act, and Solicitation of Comments" ("Memorandum"). Our comments concern Section 50.8.1 of the Memorandum: "Removal of 340B Units."

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 B through the best and most effective means possible. We understand that CMS must develop a means to identify Part B 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 that it will require all 340B covered entities that bill separately payable Part B drugs and biologicals to use the "JG" or "TB" modifier on claims to identify Medicare Part B claims

1501 M Street, N.W. 7th Floor Washington, D.C. 20005| (202) 466-6550 | www.rwc340b.org

for 340B drugs beginning January 1, 2024.[1] While CMS is requesting comments only with respect to identifying 340B drugs for calendar year 2023, RWC-340B is concerned about both the burden and ineffectiveness of requiring in-house or contract pharmacies to including a modifier to identify 340B drugs beginning in 2024. We also write to propose a practical solution 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

CMS notes that CMS guidance published on December 20, 2022 "requires all 340B covered entities to include the "JG" or "TB" modifier, as applicable, on separately payable claim lines for drugs acquired through the 340B program with dates of service beginning no later than January 1, 2024."[2] CMS also acknowledges that while these modifiers have been required since 2018 for providers that bill under the outpatient prospective payment system (OPPS), this requirement "entails operational changes to billing systems for some 340B covered entities (and other providers and suppliers as applicable)."[3]

The Memorandum states that, "[f]or claims with dates of service during 2023, CMS intends to remove units in all institutional claim lines that were billed with the "JG" or "TB" modifiers and all other units in institutional claims submitted by critical access hospitals, Maryland waiver hospitals, and non-excepted off-campus provider-based departments (PBDs)." For dates of service falling on or after January 1, 2024, CMS "intends to remove units in claim lines that were identified as being 340B units by being billed with the "JG" or "TB" modifiers." CMS states that it is "soliciting comments on the identification and removal of 340B units for calendar quarters in 2023."

We understand that CMS is "soliciting comments on the identification and removal of 340B units for calendar quarters in 2023" but urge CMS to consider the proposals below and reconsider the modifier requirement for claims on or after January 1, 2024 as well. A POS modifier requirement creates significant administrative and financial burdens for covered entities that administer 340B drugs and pharmacies that dispense 340B Part B drugs on behalf of covered entities.[4] Moreover, this methodology is 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.

[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 at 18 (Feb. 9, 2023), https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.
[2] *Id.* at 18.
[3] *Id.*
[4] Medicare beneficiaries are typically covered under Part D for self-administered drugs dispensed by a pharmacy, but some categories of drugs, such as immunosuppressive drugs and some oncology drugs, are dispensed by pharmacies for self-administration and are covered under Part B.

Known Deficiencies with Claims Identification at POS

The principal problem with CMS's proposal is that the JG and TB modifiers would have to be reported at the POS by a pharmacy. 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 that use pharmacies to dispense self-administered drugs.

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 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.[5] 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.[6]

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.[7] (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

[5] *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992, Patient and Entity Eligibility. 61 Fed. Reg. 55,156-01 (Oct. 24, 1996).
[6] 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.
[7] 42 U.S.C. §§ 256b(a)(L), (M), (N), (O).

to reach more eligible patients and provide more comprehensive services."[8] Lastly, we are concerned that a POS modifier would result in discriminatory payment practices for 340B drugs by Medicare Advantage plans because the modifier would allow the Part B 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.

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. 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.[9] Considering the inaccuracy and administrative burden imposed by POS modifiers, and the fact that this option could lead to discriminatory payments for 340B drugs by Part B plans, RWC-340B believes that a better alternative – and a more reliable way to identify Part B 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. [10] 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 B 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:

> ***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

[8] 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).
[9] 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.
[10] 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.

340B and there would be no incentive for them to become covered entities."[11] 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 involves, 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 six months from the end of each calendar quarter to submit its rebate request to manufacturers.[12] 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 six 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.

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 Medicare Advantage plans because the data is submitted directly to CMS or its vendor, rather than to the plan.

Alternative Solution

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 a Medicare Advantage 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 for a 340B drug would bear either the "JG" or "TB" modifier. . The only

[11] 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.
[12] 42 U.S.C. 1395w-3a(i)(1)(A).

difference is that, rather than submitting each 340B-identified claim individually at the POS 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 codes "JG" or "TB" 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 B rebate requirements apply only to single source drugs and biologics, including some biosimilars, but excluding vaccines and low Medicare spend drugs. 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 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

March 10, 2023

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

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

RE: Medicare Part B Inflation Rebate Guidance Comments

Dear Administrator Brooks-LaSure:

Seagen Inc. appreciates the opportunity to comment on the Initial Medicare Part B Inflation Rebate Guidance issued by the Center for Medicare & Medicaid Services (CMS) 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).*

Seagen is a global biotechnology company that develops and commercializes transformative cancer therapies. Seagen's singular mission is to make a difference for people impacted by cancer. As an industry leader in antibody drug conjugate (ADC) technology, we pioneered the science of harnessing antibodies designed to deliver cell-killing agents to cancer cells. Three of four of our approved medicines are built on this technology. We focus our research efforts on novel targeted small molecule therapies and we leverage our experience in empowered antibodies to build a portfolio of proprietary immune-oncology agents.

We offer comments below on process improvements that are needed to ensure the Medicare Part B Inflation Rebates work well for both CMS and manufacturers. We also note our appreciation for CMS's monthly manufacturer calls to solicit feedback on broader IRA implementation. Seagen has participated in these calls and we look encourage CMS to find additional ways to connect with individual manufacturers during the IRA implementation process, including creating opportunities for individual manufacturer meetings.

Specific Comments Regarding Medicare Part B Drug Inflation Rebates Paid by Manufacturers

Section 50.8.1 – Removal of 340B Units

For claims with dates of service during 2023, CMS intends to exclude units in all institutional claim lines that were billed with the "JG" or "TB" modifier and all other units in institutional claims submitted by critical access hospitals, Maryland waiver hospitals, and non-excepted off-campus provider-based departments (PBDs). For professional claims with dates of service during 2023, CMS intends to exclude all units in claims of Medicare suppliers that are listed by the Health Resources and Services Administration (HRSA) as participating in the 340B Drug Pricing Program, by using employer

identification numbers to identify these suppliers' Medicare Identification Numbers and the claims submitted with such identifiers. For claims with dates of service thereafter, by which point all 340B covered entities will be required to use the "JG" or "TB" modifier, CMS intends to exclude units by reference to such modifier.

> ***Comment:*** Seagen agrees with CMS's proposal. In addition, CMS should (1) establish a *non*-340B claims modifier (such that either a 340B claims modifier or a non-340B claims modifier is included in each claim), and (2) specify that, where a claim fails to accurately include either modifier, it will be deemed incomplete and unpayable.
>
> CMS should also clarify that its required use of a 340B or non-340B claims modifier preempts any state law prohibiting such modifier.

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

CMS states that the calculation of units of drugs that are furnished to Medicare beneficiaries who are enrolled in MA plans poses significant operational complexities and seeks comment on the best source of information to determine the number of units of a drug furnished to MA enrollees and how to remove units in accordance with section 1847A(i)(3)(B)(ii) of the Act.

> ***Comment:*** Seagen disagrees with the assumption that a Part B inflation rebate may be invoiced on units of drugs furnished to MA beneficiaries since the statute expressly defines a Part B rebatable drug as a drug "for which payment is made under **this part** [emphasis added]," i.e., Medicare Part B – not Medicare Advantage Part C (see § 1847A(i)(2)(A)). Therefore, CMS must not include Medicare Advantage units in its rebate calculations.

60. Ensuring Integrity of Part B Inflation Rebates; 60.1 Timing of Reports and Payment; 60.2 Manufacturer Suggestions of Calculation Errors in Preliminary Rebate Reports and Preliminary True-Up Reports; 60.3 Restatements and True-Up Report; 60.4 CMS Identification of Errors

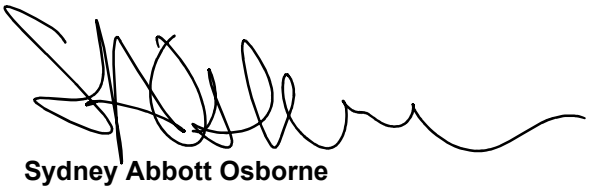
CMS states that it intends to provide all manufacturers of Part B rebatable drugs with a Preliminary Rebate Report no later than 5 months after the end of each calendar quarter (noting that reports for CY 2023 and CY 2024 may be delayed until September 30, 2025, per IRA). Manufacturers would have 10 calendar days to review the Preliminary Rebate Report for potential calculation errors. In addition, CMS would perform a single reconciliation or "true-up" approximately one year after sending the final Rebate Report to the manufacturer.

> ***Comment:*** As stated in CMS's February 2023 press release, the agency intends to submit invoices to companies in 2025. Seagen first requests clarity on a specific date or month within 2025 in which invoices will be sent to manufacturers.
>
> Secondly, we appreciate the agency's recognition that a review process is required to ensure the integrity of the rebate program, however the proposed 10 days is wholly insufficient for adequate assessment. Seagen strongly encourages CMS to employ a dispute resolution process mirroring the existing Medicaid Drug Rebate Program, allowing 60 days for manufacturers to review and submit identified discrepancies back to state agencies. To ensure the integrity of the Part B rebate program, manufacturers must be afforded sufficient time and

claims level data to review utilization errors, calculation errors, duplicate discounts, and inappropriate NDCs, etc. Many manufacturers have established protocol to fulfill Medicaid rebate requirements and it is efficient for CMS to apply a similar process within the Medicare Part B program. Anything different is too burdensome on companies given the limited implementation window.

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

Sincerely,



Sydney Abbott Osborne
Senior Director, Healthcare & Payment Policy and Provider Advocacy

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.

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