



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 Rebutable Drug on the Shortage List*
- *Part D Guidance: 40.5 Reducing or Waiving the Rebate Amount for Part D Rebutable 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

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>