Arnold Ventures

August 7, 2026

Dr. Mehmet Oz, Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Comments on the proposed rule to codify Medicare Drug Price Negotiation Program policies for IPAY 2029 and subsequent years [File code CMS-4215-P]

Dear Administrator Oz,

Thank you for the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed rule to codify Medicare Drug Price Negotiation Program policies for IPAY 2029 and subsequent years that was published in the Federal Register on June 16, 2026. We also thank you and CMS staff for your continued efforts in the implementation of the Medicare Drug Price Negotiation Program, which will lower prescription drug costs for millions of Medicare beneficiaries.[1] We recognize the importance and the difficulty of the task.

Arnold Ventures (AV) is a philanthropy dedicated to investing in evidence-based policy solutions that maximize opportunity and minimize injustice. As a philanthropy, we do not accept funding from industry or have a financial stake in policy outcomes. Our work within the health care sector is driven by the 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, FDA accountability, Medicare sustainability, and Medicaid.

This letter provides comments on the following sections of the proposed rule:

- *II.B.6.a(1) Identification of Potential Qualifying Single Source Drugs – Fixed Combination Products*
- *II.E.5. Determination of the Sum of the Plan-Specific Enrollment Weighted Amounts*
- *II.E.9. Temporary Floor for Small Biotech Drugs*

COMMENTS ON SELECT SECTIONS OF THE PROPOSED RULE

II.B.6.a(1) Identification of Potential Qualifying Single Source Drugs – Fixed Combination Products

CMS proposes a modification to its policy for aggregating fixed combination products for the purpose of determining qualifying single source drugs. This modification would ensure that a specific type of fixed combination product would be eligible for aggregation out of concern that these products would otherwise receive full-length negotiation timelines even though they largely represent repackaged versions of existing products. Specifically, fixed combination products that combine active ingredients, create a new formulation, and enable an alternative route of administration would be included in the types of fixed combination products that can be aggregated together for the purpose of selecting drugs for negotiations. This is important both for determining total sales of the product and for determining the time on the market since the first FDA approval which determines when the drug is eligible for negotiations.

Arnold Ventures supports the CMS policy for aggregating fixed combination products for the purpose of determining qualifying single source drugs, including the proposed modification. This modification would strengthen the program's integrity.

II.E.5. Determination of the Sum of the Plan-Specific Enrollment Weighted Amounts

For Part D drugs, the ceiling price may be equal to the enrollment weighted average price across all Part D plans "net of all price concessions received by such plan or pharmacy benefit managers on behalf of such plan."[2] CMS guidance has interpreted this to be the negotiated price paid to the pharmacy at the point of sale less all rebates paid by the manufacturer to the Part D plan.

Arnold Ventures recommends that CMS incorporate all price concessions from manufacturers to Part D plans, including those granted under the manufacturer discount program, when estimating the ceiling price that is based on the net price to Part D plans.[3] The manufacturer discounts lower the cost of drugs to Part D plans, and those lower prices are incorporated into the Part D plan's bid. Therefore, we believe this would meet the definition of a price concession and should be incorporated into the ceiling price.

II.E.9. Temporary Floor for Small Biotech Drugs

CMS is concerned that, in some instances, the non-Federal Average Manufacturer Price (non-FAMP) ceiling price could fall below the temporary floor for certain small biotech drugs.[4] To alleviate this concern, CMS proposes to increase an eligible drug's ceiling price above the floor by restricting the ceiling calculation to the non-FAMP in effect the year before the drug's selection into negotiations. If this ceiling price is still below the temporary floor, only then would CMS raise the ceiling to be equal to the temporary floor. However, this restriction on the ceiling price calculation would provide the small biotech manufacturer with an opportunity to raise the non-FAMP prior to their product being selected for negotiations--potentially creating a higher MFP ceiling price once the drug is selected for negotiations.

Arnold Ventures recommends that if the non-FAMP ceiling price falls below the temporary floor, CMS should simply raise the ceiling to be equal to the Temporary Floor for Small Biotech Drugs. As proposed, this CMS policy could give small biotech drugs an additional advantage over other selected drugs. It is preferable to calculate the ceiling price for all small biotech drugs selected into negotiations in the same manner as other selected drugs.

CONCLUSION

Arnold Ventures is prepared to assist with any additional information needed. Comments were prepared by Anna Anderson-Cook, PhD, Senior Fellow at Arnold Ventures and Erin Jones, Manager of Health Care at Arnold Ventures, with assistance from Andrea Noda, MPP, Vice President of Health Care, Kate Young, Director of Health Care, and Mark E. Miller, PhD, Executive Vice President of Health Care at Arnold Ventures. Please contact Andrea Noda at anoda@arnoldventures.org or Mark E. Miller at mmiller@arnoldventures.org with any questions.

Sincerely,

Andrea Noda

Vice President of Health Care
Arnold Ventures

[1] CMS. Negotiating Lower Drug Prices Works, Saves Billions. August 2024
[2] 42 USC §1320f-3(c)(2)(A)
[3] Under the Medicare Part D benefit redesign, manufacturers must provide a 10% discount on drugs in the initial phase of coverage to Part D plans, and a 20% discount on drugs in the catastrophic phase of coverage.
[4] For example, the ceiling price will often be slightly below the temporary floor for extended monopoly drugs. The non-FAMP based ceiling price for extended monopoly drugs is the lower of 65% of the inflation adjusted non-FAMP from 2020 or 65% of the non-FAMP in the year prior to selection. The temporary floor for small biotech products is usually 65% of the inflation adjusted non-FAMP in 2020