Arnold Ventures

September 18, 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Re: Comments on the Draft Guidance on Manufacturer Effectuation of the Maximum Fair Price in 2028 under the Medicare Drug Price Negotiation Program

Dear Administrator Oz,

Thank you for the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the draft guidance on manufacturer effectuation of the Maximum Fair Price (MFP) in 2028 under the Medicare Drug Price Negotiation Program issued on July 16, 2026. We also thank you and CMS staff for your continued efforts in the implementation of the Medicare Drug Price Negotiation Program, which lowers prescription drug costs for millions of Medicare beneficiaries.[1] We recognize the importance and 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 section *40.4.1.2 Retrospective Refund Amount to Effectuate the MFP and the Standardized Default Refund Amount for Drugs Payable Under Part B* of the draft guidance.

COMMENTS ON THE DRAFT GUIDANCE

40.4.1.2 Retrospective Refund Amount to Effectuate the MFP and the Standardized Default Refund Amount for Drugs Payable Under Part B

Issue 1: Identifying Whether a Claim Billed with a HCPCS Code is MFP-Eligible

Background. When a generic competitor enters the market for a small molecule brand drug that has been selected for Medicare negotiation, the MFP for the brand drug stays in effect for approximately 9 to 20 months after the first generic drug competitor has been marketed.[2] Unlike for biosimilar products, where biosimilars and their brand counterparts are each placed in separate billing codes, small molecule brand products and their generic counterparts are currently included in the same Healthcare Common Procedure Coding System billing code (HCPCS code). Being included in the same billing code maximizes price competition among generic drugs and their brand counterparts because generic drugs with lower acquisition costs are more profitable for providers to administer.[3] The resulting blended Average Sales Price (ASP) declines over time as generic market share grows. In this draft guidance, CMS is considering whether to continue to place generic drugs in the same billing code as their selected brand drug counterparts.

Arnold Ventures strongly recommends that CMS continue the policy of placing brand-name drugs and their therapeutically equivalent generic drugs in the same billing code, even when the brand-name drug is a selected drug with an MFP. This policy promotes generic competition and reduces Part B spending in the long term. The alternative of giving each generic drug its own separate billing code when its brand counterpart is a selected drug with an MFP would undermine price competition and eventually increase spending on multiple source drugs in Part B.

The third option outlined in the draft guidance, which would place generic drugs in a consolidated, but separate, billing code from the brand product is less desirable because it creates the appearance of therapeutic differences between products when there are none. Additionally, this approach would require a transition to a single consolidated billing code across the brand drug and its therapeutically equivalent generic alternatives once the MFP is no longer in effect in order to assure that the generic drugs are more profitable for providers to administer than their brand counterparts.

Issue 2: Calculating the Standard Default Refund Amount for Selected Drugs Payable Under Part B When Billed with a HCPCS Code

Background. When a provider purchases a Medicare Part B drug from a manufacturer or wholesaler, the drug's negotiated price does not necessarily apply at the time of purchase. That is because the provider cannot know in advance whether the drug will be administered to a Medicare beneficiary who is eligible to receive the drug at the MFP. As a result, providers of Part B drugs will often buy the drug at a price that exceeds the MFP. To resolve this issue, one option CMS proposed is that manufacturers can effectuate the MFP by reimbursing providers a Standard Default Refund Amount (SDRA), which approximates the difference between the acquisition cost to the provider for the Part B drug and its MFP.

Arnold Ventures recommends that CMS, in estimating provider acquisition costs in the SDRA formula, use the Wholesale Acquisition Cost (WAC). CMS has already codified that sales to Medicare beneficiaries at the MFP are to be included in the calculation of the ASP.[4] As sales of a particular Part B drug at the MFP become more widespread, it is likely that this will put downward pressure on the ASP and it will fall below the average acquisition cost to providers for the drug. Therefore, an SDRA formula equal to the difference between an ASP inclusive of the MFP and the MFP will not fully compensate providers for the difference between their acquisition cost and the MFP. Though there are limitations to linking the SDRA to the WAC price, it is preferable to the proposed use of the ASP.

CONCLUSION

Arnold Ventures is prepared to assist with any additional information needed. Comments were prepared by Anna Anderson-Cook, PhD, Senior Fellow and Erin Jones, Manager of Health Care at Arnold Ventures with assistance from Kate Young, Director of Health Care. Please contact Andrea Noda, Vice President of Health Care at anoda@arnoldventures.org or Mark E. Miller, Ph.D. Executive Vice President of Health Care 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] See the CMS proposed rule to codify the Medicare Drug Price Negotiation Program, Table 1 on page 36267. https://www.govinfo.gov/content/pkg/FR-2026-06-16/pdf/2026-12059.pdf
[3] See the Medpac June 2019 report, Chapter 3, Medicare payment strategies to improve price competition and value for Part B drugs.
[4] See footnote 81 on page 36333 of the proposed rule to codify policies established in guidance documents for the Medicare Drug Price Negotiation Program for initial price applicability year 2029 and beyond (CMS-4215-P) issued on June 26, 2026.