



June 26, 2025

Dr. Mehmet Oz  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
P.O. Box 8016  
Baltimore, MD 21244-8016

*Submitted electronically via regulations.gov*

Re: Medicare Drug Price Negotiation Program Draft Guidance

Dear Administrator Oz:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to the Medicare Drug Price Negotiation Program Draft Guidance.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP's nearly 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.

### **Downstream Impacts**

AMCP recognizes the importance of efforts to make prescription drugs more affordable for Medicare beneficiaries. We urge CMS to continually and rigorously oversee the program's implementation and its broader effects to ensure that it does not unintentionally hinder innovation and the development of new therapies. CMS should monitor the downstream impact of the Medicare Drug Price Negotiation Program on innovation and drug development and take appropriate action as needed to ensure that the United States remains the leader in pharmaceutical innovation.

### **Part B Drugs**

The IPAY 2028 round of negotiations will see a substantial expansion of the Medicare Drug Price Negotiation Program, adding drugs reimbursed under Medicare Part B. While Part D drugs are typically dispensed by pharmacies with well-established payment processes with health plans and pharmacy benefit managers (PBMs), Part B drugs are typically administered in clinical settings where providers purchase the drug up front and are then reimbursed using one

of several methodologies.<sup>1</sup> CMS should consider the potential unintended consequences of this new environment on providers and patients.

To improve patient access to negotiated drugs, provider participation must be encouraged. Providers would benefit from detailed implementation guidance specific to billing for Maximum Fair Price (MFP) for Part B drugs. CMS will need to delineate how providers submit claims for drugs subject to the MFP with updated coding and reconciliation protocols. Such guidance will help providers obtain timely reimbursement and will help to ensure continued patient access to their needed medications.

Because providers in smaller practices are unlikely to have a reimbursement department with direct access to CMS updates, CMS should proactively consider all options for disseminating timely guidance and MFP-related billing instructions to providers. This will enable them to bill correctly and avoid reimbursement denials or overcharges for patients. CMS should also ensure that technical assistance is available to smaller and rural practices that may encounter greater difficulty adapting to major billing changes.

AMCP is also concerned about the potential for providers to avoid stocking a particular negotiated Part B drug if their financial incentives don't align, such as if MFP reimbursement is less than the acquisition cost for the drug, there are narrow margins on the drug, or there are regional differences impacting the market. CMS can mitigate such potential disruptions to patient access by proactively monitoring provider participation rates, regional access patterns, and other patient access issues. CMS should also institute temporary transition payments or other safeguards during the early phases of implementation to facilitate provider uptake.

## **Renegotiation**

AMCP recommends that CMS further define the operational details of renegotiation to clarify criteria, enhance transparency, and build patient engagement into the processes. CMS should ensure that the renegotiation process includes structured opportunities for public engagement such as listening sessions, comments, and other avenues for input. AMCP believes that a formal notice-and-comment process would allow new evidence to be considered and would give patients, clinicians, and other affected parties the opportunity to submit updated clinical data, real-world outcomes, and patient perspectives. An evidence-based approach is needed so that the program remains responsive to evolving therapies while protecting access to care.

## **Effectuation of the MFP**

Effectuating the MFP is the most important piece of the puzzle in the Medicare Drug Price Negotiation Program as it allows payers and patients to benefit from CMS' negotiations. CMS must ensure that systems are transparent, accurate, and include patient safeguards. AMCP applauds CMS' ongoing development of the Medicare Transaction Facilitator (MTF) program and appreciates the additional operational details included in the draft guidance. AMCP believes that additional clarity is needed around transparency, accountability, and procedural safeguards

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<sup>1</sup> <https://www.cms.gov/cms-guide-medical-technology-companies-and-other-interested-parties/payment/part-b-drugs>

to mitigate for circumstances when the MFP is incorrectly applied. Additionally, notification and refund processes are needed for when a patient is charged more than the MFP.

## **Conclusion**

AMCP appreciates CMS' work to expand the Medicare Drug Price Negotiation Program to include Part B drugs, to clarify expectations, and to formalize criteria for renegotiations, all while focusing on patient input and real-world evidence. AMCP encourages CMS to fine tune its operational procedures, improve transparency, and incorporate additional safeguards. These additional refinements will result in additional savings as well as improvements in care, access, and outcomes.

AMCP appreciates your consideration of AMCP's concerns and looks forward to continuing work on these issues with CMS. If you have any questions regarding AMCP's comments or would like further information, please contact Vicky Jucelin, AMCP's Manager of Regulatory Affairs, at [vjucelin@amcp.org](mailto:vjucelin@amcp.org) or (571) 858-5320.

Sincerely,

A handwritten signature in cursive script, appearing to read "S. Cantrell".

Susan A. Cantrell, MHL, RPh, CAE  
Chief Executive Officer