AMA
AMERICAN MEDICAL ASSOCIATION

John Whyte, MD, MPH
CEO, EXECUTIVE VICE PRESIDENT

john.whyte@ama-assn.org

August 14, 2026

The Honorable Mehmet C. Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

Re: CMS-4215-P: Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program

Dear Administrator Oz:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule to codify policies governing the Medicare Drug Price Negotiation Program. The AMA has long supported Medicare drug price negotiation as an important tool for improving the affordability and accessibility of prescription medications, and we commend CMS for moving forward with codifying the program in regulation.

As CMS finalizes these policies, we offer the following comments on provisions that are particularly important to ensuring a transparent, clinically grounded, and methodologically rigorous negotiation process. Specifically, we urge CMS to strengthen transparency throughout drug selection and price determination; establish clear standards for evaluating comparative clinical evidence and incorporating physician and patient input; and ensure that manufacturer-specific factors, including federal investment, financial returns, and anticompetitive behavior, are meaningfully reflected in negotiated prices. We also emphasize the importance of ensuring that future policies governing implementation of negotiated prices preserve patient access to physician-administered drugs.

Identification and Transparency in Drug Selection (§§ 429.100–429.135)

For each initial price applicability year beginning with 2029, CMS proposes to publish a ranked list of up to 30 top negotiation-eligible drugs, including the 20 drugs selected for negotiation. The AMA supports this proposal and urges CMS to provide enough information for the public to understand and evaluate each selection determination. At a minimum, CMS should identify the data period and expenditure calculations used, explain any exclusion from or delay in selection, and disclose any material assumptions used to aggregate spending across dosage forms and strengths. The agency should carry this same level of transparency through each subsequent stage of the negotiation process.

Confidentiality and Public Disclosure (§ 429.300)

The AMA is concerned that CMS' proposed confidentiality policy could unnecessarily limit public understanding of how negotiated prices are determined. CMS proposes to categorically deem several manufacturer-submitted data elements proprietary unless already publicly available, including research and development costs, production and distribution costs, pending patent information, and U.S. market, revenue, and sales-volume data. At the same time, CMS recognizes that information regarding prior federal financial support, approved patents and exclusivities, and other publicly available information would not be proprietary.

The AMA urges CMS to avoid interpreting confidentiality protections more broadly than required by law. Robust public transparency is essential to ensuring confidence in the negotiation process. CMS should disclose enough information for the public to understand how it reached each maximum fair price (MFP), evaluate the rigor of the methodology and evidence underlying its decisions, and assess how the statutory negotiation factors affected the final price. Overly broad confidentiality protections would make that scrutiny difficult and risk obscuring the basis for CMS' decisions.

CMS should therefore assess confidentiality on an item-by-item basis and disclose underlying data whenever permissible. When CMS cannot disclose the underlying data, it should provide aggregated values, ranges, calculations, or other information sufficient to show how those data influenced the MFP. CMS' proposal to publish narrative explanations, redacted negotiation information, and redacted submissions provides an important foundation, but those disclosures should provide enough detail for the public to meaningfully evaluate the methodology and basis for the final negotiated price.

Clinical Evidence and Negotiation Factors (§§ 429.505–429.510)

Clinical Evidence and Comparative Effectiveness (§§ 429.505(d)–(e), 429.510(b)–(e))

The AMA supports CMS' proposal to consider a broad body of evidence when assessing a selected drug and its therapeutic alternatives, including peer-reviewed literature, real-world evidence, clinical practice guidelines, Medicare data, and clinician and patient input. We also appreciate the agency's attention to methodological rigor, study limitations, risk of bias, generalizability, and the degree of certainty associated with available evidence.

However, we urge CMS to establish a clearer framework for evaluating a selected drug when head-to-head evidence against relevant therapeutic alternatives is limited or unavailable. In those circumstances, CMS should identify the evidence gap, explain the indirect or observational evidence on which it relies, and account for the resulting uncertainty when evaluating comparative clinical benefit and developing the MFP.

Even where comparative evidence is available, however, it may not capture clinically meaningful differences between therapies that should inform the negotiation process. This is particularly important when CMS evaluates whether a therapeutic alternative is an appropriate comparator. For example, two anticoagulants may have similar efficacy in preventing thromboembolic events but differ in bleeding risk, dosing frequency, and laboratory monitoring burden—differences that can materially affect treatment selection, patient adherence, and real-world use. Because such considerations may not be fully reflected in comparative studies, CMS should establish a consistent and accessible process for obtaining input from physicians and patients and incorporate that input when evaluating therapeutic alternatives and comparative clinical benefit.

Consideration of Manufacturer-Specific Factors (§ 429.510(f))

The AMA supports CMS' proposal to consider the manufacturer-specific factors collectively and adjust the preliminary price accordingly. However, CMS should examine what these factors reveal about the manufacturer's investment and financial returns rather than treating them as isolated facts. When assessing research and development expenditures, for example, CMS should consider not only the manufacturer's claimed investment, but also the extent to which that investment has already been recouped through U.S. and global revenues, as well as the degree to which the innovation was underwritten by federal taxpayers. Similarly, when evaluating patent and exclusivity information, CMS should consider whether manufacturers have used anticompetitive strategies such as patent thickets, product hopping, and other forms of evergreening to delay competition and sustain higher prices and adjust the preliminary price downward accordingly.

Development and Explanation of the MFP (§§ 429.510–429.520)

In presenting its initial offer, CMS states it will provide the manufacturer a "concise justification" describing the statutory factors considered, the methodology used, and evidence CMS found compelling. The AMA urges CMS to extend similar transparency to the public when it publishes the final MFP. The explanation should identify the starting point; the therapeutic alternatives considered and their prices; the evidence used to assess comparative clinical benefit; areas of uncertainty; the effect of unmet medical need and therapeutic advance; and how the manufacturer-specific factors affected the negotiation, including the direction and relative magnitude of material adjustments. Without this information, physicians, patients, and other interested parties cannot assess whether an MFP reflects a rigorous evaluation of the evidence and statutory factors.

Part B Drugs and Future MFP Effectuation Policies

CMS states that it will address in future rulemaking the requirements governing how manufacturers provide access to the MFP beginning in 2029. For physician-administered drugs, those requirements will determine whether physician practices and hospitals can purchase selected drugs at the MFP or must pay more upfront and recover the difference later. The AMA strongly urges CMS to require manufacturers to provide prospective access to the MFP at the time of acquisition rather than rely on retrospective refunds. Requiring practices to purchase high-cost drugs above the MFP and await reimbursement would force them to finance the difference, creating substantial cash-flow and inventory risk. Prospective access would better align acquisition costs with Medicare payment and reduce the risk that practices, particularly smaller and independent practices, will be unable or unwilling to continue furnishing affected therapies. CMS should therefore establish prospective MFP access as the default for Part B drugs and permit retrospective reconciliation only when prospective access is operationally infeasible.

Conclusion

The Medicare Drug Price Negotiation Program represents a significant step toward making prescription medications more affordable and accessible for Medicare beneficiaries. As CMS places the program on a permanent regulatory footing, it has an opportunity to build on that progress. The AMA looks forward to working with CMS on the implementation of the program. The final rule should provide greater visibility into how CMS reaches its decisions; ensure that physicians and patients inform judgments about the clinical value of treatment options; and account for manufacturer investment, financial returns, and anticompetitive practices in negotiated prices. A program built on that foundation will be better positioned to secure lower prices while maintaining confidence in the decisions that produce them.

The AMA appreciates the opportunity to comment on this proposed rule. Please reach out to me directly at 312-464-5288 or John.Whyte@ama-assn.org if you have questions or need further information.

Sincerely,

John Whyte, MD, MPH