



August 17, 2026

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Attn: CMS-4215-P
P.O. Box 8013
Baltimore, MD 21244

Re: Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program
Proposed Rule (CMS-4215-P)

Dear Administrator Oz:

The Hematology/Oncology Pharmacy Association (HOPA) appreciates the opportunity to comment on the proposed rule implementing additional provisions of the Medicare Drug Price Negotiation Program under the Inflation Reduction Act. HOPA is a non-profit professional organization for hematology/oncology pharmacy practitioners and their associates. The organization is comprised of approximately 4,000 members who share a common mission to provide the best possible cancer care. HOPA's membership includes not only hematology/oncology pharmacists, but also pharmacy interns, residents, students/trainees, technicians, researchers, and administrators that specialize in hematology/oncology practice. Members serve in clinical and academic roles at cancer centers, inpatient/outpatient hospitals, clinics, physician offices, community and specialty pharmacies, home health practices, universities, and other healthcare settings across the country.

HOPA supports efforts to improve the affordability of prescription drugs for Medicare beneficiaries. However, as CMS continues implementation of the Medicare Drug Price Negotiation Program, it is essential that operational policies do not inadvertently reduce patient access to oncology medications or place unsustainable financial and administrative burdens on the providers and pharmacies that deliver cancer care. Oncology practice is unique, with many therapies requiring complex clinical management, individualized treatment decisions, and coordination across multidisciplinary care teams. We encourage CMS to continue refining the program to ensure that its implementation supports, not hinders, patient access to high-quality cancer care.

Maximum Fair Price (MFP) Effectuation

HOPA's primary concern relates to the current rebate-based process used to effectuate the Maximum Fair Price (MFP). Under the current model, pharmacies must purchase negotiated drugs at the full acquisition cost and subsequently seek reimbursement from manufacturers after dispensing the medication. While the statute envisions timely reimbursement, many pharmacies continue to experience significant delays of 90-120 days before receiving payment.

This approach effectively requires pharmacies to finance the negotiated discount, often for several months. Community oncology pharmacies and health-system pharmacies may be required to carry hundreds of thousands of dollars in outstanding costs while waiting for manufacturers to process rebate



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payments. This creates unnecessary financial risk for providers whose primary mission is delivering patient care rather than financing a federal pricing program.

HOPA encourages CMS to explore alternatives that eliminate pharmacies from the rebate and negotiation process whenever possible. Rather than relying on providers to purchase drugs at full price and await reimbursement, CMS should work toward a mechanism that omits providers from the workflow and allows CMS to directly seek the rebate from pharma. This would allow CMS to know exactly how many products were purchased for their patients and directly ask for a rebate. Additionally, pharmacists are already required to code for 340b drug products meaning CMS already knows the quantity of drugs needed. Such an approach would reduce administrative complexity while ensuring that negotiated savings reach Medicare beneficiaries without creating financial instability for oncology practices.

Administrative Burden on Oncology Providers

Oncology practices already manage significant administrative responsibilities, including prior authorization requirements, benefit verification, appeals, manufacturer assistance programs, and complex payer-specific billing requirements.¹

The MFP effectuation process adds another layer of operational complexity. Pharmacies and providers must identify eligible Medicare beneficiaries, distinguish negotiated claims from commercial claims, comply with manufacturer-specific documentation requirements, monitor reimbursement timelines, and prepare for audits. These responsibilities require additional staffing, technology investments, and workflow changes that divert resources away from direct patient care and unintentional increase the cost of care. Community oncology practices may be particularly affected because they often lack the administrative infrastructure available to larger health systems.

Additionally, mergers and acquisitions are common in oncology and biotech, and there is concern for administrative disruptions during an ownership transition that could delay contracting, rebates, distribution arrangements, or communications affecting provider access.

HOPA encourages CMS to continue simplifying operational requirements, standardizing manufacturer processes where possible, and minimizing documentation requirements that do not directly contribute to program integrity.

Protecting Patient Access to Oncology Care

CMS should continue to prioritize maintaining timely patient access to cancer treatment throughout implementation. HOPA is concerned that the administrative and financial burdens associated with negotiated drugs may unintentionally influence treatment decisions or dispensing practices. If pharmacies experience significant operational challenges associated with MFP drugs, there may be incentives to choose clinically appropriate alternatives that are not yet subject to negotiation merely because they are operationally easier to administer.

Smaller community pharmacies may determine that they cannot continue dispensing certain negotiated oncology medications if reimbursement delays create unacceptable financial risk. Patients could

¹ <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2021.00036>



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subsequently be required to obtain medications from larger specialty pharmacies located farther from their treatment team, disrupting care coordination, and reducing access to local oncology services.

These challenges are likely to become even more significant as negotiated pricing expands to physician-administered oncology therapies under Part B. CMS should closely monitor implementation to ensure that payment policies do not inadvertently reduce patient access or threaten the financial viability of community oncology programs.

Expansion of the Negotiation Program to Medicare Part B Drugs

As noted, HOPA is concerned about the upcoming expansion of negotiated pricing to Medicare Part B drugs beginning with Initial Price Applicability Year 2028. Unlike many Part D medications, oncology Part B therapies are frequently administered through infusion centers and physician offices. These providers purchase medications before administration and rely on timely reimbursement to maintain adequate inventory and continue offering treatment within their communities.

Applying the existing rebate model to Part B drugs could have negative consequences for oncology providers. Infusion centers and community oncology practices often operate with limited financial margins and may not have sufficient cash flow to absorb lengthy reimbursement delays associated with negotiated pricing.

CMS should carefully evaluate how implementation will affect community oncology programs, particularly rural and independent practices that provide care close to where patients live. Financial pressures resulting from delayed manufacturer reimbursement could accelerate consolidation of oncology care into larger health systems and reduce treatment options in rural communities.

In addition, HOPA requests that CMS provide clear guidance regarding Medicare beneficiary cost-sharing for negotiated Part B drugs. Stakeholders need certainty regarding whether beneficiary coinsurance will be calculated based on the Maximum Fair Price or another payment benchmark, such as ASP. Clear communication will help providers educate patients and avoid unnecessary confusion during implementation.

Renegotiation Policies and Oncology Innovation

HOPA appreciates the agency's efforts to establish policies governing future renegotiation of selected drugs. As CMS considers the role of additional clinical evidence in future negotiations, we encourage the agency to recognize the unique nature of oncology treatment. Cancer care frequently relies on medically accepted off-label uses supported by nationally recognized clinical compendia, including the National Comprehensive Cancer Network Clinical Practice Guidelines and Compendium. Medicare has long recognized these evidence-based indications for coverage purposes, allowing patients timely access to emerging standards of care, and disincentivize manufacturers in future drug development.

HOPA encourages CMS to maintain consistency with existing Medicare coverage policy when considering clinical evidence during renegotiation. Failure to appropriately recognize established off-label oncology indications could create unintended disincentives for innovation and limit patient access to evidence-based therapies.

Fixed Combination Products and One-Time Therapies



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HOPA also encourages CMS to consider the unique characteristics of fixed combination products and one-time therapies during implementation of the negotiation program. Combination oncology therapies continue to advance patient care by improving treatment effectiveness, simplifying administration, and reducing treatment burden. Transformative therapies such as CAR-T cell therapy and future gene and cell therapies represent significant advances in cancer treatment and require thoughtful valuation methodologies that recognize their long-term clinical benefits. Certain emerging oncology products rely on novel formulations, delivery technologies, or fixed combinations. These novel drugs could be compared to and combined with existing oncology products which may be included in premature negotiations. Including these drugs and oncology products in negotiations may disincentivize manufacturers to invest in them, therefore decreasing the number of products available or accessible to oncology patients. This is especially important for therapies serving rare oncology populations with high unmet needs; therefore CMS should ensure continued incentives for therapies serving these populations. CMS should provide clarification on how the agency will evaluate combination products and ensure that policies governing these products continue to support innovation while preserving patient access to breakthrough therapies.

Conclusion

HOPA appreciates the opportunity to submit these comments on Medicare's Drug Price Negotiation Program. We appreciate CMS's continued engagement with stakeholders and look forward to working collaboratively to ensure successful implementation of the program while maintaining access to high-quality oncology care. Please reach out to Brooke Boring at bboring@hoparx.org with any questions or if we can provide additional information.

Sincerely,

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President
Hematology/Oncology Pharmacy Association*