COMMUNITY ONCOLOGY ALLIANCE

Dedicated to Advocating for Community Oncology Patients and Practices

1225 New York Avenue, NW, Suite 600, Washington, D.C. 20005
(202) 729-8147 | communityoncology.org

August 10, 2026

The Honorable Mehmet Oz, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4215-P
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted electronically to: http://www.regulations.gov

RE: Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program Proposed Rule

Dear Administrator Oz:

On behalf of the Board of Directors of the Community Oncology Alliance ("COA"), we are submitting this comment letter regarding the Medicare Drug Price Negotiation Program ("MDPNP") and Medicare Prescription Drug Benefit Program Proposed Rule ("Proposed Rule") (CMS-4215-P).

COA is an organization dedicated to advocating for the complex care and access needs of patients with cancer and the community oncology practices that serve them. COA is the only nonprofit organization in the United States dedicated solely to independent community oncology practices, which serve the majority of Americans receiving treatment for cancer. Since its grassroots founding close to 25 years ago, COA's mission has been to ensure that patients with cancer receive quality, affordable, and accessible care in their own communities where they live and work.

COA is committed to providing solutions to the challenges that community oncology patients and physicians face throughout the care journey. We seek to ensure that cancer care is delivered with the utmost quality and in an accessible and affordable manner.

COA appreciates the work of the Centers for Medicare & Medicaid Services ("CMS") towards the MDPNP's stated goal of lowering drug costs for beneficiaries and appreciates the opportunity to provide comments on the Proposed Rule. However, COA has concerns that the MDPNP will also have unintended consequences on patient access to oncology treatments.

COA's most urgent concerns relate to the financial, administrative, and operational challenges of Maximum Fair Price ("MFP") effectuation for community oncology practices and their patients. COA will address those issues separately in response to CMS's recently issued *Draft Guidance on Manufacturer Effectuation of the Maximum Fair Price in 2028 under the Medicare Drug Price Negotiation Program* with concerns and recommendations.[1] This letter focuses on additional provisions of the Proposed Rule that will affect cancer therapy innovation, formulary access, physician-directed treatment, public engagement, and one-time therapies.

[1] Centers for Medicare & Medicaid Services. Draft Guidance on Manufacturer Effectuation of the Maximum Fair Price in 2028 under the Medicare Drug Price Negotiation Program. 16 July 2026. Available Here.

In summary, COA recommends CMS:

- **Maintain its existing fixed combination product policy.** A narrower version may reduce the development of subcutaneous versions of oncology therapies. These products reduce treatment time and costs and are aligned with patient and provider preferences**.**
- **Add an additional step to its formulary review policy and confirm that any changes in tier placement would not result in higher patient cost-sharing for the selected drug compared to the prior plan year.** CMS should **not approve plans that increase cost-sharing for selected drugs**, which would run counter to the MDPNP's goal of lowering drug costs.
- **Ensure that Medicare Advantage ("MA") plans do not implement step therapy protocols for Part B drugs selected for negotiation that adversely impact patient access to these drugs**, and that step therapy policies do not inhibit provider autonomy in prescribing decisions.
- **Commit to continue holding town hall meetings as an additional avenue for clinically focused feedback.** COA further recommends that CMS expand town halls focused specifically on operational concerns and patient access impacts of the MDPNP, given that operational burden on independent practices directly affects patients' ability to access negotiated drugs.
- **Apply a nuanced approach to calculating the 30-day equivalent supply for one-time therapies** to ensure that the proposed calculation does not distort MFP calculations for high-cost, one-time cancer therapies.

Our detailed comments are below.

I. Modification to Fixed Combination Product Policy for Drugs That Are New Formulations

COA is concerned that CMS's proposed narrowing of its fixed combination product policy, under which new formulations that enable an alternative route of administration would be aggregated with the original product, will reduce the development of patient-preferred formulations of oncology therapies.

Subcutaneous formulations provide significant benefits to both patients and community oncology practices. Patients generally prefer subcutaneous to IV administration, and providers benefit from reduced treatment time and lower health care resource utilization. A 2025 systematic literature review of oncology therapies found that subcutaneous administration was associated with savings in both provider and patient time, direct and indirect cost savings, increased treatment satisfaction, and was generally preferred by patients and providers.[2] Thus, regardless of CMS's intent to target negotiation avoidance behavior, by treating these reformulations as extensions of the original product rather than as distinct innovations, CMS discourages formulation innovation, the very development that reduces burden on patients and practices. Additionally, the agency's expectation that this change would currently affect only biological products licensed under biologics license applications further harms oncology innovation, as the products where new formulations are often developed are biologics.

Although COA recognizes CMS's interest in preventing reformulations designed principally to avoid or delay negotiation, the agency should distinguish such products from clinically meaningful innovations that materially reduce treatment time, resource utilization, or patient burden.

Recommendation

COA urges CMS not to narrow its fixed combination product policy, as it may reduce the development of subcutaneous treatments. Subcutaneous versions of oncology therapies reduce treatment time and costs and are aligned with patients' and providers' preferences**.**

[2] George S, et al., "Systematic literature review of intravenous versus subcutaneous administration of oncology therapies: A clinical, economic and patient perspective." September 2025. *Cancer Treatment Reviews*. Available Here.

II. Medicare Part D Formulary Requirements

CMS's proposal to codify, for 2029 and subsequent years, the formulary inclusion requirements and review policies previously implemented through guidance does not add specific utilization-management or tier-placement protections for selected drugs, potentially leaving patients exposed to increased cost-sharing and access barriers. CMS states it will continue to monitor formulary placement trends and enforce general formulary requirements, but it is not requiring specific protections for selected drugs. While the impacts of the Inflation Reduction Act ("IRA") on oncology drug placement are still emerging since only one oncology drug was selected for initial price applicability year ("IPAY") 2026, evidence is emerging regarding the impacts of the IRA on formulary placement. The number of oncology drugs selected for negotiation is increasing, and COA will be monitoring for further impacts on patient access.

A recent industry analysis of 2026 Part D formularies found that seven of the 10 negotiated drugs are predominantly placed on tier 3, while three (including Imbruvica) remain primarily on tier 5, the specialty tier associated with the highest patient cost-sharing. As manufacturers have reduced rebates for drugs selected for negotiation, these drugs were much less likely to be on generic or preferred tiers, compared to 2025 placement. Additionally, plans are using coinsurance more frequently on tier 3, going from 38 percent of general enrollment Medicare Advantage prescription drug plans in 2025 to almost 59 percent in 2026.[3] All this translates to potentially higher patient cost-sharing and access risks for selected drugs on formularies.

Recommendation

While CMS will assess any instances where Part D sponsors place selected drugs on non-preferred tiers and instances where a selected drug is placed on a higher cost-sharing tier than non-selected brand drugs in the same class, we encourage CMS to add an additional step to confirm that any changes in tier placement would not result in higher patient cost-sharing for the selected drug compared to the prior plan year. **CMS should not approve plans that increase cost-sharing for selected drugs, which would run counter to the MDPNP's goal of lowering drug costs.**

III. Medicare Advantage Plans' Use of Step Therapy for Part B Drugs

CMS does not address MA "fail-first" step therapy for Part B drugs in the Proposed Rule, despite having sought comments on how to best monitor this issue in the IPAY 2028 Draft Guidance and despite CMS's prior acknowledgement of the compliance and data challenges involved. This leaves community oncology practices and their patients without any new protections, even as step therapy continues to disrupt treatment decisions, delay access to physician-recommended therapies, and add administrative burden that independent practices are not equipped to absorb.

The results from COA's 2026 Community Oncology Utilization Management Impact Survey of 110 oncology professionals in independent practices nationwide underscore the need for protection against adverse step therapy policies.[4] The survey found that 92.1 percent of respondents reported that step therapy has made utilization management more time-consuming over the last five years, and 96.6 percent reported observing patients with cancer struggle as a direct result of insurer-imposed step therapy. Additionally, 96.6 percent of respondents said insurance company policies interfere with patients' access to treatment their physician recommends first.

For patients with cancer, time is clinically critical. Step therapy can force a patient to try and fail a plan-preferred drug before receiving the treatment selected by the treating oncologist, delaying initiation of the therapy the physician believes is most appropriate based on the patient's diagnosis, disease stage,

[3] Knable L, et al., "Part D Formularies Enter a New Era in 2026." Oliver Wyman. Available Here.
[4] Community Oncology Alliance. "COA 2026 Utilization Management Survey." 10 February 2026. Available Here.

biomarkers, prior treatment, comorbidities, and anticipated toxicity. These delays can permit disease progression, prolong symptoms, expose patients to unnecessary toxicity, and disrupt carefully sequenced treatment plans. Step therapy therefore is not merely an administrative burden; when inappropriately applied, it can directly interfere with clinical decision-making and jeopardize timely access to medically necessary cancer care.

Recommendations

CMS should ensure that MA step therapy policies for Part B drugs selected for negotiation do not delay or override physician-recommended oncology treatment. At a minimum, CMS should require a clear and rapid exceptions process; prohibit step therapy when the required alternative is contraindicated, previously unsuccessful, or otherwise clinically inappropriate; protect patients who are stable on an existing therapy; and monitor plan-level data regarding denials, exceptions, appeals, and time to treatment. The treating oncologist's determination of medical necessity and clinical appropriateness should govern the exception decision unless the plan demonstrates, based on applicable clinical evidence and nationally recognized treatment guidelines, that the prescribed treatment is inappropriate for the individual patient.

IV. Public Engagement Events

COA is concerned that the Proposed Rule represents a step backward from the commitment CMS made in the IPAY 2028 Final Guidance to host one town hall meeting for all selected drugs. In the Proposed Rule, CMS states it "may" host a town hall meeting, rather than ensuring such a meeting, leaving oncologists, patients, and advocacy organizations with less certainty that they will have a dedicated opportunity to share clinical perspectives with CMS as more oncology drugs enter the negotiation process. COA supports maintaining multiple mechanisms for the public to provide feedback on selected drugs, including via public engagement events and the Drug Price Negotiation Program Information Collection Request. COA also encourages CMS to host separate provider- or practice-level roundtables to provide operational perspectives and patient access impacts, regarding the negotiation program.

Recommendations

COA strongly recommends that CMS commit to continuing to hold town hall meetings as an additional avenue for clinically focused feedback. COA further recommends that CMS develop new town halls focused specifically on operational concerns and patient access impacts of the IRA, given that operational burden on independent practices directly affects patients' ability to access negotiated drugs.

V. Calculation for a 30-Day Equivalent for a Drug Administered One-Time (Including Cancer Drugs)

CMS proposes a new approach to calculating a 30-day equivalent supply for drugs typically administered once, such as some vaccines, cancer therapies, and gene therapies. This would treat a single claim as if it were a 12-month treatment episode rather than a standard 30-day refill cycle. COA is concerned that applying this standardized denominator to one-time cancer therapies risks distorting MFP calculations for these products, given that community oncology practices and treatment centers administering them often rely on payment structures fundamentally different from those used for drugs administered on a recurring basis.

One-time oncology therapies are clinically and economically distinct from drugs administered on a recurring schedule. These therapies may offer patients with serious or life-threatening conditions – including patients with few remaining treatment options – a single treatment intended to provide durable clinical benefit. A methodology that does not account for one-time administration, the expected duration of benefit, specialized treatment-site requirements, and extraordinary acquisition and carrying costs could produce an MFP that is disconnected from the realities of furnishing the therapy. If oncology practices and

treatment centers cannot acquire and administer these products without assuming unsustainable financial exposure, patients may experience treatment delays, be forced to travel to distant facilities, or lose access to the therapy altogether.

One-time cell and gene therapies used in oncology and related conditions span a wide cost range but offer significant clinical benefit, with per-treatment prices reported between roughly $373,000 and $4.25 million, depending on therapy.[5] Because of this cost, providers, manufacturers, and payers have increasingly moved toward alternative payment structures for these products, including outcomes-based agreements and annuity models tied to sustained patient response. Treating a one-time therapy's single claim as equivalent to a full 12-month treatment episode for purposes of calculating a 30-day equivalent may not accurately reflect these payment realities or allow for accurate comparison to therapeutic alternatives with different treatment frequencies. If CMS cannot reliably account for this complexity, the resulting MFP could limit community oncology practices' ability to supply the drug to patients because of the mismatch between reimbursement and acquisition and significant Average Sales Price erosion.[6,7] Over time, a methodology that systematically undervalues one-time therapies could also weaken incentives to invest in the development of next-generation treatments for patients with limited or no effective alternatives.

Recommendations

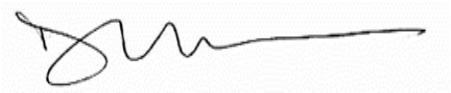
CMS should establish an appropriately tailored methodology for calculating the 30-day equivalent supply of one-time therapies that accounts for their single-administration dosing, expected duration of benefit, specialized delivery requirements, acquisition and carrying costs, and distinct payment arrangements. Before applying the methodology, CMS should evaluate its likely effect on practice participation and patient access and establish safeguards to prevent an MFP calculation from making these therapies financially infeasible for treatment sites to furnish.

Conclusion

Thank you for the opportunity to share our concerns and priorities related to the MDPNP. We look forward to providing more detailed comments on MFP effectuation policy in response to the recently released guidance.

Thank you for your consideration of these comments. COA is available to discuss the concerns and recommendations in this letter and can be contacted at debra.patt@usoncology.com and tokon@COAcancer.org. We look forward to working with you on promoting the health and well-being of Americans with cancer.

Sincerely,



Debra Patt, MD, PhD, MBA, FASCO
President

Ted Okon, MBA
Executive Director

[5] Buntz B. "With prices topping $4 million, high stakes define cell and gene therapy landscape." 26 April 2024. Available Here.
[6] Avalere Health Advisory. "Commercial Spillover Impact of Part B Negotiations on Physicians." 16 September 2024. Available Here.
[7] Avalere Health. Provider Perspectives on Medicare Drug Price Negotiation: Implications for Part B Beneficiary Access, Practice Operations, and Reimbursement. 9 September 2025. Available Here.