AMERICAN COLLEGE of RHEUMATOLOGY
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August 17, 2026

The Honorable Mehmet Oz, MD
Administrator, Centers for Medicare & Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244

Sent electronically via regulations.gov

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

Dear Dr. Oz,

The American College of Rheumatology (ACR), representing over 10,400 rheumatologists and rheumatology interprofessional team members, appreciates the opportunity to respond to the proposed rule codifying the Medicare Drug Price Negotiation Program (MDNP). The ACR is strongly supportive of the goals of MDNP, as high drug costs make many of the medications used to treat chronic autoimmune conditions—including rheumatoid arthritis, psoriatic arthritis and lupus—inaccessible to the rheumatology patient population. To ensure that the MDNP achieves its goals of lowering prescription drug costs and increasing access to care for Medicare beneficiaries, we urge CMS to:

1) Ensure that physicians are adequately compensated for in-office administration of Part B drugs that have been subject to negotiation
2) Narrow the scope of the provision in the proposed rule that would aggregate fixed-combination products that differ only by route of administration to ensure that this new policy does not undermine physician autonomy in clinical decision-making

Earlier this year, CMS announced the first-ever inclusion of Part B drugs within the MDNP. ACR members provided stakeholder input on the selection of drugs through the townhall process. Many of the drugs selected for negotiation (particularly Orencia, Cosentyx, Xeljanz and Cimzia) are critical for rheumatology patients, with tens of thousands of Medicare beneficiaries relying on them to manage their rheumatologic conditions.

However, the ACR remains concerned that MDNP negotiations may inadvertently limit patient access to Part B medications administered in a physician's office or other outpatient setting. Medicare Part B generally reimburses Average Sales Price (ASP) + 6% for physician-administered drugs. Under the MDNP, once a Part B drug's price has been negotiated, healthcare practitioners will be reimbursed at a Maximum Fair Price (MFP) + 6% for infusing it, potentially leading to payment gap because the practice's acquisition cost for the drug almost assuredly will not fall in tandem with the drop in reimbursement from ASP to MFP.

This payment gap may lead to rheumatology practices discontinuing these treatments as they're unable to cover the loss, thus limiting the availability of facilities and patient access. The program's pricing model fails to account for the costs that these rheumatology practices absorb

daily: acquisition costs, handling and storage requirements, clinical oversight, patient education, adverse event management, and the overhead of maintaining a safe infusion facility for patients.

The ACR urges CMS to close this loophole, so that rheumatologists can continue to offer these crucial therapies to their patients. If rheumatology practices discontinue administering these drugs, patients will either lose access altogether or may need to receive these treatments in more costly hospital settings. The ACR is in support of the Protecting Patient Access to Cancer and Complex Therapies Act (H.R. 4299) which would address this issue by reverting physician reimbursement for administering Part B drugs under Medicare to the ASP standard. **We urge CMS to explore regulatory solutions that would prevent rheumatologists from being caught in the middle of MDNP negotiations, such as allowing manufacturers to make direct payments to CMS for the savings realized for negotiated drugs downstream of the physician acquisition and reimbursement steps, therefore allowing physicians to be kept whole for the drug's acquisition cost.**

Additionally, the ACR is concerned that the provision of the proposed rule that would modify CMS 'treatment of certain fixed-combination products could have unintended consequences for physicians and patients. Historically, CMS has treated fixed-combination products as distinct products for the purposes of identifying single-source drugs that qualify for negotiation. The proposed rule would create an exception to this policy for products where an additional ingredient is added for the purpose of creating a new formulation that enables an alternative route of administration (for example, situations where an intravenous biologic is reformulated to enable an alternative route of administration).

The ACR supports CMS 'aim in proposing this policy: upholding program integrity by ensuring that manufacturers do not reformulate products simply to avoid eligibility for negotiation. **However, we are concerned about the potential ripple effects of CMS treating alternative routes of administration as clinically insignificant. Alternative routes of administration can reduce treatment time, lessen dependence on infusion facilities, permit care in a physician office or home setting, reduce demands on clinical staff, improve adherence, or make treatment more manageable for patients and caregivers**. These benefits may arise even when the added ingredient does not independently treat the underlying disease.

Furthermore, the ACR is concerned that by aggregating products, even when they differ in route of administration, CMS may be setting a precedent that determines how these products are treated in other Medicare reimbursement contexts. For example, earlier this year, the Medicare Administrative Contractor CGS indicated that it would not reimburse physicians for intravenous infusion of the biologic Orencia because a subcutaneous formulation was available. Policy decisions like this, which ignore the clinical significance of alternative routes of administration, undermine physician autonomy in medical decision-making.

If CMS does finalize this policy regarding the treatment of fixed-combination products, the agency should, at a minimum:

1) limit the policy to the specific category of biologics that have been identified as presenting program integrity concerns;

2) publish a product-specific explanation of each aggregation decision;

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3) codify in regulatory text that aggregation is solely for purposes of the Negotiation Program and creates no presumption regarding clinical interchangeability, therapeutic equivalence, medical necessity, coverage, benefit category, preferred route of administration, or physician selection of route in any other Medicare policy or claims-adjudication context

The ACR remains in support of the goals of the MDNP and the cost savings that the program has already realized for patients (with aggregated estimated savings of $1.5 billion in personal out-of-pocket costs projected by CMS for 2026). We hope that the program can continue its record of success while closing these regulatory loopholes that threaten the financial stability and autonomy of physician practices.

Please contact Sweta Haldar, MSPH, ACR Manager of Regulatory Affairs, at shaldar@rheumatology.org or (202) 807-5262 should you have any questions or if we can provide additional assistance.

Sincerely,

Christopher Phillips, MD
Chair, American College of Rheumatology Committee on Rheumatologic Care