NORM
National Organization of Rheumatology Management

June 25, 2025

Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201
IRARebateandNegotiation@cms.hhs.gov

Re: Medicare Drug Price Negotiation Program Draft Guidance - Initial Price Applicability Year 2028

Dear Administrator Oz:

On behalf of the National Organization of Rheumatology Management (NORM), we appreciate the opportunity to provide comments on the Medicare Drug Price Negotiation Program Draft Guidance for Initial Price Applicability Year 2028. NORM promotes education, expertise and advocacy for rheumatology managers and their practices. The Organization's members manage the day-to-day operations of rheumatology practices and have firsthand experience navigating regulatory obstacles facing successful healthcare practices and supporting the financial sustainability of rheumatology practices. NORM provides value across the nation by cultivating a thriving community of rheumatology managers and physicians who are focused on supporting our patients and pursuing excellence in medical practice management.

In addition to the clinical services rheumatology practices provide and are reimbursed for, rheumatology practices also generate revenue through the administration of prescription drugs that patients are not able to self-administer, including injections administered by a health care provider and infusions. Rheumatology infusions are intravenous treatments that manage and treat autoimmune and inflammatory conditions, such as rheumatoid arthritis. These infusions are administered by a licensed healthcare provider and can be a valuable option when oral medications or other treatments are not effective or clinically appropriate.

Medicare Part B reimburses rheumatology practices for these administered drugs based on manufacturer-reported average sales prices (ASPs), plus an add-on payment to account for practice acquisition costs. As currently outlined within the draft guidance, the ASP would significantly drop if the calculation of this *average* sales price were to include the Medicare negotiated Maximum Fair Price (MFP). According to CMS estimates, the MFP could lower the net spending on prescription drugs by 22%.[i] If applied to Part B drugs, a 22% drop in the ASP would also significantly drop our percentage-based add-on payment, leading to a detrimental cut to this essential provider reimbursement. Rheumatology practices already experience insufficient ASP-based payments for select biologic drugs, which are putting these practices "underwater" and making it extremely difficult for practices to offer these medications. Therefore, we have a very clear understanding of what underwater reimbursement would do to rheumatology practices across the country if the MFP were to be included within the ASP calculation.

As currently proposed, inclusion of the MFP within the ASP calculation would make it nearly impossible for rheumatology practices to continue to administer these medications without a *significant* change to the way in which the provider add-on payment is calculated. Underwater reimbursement forces practices to choose between administering therapies at a loss or referring patients to hospital outpatient departments,

which increases Medicare program spending and worsens patient access to care. They may also drive prescriptions to be filled by specialty pharmacies, further lining the pockets of pharmacy benefit managers that continue to drive up the price of prescription drugs.

Without adequate reimbursement that keeps pace with the actual cost of running a physician practice, our offices—particularly in rheumatology—face growing financial instability and even staff layoffs. Rising expenses for staffing, technology, medical supplies, and rent are compounded by increasing administrative burdens, placing significant strain on already stretched resources. These challenges are especially acute in smaller or rural settings, where margins are thin and resources are limited.

Unfortunately, this inadequate reimbursement model would exacerbate problems within the existing system that already increasingly disadvantages community-based rheumatology practices. Independent medical practices are under incredible financial pressure, which has contributed to medical practice consolidation and created access challenges for patients across the country. According to the American Medical Association, Medicare physician payment has declined 33% since 2001, adjusted for inflation. Insufficient reimbursement challenges also contribute to continued consolidation in the healthcare system, as physician practices are increasingly acquired by hospitals and large health systems with greater financial resources. The result is a shift of services into more expensive settings—raising total costs for the Medicare program and its beneficiaries, while reducing patient access and choice.

Furthermore, the draft guidance also suggests two potential methods by which the pharmaceutical manufacturer can provide access to the MFP for Part B drugs to medical practices. This includes a prospective process whereby the price paid by the dispensing entity or Part B provider when acquiring the drug is no greater than the MFP and a retrospectively process whereby reimbursement is calculated as the difference between the dispensing entity or Part B provider's acquisition cost and the MFP. As practice managers of rheumatology practices across the country, we have serious concerns with any method that would require the medical practice to carry the financial responsibility for drugs that will not be fully reimbursed. Rheumatology practices operate on extremely thin margins and cannot afford to purchase Part B drugs at a cost that is higher than reimbursement while they wait for the pharmaceutical manufacturer to reimburse the medical practice for that medication. We strongly caution CMS against adopting a retrospective method for negotiated drugs.

On behalf of rheumatology managers and their practices, we strongly urge CMS to exercise its authority to maintain ASP calculations without the inclusion of the MFP for Part B drugs and to implement procurement processes that do not place financial hardship on medical practices. Should you have any questions or would like to set a time to discuss our comments in more detail, please contact Andrea Zlatkus, CMPM, CRMS, CRHC, Executive Director of NORM, at andrea@normgroup.org.

Sincerely,

Michelle A. Owen, CPC
President, NORM

[i] Centers for Medicare & Medicaid Services. "Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026." August 2024.