National Organization of Rheumatology Management

May 27, 2025

The Honorable Pamela Bondi, JD
Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530

The Honorable Andrew N. Ferguson
Chairman
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

RE: Requests for Information on Anticompetitive Regulations (docket nos. ATR-2025-0001 and FTC-2025-0028-0001)

Dear Attorney General Bondi and Chairman Ferguson,

On behalf of the National Organization of Rheumatology Management (NORM), thank you for the opportunity to provide feedback on your request for information (RFI) regarding anticompetitive regulations. NORM members manage the day-to-day operations of rheumatology practices and have firsthand experience navigating regulatory obstacles that undermine patient care and the financial sustainability of rheumatology practices.

Medicare Physician Payment Reform

Physicians have faced payment cuts for five consecutive years since 2020—and overall, Medicare physician payments have declined by 33% since 2001 when adjusted for inflation[1]. Unlike other Medicare payment systems, updates to the Medicare physician fee schedule (PFS) are not tied to a measure of inflation, such as the Medicare Economic Index (MEI). Instead, PFS payment updates are set in statute and, beginning in 2026, are fixed at 0.25% or 0.75%, depending on participation in the Quality Payment Program (QPP)—rates that fall far short of actual cost growth

The erosion of Medicare payment rates disproportionately affects rheumatologists, who provide complex, resource-intensive care such as biologic therapy management for patients with chronic autoimmune diseases, with the greatest impact on those in independent, small, and rural practices. In a specialty already grappling with workforce shortages and rising rates of autoimmune disease, this financial pressure threatens both practice viability and patient access to timely, specialized care.

Instability in the PFS is exacerbated by budget neutrality policies that trigger across-the-board cuts whenever projected spending on changes exceeds $20 million—even when those projections later prove inaccurate. For example, CMS significantly overestimated utilization of Transitional Care Management (TCM) services in 2013, resulting in billions in permanent payment reductions[2]. More recently, CMS appears to have overestimated the use of HCPCS code G2211, a complex care "add-on" code, further compounding downward pressure on the conversion factor[3]. These reductions are not reversed, even when actual utilization falls short.

Additional stress on practice sustainability has come from CMS's phased update of clinical labor cost data, implemented in 2022, which redistributed payment away from services furnished by rheumatologists, including drug administration services. The impact was particularly challenging because clinical labor inputs had not been updated in nearly two decades. Had these updates occurred on a regular schedule (e.g., every 5 years), the payment shifts would likely have been less severe.

[1] https://fixmedicarenow.org/sites/default/files/2025-01/Medicare%20Gap%20Chart_2025.pdf
[2] https://www.ama-assn.org/system/files/medicare-basics-budget-neutrality.pdf
[3] https://searchlf.ama-assn.org/letter/documentDownload?uri=/unstructured/binary/letter/LETTERS/lfb.zip/2025-5-9-Letter-to-Klomp-re-HCPCS-G2211.pdf

Stagnant payment updates, inflexible budget neutrality rules, and irregular practice expense updates continue to push small, rural, and independent rheumatology practices toward consolidation.

NORM supports FTC and DOJ engagement with CMS and Congress to:

- *Tie future PFS updates to the MEI, as recommended by the Medicare Payment Advisory Commission (MedPAC) (see forthcoming June 2025 Report to the Congress);*
- *Permit retrospective corrections to budget neutrality adjustments when utilization is overestimated; and,*
- *Ensure regular, timely updates to practice expense data to reflect the actual cost of care.*

Pharmacy Benefit Manager (PBM) Reform

The consolidation of the PBM industry—where three PBMs control over 80% of the prescription drug market—has created anticompetitive dynamics that harm providers and patients alike. As a member of the Alliance for Transparent and Affordable Prescriptions (ATAP), NORM supports and echoes the detailed recommendations submitted by ATAP in response to this RFI.

PBM-driven formulary design, rebate-driven exclusions, and utilization management tactics—like step therapy—create administrative burden, delay care, and force rheumatologists and their patients to navigate unnecessary barriers to evidence-based treatments. These practices not only interfere with the physician-patient relationship, but also push care toward hospital outpatient settings, increasing overall Medicare costs.

NORM supports FTC and DOJ engagement with CMS and Congress to:

- *Mandate 100% rebate pass-through to patients at the point of sale;*
- *Delink PBM compensation from list prices and shift to fixed-fee models;*
- *Ban spread pricing and anti-competitive pharmacy steering; and*
- *Strengthen oversight and transparency of PBM practices in Medicare Advantage and other federal programs.*

"Underwater" Biosimilars

Medicare Part B drug payment relies on manufacturer-reported average sales prices (ASPs), a system that increasingly disadvantages community-based rheumatology practices. Due to the influence of manufacturer rebates and discounts—often aimed at achieving formulary preference or "fail first" status in Medicare Advantage and commercial plans—the reported ASPs for many biosimilars have fallen below the acquisition costs providers must pay. This phenomenon, known as "underwater" biosimilar reimbursement, forces practices to choose between administering these therapies at a loss or referring patients to hospital outpatient departments, which increases Medicare program spending and worsens patient access to care. Given the critical role of biosimilars in managing autoimmune diseases, failure to address this reimbursement shortfall jeopardizes the financial stability of rheumatology practices and undermines policy goals of promoting biosimilar adoption. Addressing the distortion in ASP-based reimbursement would protect patient access, foster biosimilar adoption, and help sustain independent rheumatology practices.

NORM supports FTC and DOJ engagement with CMS and Congress to address this challenges, which could include removing rebates from the ASP calculation for biosimilars or temporarily allowing reimbursement for biosimilars at WAC+3% until ASPs better reflect actual market acquisition costs. In the meantime, we strongly support and urge modifications to step therapy policies, as discussed in the section below.

Prior Authorization and Step Therapy

In 2018, CMS issued subregulatory guidance permitting Medicare Advantage plans to apply prior authorization and step therapy protocols to Medicare Part B drugs. In rheumatology, these utilization controls frequently delay or deny timely access to essential treatments for patients with progressive, debilitating conditions such as rheumatoid arthritis, psoriatic arthritis, and systemic lupus erythematosus. Step therapy protocols often require patients to fail a preferred medication—even when it is medically inappropriate or unaffordable—before gaining access to the therapy their physician initially prescribed. This has been particularly problematic for certain biosimilars that are in "fail first" position and where the rheumatologists' acquisition cost exceeds reimbursement.

Prior authorization and step therapy policies place a disproportionate burden on rheumatology practices, which must devote significant time and resources to securing approvals and navigating appeals processes that vary widely across plans. For small practices, this administrative overhead diverts limited staff from patient care, increases operating costs, and contributes to consolidation by making independent practice financially unsustainable. Compounding the issue, CMS' electronic prior authorization (ePA) rulemaking excluded both Part B and Part D medications—failing to streamline access to the very therapies most affected. Ensuring timely access to physician-prescribed treatments would reduce administrative waste, lower Medicare costs by preventing disease complications, and preserve access to community-based rheumatologic care.

NORM supports FTC and DOJ engagement with CMS and Congress to:

- ***Rescind or revise the 2018 guidance that permits Medicare Advantage plans to impose step therapy and prior authorization on Part B drugs—particularly for "underwater" biosimilars that already face access and reimbursement challenges; and***
- ***Advance rulemaking to apply ePA requirements to medications, including those covered under both Part B and Part D.***

Self-Administered Drug (SAD) Exclusion List

Medicare's Self-Administered Drug (SAD) Exclusion List policies create unnecessary barriers to care for rheumatology patients. The criteria used to determine whether a drug is "usually" self-administered are outdated and do not account for real-world patient limitations, particularly among the Medicare populations served by our practices.

Many rheumatologic therapies have a self-administered formulation but are difficult or impossible for patients with physical or cognitive impairments to use without assistance. When these drugs are moved to the SAD Exclusion List, the physician-administered formulations are no longer covered under Part B, forcing beneficiaries to pay out-of-pocket, "non-medically switch" their therapy, or go without necessary treatment. These policies create barriers to care, and drive up Medicare spending, as confirmed by recent reports from the Department of Health and Human Services (HHS) Office of Inspector General (OIG) reports showing higher costs when drugs like Stelara are covered under Part D instead of Part B.

Ensuring appropriate Part B coverage for physician-administered therapies would lower Medicare costs and protect access to medication therapy for patients with autoimmune diseases.

NORM supports FTC and DOJ engagement with CMS to modify the SAD Exclusion List criteria to better reflect patient needs and clinical realities, and to require greater transparency from Medicare Administrative Contractors when making SAD Exclusion List determinations. Additional details on our requests can be found in a stakeholder letter to Health and Human Services Secretary Kennedy.

Coding Edits

Rheumatology practices also face unnecessary administrative burdens related to outdated Medically Unlikely Edits (MUEs) applied to drug codes. A particularly problematic example is the MUE for J1602 (golimumab), which limits coverage to 300 units per claim. Simponi is weight-based, and many Medicare beneficiaries with rheumatoid

arthritis, psoriatic arthritis, or ankylosing spondylitis require doses exceeding this limit based on FDA labeling and standard clinical practice.

Patients with obesity—who are at increased risk of severe disease progression—frequently require higher doses. When MUEs do not align with clinical realities, practices must endure repeated claim denials and appeals, adding unnecessary administrative expense and delaying treatment for vulnerable patients.

NORM supports FTC and DOJ engagement with CMS to revise the MUE for J1602 to 400 units. This update would reduce burdensome appeals, support evidence-based dosing practices, and ensure that overweight and obese Medicare beneficiaries receive the appropriate care their clinical condition demands.

Merit-based Incentive Payment System (MIPS)

Rheumatology practices—particularly smaller, independent practices—face significant challenges under the Quality Payment Program (QPP), especially with the Merit-based Incentive Payment System (MIPS). Rather than supporting improvements in patient care, MIPS imposes costly, frequently changing reporting requirements that divert time and resources from patients. Despite these substantial investments, there is no evidence that MIPS has improved outcomes, reduced costs, or driven meaningful changes in physician behavior that advance healthcare quality. Indeed, we are especially disappointed that CMS implemented a rheumatoid arthritis (RA) cost measure beginning with the CY 2025 performance period/2027 MIPS payment year, despite significant concerns raised by NORM and other stakeholders, and a "do not recommend" final vote from CMS' consensus-based entity. From the outset, we shared with CMS that this flawed cost measure fails to reflect the complexity of rheumatologic care and is poised to penalize practices without improving quality or outcomes.

NORM supports FTC and DOJ engagement with CMS to eliminate MIPS, as it has failed to achieve its intended goals and only imposes unnecessary burden and cost on physician practices. At a minimum, we strongly urge expansion of exemptions so that small practices are no longer forced to participate in a program that adds no value to beneficiary care.

Network Adequacy

Inadequate access to specialty care is an ongoing challenge that has become even more difficult in the rheumatology field. CMS' network adequacy criteria for MA plans does not meaningfully ensure access to the specialty care needs of patients with chronic and complex conditions. Our members frequently report that patient's contact them for an appointment after enrolling in an MA plan, only to find out that their rheumatologist is not "in-network" and they must find care elsewhere. Many of these patients are on medication therapy that follows a rigid protocol; losing access to their rheumatologist not only disrupts their treatment regimen, but puts them at risk of losing access altogether if another practice is unable to offer the care.

As an example, several members in Florida reported that a significant number of their practices were terminated from a large MA plan's network, drastically reducing access for permanent residents, seasonal "snowbirds," and Employer Group Waiver Plan (EGWP) enrollees. The impact has included longer wait times, fragmented care, and avoidable disease progression due to delays in accessing care. According to CMS and the plan, quantitative standards used to make network adequacy determinations (i.e., physician-to-beneficiary ratio and time-and-distance standards) were met and the plan's network was adequate. We submit, however, that CMS' quantitative standards are flawed, particularly in rheumatology where increased rates of autoimmune diseases and ongoing workforce shortages are prevalent.

To address our concerns and that of our patients enrolled in MA plans, NORM supports FTC and DOJ engagement with CMS to adjust physician-to-beneficiary ratio and time-and-distance standards to reflect the actual needs of beneficiaries, particularly in specialties with critical workforce shortages, including rheumatology. Recognizing the relationship between network adequacy and provider directories, we further recommend strengthening of

enforcement of accurate, real-time provider directories and to populate those directories based on the information practices provide to CMS when enrolling in the Provider Enrollment, Chain, and Ownership System (PECOS) system. Plans that fail to meet these standards to face penalties for non-compliance, including termination from the Medicare program. Finally, we urge CMS to prohibit MA plans from using audit participation (i.e., chart reviews) as a condition of network inclusion, and to require clear clinical justification for each record request.

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We appreciate your attention to these pressing issues and welcome further engagement with FTC and DOJ on policies to support fair competition, eliminate undue burden, and protect access to specialty care. As a key stakeholder representing the voice of rheumatology practice management, NORM remains committed to constructive dialogue and collaboration to advance meaningful reform. Please contact Andrea Zlatkus, CMPM, CRMS, CRHC, Executive Director of NORM, at andrea@normgroup.org if you have any questions or would like to set up a time to discuss these comments in more detail.

Sincerely,

Michelle A. Owen, CPC
President, National Organization of Rheumatology Management