September 10, 2025

Mehmet Oz, MD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Submitted electronically via www.regulations.gov

RE: Medicare and Medicaid Programs; CY 2026 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program

Dear Administrator Oz,

The National Organization of Rheumatology Management (NORM) is a 501(c)6 organization representing rheumatology managers, physicians and patients. Our mission proclaims we are a forum by which we promote and support education, expertise and advocacy for access to care of our rheumatology practices and their patients.

On behalf of our manager members, I am writing to provide feedback on proposals contained in the aforementioned proposed rule.

Payment Update
Our practices will now realize modest year-over-year increases in Medicare payments, driven by the Medicare Access and CHIP Reauthorization Act (MACRA) statutory update of 0.75% (for QPs) or 0.25% (non-APM). When paired with other updates in CY 2026, including a temporary one-time 2.5% congressional increase from the *One Big, Beautiful Bill Act (H.R. 1)* and a 0.55% budget neutrality adjustment tied to the efficiency adjustment proposal, the CY 2026 conversion factors are $33.5875 for qualified participants (QPs) in advanced APMs and $33.4209 for non-qualifying participants (non-QPs). While this year's update is a welcome change from the repeated threat of cuts, it is temporary, and the budget neutrality offset largely relies on a policy that disproportionately harms drug administration services, which is a significant part of our practices service mix.

Our operating costs continue to climb, especially for smaller practices in rural areas and those serving underserved communities. The ongoing Medicare sequester (2.0%) and impending PAYGO sequester (4%) compound these pressures, forcing practices to make difficult decisions about whether to merge with a health system, sell to private equity, or shutter their doors. All of

these options come with consequences to the Medicare program and beneficiaries in the form of higher costs and reduced access.

We continue to urge CMS to work with lawmakers on Capitol Hill on a long-term solution to the Medicare physician payment system that includes a permanent link to the Medicare Economic Index (MEI). In addition, given the constraints on CMS' ability to adjust the PFS payment update for inflation, ***we urge a more comprehensive evaluation of how coding and payment policy changes impact budget neutrality, and ultimately, the conversion factor.*** Further, and to return overpayments to the Medicare program and taxpayers, and potentially lowering the cost of a long-term fix to the Medicare physician payment system, ***we also urge CMS to increase the coding intensity adjustment for Medicare Advantage plans beyond the current 5.9% minimum.***

Efficiency Adjustment

NORM strongly opposes CMS' decision to apply the proposed efficiency adjustment (EA) policy to drug administration services. While we support the overall policy concept as a rebalance toward cognitive work that does not gain efficiency – and appreciate that it boosts the conversion factor through the budget neutrality adjustment and holds evaluation and management (E/M) visits and care management harmless – including drug administration codes is wholly inappropriate. These services are even more strictly time-bound than the exempted E/M and care management services and cannot be performed more "efficiently" without compromising patient safety.

Under the proposal, CMS would establish an efficiency adjustment to the work RVUs, as well as corresponding updates to the intraservice portion of physician time inputs, for non-time-based services. The agency's rationale is that both the intraservice portion of physician time and the work intensity – including mental effort, technical effort, physical effort, and risk of patient complications – decrease as a practitioner develops expertise in performing a service. As expertise develops, CMS asserts that learning leads to enhanced familiarity with the service, recognition of anatomic variations, and greater confidence in handling unexpected challenges.

We agree with CMS' decision to exclude E/M visits, along with other services such as care management. However, applying this policy to drug administration ignores the fact that these services are inherently time-based. For infusion services, FDA label instructions specify the infusion rate, dictating exactly how quickly or slowly a medication must be delivered for safety and effectiveness – parameters that cannot be altered without compromising patient care. CMS' stated rationale for the EA – that with expertise, practitioners can become more familiar with a service, recognize variations in anatomy, and gain confidence in handling unexpected challenges – may apply to certain procedural services, but it does not apply to drug administration. No amount of experience or familiarity can reduce the intraservice time or work intensity dictated by the drug's administration requirements.

If CMS finalizes the EA policy, we urge the agency to exempt all drug administration services – hydration, therapeutic, and chemotherapy – from its scope, including the following codes:

96360 - Hydration, intravenous infusion, initial	96406 - Chemotherapy, intralesional, more than 7 lesions
96361 - Hydration, intravenous infusion, each additional hour (List separately in addition to code for primary procedure)	96409 - Chemotherapy, intravenous push, single drug
96365 - Therapeutic, prophylactic, or diagnostic intravenous infusion, initial, up to 1 hour, including pre- and post-infusion services	96411 - Chemotherapy, intravenous push, each additional drug (List separately in addition to code for primary procedure)
96366 - Therapeutic, prophylactic, or diagnostic intravenous infusion, each additional hour (List separately in addition to code for primary procedure)	96413 - Chemotherapy, intravenous infusion, up to 1 hour, single drug
96367 - Therapeutic, prophylactic, or diagnostic intravenous infusion, each additional sequential infusion of a new drug/substance (List separately in addition to code for primary procedure)	96415 - Chemotherapy, intravenous infusion, each additional hour (List separately in addition to code for primary procedure)
96368 - Therapeutic, prophylactic, or diagnostic concurrent infusion (List separately in addition to code for primary procedure)	96416 - Chemotherapy, prolonged intravenous infusion, requiring the use of a portable or implantable pump
96369 - Subcutaneous infusion for therapeutic, prophylactic, or diagnostic purposes (up to 1 hour)	96417 - Chemotherapy, intravenous infusion, each additional sequential infusion of a new drug (List separately in addition to code for primary procedure)
96370 - Subcutaneous infusion, each additional hour (List separately in addition to code for primary procedure)	96420 - Chemotherapy, intra-arterial push technique
96371 - Subcutaneous infusion, restart of infusion (List separately in addition to code for primary procedure)	96422 - Chemotherapy, intra-arterial infusion, up to 1 hour
96372 - Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	96423 - Chemotherapy, intra-arterial infusion, each additional hour (List separately in addition to code for primary procedure)
96373 - Therapeutic, prophylactic, or diagnostic injection; intra-arterial	96425 - Chemotherapy, infusion method
96374 - Therapeutic, prophylactic, or diagnostic injection; intravenous push, single or initial substance/drug	96440 - Chemotherapy, administration into pleural cavity, requiring thoracentesis
96375 - Therapeutic, prophylactic, or diagnostic injection; each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)	96446 - Chemotherapy, administration into peritoneal cavity via indwelling catheter or port
96377 - Application of on-body injector (includes cannula insertion)	96450 - Chemotherapy, administration into CNS (e.g., intrathecal), requiring and including spinal puncture
96380 - Administration of RSV monoclonal antibody, intramuscular, counseling provided	96521 - Refilling and maintenance of portable pump
96381 - Administration of RSV monoclonal antibody, intramuscular, injection only	96522 - Refilling and maintenance of implantable pump or reservoir for drug delivery, systemic (e.g., intravenous, intra-arterial)
96401 - Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic	96523 - Irrigation of implanted drug delivery device
96402 - Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic	96542 - Chemotherapy injection, subcutaneous or intramuscular
96405 - Chemotherapy, intralesional, up to and including 7 lesions	

Commented [EG1]: NORM: Could your folks take a look at this list and strikethrough the codes that should NOT be on the list? I know some of these are not what you do.

This would preserve the policy's intent to rebalance toward cognitive work, maintain patient safety, and avoid imposing financial harm on practices delivering these essential, time-dependent services.

Practice Expense
CMS is proposing changes to the allocation of indirect practice expense (PE) relative values that would increase the weight assigned to office-based services. For rheumatology practices, this proposal offers some improvement in the value of drug administration services, which remain undervalued relative to the resources required to safely deliver complex biologics and other infused or injected therapies.

However, this proposal does not resolve the broader challenge that the PFS update process fails to keep pace with actual practice costs, nor does it address CMS's difficulty in maintaining up-to-date direct PE inputs. For example, the transition to new clinical labor pricing inputs over the last four years significantly lowered the value for drug administration services at a time when costs were increasing, creating additional financial strain for practices.

We appreciate that CMS recognizes that long delays in updating direct practice expense inputs are problematic, and we would support a policy for making these updates every 4 years. A regular update cycle would help ensure that payment rates reflect the real costs of delivering care and would better sustain patient access to rheumatology services in the office setting.

Telehealth: Virtual Presence
NORM appreciates CMS' proposal to permanently adopt a definition of direct supervision that allows "immediate availability" of the supervising practitioner using audio/video real-time communications technology (excluding audio-only), for all services described under § 410.26 (for services incident to a physician's or other practitioner's professional service), except for services that have a global surgery indicator of 010 or 090. However, our practices believe additional oversight may be necessary, particularly for office-based infusions.

As CMS explained in its finalized policies addressing non-chemotherapy administration of complex drugs or biologic agents in the CY 2025 PFS final rule, oversight by trained professionals is required due to the risk of severe adverse reactions. ***For CMS to closely monitor virtual presence and to better understand its impact on beneficiary care and safety, NORM recommends that CMS implement a billing modifier that practices can append to claims to indicate virtual presence was used to fulfill direct supervision requirements. At a minimum, CMS should require that virtual presence is documented in the beneficiary's medical record.***

ASP Issues
CMS is proposing several policies related to Average Sales Prices (ASP) that will negatively impact our practices and access to care. First, CMS proposes clarifying that, consistent with its interpretation of the statute, drugs selected for negotiation and sold at the Maximum Fair Price (MFP) will be included in ASP. Second, CMS proposes clarifications related to price concessions and bona fide service fees (BFSFs), which it anticipates would result in more payments being treated as price concessions rather than BFSFs. Both policies are expected to lower ASPs, and therefore, Medicare's reimbursement.

As we have shared repeatedly, our practices are already experiencing "underwater" reimbursement for certain Part B drugs, including some biosimilars. This challenge stems largely from the perverse incentives embedded in formulary design and the inclusion of manufacturer rebates in ASP calculations. These rebates, often paid to secure "fail first" placement, do not reduce providers' acquisition costs yet artificially depress ASP, driving reimbursement below our costs.

Policies that allow further reductions in ASP, disconnected from providers' actual acquisition costs, will only exacerbate this problem. ***We urge CMS to proceed cautiously, as lowering ASP below acquisition costs risks destabilizing practices and restricting beneficiary access to critical medication therapies. Further, NORM urges the agency to work with Congress to also remove manufacturer rebates from the ASP calculation. Finally, NORM also recommends that CMS continue publishing ASP data for negotiated drugs, which remains an important tool for practices to assess payments from other payers.***

Merit-Based Incentive Payment System (MIPS)

We continue to be disappointed that CMS has implemented the Rheumatoid Arthritis (RA) Cost Measure cost measure, which was included in the Advancing Rheumatology Patient Care MIPS Value Pathways (MVPs) starting with the CY 2025 performance period/2027 MIPS payment year, particularly given the concerns NORM raised in prior comments and the "do not recommend" final vote from CMS' consensus based entity. ***We urge CMS to work with its contractor address the concerns with the flawed cost measure that have been raised by NORM, as well as many other stakeholders, in prior comments.***

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Further, we are concerned that CMS intends to propose ending traditional MIPS in the future, at which point MVPs would become mandatory. While CMS has not yet determined a date, the agency has previously anticipated fully transitioning to MVPs by the CY 2029 performance period. ***Until foundational concerns have been addressed with the MIPS program, and issues with the current MVPs are corrected, CMS should retain the traditional MIPS program.***

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NORM appreciates the opportunity to provide comments on the aforementioned issues of importance to our practices. We believe these recommendations will significantly improve data and information collection and use, thereby enhancing patient care and administrative efficiency within MA plans. Should you have any questions or would like to set a time to discuss these issues in more detail, please contact Andrea Zlatkus, CMPM, CRMS, CRHC, Executive Director, NORM, at andrea@normgroup.org.

Sincerely,

President

National Organization of Rheumatology Management