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Coalition of State Rheumatology Organizations

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September 3, 2024

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1807-P
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850

Submitted electronically via Regulations.gov

RE: CY 2025 Payment Policies under the Medicare Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies

Dear Administrator Brooks-LaSure,

The Coalition of State Rheumatology Organizations (CSRO) is comprised of over 40 state and regional professional rheumatology societies whose mission is to advocate for excellence in the field of rheumatology, ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease. Our coalition serves the practicing rheumatologist.

Through the Alliance of Specialty Medicine, CSRO provides feedback on several proposed policies in the aforementioned rule that broadly impact specialists and subspecialists, including the decline in Medicare reimbursements to physicians. Below, however, CSRO highlights additional issues that uniquely impact our members and the beneficiaries they serve.

Valuation of Services: Non-chemotherapy Administration

CSRO has been at the forefront of addressing inappropriate "down coding" of complex drug administration services by the Medicare Administrative Contractors (MACs), advocating tirelessly to ensure that Medicare policies reflect the true complexity of the services practicing rheumatologists provide to Medicare beneficiaries. This advocacy, along with that of a CSRO-led coalition of medical specialty and trade organizations, caused CMS to issue a Technical Direction Letters (TDL) to its MACs; release a program transmittal outlining the substance of the TDLs, prompting the MACs to retire problematic "Billing and Coding" articles; a request for information in the CY 2024 PFS rulemaking; and, proposals in this CY 2025 PFS rulemaking to address our concerns more permanently. ***These actions are significant and reflect the hard work and dedication of the Agency and its staff toward ensuring beneficiary access to in-office drug administrations.***

Recognizing the need for a standardized approach to determining the complexity of drug administration services, CSRO developed a comprehensive

rubric titled *"Considerations for Classifying Medications as Highly Complex."* The rubric offers a detailed framework that considers:

- AMA CPT Requirements: Including physician supervision, advanced training and competency for staff, and patient risk factors.
- Medicare Valuation: Aligning the work, clinical labor, supplies, and equipment with the true complexity of the service.
- Additional Clinical Factors: Such as pre-treatment lab requirements, treatment schedules, and the severity of potential adverse events.

We are encouraged that CMS has incorporated elements of CSRO's rubric into its proposed updates to the Medicare Claims Processing Manual, which represents a significant advancement toward ensuring that complex drug administration services are appropriately recognized and reimbursed. ***We strongly support CMS' proposal and urge CMS to make these Manual revisions without delay.***

CSRO, along with its coalition partners, also urge CMS to take additional steps that would ensure consistent application of its policies across the Medicare program and prevent unwanted program integrity audits. Specifically, CSRO urges CMS to:

- **Establish clear documentation guidelines** that allow physicians to demonstrate in the medical record that the complex drug administration service code reported on their claims meets the revised criteria.
- **Create a Medicare Learning Network (MLN) article** to educate practices on the updated criteria and documentation requirements, and require MACs to post this resource on their respective websites.
- **Prohibit program safeguard contractors, including MACs, from initiating retroactive program integrity audits or recoupments** for complex drug administration services for dates of service from August 12, 2022, until the effective date of the Manual revisions.

We appreciate CMS' consideration of these recommendations, and again, applaud CMS for its ongoing efforts to ensure beneficiary access to complex drug administration services in the office setting.

"Underwater" Biosimilars

Rheumatology practices continue to face significant challenges accessing biosimilar medications, as the acquisition cost far exceeds Medicare and private payer rates. The challenges are so severe that CSRO has urged private payers, including Medicare Advantage plans, to immediately remove utilization management requirements associated with these medications so our patients can access an alternative drug that is not "underwater."

In this rule, CMS proposes to address the issue of underwater medications, including biosimilars, by addressing circumstances where a manufacturer's Average Sales Price (ASP) for at least one National Drug Code (NDC) within the billing and payment HCPCS code is negative or zero. Unfortunately, CMS' proposals – and the alternative proposals considered – will not immediately correct the challenges our practices face acquiring underwater biosimilars.

CSRO has joined a coalition led by the American College of Rheumatology (ACR), comprised of over 40 rheumatology practices and physician specialty societies, urging CMS to work with Congress to amend Section 1847a of the Social Security Act [42 U.S.C. 1395w–3a], so that CMS could include an 8% add-on to the actual acquisition cost, as well as exclude manufacturer rebates from the ASP calculation. We recognize there could be some operational challenges under this approach, but these options would

allow rheumatologists to make underwater biosimilars available to patients. ***It is imperative that CMS work with Congress to amend the statute, enabling fair and adequate reimbursement for biosimilar medications and preserving beneficiary access.***

Quality Payment Program: Cost Performance Category

On behalf of rheumatologists in private practice and the patients they serve, CSRO opposes the inclusion of the flawed Rheumatoid Arthritis (RA) cost measure beginning with the CY 2025 performance period/2027 MIPS payment year. CSRO recommends that CMS work with its contractor address the concerns that have been raised by stakeholders before this measure is included in the MIPS program.

CSRO is acutely aware of the significant impact medication costs have on managing RA episodes of care. With a longstanding commitment to developing cost measures and value-based models that address expenses within rheumatologists' control, CSRO has consistently championed targeted initiatives. Notably, we engaged in a multi-year dialogue with then-CMS Administrator Seema Verma and CMMI Deputy Director Amy Bassano, proposing a rheumatologic demonstration aimed at eliminating formulary restrictions and utilization management barriers, while also promoting predictive drug-response testing and imposing cost-sharing limits for beneficiaries enrolled in RA-specific chronic condition special needs plans (C-SNP) within Medicare Advantage. Regrettably, progress on this demonstration concept was sidelined due to CMS' competing priorities and a change in Administration.

It is important to emphasize that our opposition to the RA cost measure is not a blanket resistance to cost measurement, as was asserted by Acumen. Instead, it reflects our concern that the measure fails to adequately differentiate the appropriateness of costs in relation to quality and patient outcomes, and does not offer meaningful, actionable insights for improving costs, nor care. CSRO is not alone in its concerns about the proposed measure: the American Medical Association (AMA), the American College of Physicians (ACP), and America's Health Insurance Plans (AHIP), have also weighed in with concerns and recommended improvements.[1] This feedback prompted the Pre-Rulemaking Measure Review (PRMR) Clinician Committee to vote against the inclusion of this measure in MIPS.[2] CMS' proposal to adopt this measure against the PRMR recommendation is confusing and calls into question the consensus based entity's utility if CMS intends to ignore their input.

To support its proposal for including the RA cost measure in the MIPS program, CMS highlights that the Acumen-convened Rheumatoid Arthritis Clinician Expert Workgroup, which advised on the measure specifications, included representatives from 11 professional societies including key rheumatology organizations. Notably, we found that – of the rheumatologist experts – only one achieved a total MIPS score above the performance threshold and was successful in the cost category; the other rheumatologists either did not participate or fell below the threshold due to poor performance in the cost category.[3] We are concerned that Acumen's experts might not have fully understood the clinical nuances of this measure. ***It is imperative that CMS direct Acumen to re-convene the workgroup and re-evaluate the validity of this measure rather than trying to rush it through adoption simply for the sake of expanding the MIPS cost measure inventory.*** Taking a step back to do this right is especially critical now that CMS has uncovered more general problems with its cost measure scoring methodology.

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[1] https://p4qm.org/sites/default/files/2024-01/Compiled-MUC-List-Public-Comment-Posting.xlsx
[2] Pg. 31 https://p4qm.org/sites/default/files/2024-02/PRMR-2023-MUC-Recommendations-Report-Final-.pdf
[3] https://data.cms.gov/provider-data/dataset/a174-a962

Fair cost measurement and attribution would require CMS to remove a number of barriers that limit the range of therapies that rheumatologists can select for Medicare beneficiaries (i.e., rescinding the 2018 Step Therapy Memorandum, establishing a by-pass mechanism for medications on the Self-Administered Drug (SAD) Exclusion List, eliminating Part D formulary restrictions and prohibiting non-medical switching, and making reasonable payment for biosimilars that are currently "underwater"). Until these actions are taken or accounted for, ***CSRO must oppose the inclusion of the RA cost measure in the CY 2025 performance year/2027 payment year.***

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Thank you for considering our feedback on these important issues to practicing rheumatologists who care for Medicare beneficiaries. Please do not hesitate to contact us at info@csro.info should you require additional information.

Sincerely,

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