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January 26, 2026

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 Program; Contract Year 2027 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program

Dear Administrator Oz,

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.

In addition to comments submitted through the Alliance of Specialty Medicine, CSRO also responds to CMS' Request for Information on Future Directions in Medicare Advantage regarding the use of utilization management (UM) tools in the Medicare Advantage (MA) program, including step therapy.

Request for Information on Future Directions in Medicare Advantage

CSRO is deeply concerned about ongoing access challenges faced by MA enrollees when step therapy is applied to physician-administered biosimilar drugs. Biosimilars were intended to provide a lower-cost alternative to originator biologic, and CMS has encouraged their adoption on plan formularies. Unfortunately, CMS well-intended efforts have been undermined by a rebate-driven pricing model that incentivizes manufacturers to offer large rebates to MA plans and their pharmacy benefit managers (PBMs) in exchange for preferred formulary placement, often in fail-first positions.

As we have shared with CMS leadership and Congressional offices, many rheumatology practices report that certain physician-administered biosimilars are "underwater," meaning they are reimbursed at rates below the physician office's acquisition cost. This is because large manufacturer rebates have significantly lowered the Average Sales Price (ASP), which serves as the basis for Medicare and private payer reimbursement for these therapies. The resulting decline in ASP has made it financially unsustainable for practices to purchase and administer these biosimilars and, in many cases, requires patients to be referred to the more costly hospital outpatient department (HOPD). In some

instances, however, hospitals also face acquisition-cost constraints, resulting in treatment delays or patients forgoing care altogether.

Compounding this problem are Medicare's step therapy requirements imposed by MA plans, where enrollees are prevented from accessing any therapeutically equivalent medication when the plan-mandated, fail-first biosimilar cannot be furnished by their physician. Because enrollees are required to try and fail the plan-preferred biosimilar before accessing another therapy – including another biosimilar or reference biologic – they may be left without any viable treatment option when the required drug is underwater and cannot be administered. By contrast, Original Medicare does not impose step therapy requirements, allowing physicians to prescribe a clinically appropriate therapeutic equivalent when a biosimilar cannot reasonably be acquired and furnished.

While congressional action is necessary to address the underlying rebate-driven pricing system, CSRO believes that CMS has authority to take immediate steps to protect timely access to care for MA enrollees. CMS' regulations at 42 CFR § 422.112 (Access to Services) already require MA plans to ensure that enrollees have access to all covered services and continuity of care through in-network providers, or to arrange for care at in-network cost sharing when in-network access is unavailable. Importantly, MA plans retain discretion in how they meet these obligations, but enrollees must have a viable treatment pathway when a plan-mandated step-therapy drug cannot be delivered by network providers. However, these requirements have not ensured that enrollees maintain such a pathway, necessitating a more explicit standard. As such, ***CSRO urges CMS to propose rulemaking that would establish a "formulary adequacy standard," tying step-therapy protocols to the availability of physician-administered drugs within a plan's network, while prioritizing continuity of care with the patient's established physician.***

Under a formulary adequacy standard, MA plans would be required to ensure that any physician-administered drug placed in a fail-first position is available for administration by the enrollee's treating provider, and if not, allow the provider to administer an alternative therapy (e.g., another biosimilar or the reference biologic). Importantly, CSRO recognizes that section 1854(a)(6)(B)(iii) limits CMS' ability to interfere in payment arrangements between MA organizations and contracted providers; however, such a standard would not affect payment negotiations or require coverage of more expensive therapies. Rather, it would ensure that step-therapy requirements are imposed only when the plan-mandated drug is reasonably available for furnishing by network providers, reflecting an important beneficiary access safeguard.

Thank you for considering our feedback on these important issues to practicing rheumatologists who care for enrollees in Medicare Advantage and Part D plans. Please do not hesitate to contact us at info@csro.info should you require additional information.

Sincerely,



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President



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