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Coalition of State Rheumatology Organizations

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January 24, 2025

Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

**Re: CY 2026 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs Proposed Rule (CMS-4192-P)**

Dear CMS Administrator:

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 enrollees access to care from specialists and subspecialists. Below, however, CSRO highlights an issue that uniquely impacts enrollees with rheumatologic disease and the rheumatology practices that serve them.

## Formulary Inclusion and Placement of Generics and Biosimilars

*Background*

In this rule, CMS highlights concerns that Part D sponsors and their PBMs engage in practices that favor more expensive brand drugs and reference products over generics, biosimilars, and other lower cost drugs in terms of formulary placement or nonplacement, referring to findings in recent reports from the Federal Trade Commission and the Health and Human Services Office of Inspector General. As a result, CMS clarifies that, to be compliant with Part D requirements, Part D plan formularies – inclusion, as well as tier placement and utilization management – must provide beneficiaries with broad access to generics, biosimilars, and other lower cost drugs.

CMS discusses plans to include an additional step in the formulary review process to check that Part D sponsors provide broad access to generics, biosimilars, and other lower cost drugs. The Agency also said it will holistically review whether a plan's formulary and UM practices with respect to these drugs constitute a drug UM program that is 'cost-effective,' 'reasonable and appropriate,' and inclusive of 'incentives to reduce costs.' This review, per CMS, would encompass an evaluation of

whether the formulary includes generics, biosimilars, and other lower cost drugs, when available, for brand drugs and reference products, and whether the generics, biosimilars, and other lower cost drugs are placed on a lower formulary tier than the brand drugs or reference products. Further, CMS said it would also review whether a formulary incorporates fewer utilization controls on brand drugs and reference products than on lower cost alternatives.

In light of the above, CMS requested comments on: (1) the prevalence of manufacturer rebates and the extent to which such rebates influence formulary decisions that reduce Part D beneficiaries' access to generics, biosimilars, and other lower cost drugs; and (2) whether further programmatic actions within CMS's current statutory authority are necessary to prevent Part D formularies from excluding or disfavoring coverage of generics, biosimilars, and other lower cost drugs. Based on feedback, the Agency may consider further steps in future rulemaking or guidance to promote broad access to generics, biosimilars, and other lower cost drugs for Part D beneficiaries.

*Beneficiary Access to Physician-Administered Biosimilar Drugs*

***CSRO strongly supports efforts to ensure beneficiary access to biosimilar medications, including the review process described in the rule.*** Biosimilars are vital for treating chronic rheumatologic conditions such as rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and lupus, among other diseases. These therapies alleviate pain and dysfunction while reducing costly disease-related complications, including joint damage, surgery and hospitalizations.

In our experience, most plans have included biosimilars on their formularies. However, ***two primary challenges hinder enrollee access to physician-administered versions of biosimilar medications, particularly in certain populations, including those that face disability and other factors***.

- **Low Average Sales Price (ASP) for Physician-Administered Biosimilars**. Although the *Inflation Reduction Act* temporarily increased the ASP add-on for some biosimilars from 6% to 8%, the ASP for most biosimilars is significantly lower than their acquisition cost. Low ASPs are the result of manufacturer rebates paid to plans, which artificially depress ASP. When the ASP is below acquisition cost, rheumatology practices cannot afford to "buy and bill" the drugs. CMS recently finalized a policy to address when manufacturers report zero or negative ASPs for biosimilars, but this will not boost ASP above acquisition costs in the near term, nor is it likely to meaningfully improve the ASP in the long term.

- **Step Therapy Requirements**. Manufacturers have "over-rebated" their biosimilars to ensure fail-first position on plan formularies. Being in fail-first position means the enrollee must "try-and-fail" the biosimilar medication before accessing an alternative therapy. But, if the practice cannot afford the mandated biosimilar, the enrollee is left with few options. Most rheumatology practices are forced to refer them to the hospital for care, increasing costs and disrupting continuity. Recently, we have learned that some hospitals face the same financial challenges and cannot afford these medications either, meaning enrollees are without access to care.

CSRO, along with a coalition of patient and provider organizations, have urged CMS to find a way to address the Part B reimbursement challenges within their authority, as well as to withdraw the 2018 step therapy memorandum to ensure access to care. They have also shared these concerns with Congressional leaders, urging them to address the reimbursement challenges under the current ASP methodology. In the meantime, ***CMS should proceed with the review process described in the rule. In addition, CMS should withdraw its 2018 step therapy memorandum to ensure patients can access affordable physician-administered biosimilars until a long-term solution to the ASP for biosimilars has been established.***

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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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