AMERICAN COLLEGE of RHEUMATOLOGY
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January 4, 2024

The Honorable Chiquita Brooks- LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services

Sent electronically via regulations.gov

RE: [CMS-4205-P] Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications

Dear Administrator Brooks-LaSure,

The American College of Rheumatology (ACR), representing over 8,500 rheumatologists and rheumatology interprofessional team members, appreciates the opportunity to respond to the Contract Year 2025 Medicare Advantage Policy and Technical Changes and Medicare Prescription Drug Benefit Program proposed rule as published in the Federal Register on November 15, 2023. The ACR supports efforts to ensure Medicare Advantage enrollees have access to quality, equitable, and affordable care.

Rheumatologists provide ongoing care for patients with complex chronic and acute conditions that require specialized expertise. Rheumatologists, rheumatology physician assistants, and nurse practitioners provide face-to-face, primarily non-procedure-based care and serve patients with severe conditions that can be difficult to diagnose and treat, including rheumatoid arthritis and other forms of inflammatory arthritis, vasculitis, systemic lupus erythematosus, and multiple other debilitating diseases.

Medicare Advantage and prescription drug plans must promote and protect access to high-quality, affordable health care and health insurance in today's value-based care environment. ACR has long supported policies that make treatments, including biosimilars, accessible to patients. While we recognize the need to advance the availability and use of biosimilars, we caution against policies that will jeopardize our patients.

<u>Access to Reference Product if Medically Necessary</u>

Biologics have provided patients suffering from rheumatic diseases with a better quality of life by reducing or eliminating debilitating joint pain, inflammation, and organ damage. Due to the complexity of rheumatic diseases, finding an appropriate treatment is challenging. When a treatment works appropriately for the patient's disease, altering that medication may harm the patient's health.

The proposed rule will allow Part D plan sponsors to substitute biosimilars that are not deemed interchangeable with a reference product as "maintenance changes" in the formulary. The ACR believes biosimilars improve patient access to life-altering treatments and we support the use of biosimilars in the healthcare system. However, we note that, while biosimilars are highly similar to their reference products, small differences may lead to a reduction in effectiveness and/or tolerability for any given unique patient.

For this reason, CMS must include provisions within the policy that will easily allow patients who have been stable on a reference biologic to revert to the reference product if they do not respond to the biosimilar in the same way they did to the reference product. Patients must have access to the right treatment at the right time and must have the opportunity to access a reference product if needed. **We urge CMS to update the proposed policy to allow patients to access the reference product if medically necessary due to failure or intolerance of the biosimilar product.**

Formulary Change Frequency

As stated, the ACR recognizes and appreciates the role of biosimilars. However, we are strongly opposed to continuing formulary changes quarter by quarter or year by year. We recognize that formulary changes in preferred products are often driven by rebates offered by manufacturers, and/or price differences. Currently there are at least eight biosimilar similar versions of Humira (adalimumab). While switching from one version to another may usually be well tolerated by a patient, we worry that financial incentives may lead payers to continually switch one product to another when a different manufacturer offers a better deal, and we feel strongly that repeated changes from one biosimilar to another needlessly exposes patients to risk of differential treatment response and/or of side effects. For Part D beneficiaries whose life and function depend upon a steady response to an effective treatment, an ongoing cycle of changing formularies would be detrimental to their health and well-being. **We urge CMS to ensure there are guardrails within these policies to ensure that there are not continual biosimilar substitutions throughout the year.**

The ACR appreciates the tremendous role biosimilars can play for Part D beneficiaries. We offer support for the ongoing accessibility of these life-altering treatments; however, we urge CMS to create appropriate guardrails and exemptions that will ensure that the right patient receives the right treatment at the right time. We welcome the opportunity to serve as a resource to CMS as biosimilars continue to be incorporated into the Part D program. Please contact Amanda Grimm Wiegrefe, MScHSRA, Director of Regulatory Affairs, at awiegrefe@rheumatology.org with any questions.

Sincerely,

Christopher Phillips, MD
Chair, ACR Committee on Rheumatologic Care