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December 21, 2023

Ms. Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4205-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program and Medicare Prescription Drug Benefit Program

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. Today, we write to share feedback on policies described in the aforementioned proposed rule.

Substituting Biosimilar Biological Products for Their Reference Products as Maintenance Changes

Building on an as-yet-unfinalized previous proposal related to *interchangeable* biosimilars, CMS proposes to deem substitution of *non-interchangeable* biosimilars as "maintenance changes" to formularies. CMS further proposes to define biosimilars as including both non-interchangeable and interchangeable biosimilars, thus erasing any distinction between the two kinds of biosimilars for purposes of formulary changes.

Because of the negative potential impacts on continuity of care, we must oppose these proposals. Patients who need expensive medications for chronic conditions are often subject to insurer-imposed switches and utilization management protocols that defy belief. Allowing non-interchangeable biosimilars to be switched in and out throughout the year as simple maintenance changes will exacerbate this issue for Medicare beneficiaries by eliminating the procedural protections applicable to non-maintenance changes, including a requirement that CMS approve such changes before they can be implemented. Additionally, beneficiaries affected by a non-maintenance mid-year change are exempted from that change for the remainder of the contract year, which prevents abrupt disruptions in care. CMS seems to acknowledge the potential for disruptions in care through its proposal to require a thirty-day notice period for beneficiaries of a proposed mid-year switch to a biosimilar, so that beneficiaries can obtain a new prescription if necessary. The fact that a new prescription may be needed indicates in and of itself that switching to a non-interchangeable biosimilar is not the same as switching to a generic, which would not require a new prescription. For these reasons, we urge CMS not to finalize this policy.

Marketing and Communications Requirements for Special Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.2267); Mid-Year Notice of Unused Supplemental Benefits (§§ 422.111(l) and 422.2267(e)(42)); Agent Broker Compensation

Rheumatology patients who are approaching their "Medicare birthday" are frequently the target of grisly marketing campaigns, where plans representatives promise a continuation of private health plan benefits once they are Medicare eligible, but later discover their rheumatologist is out of network and their current medications therapies are off-formulary, not preferred, or cost-prohibitive. We appreciate that CMS heard CSROs concerns and finalized major reforms to how Medicare Advantage plans are marketed in 2024.

For 2025, CMS proposes additional marketing reforms, including enhanced disclaimers for Special Supplemental Benefits for the Chronically Ill (SSBCI), the establishment of standards to ensure adequate notice is provided by MA plans to their enrollees regarding supplemental benefits coverage, and revisions to the compensation that plans may provide their agents and brokers. ***We strongly support all of these proposals and urge CMS to make them final.***

In addition, as we recommended for 2024, ***we urge CMS to impose high penalties on plans that fail to comply with all of its revised marketing requirements, which should include civil monetary penalties, suspensions, and for the most abusive actors, permanent bans from program participation.***

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Thank you for considering our comments on the development of RA-focused episode-based cost measure. Please do not hesitate to contact us at info@csro.info should you require additional information.

Sincerely,

Gary R. Feldman, MD, FACR
President

Madelaine A. Feldman, MD, FACR
Vice President, Advocacy & Government Affairs