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Coalition of State Rheumatology Organizations

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February 13, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4201-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage 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.

In addition to comments provided by way of the Alliance of Specialty Medicine, CSRO provides additional feedback on the unique impact of CMS' proposals on rheumatologists and their patients.

Utilization Management Requirements

Utilization management (UM), such as prior authorization (PA) and step therapy, hinders enrollee access to medically necessary care and treatment, especially for those with rheumatic disease. These individuals require advanced diagnostic testing and complex medication therapies to diagnose, treat and manage their condition, yet face tremendous barriers receiving needed "items and services" – including physician-administered drugs ("Part B drugs") – under the current regulatory landscape. Once finalized, CMS' reforms will go a long way in addressing many of these challenges, forcing Medicare Advantage Organization (MAO) to begin prioritizing their enrollee's needs over their own profits. Disappointing, however, is CMS' exclusion of pharmacy-dispensed medications ("Part D" drugs), from its utilization reform proposals. Medications used in rheumatic disease straddle both Parts B and D, and the policies being proposed should apply to both. ***We urge CMS to apply its UM policies to Part D drugs.***

In addition, we are deeply concerned that CMS has excluded step therapy from its reforms – policies that are arguably the most problematic for rheumatology practices and known to reduce treatment effectiveness in patients with certain rheumatic diseases[i]. CMS' rationale for this decision is multifold, including that there tends to be more than one drug with demonstrated success in treating a certain condition and that it is not always obvious what the clinically superior drug is for certain conditions, while there may be a significant difference in pricing. These points are not completely baseless. Even with adherence to the American College of Rheumatology (ACR) guidelines, identifying the right therapy for rheumatoid arthritis (RA) patients involves a "try-and-fail" approach. However, unlike step therapy policies that are *financially-motivated*, society guidelines are *grounded in science*. Moreover, when coupled with a rheumatologist's judgement and clinical expertise, patients

can be directed to medications that are most likely to result in low disease activity, and even remission. By maintaining step therapy, CMS is allowing MAOs to usurp physician decision making and put their profits over enrollees.

Equally frustrating is CMS' stance that step therapy policies put MAOs in a better position to negotiate lower prices with drug manufacturers and reduce beneficiary cost-sharing. In contrast, MAOs generally impose step therapy policies to medications that are associated with the highest rebates, monies that are not passed on to patients or used to lower their out-of-pocket drug spend. Step therapy is so problematic that more than half of states have enacted legislation in an attempt to curb this practice.

When CMS issued its 2018 step therapy guidance, CSRO was among many provider and patient groups to raise strong objections and urge withdrawal – positions we continue to hold. ***We again ask CMS to rescind its 2018 step therapy memo. At a minimum, CMS should ensure that the memo's continuity of care provisions are aligned with those proposed in this rule.*** Specifically, the 2018 step therapy memo should be revised such that any new enrollee undergoing an active course of treatment is not subjected to new or additional UM requirements, including step therapy, for the first 90 days of enrollment.

Medicare Advantage Marketing

We have shared before that our 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. As a result of these experiences relayed by our patients, CSRO called on CMS to hold plans accountable for their misleading marketing and false claims, and to suspend or bar those plans from the program as well as impose civil monetary penalties.

We are grateful that CMS has heard these concerns and proposes significant reforms to marketing practices by MAOs and their marketing contractors. We are particularly pleased with CMS' proposals to modify the pre-enrollment checklist so plans must explain to potential enrollees the implications of choosing an MA or Part D plan. CMS' proposals would ensure potential enrollees are informed about the details surrounding the plan for which they are enrolling, to include whether their doctors are in the network, if their medications are on the plan's formulary, and how cost-sharing will change. ***We urge CMS to finalize its proposed marketing reforms. Further, CMS must impose high penalties on plans that fail to comply with these requirements, which should include civil monetary penalties, suspensions, and for the worst actors, permanent bans from program participation.***

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Thank you for considering our comments, and we look forward to working with you as you finalize policies outlined in this proposed rule. Please do not hesitate to contact us at info@csro.info should you require additional information.

Sincerely,

Madelaine A. Feldman, MD, FACR
Vice President, Advocacy and Government Affairs
Coalition of State Rheumatology Organizations

[i] https://pubmed.ncbi.nlm.nih.gov/31177506/