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Coalition of State Rheumatology Organizations

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555 E. Wells Street, Suite 1100
Milwaukee, WI 53202-3823
Phone: 414-918-9825
Email: info@csro.info
Website: www.csro.info

September 21, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
Office for Civil Rights
Attention: 1557 NPRM (RIN 0945-AA17)
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue SW
Washington, DC 20201

RE: Nondiscrimination in Health Programs and Activities (1557 NPRM (RIN 0945-AA17))

Dear Secretary Becerra:

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 in response to the aforementioned proposed rule.

Section 1557 Compliance Requirements for Providers

CSRO is committed to ensuring that patients do not face discrimination based on race, color, national origin, age, disability, or sex, consistent with Section 1557 of the Patient Protection and Affordable Care Act (PPACA, or ACA). In addition, we strongly support the Department's reinterpretation of "federal financial assistance" such that its nondiscrimination prohibitions would extend to Medicare Part B providers, such as physicians and other outpatient providers. However, our coalition is deeply concerned about the compliance burdens that will be created as a result of the proposed requirements for physicians' offices related to Section 1557 compliance. Specifically, we are concerned about the resources needed to write and implement Section 1557–specific policies and procedures, identify a Section 1557 Compliance Coordinator, and train practice employees on new nondiscrimination standards.

Rheumatology practices are grossly under-reimbursed for the patient care they provide, particularly when compared to other types of health care providers and Medicare Advantage plans. Since the inception of the resource-based relative value scale, the Medicare Physician Fee Schedule (PFS) conversion factor has remained consistently flat. And, with passage of the Medicare Access and CHIP Reauthorization Act of 2015, physician payments no longer incorporate inflation, which has reached record levels in recent months.

In addition to unsustainable payments, rheumatology practices face increasing administrative burdens, primarily associated with utilization management such as prior authorizations, step therapy, and other tactics, which divert clinical and administrative staff away from direct patient care and related activities. This is on top of the punitive quality reporting and program integrity audits. Simply stated, our practices cannot afford another unfunded mandate in the current environment.

As such, we ask the Department not to create additional administrative burdens on already overburdened physicians' offices. If the Department finalizes these requirements despite this concern, then at a minimum ***we seek your assistance in helping rheumatology practices with compliance.*** Specifically, ***we request that HHS develop and make available free-of-charge to the following:***

- ***Template Section 1557 policies and procedures that rheumatology offices can incorporate into their existing compliance manuals as-is;***
- ***Section 1557 educational materials and training resources, including materials that would help practices test their employee understanding of the new requirements and how to comply; and***
- ***Patient notices and other patient education materials that practices can disseminate to patients and display in their offices.***

We further request that the Department postpone any enforcement action associated with Section 1557 until after the Department has provided these educational resources and technical assistance, to allow rheumatology practices to come into compliance without penalty.

Requirements for Insurers

CSRO understands that the proposed policies in this rule would apply to all health programs and activities that fall within the Department's jurisdiction, which we understand to include Medicare, Medicare Advantage, and Part D Prescription Drug Programs. With that in mind, ***we urge the Department to direct the Centers for Medicare and Medicaid Services (CMS) to eliminate the Self-Administered Drug (SAD) Exclusion List policies, which we believe to be discriminatory against patients with physical, behavioral, or other disabilities.***

Many medications – particularly highly complex drugs and biologics – have a "physician-administered" formulation and a "self-administered" formulation. By law, Medicare Part B does not cover drugs which are "usually"[1] self-administered "by the patient."[2] To implement this statutory distinction, CMS has directed its Medicare Administrative Contractors (MACs) to determine whether medications are usually self-administered by the patient via use of criteria established in subregulatory manuals – in this case, the *Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services*. According to the manual, when a drug is determined by a MAC to be self-administered and is thus added to the SAD Exclusion List, it becomes **excluded from Part B coverage**. Effectively, this means that patients who are unable to administer the drug themselves – even if the inability to self-administer is due to a physical, behavioral, or other disability – must pay **entirely** out-of-pocket for the physician-administered formulation. Although this was certainly not Congress' or CMS' intent, this approach not only amounts to a *de facto* denial of coverage for disabled individuals in need of a drug on the SAD Exclusion List, it also amounts to a denial of coverage *based on the disability*, because that is what creates the inability to self-administer.

We, along with other provider organizations, have long raised concerns about the criteria MACs are required to use when making SAD Exclusion List determinations, because some are arbitrary, and others are difficult to apply. For example, it is unclear how a MAC could reasonably determine whether a medication is in fact self-administered "by the patient," given that there are no administrative datasets that would identify whether a patient actually self-administered the medication or whether another individual (e.g., caregiver, spouse, family member, friend, or physician's office) administered the

[1] See definition at 50.2, A. Usually at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf
[2] See definition at 50.2, E. By the Patient at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf

medication. In addition, there is no statutory mandate that the MACs consider a "weighted average" across labeled indications, to allow for scenarios where patients with a certain condition self-administer, while patients with another condition treated by the same drug cannot. However, that is the approach CMS has taken in its current guidance to the MACs. As a result, under CMS' current criteria, patients with certain diseases such as rheumatoid arthritis have lost access to the physician-administered formulation of certain medications (e.g., ustekinumab), simply because patients with other health conditions (e.g., psoriasis, ulcerative colitis) are more likely to self-administer that same drug. We hope that the Department agrees that these arbitrary requirements run afoul of the sentiments discussed in the proposed Nondiscrimination rule with respect to benefit design and formulary construction.

CSRO acknowledges that the Department cannot overhaul the SAD Exclusion List beyond the boundaries set by statute, and that Congressional intervention will be necessary to allow broad access to all formulations of a drug across the Department's programs. However, it is within the Secretary's authority to make revisions that would reduce discrimination associated with CMS' SAD Exclusion List. As a first step to addressing the discriminatory impact of the SAD Exclusion List, ***we urge the Department to direct CMS to eliminate the "weighted average" from its SAD Exclusion List criteria and to instead determine the prevalence of self-administration at an indication-specific level.*** This would ensure patients with certain conditions will not be denied access to the physician-administered formulation of a drug for the sole reason that patients with other conditions on that same drug can self-administer. Further, ***we urge HHS to require CMS' MACs to post on their public websites the methodology and dataset used when establishing whether a medication is "usually" administered "by the patient," and to consider data from external sources, including patient, provider, and industry organizations, in making such determinations.***

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Thank you for considering the feedback of practicing rheumatologists. Should you have any questions, please contact me at mfeldman@csro.info.

Sincerely,

Madelaine A. Feldman, MD, FACR
Immediate Past President and VP, Advocacy & Government Affairs, CSRO