Coalition of State Rheumatology Organizations (CSRO)
Written Statement Prepared for the
House Ways and Means Subcommittee on Health
Hearing on Lowering Costs for Patients: The Health of the Biosimilar Market
April 8, 2025

Chair Buchanan, Ranking Member Doggett, and members of the Subcommittee, thank you for the opportunity to submit written comments as a part of the Health Subcommittee hearing "Lowering Costs for Patients: The Health of the Biosimilar Market." The Coalition of State Rheumatology Organizations (CSRO) respectfully **urge the Congress to address reimbursement challenges for, and remove access barriers to, physician-administered biosimilars essential to the treatment and management of chronic and debilitating conditions.**

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 while working closely with patient and other provider organizations to advocate for reforms that safeguard access to care and improve patient outcomes.

Background

Biologic medications, whether reference ("brand") products or biosimilars, are vitally important therapeutic options for patients with chronic rheumatologic conditions such as rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and lupus, among other diseases. These therapies not only alleviate pain and other symptoms of systemic autoimmune diseases, but also slow disease progression, reducing costly disease-related complications, including joint damage, infections (due to increased steroid usage), increased cardiovascular risks, certain malignancies, surgeries, and hospitalizations.

Biologic medications, which may be administered by a physician under the medical benefit (Part B) or dispensed by a pharmacy under the pharmacy benefit (Part D), are generally very expensive; biosimilars were expected to offer more affordable alternatives to reference biologics, and in some cases, they have. However, patient access to certain physician-administered medications has become nearly impossible, as discussed in the paragraphs that follow.

Reimbursement for Physician-Administered Biosimilar Drugs

Many rheumatology practices follow a "buy and bill" model for physician-administered medications—meaning the physician purchases the drug directly and is later reimbursed by the

patient's health plan. Over the past two to three years, however, insurers have increasingly mandated the use of biosimilars that are reimbursed at rates lower than the physician's acquisition cost—commonly referred to as "underwater" biosimilars. To meet coverage requirements, physicians must prescribe therapies listed on the plan's formulary and follow the required sequence of use (i.e., step therapy). While biosimilar uptake for physician-administered drugs had been gradually increasing, these reimbursement challenges have created new barriers to adoption.

The disconnect between reimbursement and actual acquisition cost stems from how medications are priced and paid for. Medicare, and most private plans, reimburse physician-administered drugs based on the Average Sales Price (ASP)—a weighted average of manufacturers' sales prices that includes rebates and other price concessions—along with a 6% "add-on" to the ASP (or 8% for certain biosimilars) to help offset provider acquisition and handling costs. To secure formulary placement and "fail first" status for biosimilar medications, manufacturers pay rebates to health plans. These rebates have driven the ASP for certain biosimilars so low that, even with the 6-8% add-on, reimbursement often falls short of a provider's acquisition cost. According to a multi-specialty survey of physician and infusion practices conducted by the Underwater Biosimilars Coalition, nearly 100% of practices reported being underwater on several biosimilars—more than 70% for some medications—with some losing between $500 and $750 per infusion.

When biosimilars are reimbursed below their acquisition cost, it becomes financially unviable for physicians to administer them in the office setting. In these situations, physicians and their patients are left with few options. According to the aforementioned survey,

- more than 50% of practices reported transferring patients to the hospital settings, which increases costs and exposes immune-compromised patients to unnecessary risk;
- approximately 25% reported administering the drug at a loss, an unfair hardship on practices already facing hardship due to unsustainable Medicare physician fee schedule payments; and
- nearly 75% reported switching the patient's therapy, disrupting treatment for patients who were stable on their existing medication and potentially compromising clinical outcomes.

In many cases, hospitals also face reimbursement shortfalls and are unable to provide the mandated biosimilar, leaving beneficiaries without access to medically necessary treatment.

Addressing these reimbursement challenges will require Congressional intervention, as the Centers for Medicare and Medicaid Services (CMS) does not have the statutory authority to modify the ASP payment methodology. ***CSRO urges Congress to work with CMS to identify a***

sustainable solution that ensures patients can access physician-administered biosimilars without jeopardizing the financial viability of providers.

Beneficiary Access to Biologics, Reference Products, and Biosimilars

CMS's 2018 memorandum, *Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage*, has significantly contributed to access challenges for biosimilars. Under current policy, Medicare Advantage (MA) plans may require patients to "fail first" on a preferred biosimilar—even when its acquisition cost exceeds the plan's reimbursement. Again, this creates untenable financial pressure for physicians, who must choose between absorbing losses, referring patients to higher-cost hospital settings, or non-medically switching the patient's therapy. As noted above, hospitals are also facing reimbursement shortfalls for certain physician-administered medications; some have reported being unable to provide the plan-required biosimilar, while others have limited their infusion suites to oncology patients only. This means some beneficiaries are left without any access to medically necessary treatment.

Notably, these access barriers do not exist in original Medicare, where physicians can choose to administer another affordable biosimilar or the reference product. The misalignment between MA and original Medicare must be addressed to ensure appropriate access to treatment, particularly as more beneficiaries enroll in MA plans.

We are concerned that these challenges undermine the long-term sustainability of the biosimilar market and diminish the value these therapies were intended to bring. For example, many MA enrollees have lost access to *any* infliximab product (including other biosimilars to infliximab) because MA plans mandate use of highly-rebated "underwater" biosimilars. For these reasons, we urge **Congress to direct CMS to eliminate the 2018 step therapy policy so that beneficiaries may access an alternative affordable biosimilar or the reference product, when the formulary preferred biosimilar medications are "underwater."**

CSRO appreciates the Subcommittee's leadership in ensuring that Medicare policies promote sustainable access to biosimilars while ensuring affordability for both beneficiaries and the Medicare program. We appreciate your attention to this matter and welcome the opportunity to provide further information.