April 9, 2025

The Honorable Robert Aderholt
Chairman
Appropriations Subcommittee on Labor,
Health and Human Services, and Education
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Rosa DeLauro
Ranking Member
Appropriations Subcommittee on Labor,
Health and Human Services, and Education
U.S. House of Representatives
Washington, D.C. 20515

RE: Request for report language on access to physician-administered biosimilars

Dear Chairman Aderholt and Ranking Member DeLauro:

The undersigned stakeholders respectfully urge you to include report language in the FY 2026 Labor, Health and Human Services, Education, and Related Agencies appropriations bill to address Medicare reimbursement and access challenges for physician-administered biosimilars. Specifically, ***we request language directing the Centers for Medicare and Medicaid Services (CMS) to assess the impact of below-cost reimbursement and restrictive Medicare Advantage (MA) step therapy policies that are limiting access to these important therapies.***

Physician-administered biosimilars are essential in the treatment of chronic and debilitating conditions, including rheumatoid arthritis, psoriatic arthritis, and other serious rheumatologic and musculoskeletal diseases. They also play a critical role in managing inflammatory bowel diseases such as Crohn's disease and ulcerative colitis, as well as various neurological disorders and rare diseases. These therapies were introduced to improve access and lower costs; however, current Medicare payment policies often fall short of covering their acquisition costs. This issue stems largely from artificially low average sales prices (ASPs), which are distorted by excessive manufacturer rebates to health plans and pharmacy benefit managers (PBMs) to secure formulary placement. As a result, many biosimilars are "underwater"—reimbursed below their acquisition cost—making it financially infeasible for physicians to provide them in the office setting. Because commercial insurers also base their reimbursement rates for biosimilars off ASP, access for commercially insured children and adults is also being limited.

This challenge is exacerbated by MA plans' step therapy requirements that mandate use of these unaffordable biosimilars before patients can access alternative options. When physicians are unable to absorb financial losses or refer patients to hospital settings, access is delayed or denied entirely. This misalignment with original Medicare threatens to increase costs for the program and create unnecessary risks for patients, particularly those who are immunocompromised or unable to receive treatment in hospital settings.

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. We believe CMS must evaluate the drivers of these reimbursement and access barriers and identify solutions to ensure that

biosimilars remain a viable and accessible treatment option for all patients, including Medicare beneficiaries.

REQUESTED FY 2026 LHHS REPORT LANGUAGE –Centers for Medicare and Medicaid Services (CMS)
In light of the foregoing, we request that the following report language be included to address the reimbursement and access challenges associated with physician-administered biosimilars in the Medicare program:

> ***Reimbursement for Physician-Administered Biosimilar Drugs.*** The Committee is concerned that Medicare's reimbursement methodology, combined with the rebate-driven pricing system, results in acquisition costs for certain biosimilars exceeding payment rates, hindering physician adoption and limiting beneficiary access. The Committee understands that the ability of Medicare Advantage (MA) plans to mandate the use of unaffordable biosimilars first forces beneficiaries to receive treatment at higher-cost hospital settings, increasing Medicare spending, beneficiary out-of-pocket costs, and patient risk. Those beneficiaries who are unable to afford the hospital setting or find a hospital willing to administer the mandated biosimilar will lose access to all other biosimilars of that reference product. The Committee recognizes that a stable biosimilar market is essential to ensuring long-term Medicare savings and access to lower-cost therapies. The Committee directs CMS to assess the factors contributing to below-cost reimbursement for certain biosimilars and their impact on beneficiary access, out-of-pocket costs, and overall Medicare spending. The Committee requests that CMS submit a report within 180 days on the factors driving biosimilar reimbursement challenges, their effects on beneficiaries, and any statutory authorities needed to address the issue.
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> ***Beneficiary Access to Biologics, Reference Products and Biosimilars.*** The Committee is concerned that Medicare Advantage step therapy policies are limiting beneficiary access to certain reference products and their biosimilars, by requiring enrollees to fail first on the biosimilar that physicians may not be able to administer due to acquisition costs exceeding Medicare payment. The Committee understands these policies frequently force beneficiaries into higher-cost hospital settings and limit access to certain medications, whether the biologic reference product or its alternative biosimilars. The Committee understands that manufacturer rebates to health plans and their pharmacy benefit managers play a significant role in determining formulary placement in Medicare Advantage, which, when combined with step therapy policies, can create additional barriers to care for enrollees that are not present for beneficiaries in original Medicare. The Committee is concerned that this misalignment increases costs for the Medicare program and its beneficiaries. The Committee directs CMS to revise its step therapy policies to clarify that beneficiaries should have access to an alternative biosimilar or reference product when the step therapy-preferred biosimilar is not financially viable for physicians to administer.

On behalf of our members and the patients we serve, thank you for your continued leadership in ensuring that Medicare policies support access to high-quality, affordable therapies. We appreciate your attention to this matter and welcome the opportunity to provide further information.

Sincerely,

Coalition of State Rheumatology Organizations
American College of Rheumatology
American Gastroenterological Association
American Society for Gastrointestinal Endoscopy
Arthritis Foundation
Association of Women in Rheumatology
Crohn's & Colitis Foundation
Digestive Health Physicians Association
Infusion Alliance Foundation
Infusion Providers Alliance
Lupus and Allied Diseases Association, Inc.
National Infusion Center Association
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition
National Organization of Rheumatology Management
Spondylitis Association of America

State Organizations

Alabama Society for the Rheumatic Diseases
Alaska Rheumatology Alliance
Arkansas Rheumatology Association
Arizona United Rheumatology Alliance
California Rheumatology Alliance
Colorado Rheumatology Association
Connecticut Rheumatology Association
Florida Society of Rheumatology
Georgia Society of Rheumatology
Kentuckiana Rheumatology Alliance
Maryland Society for the Rheumatic Diseases
Massachusetts, Maine and New Hampshire Rheumatology Association
Michigan Rheumatism Society
Midwest Rheumatology Association
New York State Rheumatology Society
North Carolina Rheumatology Association
Ohio Association of Rheumatology
Rheumatology Alliance of Louisiana
Rheumatology Association of Minnesota and the Dakotas
Rheumatology Society of New Mexico
Southern California Rheumatology Society
State of Texas Association of Rheumatologists
State of West Virginia Rheumatology Society
Tennessee Rheumatology Society
Virginia Society of Rheumatology
Washington State Rheumatology Alliance
Wisconsin Rheumatology Association