January 27, 2025

Jeffrey Wu, JD
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services

Submitted electronically via regulations.gov

RE: **[CMS-4208-P] Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly**

Dear Acting Administrator Wu:

The undersigned organizations of the Underwater Biosimilars Coalition ("The Coalition") are committed to improving access to provider-administered medications, including biosimilars. The Coalition is comprised of over 40 organizations representing a broad range of providers and patient advocates nationwide. We appreciate the opportunity to respond to the U.S. Department of Health and Human Service's proposed changes to the Medicare Advantage (MA) Program and the Medicare Prescription Drug Benefit Program (Part D) for 2026. The Coalition applauds CMS for spotlighting the negative downstream impacts wrought by the leverage pharmacy benefit managers have had on biosimilar placement in formularies. Our comments are as follows.

Formulary Inclusion and Placement of Generics and Biosimilars

The Coalition supports CMS's proposal to implement a more holistic review of Part D plans' formulary and utilization management practices to determine if the biosimilars listed on their formulary constitute a utilization management program that is "cost-effective," "reasonable and appropriate," and inclusive of "incentives to reduce costs." The Coalition is a supporter of increasing beneficiary access to biosimilars, which typically provide a lower cost version of existing biologics and are vitally important therapeutic options for patients with certain chronic diseases, such as cancer, arthritis, and Crohn's disease. In addition to reducing pain dysfunction and disability related to inflammatory and genetic diseases, these medications reduce the frequency of costly disease-related complications, including cardiovascular diseases, metabolic syndromes including diabetes and osteoporosis, and expensive procedures and surgeries. Biosimilars undergo rigorous testing to demonstrate comparable safety and efficacy to their reference products (i.e., brand biologics). Biosimilars have the potential to promote a sustainable, robust market that encourages competition, cost savings, and better patient care.

The Coalition also commends CMS for shining a spotlight on the various negative impacts rebates offered to PBMs have on beneficiary access to biosimilars. The Coalition has the following comments on these impacts.

Inadequate Reimbursement of Certain Medicare Part B Biosimilars

As CMS notes, insurers and their pharmacy benefit managers (PBMs) have exerted disproportionate sway on drug formularies by pressuring pharmaceutical companies to offer them significant rebates in exchange for preferred formulary placement, including "fail first" status. PBM formulary committees fill their preferred tier with branded biologics rather than cost effective alternatives. Even if biosimilars are available and offer lower upfront costs, their adoption slows if formulary decision-makers are swayed by the larger rebates offered by the original biologic manufacturer. Limited formulary access for biosimilars increases the costs for our patients as well as our healthcare system.

When the manufacturers of biosimilars are finally able to break through and gain formulary access, it tends to be due to the massive rebates offered by drug manufacturers to PBMs, which ironically lead to limited access to biosimilars by artificially lowering the Average Sales Price (ASP) to the point that many providers' acquisition costs substantially exceed Medicare and other private health plan reimbursements. Many physician practices that directly administer drugs, including biosimilars, to patients in outpatient facilities typically engage in a practice known as "buy and bill." These practices pre-purchase drugs and bill the payer for reimbursement once the medication is administered to the patient. Margins for practices engaged in buy and bill are thin. To maintain the viability of administering drugs in this setting, reimbursement must account for not only the drug acquisition cost, but also overhead costs such as intake and storage, equipment and preparation, staff, facilities, and spoilage insurance. Reimbursement rates that do not sufficiently compensate for these costs at the current ASP formula risk putting these practices "underwater."

When biosimilars gain formulary access, they usually end up being the preferred ("required") version of the drug mandated by the payer for coverage. Unfortunately, the ASP for most biosimilar therapies continues to fall significantly short of many providers' acquisition costs – even for the first biosimilars to market– forcing providers into an untenable position. Their choices include administering the drug at a financial loss, transferring care to another site of service (e.g., a hospital), or switching the patient's therapy, which may be further complicated by "step therapy" requirements imposed by payers, including Medicare Advantage plans. Not only do these options increase financial pressure on providers, but they also contribute to higher costs to the healthcare system, Medicare, and patients, and lower the quality of care. For example, administering drugs in a hospital setting increases costs for both payers and patients, while altering treatment disrupts continuity of care and can result in suboptimal outcomes, potentially leading to worsened health conditions.

Congress increased the ASP "add-on" from 6% to 8% for qualifying biosimilar therapies for five years in Section 11403 of the *Inflation Reduction Act* (IRA), Public Law 117-169.[1] According to CMS, this temporary add-on payment has been implemented to promote greater competition within the biologic/biosimilar marketplace and to increase access to and utilization of biosimilars. However, this does not extend to all biosimilars on the market.

Unfortunately, even with this increased ASP +8% "add-on" rate, physicians remain financially underwater. This additional add-on payment is not sufficient to overcome the marked reduction in ASP caused by the rebates offered by manufacturers to PBMs, thus still leaving the providers underwater. As Congress continues to explore opportunities to increase access to biosimilars, it is imperative to address provider "underwater" biosimilar reimbursements, which will remain an obstacle to full biosimilar integration into the market if providers are unable to offer these vital medications to patients.

[1] Pub. L. 117–169

It is important to note that this scenario is at odds with bipartisan interest in reducing drug prices and expanding access to lower-cost alternatives, such as biosimilars. Moreover, even though the increase to the ASP "add-on" has not solved the issue, research has shown that the current ASP-based reimbursement system is the catalyst behind these challenges and that it needs to be changed. **The Coalition calls for CMS to work with Congress on crafting legislation that would amend Section 1847A(c)(4) to extend the Secretary's authority to use wholesale acquisition cost (WAC) + 3% until ASP reaches sustainable levels, as determined by the Secretary. We also urge CMS to withdraw the 2018 memorandum "Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage," to ensure beneficiaries can access an alternative therapy when the biosimilar reimbursement is below the ASP payment rate.**

Impact on Healthcare Costs and Treatment Choices

Biosimilars are often seen as a key mechanism for reducing healthcare costs by offering lower-priced alternatives to expensive biologics. However, if rebate-driven formulary decisions limit the use of biosimilars, the anticipated cost savings may not be fully realized. In the long term, this could prevent the healthcare system from benefiting from the potential price reductions that biosimilars can offer. Additionally, patients might be prescribed higher-cost branded biologics when biosimilars could be equally effective and less expensive. This can lead to higher out-of-pocket costs for patients.

Conclusion

The Coalition is dedicated to working with CMS to ensure that all patients have access to high quality care and that all providers are reimbursed fairly for providing it. We look forward to partnering with you on this endeavor and serving as a resource to address "underwater" biosimilars. Please contact Colby Tiner, MA at ctiner@rheumatology.org or Madelaine Feldman, MD at madelainefeldman@gmail.com if you have any questions.

Sincerely,

Organizations

Alabama Society for the Rheumatic Diseases
Alaska Rheumatology Alliance
American College of Gastroenterology
American College of Rheumatology
American Gastroenterological Association
American Society for Gastrointestinal Endoscopy
Arizona United Rheumatology Alliance
Arkansas Rheumatology Association
Arthritis and Rheumatology Consultants, P.A.
Association of Women in Rheumatology
California Rheumatology Alliance
Chicago Rheumatism Society
Coalition of State Rheumatology Organizations
Colorado Rheumatology Association
Connecticut Rheumatology Association

Crohn's & Colitis Foundation
Digestive Health Physicians Association
Florida Society of Rheumatology
Georgia Society of Rheumatology
Infusion Providers Alliance
Kentuckiana Rheumatology Alliance
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Maryland Society for the Rheumatic Diseases
Massachusetts, Maine, and New Hampshire Rheumatology Association
Michigan Rheumatism Society
Midwest Rheumatology Association
National Infusion Center Association
National Organization of Rheumatology Management
New York State Rheumatology Society
North Carolina Rheumatology Association
Ohio Rheumatology Association
Rheumatology Alliance of Louisiana
Rheumatology Association of Iowa
Rheumatology Association of Minnesota and the Dakotas
Rheumatology Society of New Mexico
Southern California Rheumatology Association
Southern California Rheumatology Society
Spondylitis Association of America
State of Texas Association of Rheumatologists
Tennessee Rheumatology Society
Texas Society of Gastroenterology and Endoscopy
Virginia Society of Rheumatology
Washington Rheumatology Alliance
West Virginia State Rheumatology Society
Wisconsin Rheumatology Association