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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 American College of Rheumatology (ACR), representing over 10,000 rheumatologists and rheumatology interprofessional team members, appreciates 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 ACR applauds CMS for spotlighting the negative downstream impacts wrought by the leverage pharmacy benefit managers have had on biosimilar placement in formularies. We also applaud CMS for extolling the positive impact the Inflation Reduction Act has had on Medicare beneficiaries' access to care by proposing to codify more of its provisions. The ACR's comments on these and other areas of the proposed rule are discussed below.

## Strengthening the Medicare Prescription Drug Plan

The ACR supports CMS's proposal to codify prior agency guidance implementing section 11202 of the Inflation Reduction Act of 2022 ("IRA"), which establishes the Medicare Prescription Payment Plan and requires each Medicare Prescription Drug Plan ("PDP") sponsor and Medicare Advantage prescription drug plan to provide enrollees with the option to pay cost-sharing under the plan in capped monthly amounts. The proposals, which would be applicable for 2026 and subsequent years, aim to ease the financial burden for those with high cost-sharing early in the year.

This will significantly improve access to essential rheumatologic treatments, reduce financial barriers, and improve patient outcomes. By ensuring that patients with conditions such as rheumatoid arthritis, systemic lupus erythematosus, psoriatic arthritis, vasculitis and other rheumatic and autoimmune diseases have access to the medications they need without the constant worry of overwhelming costs, this policy change could help enhance overall disease management, reduce health disparities, and improve quality of life for many beneficiaries.

However, careful monitoring and adjustments to avoid negative economic consequences would be necessary to maximize the positive impact of such a policy.

Importantly, the ACR also strongly encourages CMS to continue strengthening the IRA, particularly the Medicare Drug Price Negotiation Program (MDPNP). The IRA impacts rheumatology in three important ways in terms of access to medications, insurance coverage, and overall healthcare affordability for patients with chronic rheumatologic conditions.

First, one of the primary goals of the IRA is to reduce the cost of prescription drugs, which has significant implications for patients with chronic rheumatic diseases. The IRA has allowed Medicare to negotiate the prices of certain high-cost prescription drugs, including biologic agents and small molecule inhibitors. This is crucial for rheumatology, as many medications in these classes are effective treatments for rheumatologic and other autoimmune diseases, which can be extremely expensive. These drugs include TNF inhibitors, JAK inhibitors, monoclonal antibodies, selective co-stimulation modulators, phosphodiesterase inhibitors, complement inhibitors, and interleukin inhibitors (anti-IL-1, IL-6, IL-12, IL-17, and IL-12/23). The IRA's efforts to bring down the cost of these drugs has made them more affordable for older patients who rely on Medicare.

Second, the IRA has extended enhanced subsidies for marketplace insurance plans through the Affordable Care Act (ACA) through 2025. This provision helps increase access to health insurance for low- and middle-income Americans, including those with rheumatologic conditions who may have previously struggled to afford private insurance or prescription medications. With more people gaining or maintaining access to insurance, patients with rheumatic and autoimmune diseases can obtain necessary treatments and follow-up care, reducing the financial barriers to managing chronic conditions.

Finally, the IRA also includes measures aimed at promoting the use of biosimilars, which are intended to be more affordable alternatives to the reference product (i.e., the originator biologic agent). The use of biosimilars in rheumatology has the promise to provide more cost-effective options for patients, helping to reduce treatment costs while maintaining therapeutic efficacy. With a focus on increasing competition in the biologic drug market, the IRA has led to greater availability of biosimilars, which help lower the overall cost burden on patients with chronic rheumatic and autoimmune diseases.

**Formulary Inclusion and Placement of Generics and Biosimilars**

The ACR 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 ACR has long been a supporter of increasing beneficiary access to biosimilars, which typically provide a lower cost version of the reference product biologic drugs and are vitally important therapeutic options for patients with certain chronic diseases, such as cancer, rheumatic diseases, and Crohn's disease. In addition to reducing pain, dysfunction, and disability related to inflammatory autoimmune 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. In addition, biosimilars have the potential to promote a sustainable, robust market that encourages competition, cost savings, and better patient care.

The ACR also commends CMS for shining a spotlight on the various negative impacts manufacturer rebates have on beneficiary access to biosimilars. The ACR 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 significant rebates in exchange for preferred formulary placement, including "fail first" status. PBM formulary committees fill their preferred tier with originator biologics rather than cost effective alternatives due to higher rebates. 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 originator 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 offering massive rebates, which leads to reduction in their Average Sales Price (ASP) and forms the basis for drug reimbursement being below providers' acquisition costs. This occurs because rebates paid by manufacturers to PBMs are included in CMS's ASP calculation but are not passed to the providers who purchase the drugs through the commonly employed "buy-and-bill" mechanism. Margins for practices engaged in buy and bill are thin. When the acquisition cost of a biosimilar exceeds its reimbursement, a practice is "underwater" on that drug, and they would usually choose not to offer infusion of that drug in their clinic. A recent survey revealed that 97% of practices have been affected by the issue of "underwater biosimilars."[1]

The rebate process often leads the underwater biosimilar to be the payer's preferred ("required") version of the drug. Providers are then forced into an untenable position. Their choices include administering the drug at a financial loss, transferring care to another site of service, 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. For example, the cost of an infusion may double if transferred from a private clinic to an outpatient hospital infusion center. Altering treatment when not necessary for medical reasons lowers the quality of care by disrupting therapeutic continuity, which can result in suboptimal outcomes and worsened health conditions.

[1] https://csro.info/UserFiles/file/CSROExplanatoryStatement-UnderwaterBiosimilars.pdf

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.[2] 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. Unfortunately, even this increased ASP +8% "add-on" rate is not sufficient to make physicians financially whole when infusing affected biosimilars. As Congress continues to explore opportunities to increase access to biosimilars, it is imperative to address provider "underwater" biosimilar reimbursements. If providers are financially unable to offer these vital medications to patients, this will remain a barrier in being able to fully integrate biosimilar medications into the market.

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. The increased ASP "add-on" for biosimilars does not effectively incentivize their use, for the reasons noted above. The ASP formula itself, including the impact of manufacturer rebates to PBMs on the ASP calculation, needs to be revisited. The ACR calls for CMS to work with Congress on legislation that would amend Section 1847A(c)(4) of the Social Security Act to extend the Secretary's authority to use wholesale acquisition cost (WAC) + 3% to reimburse providers until ASP reaches sustainable levels, as determined by the Secretary.[3]

*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 originator biologics when biosimilars could be equally effective and less expensive. This can lead to higher out-of-pocket costs for patients.

**Strengthening Prior Authorization and Utilization Review Guardrails**

CMS is proposing significant beneficial reforms to the prior authorization process, requiring plans to adopt electronic systems for streamlining requests, maintain approvals for the duration of treatment, and ensure that clinical decisions are made based on evidence-based guidelines. Specifically, to address inappropriate prior authorization and utilization management practices that hinder access to care, CMS proposes the following modifications to existing regulations:

- Define "internal coverage criteria" and clarify that MA plans may only apply such criteria when Medicare coverage policies are insufficient. Any such criteria must be 1) Publicly available and transparent, 2) Based on current evidence and widely accepted guidelines from recognized professional medical societies or consensus-based organizations; and 3) Consistent with Medicare's regulatory requirements.

[2] Pub. L. 117–169
[3] Ibid

- Require that once a prior authorization is approved, it remains valid for the entire course of treatment, preventing the need for repeated approvals and ensuring continuity of care.
- Mandate that plans provide specific reasons for coverage denials, including the exact Medicare or plan coverage rule or guideline used in the determination, and a detailed explanation of how the criteria were applied.

The ACR supports these proposals. However, more needs to be done to ensure that prior authorization processes do not overburden providers and compromise care for MA beneficiaries. The prior authorization process is time-intensive and leads to gaps in treatment which can result in disease flares. In the 2023 American Medical Association Prior Authorization Survey, 94% of physicians reported prior authorizations delay medical care. Unclear and frequently changing coverage criteria increase the rate of inappropriate denials and further delay the prior authorization process. [4] With MA having become the predominant choice for Medicare beneficiaries, the ACR urges CMS to engage more with providers to get a better understanding of how the prior authorization processes used by MA plans are time consuming, administratively burdensome, and ultimately negatively impactful to the patients we serve. Reducing prior authorization delays could be addressed in the following ways:

First, CMS should mandate real-time decision-making for urgent services to minimize delays in patient care. Delays in urgent care can lead to adverse outcomes, particularly for individuals with rheumatologic disease. Similarly, CMS should accelerate the adoption of electronic prior authorization.

Second, the ACR encourages CMS to establish robust oversight and enforcement mechanisms to ensure compliance with the new transparency and prior authorization requirements. Without consistent enforcement, these reforms risk becoming ineffective in practice, leaving patients and providers vulnerable to continued administrative challenges.

Lastly, the ACR recommends that CMS publish data on appeals, overturns, and prior authorization outcomes on a regular basis. Publicly available data will enable stakeholders to assess system performance, identify trends, and recommend further improvements. Transparency in these areas is crucial for driving accountability and fostering a learning health system that continuously evolves to meet the needs of patients.

**Promoting Informed Choice—Format Provider Directories for Medicare Plan Finder**

CMS is proposing to require MA provider directory data be submitted for use to populate Medicare Plan Finder (MPF). In addition, it is proposing to require MA organizations to attest that this information is accurate and consistent with data submitted to comply with CMS's MA network adequacy requirements when it is submitted to CMS for the purpose of incorporating into MPF. The ACR supports these proposals.

[4] https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

**Enhancing Health Equity Analyses: Annual Health Equity Analysis of Utilization Management Policies and Procedures**

CMS proposes to revise the required metrics for the annual health equity analysis of the use of prior authorization to require the metrics be reported by each item or service, rather than aggregated for all items and services. The ACR supports this proposal.

These metrics around utilization are essential in helping improve patient care. With these metrics, rheumatologists and other care team members can verify whether procedures are positively impacting vulnerable populations. For too long, prior authorization policies by MA managed care plans have been burdensome and time-consuming and have delayed care for vulnerable populations. This delay in care is exacerbated by the fact that MA beneficiaries must also rely on patient assistant programs to subsidize the cost of prescription drugs due to MA plans not allowing the red-white-and-blue Medicare card to be used for health care. This means that MA beneficiaries are subjected to the cost-sharing protocols of commercial insurance while not being allowed to use the copay assistance for prescription drugs that is available to traditional Medicare beneficiaries. Resulting administrative burden has led some physicians to stop accepting MA patients. Further, this exposes a deep divide in prior authorization policies between the MA program and traditional Medicare.

To address the assorted problems with prior authorization policies, a range of public policies have been proposed. These have included "gold carding" at the state level and electronic prior authorization at the federal level. Some states, such as Illinois, Minnesota, Wyoming, and Vermont, have mandated timelines on prior authorization.[5] For example, in Illinois, an urgent prior authorization must be determined within 24 hours.[6] However, despite the increasing policy attention to controversial prior authorization practices, there is limited data on how prior authorization is used by MA plans and how it has changed over time. The requirement for additional information to process the authorization leads to increased burden on physicians and their staff, and results in delays in care and an increased likelihood of negative patient outcomes.

**Conclusion**

The ACR has long supported policies to increase access to care for Medicare beneficiaries. We believe many of the provisions in the proposed rule are well in line with our advocacy efforts. However, we are concerned about the future of the Medicare Drug Price Negotiation Program, particularly due to the benefits it has had for patients' access to rheumatologic treatments. We are also concerned about the continued role that rebates to PBMs play in biosimilar placement on drug formularies and the negative impact this has on rheumatologists' ability to provide high quality care to Medicare beneficiaries. We urge CMS to partner with the ACR and use us as a valued resource of expertise and information for future proposed rules that impact these areas. Please contact Colby Tiner, MA, Manager of Regulatory Affairs, at ctiner@rheumatology.org if you have any questions.

Sincerely,

[5] 10 States Have Tackled Prior Authorization Thus Far in 2024.
[6] https://idoi.illinois.gov/content/dam/soi/en/web/insurance/companies/companybulletins/cb2021-09-form-3643.pdf

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