AMERICAN COLLEGE of RHEUMATOLOGY
Empowering Rheumatology Professionals

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April 14, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted electronically

RE: Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments

Dear Administrator Brooks-LaSure,

The American College of Rheumatology (ACR), representing over 7,700 rheumatologists and rheumatology interprofessional team members, appreciates the opportunity to provide thoughts on the Medicare Drug Price Negotiation guidance that was released on March 15, 2023. We recognize that establishing this complex program is a tremendous undertaking and appreciate all opportunities for the public to participate in the process.

Rheumatologists and rheumatology healthcare professionals provide ongoing care for Medicare beneficiaries with complex chronic and acute conditions that require specialized expertise. They provide primarily non-procedure-based care to patients with severe conditions that can be difficult to diagnose and treat, including rheumatoid arthritis and other forms of inflammatory arthritis, vasculitis, systemic lupus erythematosus, and multiple other debilitating diseases. Rheumatologists and rheumatology professionals work side by side with pharmacists and PharmD's to ensure patients' access to medically necessary therapy. Early and appropriate treatment by rheumatologists and rheumatology professionals can control disease activity and prevent or slow disease progression, improve patient outcomes, and reduce the need for costly surgical or interventional procedures. The improved outcome enables our patients to continue to be more productive than they would have been without timely treatment.

Therapeutics for rheumatic diseases are as complex as the diseases they treat, and we recognize the tremendous investment in research and development that is needed to bring these innovative drugs and biologics to market. However, R&D costs do not account for soaring drug prices – prices that routinely block patients' access to medically necessary therapies. The ACR believes that, in order to allow patients access to needed treatments, all participants in the pharmaceutical marketplace, not just manufacturers, must be called upon to improve transparency, address perverse incentives, incentivize world-class innovation in drug development as well as reliable manufacturing and distribution systems, and reduce the cost borne by patients to levels that no longer preclude access to medically necessary therapy.

Ensuring Accessibility and Innovation

The ACR recognizes that this guidance outlines technical steps that will allow the agency to negotiate select drug prices with manufacturers. The drug negotiation provisions within the Inflation Reduction Act (IRA) require an aggressive timeline in order to meet the 2026 applicability deadline. We note that an aggressive timeline could lead to unintended consequences in that a relatively short interval between approval by the Food and Drug Administration (FDA) of a drug and its listing on the drug pricing negotiation list could disincentivize manufacturers from investing in new and innovative therapies. Therefore, as CMS continues to refine the program, we urge the agency to ensure that the drug pricing timeline and eligibility requirements allow for high-spend drugs to be negotiated without prejudicing innovation.

Provider and Patient Perspective

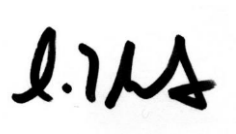
As prescribers, we sit at the nexus between innovative therapies and the patients who would benefit if they could afford them. This unique perspective will be invaluable to the successful rollout of CMS's evolving policies. Therefore, we urge CMS to ensure appropriate stakeholder and public participation, including 60- or 90-day comment periods and the inclusion of patient and provider perspectives throughout the process. Incorporating patient and provider real-world perspectives as the end-users of these products is integral to any plan to reduce drug prices.

We encourage CMS to make negotiation methodologies transparent, accessible, and understandable to all stakeholders. Along these lines, we urge CMS to publish all subsequent policies related to this program in line with the customary regulatory process, including an adequate comment period.

Finally, we urge CMS to include patient and provider groups, including the ACR, throughout the program's development. While the negotiations toward a maximum fair price are largely between the pharmaceutical industry and CMS, the implications of these negotiations are far-reaching. We appreciate that the agency recognizes the need for quarterly strategic and stakeholder meetings. We urge CMS to be candid and transparent in these discussions and allow for additional mechanisms, including listening sessions, by which others might participate to ensure the program meets all objectives and mitigates unintended consequences.

The ACR appreciates the transparency CMS has provided in the early stages of the implementation of the negotiation program. We urge continued transparency and more time for input from stakeholders. The ACR welcomes all opportunities to serve as a resource to CMS as drug negotiations begin. Please do not hesitate to contact Amanda Grimm Wiegrefe, MScHSRA, Director of Regulatory Affairs, at awiegrefe@rheumatology.org should you have any questions or need clarification.

Sincerely,



Douglas White, MD, PhD
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