



The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-5528-ANPRM  
P.O. Box 8013  
Baltimore, Maryland 21244-1850  
Submitted electronically via <http://www.regulations.gov>

**Re: [CMS-5528-ANPRM] Medicare Programs: International Pricing Index Model for Medicare Part B Drugs**

Dear Administrator Verma:

The American College of Rheumatology (ACR), representing over 9,500 rheumatologists and rheumatology interprofessional team members, appreciates the opportunity to respond to the *Medicare Programs: International Pricing Index Model for Medicare Part B Drugs Advance Notice of Proposed Rulemaking (IPI-ANPRM)*. Reducing high drug costs and improving patients' access to treatments are top priorities for the ACR. We welcome the chance to share our concerns about the impact these proposals will have on our ability to provide quality care to the 54 million Americans living with rheumatic diseases, as well as our recommendations for improving this model.

Rheumatologists provide ongoing care for Medicare beneficiaries with complex chronic and acute conditions that require specialized expertise. Rheumatologists, together with members of the rheumatology interprofessional team, primarily provide face-to-face, non-procedure-based care to patients with serious conditions that can be difficult to diagnose and treat, including rheumatoid arthritis and other inflammatory arthritides, vasculitis, systemic lupus erythematosus, osteoporosis, and multiple other debilitating diseases. Early and appropriate treatment by rheumatologists and interprofessional team members can control disease activity and prevent or slow disease progression, improve patient outcomes, and reduce the need for costly downstream procedures and care compared to care provided solely by primary care providers.

***Executive Summary***

The ACR believes that safe and effective treatments should be accessible to all patients at the lowest possible cost. We appreciate the Administration's focus on drug prices. We agree with the President that drug prices are too high and that action to reduce drug costs is long overdue. However, we want to ensure that these efforts do not limit access to treatment for

Americans with chronic illnesses, including the 54 million who live with a rheumatic disease and those who rely on Medicare drug coverage to be able to receive life-changing biologic therapies. We support policies rooted in scientific evidence that support shared decision-making between patients and providers and that decrease barriers to patients accessing treatment. Stakeholder engagement is imperative for any health policy proposals the Centers for Medicare & Medicaid Services' (CMS) and Center for Medicare and Medicaid Innovation (CMMI) are putting forward. **We are concerned that several components of the IPI-ANPRM could restrict patient access to care and appreciate the opportunity to provide our input on the IPI-ANPRM in the subsequent sections.**

### ***Model Overview and Concerns***

According to CMS, the IPI-ANPRM would test whether increasing competition for private-sector vendors to negotiate drug prices and aligning Medicare payments for drugs with prices that are paid in foreign countries, improves beneficiary access and quality of care while reducing expenditures. As we understand the model, 50 percent of physician practices and hospital outpatient departments (HOPDs) in selected geographic areas would be included in this model and participation would be mandatory for the physician practices, HOPDs, and potentially other providers and suppliers, in each of the selected geographic areas.

The ACR does not have policy on an international drug pricing index, but we do support Medicare using its authority to lower drug prices. However, **we do not support mandatory demonstration projects.** Our current policy is that we support Medicare having the ability to negotiate for reduced drug prices; however, there are many specific pricing mechanisms described in the IPI-ANPRM that the ACR cannot support without having specific details on the policy. Further, the ACR respectfully disagrees that the small differences in provider reimbursement between similar rheumatology treatments (all of which have differences among them of less than ~\$200 per patient per year) influence drug utilization. We request to see data supporting this claim.

**We are concerned that the administrative difficulties that would be associated with utilizing vendors could lead some practices to lose the ability to provide infusion services. Specifically, we are concerned that the added administrative burden of proposed interactions with the vendors in the model exceeds any inherent benefits to practices.** We believe practices could be negatively impacted if they are subjected to a mandatory demonstration which will make it more difficult for physicians and other healthcare providers, particularly those in small practices and rural settings, to administer Part B medications in their communities, creating a dire patient access issue. Additionally, without substantial changes to this model, the physician workforce shortage could also worsen, endangering patient access and increasing overall geographic disparities in access to medical care. Some areas of the country already have significant shortages of specialty physicians; therefore, we urge CMS to reconsider how a mandatory model involving such a

large and geographically diverse percentage of providers would impact the delivery of patient care. If these physician practices were to find themselves financially underwater while in this model, there would be major negative impacts on patients' access to effective care. CMS should consider offering a way for providers to exit the model in order to protect the providers and their patients from disruptions in care. Making any demonstrations such as this voluntary – by allowing physicians to choose whether to continue to buy and bill or engage with the new vendor system – would help to alleviate these concerns until the effects of the demonstration are better understood.

**The ACR believes that the current “buy and bill” system offers unparalleled patient access to life-saving and life-changing drug therapies.** This system also works well for practices by allowing participation in the terminal aspects of drug distribution, and thereby maintaining a patient-centered approach to processes such as drug acquisition, storage, inventory, appointment scheduling, compliance with HIPAA, billing and electronic record documentation. Practices invest a substantial portion of their reimbursement into these activities, enhancing patient experience and outcomes. The IPI model, as we understand it, would give vendors control over drug distribution and patient access, and potentially force practices to stop providing these services because of the untenable reduction in reimbursement by 30 percent over 5 years. According to page 31 of the IPI-ANPRM, the add-on payment amount for providing a drug would be tied to the previous year's average sales price (ASP) plus 6 percent calculations, and ASP would likely be reduced as the IPI model reduces drug prices. Although the model initially increases reimbursement from 4.3 percent to 6 percent margin, this increase is offset by additional fees payable to vendors, the increased administrative burden of working with vendors, the collection of patient cost-sharing for vendors, and the increased work of maintaining inventory. We urge CMS to consider the substantial physician burden the current IPI-ANPRM suggests and the impact this will have on providing patients with the convenient and accessible care they need.

### **ACR IPI Proposed Modifications**

To mitigate physician burden and patient barriers to care, the ACR proposes that CMS move forward with policies that would utilize its authority to reduce drug costs, with the following suggestions that would preserve elements of the current system that are working well for patients. The framework below provides modifications to the Trump administration's International Pricing Index model for a future **voluntary** demonstration and allow for reductions of drug costs without mandating use of a potentially disruptive third-party vendor.

**If CMS moves forward with a proposal such as the IPI Part B model, the ACR recommends that CMS:**

- Modify the model to be **voluntary**.
  - Reduce the scope/size of any possible demonstration project to a significantly smaller percentage of Part B drug administration.

- Ensure that there is a way for providers in the model to exit the demonstration if they find themselves financially underwater due the financial changes required by the model.
- Keep the proposed price reductions using Medicare’s authority (20% of target price per year for 5 years).
- Keep the planned increase in participant gross reimbursement from 4.3% to 6% of current ASP in the absence of the model.
- Provide incentives for participation that could include increased gross reimbursement.
  - Participation in a model that reduces drug prices and patient cost sharing could improve adherence, patient outcomes and patient and provider satisfaction. Note, however, that insurance companies and not patients generally pay the supplemental cost-sharing portion of Part B drugs in rheumatology, so it is likely that a majority of patients might not benefit from reduced out of pocket expense in the model.
- If a vendor system were to be finalized, CMS would need to increase provider reimbursement to pay for the additional expense of working with vendors such as: arranging orders, accepting delivery, processing patient-specific paperwork with protected health information, changing inventory practices, and paying new vendor fees and collecting patient cost-sharing on behalf of vendor(s). Those costs may exceed the bump from ASP + 4.3% to ASP + 6%.
  - We urge CMS to ensure the current level of patient access to medically-necessary treatments by allowing providers who have to work with third-party vendors for Part B drugs the ability to change the dose, frequency, and date of administration of a medication. These providers must also be able to stop a medication and start a new medication with minimal administrative work and threat of audit, in order to respond to patient-specific changes such as infection, surgery, disease activity, adverse effects, and patient-specific barriers to keeping appointments (e.g., transportation).
  - We caution CMS that the way in which drug inventory is managed and changed by this model could substantially increase the amount of drug wasted and cost of overhead management. (This is currently noted in cases of so-called “brown-bagging” and “white-bagging” of drug from specialty pharmacies.) This possible unintended consequence must be factored into costs and/or reimbursements to model participants.
  - Allow entities to become vendors without requiring them to work nationally or provide a certain formulary, so that practices that provide Part B drugs could consider becoming vendors themselves.
  - Provider-vendors could enhance marketplace competition and incentivize larger vendors such as distributors, pharmacies, etc., to reduce provider administrative burdens and fees, while preserving access to treatments currently being provided under "buy and bill" system.

- Consider the financial risk and administrative burden to physicians.
  - The component of the model in which providers of Part B drugs receiving drug from third-party vendors would be responsible for collecting patient cost-sharing payments could cause serious financial risks and administrative burdens to practices and patients.
  - **The ACR opposes any increased risk to patients and practices** and instead suggests that third-party vendors collect patient cost-sharing, or pay providers fees (or waive aforementioned fees) for the favor of cost collection.
- Modify the practice reimbursement during phased price reduction to the extent of CMS authority.
  - Instead of lowering reimbursement as ASP reduces, the model instead should increase reimbursement based on an acceptable inflation index. This will allow providers to continue to cover the overhead costs of the terminal aspects of drug distribution listed above, which undergo inflation, in order to maintain patient access to treatments.
  - Similarly, protect reimbursement of practices that are outside the model, for which reimbursement for services may be reduced if ASP is reduced nationwide.
  - If CMS were to consider a flat fee buy and bill option for similar drugs sharing common indications, we would advocate that it be indexed to inflation for the reasons noted above.
  - Because of the complex array of new costs inherent in a third-party vendor program (that removes a buy and bill option) coupled with the loss of control over the terminal aspects of drug distribution, the use a flat fee within such a program could be a strong disincentive for providers and keep them from participating. Therefore, CMS should seriously reconsider the use of a flat fee within a third-party vendor program.
- Enhance the model by tracking the impact on patient access, including access to Part B drugs, adherence to prescriptions, amount of out of pocket costs, and disease outcomes (disease activity, progression, or prevention - e.g. fracture prevention).
  - These would likely be new outcome measures and practices that choose not to be in the model should be reimbursed in some way for submitting these measures. This could include not counting Part B drug costs in the MIPS cost domain or added points to the overall MIPS score.

Given that the model proposal is predicated on the notion that the current system incentivizes providers to prescribe more expensive medications within Part B, consider exemptions from the model for segments of the market (specific drug class indication pairings) where the ASP price is very similar. Some protections may be needed to ensure an incentive for existing manufacturers to lower price as well as new market entrants to start with a lower price. Finally, the ACR is dedicated to ensuring that rheumatologists and the rheumatology interprofessional team have the resources they need to work with CMS

and provide patients with high-quality care. Overall, we believe that for CMS, clinicians, and patients to all achieve their objectives, payment programs must be designed to reflect the way practices treat patients.

The American College of Rheumatology appreciates the work CMS does and the opportunity to respond to this advance notice of proposed rulemaking. We look forward to serving as a resource to you and to working with the agency as you consider ways to reduce high drug costs and increase patient access to the treatments they and their providers prescribe. Please contact Kayla L. Amodeo, Ph.D., Director of Regulatory Affairs, at [kamodeo@rheumatology.org](mailto:kamodeo@rheumatology.org) or (202) 210-1797 if you have questions or if we can be of assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "P. Marchetta", with a long horizontal flourish extending to the right.

Paula Marchetta, MD, MBA  
President, American College of Rheumatology