April 8th, 2019

Department of Health and Human Services
Office of Inspector General
Attention: OIG-0936-P
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Submitted Via: https://www.regulations.gov/


Dear Ladies and Gentlemen:

The American College of Rheumatology (ACR), representing over 9,500 rheumatologists and rheumatology inter-professional team members, appreciates the opportunity to provide input on the Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees proposed rule. Rheumatologists provide care for millions of Americans, both adults and children, and are the experts in diagnosing, managing and treating arthritis and rheumatic diseases. These life-long, chronic conditions include rheumatoid arthritis, systemic lupus erythematosus, and vasculitis, among many others. Rheumatic diseases and arthritis are the leading cause of disability in the United States. Early and appropriate treatment by a rheumatologist is vital to controlling disease activity, preventing and slowing progression, improving patient outcomes, and reducing the need for costly downstream procedures and care. Rheumatologists practice in every state, the District of Columbia, and Puerto Rico, and in all communities, both urban and rural. They provide critical care for people with diseases that can be crippling, life-changing, and life-threatening.

The ACR is pleased to see the administration put a focus on transparency, access, and affordability. We are supportive of polices that will make life-changing treatments more readily accessible for rheumatology patients. We agree that higher negotiated prices lead to higher beneficiary cost-sharing, and we support CMS developing policy that would reduce beneficiary out-of-pocket costs, improve price transparency, and increase market
competition in the Medicare program. We are generally supportive of the ideas put forward in this proposed rule. However, we do have several concerns and recommendations regarding the policy proposals, including what impacts they may have on patients’ premiums, plan designs, and cost-sharing. Further, we are requesting more clarity regarding how the mechanism for passing rebates savings to patients at the point of sale would work in reality.

**Discounts and Definitions**

This proposed rule would amend the discount safe harbor at 42 CFR 1001.952(h) by adding an explicit exception to the definition of “discount.” As a result of this exception, certain price reductions on prescription pharmaceutical products from manufacturers to plan sponsors under Medicare Part D and Medicaid Managed Care Organizations would not be protected under the safe harbor. This proposal would also create a new safe harbor designed specifically for price reductions on pharmaceutical products, but only those that are reflected in the price charged to the patient at the pharmacy counter. Additionally, the proposed rule would protect certain flat fees which pharmaceutical manufacturers pay to PBMs for services.

We believe reevaluating and updating the current safe harbor is necessary, especially as the discount safe harbor has not been updated since the establishment of the Medicare Part D program. The health care market has changed drastically since that time. Along with better defining “discount”, we believe there should be additional contract standards and clear consistent definitions applied to the ways in which money flows into PBMs. The establishment of definitional agreement and consistency provides the foundation of most other policy solutions. **Therefore, we also urge the agencies to create common definitions of “rebate”, “fee”, and any other terms a PBM may use.** This will improve transparency in the drug pricing system and clarify federal and state regulation.

We also ask for more clarity regarding the mechanisms that would allow patients to receive point of sale rebates. Because the rebates to patients would happen at the pharmacy counter, we ask that the agencies evaluate and ensure that the proper channels are in place for data sharing (i.e. patient-level specific data that will need to come from the plans). **We urge the agencies to ensure that this proposed rule does not increase the time it takes for payments and products to move through the supply chain, thereby increasing the time it would take for a patient to receive a vital medication.** Additionally, if this proposal is finalized, we encourage the department to move forward with issuing separate guidance to clarify the treatment of pharmacy chargebacks in calculation of AMP and Best Price. We also believe this rule opens the door for new models in the supply/payment system. **We ask that the agencies closely monitor the marketplace for unintended consequences, such as new entities forming additional 3rd party clients or**
adding middlemen. Such additions serve to create greater confusion and complicate a system which the agencies and public seek to simplify and make more transparent.

**Behavioral Changes in the Marketplace**
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.

While newer biologic medications have brought about improved control of disease, especially in those with severe disease, the cost of these interventions is notably higher and rising yearly. It appears that the incentive for manufacturers to offer rebates on drugs increases the pressure to raise list prices. There is clear evidence of list prices escalating, and yearly price hikes have dramatically outpaced inflation despite the lack of clinically significant modifications to medications or major changes in production processes. The overall process of pricing and contracting is hidden from public view, such that the exact nature and profit margin taken by those involved is not disclosed to the largest stakeholder in this process—the patient. These dramatic increases in the cost of essential medications, together with the lack of competition for the most expensive medications and the changes in the private insurance landscape across the United States, have left many patients struggling to afford the necessary treatment for their disease.

This proposed rule is based on the premise that behavioral changes in the marketplace to reduce drug prices and Medicare spending will occur. While we encourage more transparent drug negotiations, reduced list prices of drugs, and lower patient out of pocket costs, we are concerned that changes could occur in the marketplace that would negatively impact patients. For example, we are concerned about the impact on formulary design and the cost-sharing to which patients may be subjected. **We encourage the agencies to ensure the proposed rule will actually save patients money and not shift costs to other parts of the system. Implementing additional safeguard policies will help ease this concern.** Further, we are concerned that there are no proposed policy changes that would require changes on the part of drug manufacturers. We urge the agencies to consider comprehensive policy options that would require PBMs, payers, and manufacturers to make changes that lead to reduced drug prices and out of pocket costs for patients. **The ACR encourages polices that support transparency throughout the system in a comprehensive manner. We believe a firm grasp and clear understanding of how much rebates factor into list prices of drugs is needed.**
Beneficiary Impact
In the past, the ACR has publicly urged the agencies to institute policies that require PBMs to be more transparent about their payment practices, including the true cost of prescription drugs. Providing this transparency is necessary to objectively evaluate the efficacy of drug pricing and utilization policies. We have also long encouraged policies requiring more uniformity or standardization in the ways that PBMs structure and convey their rebate programs. These policies must include requirements for providing uniform definitions of the terms used in disclosures and for specifying what constitutes a rebate versus a discount, versus a fee, versus any other payments received from a manufacturer. While we are pleased to see the agencies focusing on these areas, we remain concerned about the potential impact of the current proposed regulation on patient costs and ability to afford their medications.

The Office of the Actuary (OACT)\textsuperscript{ii} estimates a 3\% to 8\% premium increase for beneficiaries and savings of 4.6\% to 8.4\%. According to OACT, beneficiary costs would decrease on average, but the majority of beneficiaries would see an increase in their total OOP and premium costs. Most of savings would be derived from the minority of beneficiaries who utilize drugs with significant manufacturer rebates; this minority group would experience a substantial decrease in costs, and be responsible for average beneficiary cost declining across the program. The Office of the Assistant Secretary for Planning and Evaluation (ASPE) contracted Wakely Consulting Group, LLC (Wakely)\textsuperscript{iii} to provide an analysis of the impact of this proposed rule. Wakely estimates that the average beneficiary would have a premium increase of approximately 8\%, and average beneficiary cost sharing would be reduced by approximately 9.5\%. Wakely estimates that the net effect for beneficiaries would be a 2\% reduction in out-of-pocket expenses. Milliman\textsuperscript{iv} found that there would be overall cost savings on average driven by lower cost sharing and partially offset by higher premiums. However, they note that savings are not uniform and individual members would be impacted differently depending on their pharmacy spend levels.

In every analysis premium increases occur. We understand that these increases may be offset by other cost-savings and hope that beneficiaries who currently have higher costs due to chronic diseases such as RA see reduced costs. But we are cautious to support policies that would significantly raise premiums for those beneficiaries who do not benefit from a decrease in cost-sharing because any cost-savings related to certain prescription medications does not apply to them. We encourage the agencies to ensure that any increase in premiums results in fair cost savings for all Medicare beneficiaries and does not lead to a person’s inability to access care due to a rise in premium costs without a concomitant drop in cost-sharing. The ACR urges the agencies to also consider how patients will be impacted differently depending on the plan they are enrolled in, the medications they are taking, and whether they are eligible for some cost-sharing assistance. Plans should make explicitly
clear to beneficiaries the impacts on their coverage as a result of any changes in formularies, cost sharing, premiums, and utilization management requirements. Beneficiaries should also be afforded the opportunity to switch plans if the impact of the proposed rule would limit their access to treatment.

Additionally, we are concerned that in order to achieve overall savings, beneficiaries may see impacts to utilization management requirements, formulary coverage, and plans offered. Having guardrails in place to protect patients who are currently stable on a medication will be paramount. We ask that the agencies provide additional patient safeguards much like the ones the ACR suggested in our [comments](#) on the *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses* proposed rule. There is a potential that this proposed rule could cause significant disruptions in the system due to changes in plan designs and result in a reduction in beneficiary access due to an increase in utilization management such as step therapy or prior authorization.

**We request the agencies make the following explicitly clear:**

- That the provider determines if a patient “fails” a treatment, not another entity such as the insurance company.
- Exception if the treatment is contraindicated.
- Exception if the provider determines the treatment is likely to be ineffective.
- Exception if the provider determines the treatment is likely to cause a harmful reaction.
- Exception for those whose life could be in jeopardy or physical or sensory function irreparably harmed.
- Exception if the provider and patient believe the treatment is likely to impede the patient's ability to perform daily activities or responsibilities and/or adhere to the treatment plan.
- Preclude any unwritten, implicit step therapy that is handled through a different utilization management process such as prior authorization.

**Additional Regulations**

Care of those living with rheumatic disease takes place in a wide spectrum of practice settings, from solo or small practices to large hospital-based systems. As policy is developed to help slow health care expenditures, caution must be exercised to minimize the disruption in the patient-provider relationship across these settings. Any changes that are considered should always take into account the financial impact on the patient. We are also concerned that there are several proposed and planned regulatory proposals
anticipated in the coming years. We worry that there may be several unintended consequences of all of these policies happening at the same time. **We ask that the agencies consider how upcoming proposed changes could interact with this proposed rule as well as the timing of current and future proposals.** To the extent that this proposed rule would delay patient care by implementing it in January 2020, along with several other changes to the Part D program, we would be in favor of a slower implementation timeline.

The ACR is dedicated to ensuring that rheumatologists and rheumatology interprofessional team members have the resources they need to work with regulatory agencies and provide patients with high-quality care. The ACR believes that safe and effective treatments should be accessible to all patients at the lowest possible cost. We support policies rooted in scientific evidence that support shared decision-making between patients and providers and that decrease barriers to patients accessing treatment.

The American College of Rheumatology appreciates the work that the agencies do and the opportunity to respond to this proposed rule. We look forward to being a resource to you and to working with the agency. Please contact Kayla L. Amodeo, Ph.D., Director of Regulatory Affairs, at kamodeo@rheumatology.org or (202) 210-1797 if you have questions or if we can be of assistance.

Sincerely,

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

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