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April 4, 2019

Daniel R. Levinson
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

RE: RIN 0936-AA08; OIG-0936-P ("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")

To Whom It May Concern:

The Coalition of State Rheumatology Organizations (CSRO) is comprised of a group of state and regional professional rheumatology societies throughout the country formed to advocate for excellence in rheumatologic disease care and to ensure access to the highest quality care for the management of rheumatologic and musculoskeletal diseases. Our coalition serves the practicing rheumatologist in charge of patient care for these illnesses.

The products we prescribe are often expensive biologic agents. As such, we are keenly aware of the rising out-of-pocket burdens on our patients. All too often, these burdens are prohibitive and result in patients rationing their medications or abandoning treatment altogether. We thank the Administration for its attention to this critical issue and its various proposals to help lower the cost of drugs for patients.

In commercial plans, including Medicare prescription drug plans, pharmacy benefit managers (PBMs) receive rebates from pharmaceutical manufacturers. These rebates are paid to obtain formulary placement. Presently these rebates have "safe harbor" protection in the antikickback statute, but the above-referenced regulation proposes to change that. If finalized as proposed, the regulation would result in rebates from manufacturers to PBMs being considered illegal kickbacks. Thus, these payments would end, which is a positive step towards a more rational drug pricing system, for the reasons explained below.

The current system disadvantages patients, both financially and clinically. As the proposed regulation notes, a patient's coinsurance is often based on the list price, which does not reflect the rebates paid by the pharmaceutical company to the PBM. The PBMs argue that these rebates result in lower premiums, however, the regulation notes that any premium reduction for Medicare beneficiaries may be lower than it should be, due to payers under-estimating their expected rebates when they formulate their premiums for the upcoming year. Thus, beneficiaries see no benefit with regard to their out-of-pocket costs and a smaller benefit than they are entitled to with regard to their premiums. Additionally, if premiums do rise, the reduction in cost sharing for beneficiaries' medications should more than offset the nominal rise that would take place.

Moreover, the rebating system may result in preferred formulary placement for more expensive products, in cases where less expensive options are available. Here too beneficiaries are disadvantaged, as their plan design may drive them towards more expensive treatment options despite the fact that these options have no clinical benefit over cheaper alternatives. This is the case because the perverse incentives inherent in the rebate system result in formularies being designed based on financial considerations for the PBM, rather than clinical data or financial considerations for the patient. Drugs obtain favorable formulary placement if they provide a big rebate, not because they are clinically superior or cost effective for the end user – the patient.

Our rebate-centered system also drives up list prices. The list price is the starting point for negotiations and the PBM favors the product with the biggest rebate potential. Thus, a product with a lower list price starting point will not be preferred by the PBM. If a manufacturer lowers its list price, the size of the potential rebate will be smaller as well, resulting in that product being placed in a less advantageous formulary tier. As the proposed regulation states, this system is a "potential barrier to lowering drug costs."

In addition to eliminating rebates to the PBMs, the proposed rule creates a "safe harbor" incentive for pharmaceutical manufacturers to provide discounts straight to the patient at the point-of-sale. While the rule does not contain a requirement for manufacturers to provide discounts, the Administration expresses its expectation that the proposed regulation in its entirety will result in a move away from retroactive rebating, towards up-front discounting. We fully support such a transition.

The additional "safe harbor" created for flat fees to PBMs will potentially eliminate administrative fees that are tied to the list price of the drug. We trust that there will be monitoring to make certain that PBMs are not "reclassifying" rebates as administration fees based on the list price. We urge OIG to remain vigilant to ensure that other fees charged by PBMs to manufacturers do not become tied to formulary placement.

The proposed regulation provides widely ranging estimates of the potential financial impacts on beneficiaries and federal programs. The regulation acknowledges it is difficult to predict the

behavioral responses by manufacturers and other stakeholders. The most likely scenario is that all beneficiaries will experience a small premium increase and that beneficiaries with high drug costs will experience significant savings in their out-of-pocket cost-sharing obligations. This is a needed change for the current system, where most of the rebate payments are pocketed by middlemen and the remainder is used to reduce premiums for all yet disadvantages those with high out-of-pocket drug costs – effectively leveraging the sick to support the healthy.

As explained above, if the proposed rule is finalized, a large revenue stream for PBMs will end. We urge HHS to ensure that the plans do not respond by cutting costs in ways that exacerbate the already extensive utilization management restrictions. Particularly, we urge the agency to ensure that PBMs do not unduly limit product choice for patients, whether that is through allowing only one or two products per class on formulary or through making the out-of-pocket costs for patients so prohibitive for some products that it amounts to a *de facto* denial of those products. Plans must not be allowed to cherry pick patients by preventing chronically ill beneficiaries from signing up due to an overly restrictive formulary.

For these reasons, we support the elimination of rebate payments from pharmaceutical companies to PBMs and insurers. The harm done by this system is not unique to federal programs, and we urge the Administration to reach beyond Medicare and Medicaid to outlaw these payments in all markets. Should you have any questions or require additional information, please contact Dr. Madelaine Feldman, President of CSRO, at madelainefeldman@gmail.com.

Sincerely,

Alaska Rheumatology Alliance
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Coalition of State Rheumatology Organizations
Colorado Rheumatology Association
Connecticut Rheumatology Association
Florida Society of Rheumatology
Kentuckiana Rhematology Alliance
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Metro Atlanta Rheumatology Society
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