July 24, 2019

The American College of Rheumatology (ACR), representing over 9,500 rheumatologists and rheumatology interprofessional team members, appreciates the opportunity to provide feedback on The Prescription Drug Pricing Reduction Act (PDPRA) of 2019. Rheumatologists provide care for millions of Americans and are the experts in diagnosing, managing and treating arthritis and rheumatic diseases. These lifelong, 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. Reducing high drug costs and improving patients’ access to treatments are top priorities for the ACR.

The ACR is pleased to see Congress 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 and agree that high drug prices are a factor limiting patients’ access to treatments. The ACR supports policies that would reduce beneficiary out-of-pocket costs, improve price transparency, and increase market competition in the Medicare program, and we appreciate the legislation’s language that appears to improve patient out-of-pocket cost sharing for most patients in Medicare Part D. We are generally supportive of the transparency and oversight proposals put forward in the PDPRA. However, we have significant concerns regarding some of the proposals that would implement changes to Average Sales Price (ASP) policy and affect patient access to Part B drugs.

The ACR believes strongly that safe and effective treatments should be available to patients at the lowest possible cost and we believe biosimilars offer the opportunity to bring costs down. We value the legislation’s support of biosimilars, for the purposes of improving patient access to treatments. While we appreciate the idea of increasing provider reimbursement to ASP +8% for a period of 5 years to spur biosimilar uptake, and this increase in payment might be justified by the work needed to educate patients about biosimilars, we do not agree with the argument that prescribing behavior is influenced by monetary incentives and therefore have doubts that the increase would be effective.

The ACR believes that rheumatologists, like other physicians, are motivated by the best interests of their patients, not by the financial incentives in the reimbursement system. Like
other physicians, we cannot control the cost of drugs or the costs of acquiring drugs and infusing them for our patients – especially when we have limited treatment options from the outset. We believe biosimilar uptake could improve if polices align provider reimbursement and patient copayment.

Physicians who administer in-office drugs under Medicare Part B are already not receiving the full Average Sales Price (ASP) plus 6% that was mandated in the MMA 2003 legislation due to a flaw in the formula used to calculate ASP. As a result of the budget sequestration of 2013, payments of Part B covered drugs have been reduced by 1.6% to a total of ASP plus 4.3%, creating a small margin that often does not cover actual costs of handling and storage. We are further concerned that sequestration has not been addressed and encourage the Committee to consider revising sequestration along with these proposals. Also, discounts and rebates further decrease reimbursement on infusion drugs to an average of only 1-2% above the acquisition cost rather than the intended 6%. Many of these discounts benefit insurance companies and wholesale distributors, but not the physician or the patient.

Additionally, we are uncertain if the proposed maximum add-on payment of $1000 will cover all the expenses of acquisition, storage, refrigeration, tracking, cataloging and accounting, and handling of a drug as well as risk of loss or non-payment. We would like time to assess if this number would be appropriate for Rheumatologists. We would also like transparency around the methodology used to arrive at the current number. If there is a cap placed on the add-on payment it must cover all the services required to maintain access to treatments as noted above. We also believe this add-on payment must rise with inflation as costs rise and should be re-evaluated each year instead of re-evaluated after the proposed seven years (2029).

We have further concerns that changes to the ASP calculation regarding patient coupons could create unintended consequences for patient access. Because coupons currently play a critical role in maintaining access to treatment for commercially-insured patients, they should not be disincentivized until another coverage system is available to those patients. Additionally, and just as important, given the current small margin of reimbursement to providers for Part B drugs, significant changes in ASP that could come about from these policies could create a situation in which ASP reduces drastically, but the actual prices of drugs do not decline. In this situation, the provider would be unprotected from being financially underwater when acquiring and administering Part B drugs, and patients would lose access to treatment from those providers.

These changes could threaten the viability of rheumatology practices in the United States. As a result, many rheumatologists could stop providing these treatments because the payment rate does not cover their actual costs. With limited access to in-office treatments, patients will suffer and could be forced to seek treatment in hospitals with higher copayments, higher facility fees, longer travel times, and without their physician’s supervision, thereby unnecessarily increasing healthcare costs and burdens on patients and the health care system.
We appreciate your leadership and extensive work to address the exorbitant cost of drugs in this country as well as your offices’ open-door policy to work on these issues. We hope that you will consider our concerns and continue to use the American College of Rheumatology as a thoughtful resource moving forward.

Sincerely,

[Signature]

Angus B. Worthing, MD
Chair, Government Affairs Committee
American College of Rheumatology