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Coalition of State Rheumatology Organizations

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555 E. Wells Street, Suite 1100
Milwaukee, WI 53202-3823
Phone: 414-918-9825
Email: info@csro.info
Website: www.csro.info

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Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715
comments.pdab@maryland.gov

Re: New Chapter - COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits)

Members of the Maryland Prescription Drug Affordability Board:

The Coalition of State Rheumatology Organizations (CSRO) would like to share concerns regarding COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits), which implements a process for establishing an Upper Payment Limit (UPL) on medications selected by the Board. CSRO serves the practicing rheumatologist and is comprised of over 40 state rheumatology societies nationwide with a mission of advocating for excellence in the field of rheumatology and ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease.

Rheumatologic disease is systemic and incurable, but innovations in medicine over the last several decades have enabled rheumatologists to better manage these conditions. With access to the right treatment early in the disease, patients can generally delay or even avoid damage to their bones and joints, as well as reduce reliance on pain medications and other ancillary services, thus improving their quality of life.

06. Policy Review – Process for Establishing a UPL
The Board has identified a robust set of methodologies and factors to establish the UPL. We respectfully share concerns with the following criteria:

Therapeutic Class. In setting the UPL to the lowest net price among all competitor products within the same therapeutic class, the Board will significantly disrupt the market by arbitrarily cutting the most expensive products while still allowing products in the median to remain at market value. We fear this may cause manufacturers to limit the availability of the medications impacted by the UPL. This has ripple effects throughout the system, such as driving medication shortages, which the Board has recognized in its proposal.

Therapeutic class refers to all drugs that are indicated to treat a certain disease state. Within this class there can be many different mechanisms of action (MOA) for how the drug works. Assuming that patients can just "switch" to another medication that is indicated for their condition clearly ignores the fact that "how" a medication works (MOA) is just as important as to "what" condition the medication treats. Rheumatologic patients often require a highly personalized approach as we manage their chronic illnesses. This could be extremely harmful to patients who only respond to a certain mechanism of action which is now no longer available, even though there are other drugs in the same therapeutic class still available, but not helpful for their condition.

Domestic Reference. In setting the UPL to the Medicare Maximum Fair Price (MFP), the Board risks patient access as MFP is likely to under reimburse for physician administered medications. (It's important to note that the first set of MFP drugs was just selected, and implications of the program are not yet realized.) We have serious concerns that MFP will not properly account for acquisition costs of providers who "buy and bill" physician administered medications. If MFP based reimbursement drops below acquisition costs for selected drugs, independent medical practices, as well as free standing infusion centers and some hospitals, may stop offering the selected drugs until acquisition costs can meet reimbursement levels, further driving state-based drug shortage concerns and total lack of access for patients requiring that particular medication with its particular mechanism of action.

International Reference. In setting the UPL to the lowest price paid by the United Kingdom, Germany, France or Canada, the Board neglects to recognize that the pharmaceutical supply chain operates very differently in these countries than it does in the United States. The most notable difference is that pharmacy benefit managers (PBM) do not play a role in formulary construction and drug pricing in the included countries. In the United States, PBMs incentivize higher prices by choosing drugs with higher list price for preferred placement as their revenue is based on a percentage of list price. Conversely, formulary construction in the other suggested countries is completely different, with placement often based on "lowest price". We believe it is ill advised to reference these international prices when those prices are set in a way that is so vastly different than the U.S. market.

Furthermore, we encourage the Board to adopt criteria that require any UPL to also account for healthcare provider acquisition costs – including, but not limited to, intake and storage, equipment and preparation, staff, facilities, and spoilage insurance – so that healthcare providers are not responsible for personally funding the difference in healthcare costs and expenditures.

Physician Administered Medications: Rebate Proposal

The UPL currently caps provider reimbursement for a prescription drug consistent with the rate determined by the Board. It does not, however, require that providers acquire the medication at a rate sufficiently below the UPL to account for acquisition costs to the provider. To maintain the viability of administering drugs in cost-effective outpatient settings, reimbursement must account for acquisition costs, such as intake and storage, equipment and preparation, staff, facilities, and spoilage insurance. Reimbursement rates that do not sufficiently compensate for these costs put healthcare practices at risk. Furthermore, if patients are unable to receive their medications in outpatient settings, they will be forced to receive provider administered care in hospital settings, which are more expensive to the payer and to the state.

During several PDAB meetings, Executive Director York has stated that "the framework that we're putting forward… won't change reimbursement amounts to the supply chain. It's all done kind of on the back end through rebates on reconciliation."[1] While we are encouraged that the state intends to make healthcare practices that directly administer medications on an outpatient basis whole, we are concerned that none of the proposals to date have outlined this practice or even mentioned a rebate model. We urge you to immediately release Draft Proposed Regulations for Comment on this rebate model.

We appreciate your consideration, and we are happy to further detail our comments to the Board upon request.

Respectfully,

Gary Feldman, MD, FACR
President
Board of Directors

Madelaine A. Feldman, MD, FACR
VP, Advocacy & Government Affairs
Board of Directors

[1] Legislative Policy Committee. "Review of the Upper Payment Limit Action Plan approved by the Prescription Drug Affordability Board." October 22, 2024. Time: 44:20