CSRO
Coalition of State Rheumatology Organizations

BOARD OF DIRECTORS

Gary Feldman, MD
President

Madelaine Feldman, MD
VP, Advocacy & Government Affairs

Michael Saitta, MD, MBA
Treasurer

Aaron Broadwell, MD
Vice President & Secretary

Erin Arnold, MD
Director

Leyka Barbosa, MD
Director

Kostas Botsoglou, MD
Director

Michael Brooks, MD
Director

Amish Dave, MD, MPH
Director

Harry Gewanter, MD, MACR
Director

Adrienne Hollander, MD
Director

Firas Kassab, MD
Director

Robert Levin, MD
Director

Amar Majjhoo, MD
Director

Gregory Niemer, MD
Director

Joshua Stolow, MD
Director

EXECUTIVE OFFICE

Ann Marie Moss, MBA, CAE
Executive Director

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

August 26, 2024

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

Re: Setting Upper Payment Limits

The Coalition of State Rheumatology Organizations (CSRO) is comprised of nearly every active state rheumatology society in the nation, representing over 40 states, with a mission of advocating for excellence in the field of rheumatology, ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease. Our coalition serves the practicing rheumatologist.

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.

The Board is tasked with setting "an upper payment limit in a way to minimize adverse outcomes and minimize the risk of unintended consequences." It is with this in mind that we write to express concerns regarding unintended consequences of the Board's plan of action for implementing a process for setting upper payment limits. We fear this proposal may actually drive up the cost of physician administered medications instead of making them more affordable for patients, while simultaneously causing significant financial strain on physician practices throughout Maryland.

Physician Administered Medications

We appreciate that the Board has recognized the importance of considering "the cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs (HG § 21-2C-13(b))" when establishing an upper payment limit (UPL). This is critically important to healthcare providers who directly administer medications to their patients, as the UPL places these providers at significant risk if they are not able to cover acquisition costs for these medications.

As currently drafted, the UPL 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. This is highly problematic for healthcare providers who administer medications directly to patients in outpatient settings.

Healthcare practices that directly administer medications on an outpatient basis are typically engaged in a practice known as "buy and bill." These practices pre-purchase drugs and bill a payer for reimbursement once the medication is administered to a patient. Margins for practices engaged in buy and bill are thin. To maintain the viability of administering drugs in these setting – which are often more cost-effective settings

for the payer and safer for immunocompromised patients – reimbursement must account for acquisition costs, such as intake and storage, equipment and preparation, staff, facilities, and spoilage insurance.

Currently, most payers reimburse providers for the cost of the medication plus an add-on payment at a bundled rate to cover the acquisition costs and make provision of service economically viable. Reimbursement rates that do not sufficiently compensate for these costs put healthcare practices at risk. Unfortunately, the UPL outlined in the Board's proposal would prevent healthcare providers from collecting this add-on payment, making it untenable for healthcare providers in outpatient settings to administer medications that are subject to the UPL. 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.

Pharmacy Dispensed Medications

The Board has recognized that "a UPL may not be the preferred policy solution for every affordability challenge," and is therefore granted the authority to recommend other policy actions. While the Board has placed a strong emphasis on prices and costs associated with the initial steps in the pharmaceutical supply chain, it is important to note that many pharmacy benefit plans are utilizing a variety of programs that undermine the effectiveness of programs created to keep patient costs down, such as copay assistance programs. These plans, organized by pharmacy benefit managers (PBMs), are contributing significantly to patient out-of-pocket costs, driving unaffordability.

We encourage the Board to consider the role PBMs play in driving up the cost of prescription medications. If the Board pursues a UPL without any guardrails in place for the PBMs, it is likely that these middlemen will manipulate the formularies so that these newly priced drugs are put on a much higher tier, and therefore less accessible to patients. PBM business practices favor higher priced drugs because they have the potential to hear more off those medications. We strongly encourage the Board to consider mechanisms that will ensure that drug placement on the formulary remains consistent even after a UPL is implemented.

UPL Criteria

The Board has identified a robust set of methodologies and factors to establish the UPL. We respectfully have concerns with the use of several of the proposed.

Therapeutic Class. In setting the UPL to the lowest net price among all competitor products, the Board will significantly disrupt the market by arbitrarily cutting the most expensive product 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. But it also hurts patients who may respond better to certain medications over others. Rheumatologic patients often require a highly personalized approach as we manage their chronic illnesses. All patients will not be able to manage their conditions optimally if forced to switch to an alternate medication with the therapeutic class.

Small Molecule Reference. In setting the UPL to the lowest priced product with the same molecule, the Board may unintentionally limit access to biologic and biosimilar products. These complex medications are often administered by healthcare providers to patients with chronic conditions. When biosimilars were brought to the market, we hoped they would offer a more cost-effective alternative to brand biologics. Unfortunately, pharmacy benefit managers (PBMs) have created perverse incentives around formulary placement that have caused manufactures to over rebate their drugs for preferred placement, which has in turn led to a precipitous drop in the average sales price and ultimately slashed reimbursement rates. Most rheumatology practices across the country are underwater due to insufficient biosimilar reimbursement, threatening patient access. In creating a UPL based on small molecule reference, the Board may unintentionally exacerbate this problem and limit patient access to these biologic and biosimilar medications.

Domestic Reference. In setting the UPL to the Medicare Maximum Fair Price (MFP), the Board risks patient access as MFP is likely to under reimbursed 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 yet realized.) Much like our comments above, we have serious concerns that MFP will not properly account for acquisition costs. If MFP based reimbursement drops below acquisition costs for selected drugs, medical practices will suffer financial instability and may stop offering the selected drugs until acquisition costs can meet reimbursement levels.

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 PBM middlemen do not play a role in drug pricing in the included countries. Therefore, formulary construction is completely different. We believe it is ill advised to reference these international prices when the way in which those prices are set 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.

Actual Out-of-Pocket Costs

CSRO believes it is important for the Board to consider typical out-of-pocket expenses for patients when considering whether the drug should be assigned a UPL. Copay assistance programs are designed to defray cost-sharing amounts charged to the patient by the plan for their prescription drug. These programs cover most or all of the patient's cost-sharing responsibility through a direct payment at the point of sale in order to enhance affordability for patients.

We recognize that high priced drugs that do not offer copay assistance are a real financial threat to patient access, which has become more prevalent among some generic medications. However, when copay assistance programs are offered, the patient will typically pay between $0 to $25 at the pharmacy counter for their medication. Copay assistance programs also help defray costs associated with administration for the provider administered formulation, making the copay assistance program particularly generous. While a drug's cost in a vacuum may induce sticker shock, these costs are almost never what a patient actually pays for a drug at the end of the day. We encourage the Board to consider actual patient out-of-pocket costs when reviewing medications.

We appreciate the Board's consideration and are happy to provide further insights to these comments as the Board considers its recommendations to the state legislature.

Respectfully,

Gary Feldman, MD, FACR
President
Board of Directors

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