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

Leslie Del Ponte
Executive Director

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

October 15, 2024

Colorado Prescription Drug Affordability Board
Colorado Division of Insurance
1560 Broadway, Suite 850
Denver, CO 80202
dora_ins_pdab@state.co.us

Re: CO PDAB – Prescription Drug Affordability Board 3 CCR 702-9; Policy 04 - Affordability Review Policy and Procedure Date

Members of the Colorado Prescription Drug Affordability Board:

The Coalition of State Rheumatology Organizations (CSRO) appreciates the opportunity to provide feedback on the recent draft edits *Prescription Drug Affordability Board 3 CCR 702-9* and *Policy 04 - Affordability Review Policy and Procedure Date*. 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.

It is with this in mind that we write to express concerns and share recommendations on how the Board can best protect patients by ensuring access to the medications that treat rheumatologic and musculoskeletal disease.

Evaluating the Availability of Patient Assistance Programs

During the CO PDAB Stakeholder Meeting, CSRO offered recommendations on opportunities to improve the red line drafts and recognize the availability of patient assistance programs. We appreciate the PDAB staff's receptiveness to our recommendations and inclusion of edits that explicitly require evaluation of patient assistance programs, including rebates and coupons, and their influence on patient out-of-pocket costs. These patient 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. The recent language improvements will better allow the PDAB to recognize the role patient assistance program play in determining the patient's true out-of-pocket cost for mediations.

Therapeutic Alternatives are Not Appropriate Substitutions

CSRO urges the Board to recognize that not all therapeutic alternatives are therapeutically equivalent, having drastically different clinical outcomes for patients. When healthcare providers are evaluating medication substitutions, they typically consider therapeutic *equivalents* – not alternatives. Therefore, we strongly recommend that the PDAB adopt these clinical practice standards and update the draft throughout

recognizing that only therapeutic equivalents are clinically appropriate to consider for substitution.

Deeming medications "therapeutic alternatives" is a one-size fits all approach that disrupts the physician's ability to exercise their medical expertise in concert with their patient. Patients that suffer from complex chronic conditions, such as rheumatoid arthritis and other rheumatologic diseases, require continuity of care to successfully manage their condition. Patients may spend months or years of trial and error, working with their physician to find a treatment regimen that properly manages their condition. The resulting course of treatment must carefully balance each patient's unique medical history, co-morbid conditions, and side-effect balancing drug interactions. For example, studies have highlighted how patients at high risk for certain infections (TB, histoplasmosis, coccidioidomycosis) should receive a biologic over the monoclonal antibodies, whereas patients with RA inflammatory eye disease should get the monoclonal antibody over the biologic for optimal disease management.

Even slight deviations in treatment and variations between drugs, even those in the same therapeutic class, can cause serious adverse events. Aside from the needless suffering endured by the patient as they work with their physician to find the right course of treatment, any disease progression caused by a delay in appropriate treatment can be irreversible, life threatening, and cause the patient's original treatment to lose effectiveness. The Board cannot assume that a treatment that works for one patient will work for every patient.

Impact of the UPL for Physician Administered Medications

While unedited within the proposed drafts, we must implore the Board to reconsider its application of an Upper Payment Limit on physician administered 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. To maintain the viability of administering medications in outpatient settings – 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.

Furthermore, we encourage the Board to consider the role Pharmacy Benefit Managers (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.

We appreciate the Board's consideration and are happy to provide further insights into these comments at your convenience.

Respectfully,

Gary Feldman, MD, FACR
President
Board of Directors

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