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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

September 30, 2024

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

Re: Affordability Review Policy and Procedure & Department of Insurance: 3 CCR 702-9 Proposed Revisions (08/30)

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.

It is with this in mind that we write to share recommended improvements to the proposed drafts that will better protect patients by ensuring access to the medications that treat rheumatologic and musculoskeletal disease. Enclosed you will find redlined edits, per your request, to the two documents discussed during the September 24 Stakeholder Meeting. These comments primarily focus on the misuse of "therapeutic alternative" and updated text to reflect the ways in which patient assistance programs influence actual patient out-of-pocket costs.

Therapeutic Alternatives are Not Appropriate Substitutions
We strongly recommend that the Board revise its use of "therapeutic alternative" throughout the proposed drafts, as noted in CSRO's redlined text below. The PDAB law (Senate Bill 21-175) only explicitly requires the use of "therapeutic alternative" in three lines within the bill. 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 and same mechanism of action 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.

Patient Assistance Programs Influence on Actual Patient Out-of-Pocket Costs

Throughout both drafts, the Board recognizes the use of patient assistance programs, including rebates and coupons, and their influence on patient out-of-pocket costs. We encourage the Board to more consistently recognize the role of these programs in their review through the edits included below. 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.

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. In fact, expensive generics can often be cost prohibitive for patients since they do not offer copay assistance. 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 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

Enclosed: Redline Edits to the Proposed Drafts