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Business and Labor Committee Montana House of Representatives P.O. Box 200400 Helena, MT 59620-0400

Re: Support SB 447 - Remove Unnecessary Burdens from Prior Authorization

Chair Buttrey and Members of the House Business and Labor Committee:

The Coalition of State Rheumatology Organizations (CSRO) supports SB 447, which would streamline the prior authorization process by removing unnecessary burdens that delay timely access to essential medications. While several provisions are best in class, we also have recommendations on opportunities to strengthen this legislation to better protect patients.

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 diseases, such as rheumatoid arthritis, psoriatic arthritis and lupus, are 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.

Prior authorizations are typically required by health plans before the health plan confirms coverage for services or select medications. Rheumatoid arthritis medications are subject to some of the most intensive utilization management requirements in healthcare, including prior authorization and step therapy. We understand that rational, clinically driven prior authorizations can help control costs, but unfortunately this utilization management tool is often far from rational or clinically driven and also differs greatly between health plans.

According to a study published in Arthritis Care & Research,ⁱ 71% of patients required prior authorization to begin their infused medications. Remarkably, **96% of all prior authorizations** – **including ones initially denied** – **were ultimately approved**, indicating that prior authorizations serve as a delay tactic used by health plans rather than a meaningful "double-check" on clinical need. It should be noted that all patients requiring a prior authorization, particularly those patients who were initially denied and ultimately approved (82%), had a greater steroid exposure when compared to those patients not requiring a prior authorization.

Prior authorizations are incredibly burdensome for physician practices, requiring extensive staff time. They can also interrupt or delay essential care, which can be harmful for patients managing chronic rheumatologic conditions. 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. It is therefore critical that we reduce the prevalence of unnecessary prior authorizations and identify reasonable ways to streamline these processes with a focus on ensuring access to clinically appropriate medications.

Limit the Frequency of Formulary Changes

Many patients living with rheumatologic diseases require long-term, continuous treatment to maintain disease stability and prevent irreversible damage. Unfortunately, certain prior authorization practices do not reflect this clinical reality. Far too often, health plans alter their utilization review protocols and their pharmacy benefit formularies as frequently as every quarter. This means that even after a patient's treatment has been approved, the plan can revise its criteria and require reauthorization just months later—resulting in additional paperwork for providers, as well as possible disruptions in medication or loss of access for patients. That level of instability is clinically inappropriate; particularly, for patients managing chronic, complex diseases who may already face long wait times before they can meet with their specialist.

CSRO strongly believes that changes to prescription drug formularies should be made no less than the duration of the plan year or 90 days (whichever is longer) to reduce unnecessary care disruptions and ensuring that once a treatment is approved, it remains in place for a reasonable period. CSRO applauds your legislation for expanding these protections and ensuring prior authorizations approved for chronic conditions are approved for the duration of the patient's condition.

Prohibit Retroactive Denials of Authorized Care

Retroactive denials have become far too common in medicine and are harmful to both the patient and their provider, who is often left covering the expenses when the insurer rescinds coverage. As recognized by SB 447, prior authorization processes are already laborious and time consuming. All the necessary clinical data is required from the beginning of the process and yet insurance companies continue to retroactively deny approvals. Even worse, the patient and provider often have few options to appeal the retroactive denial in a timely manner that does not impact care or cause financial hardship on the medical practice. CSRO strongly supports provisions that prohibit retroactive denials and their corresponding payment claw backs.

Require Determinations by Clinically Appropriate Reviewers

When prior authorization requests are reviewed, it is essential that the utilization management entity's processor possesses appropriate clinical expertise relevant to the condition being treated. Rheumatologic diseases are complex and often require highly individualized treatment plans. These treatments should be reviewed by a specialist with an in-depth understanding of the disease process, available therapies, and patient-specific factors, such as comorbidities and prior treatment history. A physician from another specialty, such as radiology or orthopedics, would lack the necessary context to assess the full clinical rationale for a prescribed therapy, potentially leading to inappropriate denials that delay or deny access to essential care. CSRO supports provisions that require any adverse determinations—whether initial denials, step therapy overrides, or appeals—be reviewed by a physician who is board-certified or otherwise appropriately trained in the same or a related specialty as the prescribing provider.

However, CSRO cautions the legislature on the inclusion of Section 3(3):

If the health insurance issuer or its utilization review organization makes an adverse determination for a prescription drug during prior authorization, the health insurance issuer or its utilization review organization shall provide a written adverse determination notice that includes a list of reasonable therapeutic alternatives that are covered by the insurer's formulary. We are concerned that this language, as written, could unintentionally embolden insurers to assert greater authority over adverse determinations; particularly, if it codifies or expands their role in the appeals process without ensuring adequate specialty oversight. As such, we believe this is an area that warrants close attention, and we would welcome further discussion to ensure that any such provisions improve (rather than complicate) the path to appropriate care.

Impose Maximum Response Times for Responses

CSRO supports maximum response time requirements for both routine and exigent prior authorization requests. Delays in care caused by administrative processes can lead to disease progression and avoidable harm for patients with chronic, complex conditions. As such, we recommend that health plans and utilization review entities respond to routine prior authorization requests within 72 hours and to exigent requests within 24 hours. Prompt determinations will reduce unnecessary care interruptions and ensure that patients are not left waiting for access to therapies that have already been deemed medically necessary by their treating physician.

Ensure Continuity of Care

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 and co-morbidities, as well as balance the side-effects of other drug interactions. Slight deviations in treatment and variations between drugs, even those in the same therapeutic class, can cause serious adverse events.

Unfortunately, patients are regularly subjected to frequent prior authorization reviews, even when their condition has remained stable due to their current treatment. CSRO strongly believes that, once approved, patients should not be subjected to additional prior authorization reviews for at least 12 months, even if their health plan has implemented new protocols or has switched its formulary. This is critical to ensure continuity of care and maintain the patient's remission. We applaud changes to the existing law that allow for this 12-month protection.

CSRO also supports requirements for health plans to honor existing approvals when a patient changes to another plan offered by the same carrier. Patients commonly switch between health plans due to changes in employment, family status, or benefits, and they often remain with the same health insurance company. When this occurs, previously authorized therapies should remain covered without requiring resubmission of a new prior authorization. Medical necessity does not change simply because of administrative restructuring within an insurer's portfolio, and the patient's access should not be put at risk because of it.

Penalize Violations of the Law

CSRO commends the legislature for working to improve patient access to essential medications. However, SB 447 can only truly help patients and reduce health care provider administrative burdens if the state enforces the law through penalties and fines when the health plan or utilization review entity is in violation of the law. We strongly encourage the legislature to implement enforcement mechanisms that compel compliance with the law; otherwise, we are concerned that the status quo will remain and patient access will not improve.

On behalf of practicing rheumatologists throughout Montana and the patients we care for, we request that you strengthen SB 447 to truly protect patients from harmful prior authorization practices that restrict access to essential medications. These much-needed protections will help ensure the patient's continuity of care

and medication adherence, improving health outcomes and patient quality of life. We thank you for your consideration and are happy to further detail our comments upon request.

Respectfully,

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ⁱ Arthritis Care & Research. <u>Treatment Delays Associated With Prior Authorization for Infusible Medications: A</u> <u>Cohort Study</u>. September 2019.