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House Labor and Commerce Committee General Assembly Building 201 North 9th Street Richmond, VA 23219

Re: Concerns re: HB1724 – Prescription Drug Affordability Board

Chair Ward, Vice Chair Herring and Members of the House Labor and Commerce Committee:

The Coalition of State Rheumatology Organizations (CSRO) would like to express concerns regarding HB1724, which would establish a state Prescription Drug Affordability 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.

This legislation would establish a Prescription Drug Affordability Board that would have the ability to not only review the cost of prescription drugs, but also cap physician reimbursement for selected medications. We fear this proposal may actually limit patient access and 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 Virginia.

Physician Administered Medications

As currently drafted, the upper payment limit (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, including rheumatologists across the state.

Rheumatologists and other healthcare practices that directly administer medications on an outpatient basis are typically engaged in "buy and bill," whereby the medical practice pre-purchases drugs and bills the health plan 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 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.

Currently, most health plans reimburse providers for the cost of the medication plus an add-on payment at a bundled rate to cover the acquisition costs, making office-based administration economically viable. Unfortunately, the UPL outlined in the legislation 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. Reimbursement rates that do not sufficiently compensate for these costs put healthcare practices at risk. 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.

Acquiring Medications with a UPL

CSRO is also concerned that providers will be unable to source drug products at the UPL rate. Contracting between providers, their group purchasing organizations, wholesalers, and manufacturers is not geographically isolated and is often national in scope. The purchase of a drug product by a wholesaler from a manufacturer likely occurs out of state and would be outside of Virginia's ability to regulate. As a result, it is very likely that the price offered by the wholesaler to the medical practice would be significantly higher than the UPL that physician could bill for that medication. This will impede providers from acquiring these products, resulting in medication shortages and limited patient access.

PBM Formulary Manipulation

While the legislation 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 utilize a variety of tactics that undermine the effectiveness of programs created to keep patient costs down, such as copay assistance programs. These pharmacy benefit plans, organized by pharmacy benefit managers (PBMs), contribute significantly to patient out-of-pocket costs, driving unaffordability.

We encourage the legislature 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 PBMs, it is likely that these middlemen will manipulate the formularies so that these newly priced drugs are placed on a much higher tier, and therefore less accessible to patients. PBM business practices favor higher priced drugs because they have the potential to profit more off those medications. We strongly encourage the legislature to consider mechanisms that will ensure that drug placement on the formulary remains consistent even after a UPL is implemented.

Therapeutic Alternatives are Not Appropriate Substitutions

CSRO urges the legislature to amend the bill to recognize that not all therapeutic alternatives are therapeutically equivalent, having drastically different clinical outcomes for patients. When healthcare providers evaluate medication substitutions, they typically consider therapeutic equivalents – not alternatives.

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 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. 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. Therefore, we strongly recommend that the legislature recognize these clinical practice standards and update the legislation throughout recognizing that only therapeutic equivalents are clinically appropriate to consider for substitution.

Actual Out-of-Pocket Costs

CSRO believes it is important for the legislation to require 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 health 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 to improve patient affordability.

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 typically pays 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 their medication. We encourage the legislature to consider actual patient out-of-pocket costs as they review this legislation.

We appreciate your consideration and request that you do not advance HB1724. We thank you for your consideration and are happy to further detail our comments to the Committee upon request.

Respectfully,

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