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. Patients with rheumatic disease are experiencing greater barriers than ever before in accessing the medications they need, while rheumatologists must spend more time than ever before managing administrative hurdles imposed by payers. Additionally, physicians who treat Medicare patients face annual reimbursement fluctuations that stress the financial viability of their practices. As outlined below, there are several bipartisan pieces of legislation containing targeted policies to improve patient access and Medicare reimbursement stability.

PROTECTING PATIENT ACCESS TO MEDICATIONS

» *Delinking PBM compensation from drug prices*

Because management of rheumatologic disease often relies on expensive specialty medications, rheumatology patients were among the first to experience the harms from the business practices of the pharmacy benefit manager (PBM) industry. A key driver of these harmful practices is a single perverse incentive: the higher a drug's list price, the greater the income potential for the PBM. As a result, prescription drug formularies are designed to maximize revenues for PBMs, which explains how a $10,000 brand drug can gain formulary access while its $450 generic is not covered.[1] Similarly, a recent research letter published in JAMA found that the Humira biosimilars with the lowest prices – 85% less than the brand product – had the lowest coverage rates, at less than 5% coverage in Part D plans.[2] The downstream effects of these formulary design decisions are disastrous for patients when their coinsurances are based on list prices.

Delinking pricing from compensation – fully and without loopholes – is a simple yet critical step to reintroduce sanity into our drug pricing landscape. Already in the employer market, innovative PBMs are beginning to provide fully transparent models structured around flat fee compensation. **The bipartisan *Protecting Patients Against PBM Abuses Act* (H.R.2880) is an example of a strong delinking policy that would require PBMs in Medicare to accept flat fee compensation**. In the long run, this approach will improve program stewardship and beneficiary access to affordable, clinically driven coverage. **CSRO urges you to support robust delinking policies in all federally regulated markets.**

» *Protecting patients' ability to use copay assistance*

Patients with chronic conditions often need copay assistance to afford their medications, many times because of the formulary design decisions that prefer higher priced drugs. In recent years, many insurers and PBMs have instituted "copay accumulators" that prohibit cost-sharing assistance from counting toward

[1] "When the $10K brand name drug is more affordable than its $450 generic: How PBMs control the system" by Zachary Brennan, Endpoints News (Feb. 18, 2022).

[2] *JAMA Network*, Formulary Coverage of Brand-Name Adalimumab and Biosimilars Across Medicare Part D Plans (June 6, 2024).

the patient's deductible or annual limit. Many biologics for autoimmune conditions do not have a lower-cost alternative. Therefore, if a patient cannot make full use of copay assistance, the patient will likely not fill the prescription. In the case of progressive conditions like rheumatoid arthritis, the consequences of non-adherence – notably, joint damage and even joint loss – are irreversible. Several states have banned or limited the use of these programs by insurers and, just last year, a federal court struck down the regulation that permitted use of these programs in the Affordable Care Act exchanges. The Administration does not plan to appeal that ruling.

The *Help Ensure Lower Patient (HELP) Copays Act* (H.R.830/S.1375) would codify a prohibition on the use of copay accumulator programs in exchange plans. That will require insurers to apply the value of cost-sharing assistance toward a patient's cost-sharing requirements. **CSRO urges you to support the bipartisan *HELP Copays Act*.**

» *Reforming utilization management protocols*

Utilization management has become a life-or-death issue for patients in need of expensive medication to manage chronic conditions. Rheumatoid arthritis patients who switch insurance plans often have to "step through" medications they have already tried and failed in the past. Additionally, frequent formulary changes may result in stable patients having to switch medications, a practice called "nonmedical switching." This results in irrecoverable damage to the joints. A 2020 paper by the American College of Physicians found that 40% of patients stopped treatment due to nonmedical switching.

The bipartisan *Safe Step Act* (S.652/H.R.2630) requires employer sponsored plans to establish a clear, convenient process to request step therapy exceptions, and establishes a timeline for appeals. Importantly, the legislation codifies exceptions to step therapy in five specific circumstances, including for stable patients and in situations where the treatment required by the step therapy protocol is contraindicated or expected to be ineffective for the patient. **CSRO urges you to support the *Safe Step Act*.**

The bipartisan *Improving Seniors Timely Access to Care Act* (S.4532/H.R.8702) would modernize prior authorization processes in Medicare Advantage (MA). It would require that MA plans establish electronic processes meeting standards set by the Department of Health and Human Services, establish transparency requirements related to the use of prior authorization in MA, and establish patient protection standards related to prior authorization. **CSRO urges you to support the *Improving Seniors Timely Access to Care Act*.**

MEDICARE PHYSICIAN REIMBURSEMENT

» *Inflation update*.

The Medicare Physician Fee Schedule lacks a mechanism to incorporate inflationary increases into its reimbursement rates, which has created an ever-growing disconnect between the cost of providing care to Medicare beneficiaries and the program's reimbursement for that care. According to the American Medical Association, reimbursement for Medicare physicians declined by 26% from 2001 to 2023, when one adjusts for inflation in practice costs. The functional cut resulting from the lack of an inflation update is compounded by the actual cuts resulting from budget neutrality and the ongoing Medicare sequestration, so that physicians face almost double-digit reductions. Inevitably, this dynamic will lead to beneficiaries experiencing difficulty finding physicians who accept Medicare. ***CSRO urges you to support the bipartisan Strengthening Medicare for Patients and Providers Act (H.R.2474), which would provide inflation updates to the Fee Schedule based on the Medicare Economic Index (MEI)***.

» *Budget neutrality*.

The Fee Schedule is subject to a statutory budget neutrality requirement, whereby increases in spending over a certain threshold must be offset by equivalent reductions in spending that same year. That threshold is $20 million, a level set by Congress in 1992 and never updated since. The concept of budget neutrality has turned the Fee Schedule into a fixed pie, while the outdated threshold amount will result in the threshold being triggered more and more as time goes by. The budget neutrality requirement is a main contributor to the annual pattern of Congress having to avert or mitigate reimbursement reductions at the end of the year. **CSRO urges Congress to update the 1992 budget neutrality threshold and to index the new threshold on a five-year basis from there.**

» *Practice expense updates*.

To minimize payment fluctuations, the Centers for Medicare and Medicaid Services (CMS) must update data inputs on a routine basis. In 2022, CMS updated clinical labor practice expense inputs for the first time in two decades. Although that was a welcome update, the long delay meant that large increases were necessary to reflect twenty years of wage growth. That in turn triggered budget neutrality reductions once implemented. To avoid similar "shock waves" in the future, **Congress must direct CMS to update data inputs every five years at a minimum.**

» *Unique situation of buy-and-bill Part B clinicians*.

The new Medicare Drug Price Negotiation Program (MDPNP) will become fully applicable to selected Part B drugs in 2028, which is expected to result in large reductions to average sales prices (ASPs) for the selected medications. That in turn will result in reductions to reimbursement for the physicians who buy these medications at-risk for in-office administration, because reimbursement for selected drugs would be based on the maximum fair price established via the MDPNP. The legislation tried to guarantee that price point for provider acquisition, but that will be difficult to operationalize in the complex world of drug acquisition with its layers of middlemen. If MFP-based reimbursement drops below acquisition costs for selected drugs, medical practices will experience financial instability and may have to stop offering these drugs until acquisition costs can meet reimbursement levels. There is also a lack of clarity on the extent of the impact that MFPs will have on commercial ASPs and on the additional administrative burden that practices will have to incur to manage the different reimbursement rates for the same medication.

For these reasons, **CSRO urges you to support the *Protecting Patient Access to Cancer and Complex Therapies Act*** (S.2764/H.R.5391). That legislation would remove Part B providers from the middle of the MDPNP by requiring the drug manufacturers of selected drugs to reimburse Medicare directly for the difference between ASP and MFP on their products. Medicare would still obtain significant savings on Part B drugs and the bill would still guarantee beneficiaries access to MFP-based cost-sharing. This "best of both worlds" approach would keep in place the benefits of the MDPNP yet would also ensure that Part B providers are not inadvertently harmed in the process, ultimately protecting their Medicare patients' access to needed medication in the lowest-cost site of care.