CSRO
COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS

REQUEST

The Coalition of State Rheumatology Organizations (CSRO) urges Congress to **improve patient access to medications by: (1) delinking pharmacy benefit manager compensation from drug prices, (2) ensuring patients can utilize the full benefit of copay assistance, and (3) enacting commonsense guardrails around step therapy protocols**.

THE ISSUE

Successful management of rheumatologic disease often relies on expensive specialty medications. As a result, rheumatology patients were among the first to experience the harms from the business practices of the pharmacy benefit manager (PBM) industry, including nonsensical formulary construction, nonmedical switching, and harmful utilization management protocols. A key driver underlying these harmful practices is a simple perverse incentive: the higher a drug's list price, the greater the income potential for the PBM.

THE SOLUTIONS

(1) Delinking PBM Compensation from Drug Prices

Currently, 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, the Office of the Inspector General found that about a third of formularies in Medicare Part D excluded certain biosimilars from coverage even though these same formularies covered the reference products.[2] These formulary design decisions are disastrous for patients who pay coinsurances based on list prices.

A rational system would construct formularies based on efficacy, safety, and lowest cost to the patient, but as long as PBM compensation increases commensurate with list prices, we will never arrive at such a system. That is why delinking prices from PBM income is a critical, foundational reform. There are two bipartisan legislative proposals that would require delinking in Medicare Part D:

[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] "Medicare Part D and Beneficiaries Could Realize Significant Spending Reductions With Increased Biosimilar Use" by Suzanne Murrin, Deputy Inspector General for Evaluations and Inspections, Office of Inspector General, U.S. Department of Health and Human Services (March 2022).

» In the House, the *Protecting Patients Against PBM Abuses Act* (H.R.2880) would require PBMs in Part D to take flat fee compensation for their services, among other reforms. This legislation is led by Rep. Buddy Carter (R-GA) and Rep. Lisa Blunt Rochester (D-DE).
» In the Senate, the *Patients Before Middlemen Act* would similarly require PBMs in Part D to accept flat dollar *bona fide* service fees. This legislation is led by Sen. Bob Menendez (D-NJ) and Sen. Marsha Blackburn (R-TN).

Delinking pricing from compensation 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. Requiring that PBMs who want to participate in Part D accept flat fee compensation would enable Medicare beneficiaries to benefit from such market innovation as well. In the long run, this approach will improve program stewardship and beneficiary access to affordable, clinically driven coverage. **CSRO urges you to cosponsor the *Protecting Patients Against PBM Abuses Act* (House) or the *Patients Before Middlemen Act* (Senate)**.

(2) Protecting Patients' Ability to Use Copay Assistance

Patients with chronic conditions often need copay assistance to afford their medications. In recent years, many insurers and PBMs have instituted "copay accumulators" that prohibit cost-sharing assistance from counting toward the patient's deductible or annual limit. In the *2021 Notice of Benefit and Payment Parameters (NBPP)*, the Centers for Medicare and Medicaid Services allowed insurers to use accumulators in the exchange markets, unless a state law is in place to prohibit it. Biologics for autoimmune conditions have high out-of-pocket costs for patients and many of these products do not yet have a low-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.

The *Help Ensure Lower Patient (HELP) Copays Act* (H.R.830/S.1375) would undo the 2021 NBPP's harmful policy by prohibiting the use of copay accumulator programs in exchange plans. This will require insurers to apply the value of cost-sharing assistance toward an enrollee's cost-sharing requirements. This legislation is led by Rep. Buddy Carter (R-GA) and Rep. Nanette Barragán (D-CA), and by Sen. Tim Kaine (D-VA) and Sen. Roger Marshall (R-KS). **CSRO urges you to support the bipartisan *HELP Copays Act*.**

(3) *Reforming Step Therapy Protocols*

Utilization management has become a life-or-death issue for patients in need of expensive medication to manage chronic conditions. Step therapy requires a patient to try and fail one or more specific medication(s) preferred by the insurer before the patient can advance to the medication preferred by their treating clinician. Rheumatoid arthritis patients who switch insurance plans often have to "step through" medications they have already tried and failed in the past. Additionally, year-over-year

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. This legislation is led by Rep. Brad Wenstrup (R-OH) and Rep. Raul Ruiz (D-CA), and by Sen. Lisa Murkowski (R-AK) and Sen. Maggie Hassan (D-NH). **CSRO urges you to cosponsor the bipartisan *Safe Step Act*.**

Coalition of State Rheumatology Organizations
555 East Wells Street, Suite 1100 | Milwaukee, WI 53202
Phone: 414.918.9825 | Email: info@csro.info | Website: www.csro.info

@CSROadvocacy