2021 Advocacy Day: Issue Brief
Patient Access to Prescription Drugs

REQUEST

The Coalition of State Rheumatology Organizations (CSRO) urges members of Congress to **protect access to Part B medications by rejecting further cuts to provider reimbursement for administering these medications, and instead pursue proposals to maximize access to the most cost-effective setting for medical benefit drug administration: the physician's office.**

BACKGROUND

Practicing rheumatologists are keenly aware of the financial burdens on patients posed by rising out-of-pocket costs for medications. Given that most beneficiaries have Medicare Part B wraparound coverage, the drugs covered by Part B provide a more accessible option for patients who cannot afford the large out-of-pocket cost exposures of Part D. Yet many of the proposed reforms for Part B in recent years would significantly reduce patient access to the more accessible option of Part B, while leaving intact the large out-of-pocket burdens of Part D.

Additionally, these proposed reforms would have reduced access to the most efficient delivery setting in Part B by cutting physician reimbursement for administering these drugs. Currently, there are three settings where patients may receive Part B drugs: a hospital outpatient department, their physician's office, or, for some medications, their home. The physician's office is both the most cost-effective and the safest: it recently has been shown that there is a 25% increase in significant adverse events in patients receiving biologic infusions at home compared with those receiving infusions at a facility, such as a physician's office. Reductions to reimbursement for drug administration hit office-based infusion the hardest, because specialty practices – particularly those in underserved and rural areas – do not have the margins to absorb these cuts.

Despite this, all three Part B drug payment reform models proposed since 2016 would have reduced access to medication administration in the physician's office. Infusible medicines generally treat debilitating diseases, such as rheumatoid arthritis, where even a few weeks of delay can result in severe pain and irreversible joint damage. The loss of access for patients was explicitly acknowledged by the agency in the most recent reform proposal, when it stated that a portion of the projected savings was "attributable to beneficiaries not accessing their drugs through the Medicare benefit, along with the associated lost utilization." In other words, a portion of the estimated savings were not the result of reduced prices, but of reduced spending due to denial of access. Thankfully, none of these models were ultimately implemented due to stakeholder concern and, most recently, a court order.

A better approach is to focus on capturing the potential savings from ensuring that beneficiaries utilize the most cost-effective setting to receive their Part B medications. A recent Employee Benefit Research Institute Issue Brief found that employers and their employees could save as much as 36%, depending on the medication, just from eliminating the differentials between sites of administration for non-oncology specialty drugs. Rather than enacting reimbursement reductions that would do nothing to reduce the price of medications and that, furthermore, would result in physician's offices being unable to continue offering infusion services, Congress must focus on reforms that will maximize use of the most cost-effective setting for administration of these medications.

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2021 Advocacy Day: Issue Brief
Medicare Payment Policy

REQUEST

The Coalition of State Rheumatology Organizations (CSRO) urges members of Congress to **extend financial relief to physicians facing the looming threat of sequestration and Medicare conversion factor reimbursement cuts**. Specifically, we urge Congress to: (1) Maintain the 3.75% increase to the conversion factor through at least calendar years 2022 and 2023; (2) Extend the moratorium on the 2% Medicare sequester through the end of CY 2023; and, (3) Provide relief from the statutory 4% Pay-As-You-Go Act of 2010 (PAYGO) sequester, expected to impact Medicare physicians starting in January 2022.

We appreciate that Congress provided a temporary increase to mitigate reimbursement cuts resulting from a budget neutrality adjustment to the calendar year (CY) 2021 Medicare Physician Fee Schedule (MPFS) conversion factor and acted to temporarily suspend the 2% Medicare sequestration cuts through December 2021. However, without further congressional action, Medicare physicians face a cumulative reimbursement cut of as much as 9% in addition to the other budget neutrality reductions that have been proposed for the CY 2022 MPFS conversion factor.

BACKGROUND

Medicare Conversion Factor. Changes to the codes for office and outpatient evaluation and management (E/M) services that the Centers for Medicare & Medicaid Services (CMS) implemented as a part of its CY 2021 MPFS final rule increased Medicare spending by approximately $10.2 billion. A statutory budget neutrality rule requiring any increases in Medicare payments to be offset by corresponding decreases resulted in an adjustment to the conversion factor of -10.2%. The *Consolidated Appropriations Act, 2021* modified the MPFS final rule by providing a 3.75% increase in MPFS payments for CY 2021, mitigating the negative impact on physicians and reducing the CY 2021 conversation factor by -3.3%. This payment provision is set to expire on January 1, 2022.

Sequestration. In April 2021, legislation was signed into law to extend the moratorium on collection of the 2% Medicare sequester through the end of CY 2021. Beginning on January 1, 2022, that 2% Medicare payment cut will be reinstated. In addition, the Congressional Budget Office (CBO) recently determined that the latest COVID relief package, the *American Rescue Plan,* will trigger the statutory Pay-As-You-Go Act of 2010 and mandate Medicare spending reductions of an estimated 4%, or $36 billion, next year. Therefore, in addition to the 2% sequestration cut, providers will see an additional 4% sequestration cut to Medicare reimbursement rates on January 1, 2022.

CSRO urges Congress to **intervene to prevent the reductions in Medicare physician reimbursement that will become effective on January 1, 2022 and preserve Medicare beneficiaries' timely access to rheumatologic care**. We stand ready to work with you to extend critical financial relief to providers and to delay cuts to Medicare reimbursement as the public health emergency continues.

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2021 Advocacy Day: Issue Brief
Utilization Management

REQUEST

The Coalition of State Rheumatology Organizations (CSRO) urges members of Congress to **protect patients by enacting commonsense guardrails around utilization management**. Specifically, we urge you to cosponsor:

- *Improving Seniors Timely Access to Care Act* (H.R. 3173), which would make a number of improvements to prior authorization in Medicare Advantage, including for medical benefit drugs.
- *Safe Step Act* (S. 464/H.R. 2163), which would establish a clear, transparent, and streamlined appeals process for step therapy protocols in employer-sponsored plans.

BACKGROUND

Utilization management has become a serious issue for all patients, including Medicare beneficiaries. The Office of the Inspector General examined denial rates in Medicare Part D for 2017 and found that, in 73% of cases, denials were wholly or partially overturned when appealed. This indicates that insurers are leveraging initial denials as a way to delay paying for medically needed care. Additionally, 88% of insurer contracts audited by the Centers for Medicare and Medicaid Services (CMS) in 2017 were cited by the agency for at least one violation resulting in inappropriate rejections – and the most common violation consisted of plans imposing utilization management requirements that were not approved by CMS.

Prior Authorization: *The Improving Seniors Timely Access to Care Act* (H.R. 3173)

Rheumatoid arthritis medications are subject to some of the most intensive utilization management requirements in healthcare, including prior authorization (PA) and step therapy. While rational, clinically driven utilization management can help control costs, unfortunately utilization management in its current form is neither rational nor clinically driven, and the requirements differ greatly from insurer to insurer.

This has serious consequences for patients. A recent study on prior authorization in rheumatology found that 71% of the studied patients required PA to begin their infused medications. Remarkably, 96% of all PAs – including ones initially denied – were ultimately approved, again indicating that PA serves more as a delay tactic than a meaningful "double-check" on clinical need.

The bipartisan *Improving Seniors Timely Access to Care Act* (H.R. 3173) would institute much-needed protections for patients by establishing an electronic PA process in Medicare Advantage, creating transparency around the processes used by insurers, ensuring that plans adhere to evidence-based medical guidelines and that requests are reviewed by qualified medical personnel, and minimizing the use of PA for routinely approved services.

Step Therapy: *The Safe Step Act* (S. 464/H.R. 2163)

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 their treating clinician prescribed. 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." Since RA is a progressive disease, this results in irrecoverable damage to the joints. A recent paper by the American College of Physicians found that 40% of patients stopped treatment as a result of nonmedical switching. The paper also noted that,

"In a study of rheumatology patients who tried a nonpreferred drug in the formulary, 11% never obtained treatment."

The bipartisan *Safe Step Act* (S. 464/H.R. 2163) requires employer sponsored plans to establish a clear, convenient, and readily available process to request step therapy exceptions, and establishes a timeline for appeals. The legislation also 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.

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On behalf of the rheumatology patients we serve, CSRO thanks the bipartisan cosponsors of the *Improving Seniors Timely Access to Care Act* and the *Safe Step Act* and urges Congress to advance these important pieces of legislation.

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