CSRO
Coalition of State Rheumatology Organizations

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Administrator Oz, MD
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5545-P & CMS-5546-P
P.O. Box 8013,
Baltimore, MD 21244-8013
Submitted electronically

Re: CMS-5545-P – Global Benchmark for Efficient Drug Pricing (GLOBE) Model
CMS-5546-P – Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model

Dear Administrator Oz:

On behalf of the Coalition of State Rheumatology Organizations (CSRO), we would like to express our concerns over the recent suggestions to incorporate a Most Favored Nation (MFN) policy for prescription drugs within the Global Benchmark for Efficient Drug Pricing (GLOBE) Model and Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model. CSRO believes these models could unintentionally harm patient access to essential medications, including those directly administered by rheumatologists and their practice partners, and therefore encourages CMS to withdraw this proposal and pursue alternative policies that will create direct savings for patients.

CSRO serves the practicing rheumatologist 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.

White Bagging

Within the GLOBE Model, CMS states that it anticipates "there would be some collaboration between manufacturers and providers to incentivize the increased use of white-bagging, where drugs would be reimbursed for under the Part D benefit while still being administered in an office/facility setting." Much to the frustration of rheumatologists and other buy-and-bill providers, health plans and their pharmacy benefit managers (PBMs) are already disrupting patient care by implementing mandatory white bagging policies where the patient is required to use specific specialty pharmacies, typically owned by the PBM, to acquire the provider-administered medication. These white bagging policies, which boost the profits of PBMs and their vertically integrated pharmacies, have become all too common. In fact, UnitedHealthcare implemented mandatory specialty pharmacy white bagging policies, which in 2024 applied to over 100 specialty medications.[i]

While we recognize that potential use of white bagging applies outside of traditional Medicare, we are concerned that the unintentional ripple effects of the GLOBE Model could drive white bagging among Medicare Advantage and private insurance beneficiaries. An increase in white bagging would not be in the best interest of patients or their health care providers, as white bagging:

- **Increases patient out-of-pocket costs.** By way of comparison, when actual receipts were compared in an employer funded plan, CSRO found that the specialty pharmacy cost to the employer health plan was 3-4 times higher when then medication was obtained through specialty pharmacy as compared to the same medication obtained through buy-and-bill through the physician's office. The employee's cost with buy-and-bill was $25, compared to $500 when mandated specialty pharmacy was used.
- **Shifts patient cost-sharing.** When patients receive their medications via buy-and-bill at an office-based setting, health plans impose no or minimal patient cost sharing obligation.[ii] However, if the drug is switched to Part D through white bagging, it can be cost prohibitive for patients, as patients are faced with coinsurance and deductibles for specialty medications.
- **Risks product integrity.** White bagging policies do not allow providers to control the handling, preparation, and storage conditions of the drug prior to its administration. In a national survey of rheumatologists, 69% of respondents indicated they experienced operational and safety issues associated with white bagging.[iii] Improper handling of these specialty medications can have serious consequences for patients, and white bagging does not allow the provider to control and prevent adverse events.
- **Causes delays in care.** These policies can also cause delays in receiving the medication, such as failed delivery, incorrect medications, prior authorization issues, and out of stock medications. When medications are mishandled or improperly dosed by outside entities, patients face delays in treatment, which can have serious implications for the health and maintenance of their chronic condition.
- **Drives waste.** When white bagged, the medication dispensed by the specialty pharmacy is assigned to a specific patient. If the patient's provider determines that the patient's medication must be changed during their pre-administration evaluation, the initial medication is no longer of use. In fact, it is required to be disposed of since it cannot be administered to anyone other than the original patient.

White bagging also imposes additional burdens on physician practices, including increased liability and complex inventory management. Unfortunately, providers can still be held liable for adverse events caused the medication dispensed by the specialty pharmacy even when the provider had no control over the medication. These safety and liability concerns can be avoided when the provider is able to source products from their own inventory for in-office administration. These policies also require physician practices to maintain separate, patient-specific product inventory, which requires more granular inventory management, increased staff time and additional costs to the medical practice.

CSRO cautions CMS to monitor increases in white bagging inside and outside of the GLOBE Model as it can further empower health plans and their PBMs, lead to increased patient cost-sharing, delays and loss of access to treatment, and increase liability concerns for private practices.

Maintain the ASP

Unlike previous models to import international drug pricing to the United States, the GLOBE Model does not directly influence the Average Sales Price (ASP) or its corresponding provider administration add-on payment. CSRO appreciates that CMS has accounted for the financial challenges that providers would face if the international drug pricing was directly incorporated into the ASP instead of through the proposed rebate model. We caution that market dynamics in response to this Model may still cause drug prices, and thus the ASP, to fluctuate. We encourage CMS to ensure that providers remain whole in both acquisition of the product and through the administration fees.

Beneficiary Cost Sharing & Utilization Management

CSRO appreciates that the GLOBE Model accounts for beneficiary cost-sharing "by taking the lesser of 20 percent of either the standard payment amount or the adjusted GLOBE model benchmark." As we mentioned previously, Part B drugs are complex, specialty medications, and therefore typically more expensive. While billed through the medical benefit, patient cost-sharing responsibilities can still be out of reach for many patients with chronic conditions. We appreciate CMS's consideration of these expenses for the beneficiaries within the GLOBE Model.

However, we are frustrated that CMS has not extended those same beneficiary cost-sharing savings within the GUARD Model. In fact, according to CMS, Medicare Part D beneficiaries may actually experience increased costs due to higher premiums and cost sharing, with a projected $3.6 billion increase in costs for Part D beneficiaries throughout the Model's lifespan. CSRO believes this is counterproductive to the Administration's goals of improving healthcare affordability and urges CMS to reconsider beneficiary cost-sharing calculations within the GUARD Model.

CSRO is also concerned that the GUARD Model could alter incentives within the supply chain, specifically among manufacturers, health plans and pharmacy benefit managers. These changes could increase changes to the prescription drug formulary and drive utilization management, such as prior authorization, step therapy and non-medical switching. These utilization management tools are extremely harmful to patient continuity of care and patient adherence to their medication. Patients with chronic conditions require seamless access to their medications, without these utilization management barriers. We caution CMS to monitor any future activities by the health plans and their pharmacy benefit managers that may exacerbate the use of utilization management.

Beneficiary Protections & Quality Measures

CSRO is concerned that the planned evaluation of the Models and the associated quality measures may not be sufficient to detect unintended access and affordability consequences within and outside the Models, and urges CMS to take the following actions:

- **Strengthen monitoring and oversight to prevent unintended access disruptions.** CSRO urges CMS to improve its ability to identify alternative drug distribution arrangements involving provider-administered therapies, such as white-bagging and brown-bagging, by requiring pharmacies to report the National Provider Identifier (NPI) of the practice to which a provider-administered drug is shipped, enabling more effective linkage of Medicare Part D pharmacy data with Part B claims data and closer scrutiny of claims patterns that may indicate disruptions in provider-controlled drug acquisition.
- **Monitor utilization management practices and beneficiary cost exposure under both Models**. CMS should track changes in prior authorization, step therapy, formulary exclusions, and non-medical switching to assess whether beneficiaries with rheumatologic conditions experience increased barriers to timely and appropriate treatment. CMS should also evaluate beneficiary cost exposure more comprehensively, including the combined effects of premiums, cost sharing, and cumulative out-of-pocket spending, particularly for patients requiring long-term therapy with specialty medications.

On behalf of practicing rheumatologists throughout the United States, we thank you for your attention to these concerns. CSRO respectfully urges CMS withdraw this proposal and instead pursue alternative policies that will create direct savings for patients. We thank you for your consideration and encourage you to contact CSRO (jfrasco@hhs.com) with any additional questions you may have.

Respectfully,

Aaron Broadwell

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President
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[i] United Healthcare. Medication Sourcing Protocol – Requirements to use a participating specialty pharmacy for certain medications. December 2024.

[ii] Drug Channels. White Bagging Update 2023: Saving Money or Shifting Costs?. September 2023.

[iii] Coalition of State Rheumatology Organizations. National survey of rheumatology practices, data available upon request.