The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services 200 Independence Avenue S.W., Ste 314G Washington, D.C. 20201

February 20, 2024

Re: Withdraw Medicaid Rebate Stacking Policy from MDRP to Protect Providers & Patients

Dear Secretary Becerra and Administrator Brooks-LaSure,

We write to express our deep concerns with the proposed rebate "stacking" rule changes in the Medicaid Drug Rebate Program (MDRP). As proposed in the rule, "Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program," Medicaid rebate stacking would harm infusion providers and patients by severely limiting access to lifesaving, provider-administered treatments in the lowest-cost care settings while simultaneously putting patient privacy in jeopardy. We urge the Centers for Medicare & Medicaid Services (CMS) to omit the "stacking" policy from the final rule to protect patients who rely on access to in-office drug administration.

States rely on the Medicaid Drug Rebate Program (MDRP) to ensure their Medicaid beneficiaries can access critical therapies. Today, 780 drug manufacturers participate in the MDRP, providing rebates to infusion providers who care for patients managing some of the most complex health conditions we know. Commonly referred to as the "stacking" policy, CMS is proposing rule changes that would require drug manufacturers to aggregate or "stack" all drug discounts provided to separate stakeholders throughout the healthcare supply chain, like pharmacies, wholesalers, or infusion providers, to determine the "best price" in Medicaid. This CMS proposal would create an artificial price that manufacturers will not be able to sustain. The proposal would disrupt the MDRP and harm providers who rely on manufacturer rebates to care for patients who require access to cutting-edge treatments.

Negative Impact on Providers

The CMS "stacking" policy would demand participating drugmakers offer a "best price" that is an aggregate of all possible discounts in the entire supply chain, creating an unrealistic and unfair baseline price. In response, drugmakers may stop providing voluntary drug discounts that allow infusion providers to deliver low-cost care to patients. Community-based, non-hospital infusion sites are a more affordable, more convenient care option for infusion patients. However, without these vital drug discounts, infusion providers may be unable to acquire and deliver essential medicines, forcing patients to skip treatments, receive care in a higher-cost setting, or forgo treatment altogether.

Privacy & Administrative Concerns

The "stacking" policy demands extensive tracking of prices through the healthcare supply chain, potentially compromising patient privacy. Today, drug manufacturers evaluate the "best price" on a customer-by-customer basis and are not required to follow a drug through the supply chain to track discounts for all entities eligible for the "best price." However, to determine "best price" under a stacking policy, a manufacturer would require access to detailed information, including a patient's identifying information and payer information, to accurately know if a discount was paid on a drug reimbursed by the patient's insurer or by the federal government. That creates new privacy concerns for patients. Additionally, this requirement poses a significant logistical challenge for providers, as it complicates the process of ensuring patient privacy while navigating the complexities of discount tracking.

Threat to Innovation & Care Delivery

The current methodology for the MDRP enables non-hospital, community-based infusion centers to offer affordable, accessible, and efficient patient-centered care to those who require cutting-edge treatments. The proposed "stacking" policy will disincentivize competition among drug manufacturers to offer lower prices for these complex treatments. And with pricing uncertainty, drug manufacturers will likely be reluctant to invest in future research efforts for new medicines, stifling medical innovation.

As providers, our goal is to ensure that vulnerable populations have access to essential treatments in high-quality, cost-efficient settings. The "stacking" policy, as proposed, poses a significant threat to our ability to provide the most optimal care to Medicaid beneficiaries. While we commend CMS for exploring strategies to reduce costs for Medicaid beneficiaries and others in the supply chain, it is critical to assess every policy in terms of its broader effects on the healthcare system to prevent unforeseen, negative outcomes. We urge CMS to withdraw this proposal and work collaboratively with all stakeholders, including infusion providers, to develop policies that truly benefit patients without disrupting access, innovation, and patient privacy.

Thank you for your attention to this critical matter.

Sincerely,

American College of Rheumatology
American Gastroenterological Association
Coalition of State Rheumatology Organizations
National Infusion Center Association
National Organization of Rheumatology Management
Rheumatology Nurses Society