July 15, 2020

RE: CMS-2842-P (Proposed Rule: "Medicaid Program: Establishing Minimum Standards in Medicaid State Drug Utilization Review and Supporting Value-Based Purchasing for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability Requirements")

Submitted electronically via regulations.gov

Dear Administrator Verma:

The Coalition of State Rheumatology Organizations (CSRO) is comprised of a group of state and regional professional rheumatology societies throughout the country formed to advocate for excellence in rheumatologic disease care and to ensure access to the highest quality care for the management of rheumatologic and musculoskeletal diseases. Our coalition serves the practicing rheumatologist in charge of patient care for these illnesses. While the above-referenced rule addresses a wide range of issues, we limit our comments to the agency's proposal to factor the value of copay assistance programs into Medicaid best price and average manufacturer price (AMP) calculations.

Currently, the value of manufacturer-provided assistance programs such as copay assistance is excluded from best price and AMP calculations, *as long as the full value of these programs is passed onto the patient*. Manufacturers make reasonable assumptions that the value of these programs accrues fully to the patient, either at the point-of-sale or as a rebate provided after the prescription has been filled.

In the proposed rule, CMS notes that, in situations where an insurer or a pharmacy benefit manager (PBM) uses a so-called copay accumulator adjustment program, the full value of patient assistance programs is not passed onto the patient. Thus, CMS proposes to require incorporation of the value of patient assistance programs into the calculation of best price, unless the manufacturer can "ensure" the full value of these programs is passed onto the patient. CMS states its belief that "manufacturers have the ability to establish coverage criteria around their manufacturer assistance programs to ensure the benefit goes exclusively to the consumer or patient." CMS proposes a corresponding proposal in the context of AMP.

As we have noted in comments on other proposals, low-cost therapeutic equivalents do not exist for many products in rheumatology. In those cases, the availability of copay assistance does not drive brand adherence; rather, it makes the difference between the patient being able to afford the prescription, or not. Unfortunately, the use of accumulator adjustment programs will undoubtedly only increase since CMS recently finalized a rule expressly empowering exchange plans to use these programs in states that allow them.

However, given the well-documented opacity of the PBM industry, it is unclear how manufacturers could determine whether a patient's plan has an accumulator program. In fact, one of the main issues with copay accumulators is that often even *the patients themselves* do not know whether their plan has one in

place, until their copay assistance runs out and they realize the value thereof was pocketed by their insurer rather than applied to their deductible spending. This confusion results in part from the lack of insurance industry standards around the naming and disclosure of these programs, which allows a PBM to euphemistically name such a program a "Benefit Plan Protection Program" or an "Out of Pocket Protection Program." Yet, the only party who benefits from the "protection" of a copay accumulator is of course the PBM itself, as the only purpose of such a program is to shift costs onto patients.

Even if drug companies could proactively determine when a copay accumulator will be used, they cannot leverage their assistance programs to prevent insurers and PBMs from doing so. If they could, copay accumulators wouldn't exist.

If this proposal is finalized, manufacturers may stop offering assistance programs because they would be unable to reliably determine that the value of their programs is being passed onto the patient and, thus, be at risk of noncompliance with best price requirements due to circumstances beyond their control. A loss of assistance would be detrimental to rheumatology patients who need expensive specialty drugs for which there is no lower-cost alternative.

Finally, the proposal establishes yet more misaligned incentives in drug pricing. Medicaid beneficiaries have access to statutorily low prices but are prohibited from using copay assistance. Conversely, commercial beneficiaries struggle with high list prices but have the benefit of copay assistance. The proposal seeks to drive down Medicaid prices by curtailing the use of copay assistance in the commercial market, leaving commercial beneficiaries with no relief on list prices *and* no help with out-of-pocket costs.

Instead of creating more misaligned incentives, we urge the Administration to tackle the true underlying cause of high list prices: the current system of price concessions in exchange for formulary access. Requiring drug companies to compete on price to the patient rather than the size of the price concession to the PBM would alleviate the need for copay assistance programs in the first place.

As physicians who care for patients in need of products that are often without low-cost therapeutic equivalents, we must oppose this proposal for the reasons outlined herein. Please do not hesitate to reach out if you have questions or require additional information.

Sincerely,

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CSRO Federal Advocacy