April 8, 2019

Mr. Aaron Zajic
Office of the Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue SW
Washington, DC 20201

Re: OIG-0936-P Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees

Dear Mr. Zajic:

The Medicaid and CHIP Payment and Access Commission (MACPAC) appreciates the opportunity to comment on the U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) proposed rule: OIG-0936-P Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 84 Fed. Reg. 2340 (February 6, 2019).

MACPAC is a non-partisan legislative branch agency that provides policy and data analysis and makes recommendations to Congress, the Secretary of HHS, and the states on a wide range of topics related to Medicaid and CHIP. The Commission recognizes the challenges that high drug prices have created for all payers and has focused its work on analyzing the drivers of drug spending in Medicaid and on identifying policy options to help control program spending.

The proposed rule eliminates safe harbor protection for drug rebates paid by drug manufacturers to Medicare Part D plans and Medicaid managed care organizations (MCOs), either directly or through pharmacy benefit managers (PBMs) acting under contract with Medicare Part D plans or Medicaid MCOs. The proposed rule would establish new safe harbors for drug manufacturer discounts provided at the point of sale (POS) that reduce the price paid by the

beneficiary and for fixed-fee payments from drug manufacturers to PBMs for certain services rendered on behalf of the manufacturer.

Concerns about the impact on Medicaid

The Commission discussed the notice of proposed rulemaking at its March 8, 2019 public meeting, noting that the proposed changes to the safe harbors are primarily focused on creating discounted prices at the point of sale and changing beneficiary cost sharing for Medicare Part D beneficiaries. The goal of these changes is not particularly relevant to Medicaid, due to the nominal cost sharing for Medicaid beneficiaries and the statutory rebates that Medicaid receives.

At the same time, Medicaid could be affected with respect to supplemental rebates, treatment of chargebacks, elimination of the safe harbor for current rebates negotiated by Medicaid MCOs, and changes in manufacturer prices in response to the proposed rule. The Centers for Medicare & Medicaid Services Office of the Actuary projects that the rule would slightly increase Medicaid spending, although different assumptions can lead to a wide range of estimates. The Commission has concerns about these uncertainties and the potential for increased Medicaid spending. Because Medicaid is not the primary focus of the rule, we ask the OIG to consider ways to limit the effects on Medicaid.

Supplemental rebates

In the preamble to the proposed rule, the OIG commented that it believes that state supplemental rebates will not be affected. However, given that supplemental rebates are not defined in statute (i.e., section 1927 of the Social Security Act), this protection is not explicit. Supplemental rebates are an important tool for states in controlling drug spending; 46 states and the District of Columbia have such agreements, collecting about $1.2 billion in supplemental rebates during fiscal year 2017. To ensure that state Medicaid programs retain the ability to negotiate supplemental rebates, the Commission suggests that the OIG include specific language in the final rule that would protect supplemental rebates under the safe harbor.

Treatment of chargebacks

The OIG also indicated that it may issue separate guidance to clarify how chargebacks would be treated in calculations of average manufacturer price (AMP) and best price. We consider such clarifications to be critical due to their potential impact on the amount of rebates Medicaid receives. Moreover, such guidance should be in place before the final rule goes into effect to ensure that Medicaid receives the appropriate rebates.

Medicaid managed care

The proposed rule would eliminate the safe harbor for the current rebates that a Medicaid MCO negotiates with a drug manufacturer in exchange for preferred status on its formulary and fewer utilization restrictions. A new safe harbor would allow manufacturers to provide POS discounts; as noted above, these will not particularly affect cost sharing for Medicaid beneficiaries as they typically pay a low, fixed dollar copayment. Because POS discounts could have less ability to steer market share compared to

existing plan rebates and will do little to reduce Medicaid beneficiaries' already nominal out-of-pocket costs, drug manufacturers may choose to reduce price concessions to Medicaid MCOs. This would lead to higher net costs for plans, and thus, require states to make higher capitation payments.

While states may be able to offset an increase in capitation rates with new supplemental rebates, programmatic changes required to accomplish that offset may not be preferred from a policy perspective to the extent that they increase fragmentation of care or reduce flexibility. For example, both MCOs and states generally prefer to have the drugs carved-in to facilitate care management, and many states prefer to keep MCOs at risk for managing the drug benefit. A drug carve-out may reduce plans' incentives to manage drug utilization as they are no longer at risk for these costs. Keeping drugs carved in but including the managed care enrollees in state supplemental rebates would require the plans to follow the state's preferred drug list and may reduce the MCOs' flexibility to manage beneficiaries' care. As a result, the Commission asks that the OIG consider whether it has the legal authority to retain the safe harbor for Medicaid MCOs, by excluding the Medicaid program from the rule altogether or by distinguishing treatment under Medicare and Medicaid in light of differing beneficiary cost-sharing protections.

Manufacturer prices

Under the proposed rule, drug manufacturers may choose to convert some or all of their existing rebates into POS discounts or lower list prices. While lower list prices would lower Medicaid gross drug spending, the decrease in list price would also lower the calculation of AMP. Moreover, the inflationary rebate would also be lower because the current AMP would not be as high relative to the baseline AMP, compared to where it was before the manufacturer lowered the price. Lowering list prices could lead to rebate reductions that outweigh the reduction in prices, and thus, result in an increase in net Medicaid drug spending.

The Commission asks the OIG to consider other regulatory changes or guidance that could reduce this uncertainty and minimize the potential effects to Medicaid. For example, the Commission discussed whether it would be possible to rebase the inflationary rebate when the final rule goes into effect to minimize the potential effect that lower list prices could have on the net price Medicaid pays.

Sincerely,

Penny Thompson, MPA
Chair

cc: The Honorable Charles Grassley, Chair, Senate Finance Committee
The Honorable Ron Wyden, Ranking Member, Senate Finance Committee
The Honorable Frank Pallone Jr., Chair, House Energy & Commerce Committee
The Honorable Greg Walden, Ranking Member, House Energy & Commerce Committee