July 16, 2018

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Secretary Azar:

The Medicaid and CHIP Payment and Access Commission (MACPAC) appreciates the opportunity to respond to the request for information (RFI) from the U.S. Department of Health and Human Services (HHS) concerning the Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, 83 Fed. Reg. 22692 (May 16, 2018).

MACPAC is a non-partisan legislative branch agency that provides policy and data analysis and makes recommendations to Congress, the HHS Secretary, 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.

Medicaid currently receives substantial rebates on prescription drugs that reduce gross drug spending by more than half. As a result, Medicaid pays one of the lowest net prices of any payer. In exchange for these rebates, states generally must cover all of a manufacturer's products. Accordingly, the Commission's view is that any changes to the program require substantial analysis of the impact that such changes would have on Medicaid expenditures and beneficiary access.

MACPAC supports HHS's efforts to ensure that appropriate rebates are paid to the Medicaid Drug Rebate Program as these actions are consistent with our recommendations. In our June 2018 report to Congress, the Commission

made two targeted recommendations to help ensure Medicaid receives proper drug rebates by:

- closing a loophole in current law that allows a manufacturer to sell its authorized generic at a low price to a corporate subsidiary and reduce the rebate obligation for its brand drug, and
- giving the HHS Secretary clear authority to impose intermediate financial sanctions on manufacturers that misclassify a brand drug as a generic to lower their rebate payments.

We plan to extend this work into the year ahead to determine whether additional policy levers may be needed—and if so, what form they should take—to help manage prescription drug spending while also ensuring that Medicaid beneficiaries can continue to benefit from advances in scientific research and maintain appropriate access to much needed medications.

MACPAC supports HHS's goal of lowering drug prices and encouraging use of value-based arrangements. We are aware that the best price provisions of the Medicaid Drug Rebate Program may create some challenges for other payers as they seek to develop new payment and rebate arrangements; however, we urge that HHS carefully consider how any change to components of the Medicaid Drug Rebate Program could potentially lower manufacturer rebates and thus ultimately raise costs for the Medicaid program to the states and the federal government. Below we offer general observations and technical comments to questions posed in the RFI.

State demonstrations

Several states have expressed interest in obtaining additional flexibility to adopt widely used commercial tools to manage increasing drug costs, such as a closed formulary that excludes certain drugs. The Commission plans to examine how Medicaid's existing tools for managing drug utilization compare to other payers and how the use of additional tools such as closed formularies could affect state programs and beneficiaries. Such analyses might include, for example, whether closed formularies could yield additional savings to states and how this might affect beneficiary access.

Additionally, the Commission has heard from state officials who express concern with the requirement that states cover all new covered outpatient drugs as soon as they enter the market. These officials stated that it can be difficult to determine appropriate coverage of these drugs without having sufficient time to assess the effectiveness of a drug or determine coverage and prior authorization criteria that align with the drug's labeling and medically accepted indications. This may be particularly true for drugs receiving accelerated approvals from the U.S. Food and Drug Administration. We are also aware of concerns that state processes may result in unnecessary delays in coverage. The Commission will conduct further analysis of this issue and evaluate possible policy responses, such as allowing state officials to exclude a newly approved drug from coverage for a specified period of time while they develop appropriate coverage criteria.

Value-based arrangements and other exclusions of certain payments, rebates or discounts from the determination of average manufacturer price and best price

Best price. Some stakeholders have stated that the best price provision in the Medicaid Drug Rebate Program creates disincentives for manufacturers in developing certain value-based arrangements with commercial payers. MACPAC has heard from experts, however, that best price may be just one of several factors that may affect the feasibility of value-based arrangements. Moreover, we understand that some manufacturers see best price as an issue, and some of them do not, depending on the circumstances.

It is important to note that prices negotiated by Medicare Part D plans and by states under Medicaid supplemental rebate contracts are exempt from best price, but value-based arrangements still have been slow to develop under both programs. This may be due to the inherent difficulty in developing appropriate measures that demonstrate value, and the collection and reporting of these data. Measuring outcomes can be expensive and payers must ensure that the value received from an outcomes-based contract is worth the cost to measure it.

MACPAC encourages HHS to consider carefully how excluding value-based arrangements or other rebates and discounts could potentially reduce the rebates received by the Medicaid program. In addition, federal action could facilitate adoption of value-based arrangements by state Medicaid programs. For example, states must have Medicaid supplemental rebate contracts approved under the state plan by the Centers for Medicare & Medicaid Services (CMS), which can be a lengthy process. Any guidance from CMS that clarifies how certain rebates, discounts, and pricing arrangements interact with best price or provides a template for a value-based supplemental rebate contract would be helpful to states.

Average manufacturer price (AMP). AMP is a measure of the average price paid for a drug to manufacturers by wholesalers and retail community pharmacies. AMP is a confidential price that was developed for the calculation of the Medicaid rebates and is not commonly used to determine payments made by other payers. Accordingly, actions that lower AMP would reduce the rebates owed by manufacturers, but would not likely result in lower list prices. The Commission has generally been supportive of policies that ensure AMP accurately reflects the price of drugs paid by wholesalers and retail community pharmacies. MACPAC encourages HHS to consider the extent to which excluding certain rebates or discounts from the calculation of AMP potentially could reduce the rebates received by the Medicaid program.

Affordable Care Act taxes and rebates

The Patient Protection and Affordable Care Act (ACA, P.L. 111-148, as amended) increased the amount of Medicaid drug rebates by increasing the minimum rebate amounts, creating an alternative rebate for line extension drugs, and extending drug rebates to Medicaid managed care. While the RFI raises the question of how such rebates have led to cost shifting to other payers, it is not clear that these changes increased total rebates for all manufacturers. Some of these changes in Medicaid rebate under the ACA may have

replaced other rebates the Medicaid program was receiving already. For example, many drugs may have had supplemental rebate agreements in place before the ACA. In such circumstances, supplemental rebates generally are established around a guaranteed net price after all rebates are taken into account. Thus, an increase in federal rebates is offset by a corresponding decrease in the state supplemental rebates.

Long-term financing models

State Medicaid programs have raised concerns about the ability to finance the growing number of high-cost drugs on increasingly stretched budgets. Even when such agents are highly effective, the costs may be borne by one payer while the benefits may accrue to another payer in the form of reduced future health expenditures. The RFI asks how Medicaid and Medicare should account for the cost of disease averted by a curative therapy paid for by another payer. We would point out that the reverse situation should also be considered— that is, other payers may need to account for the savings that can be attributed to a disease cured by a therapy paid for by Medicaid.

We appreciate the opportunity to respond to this request for information and hope that our comments are helpful as you consider proposals to reduce drug prices and spending.

Sincerely,

Penny Thompson, MPA
Chair

cc: Seema Verma, Administrator, Centers for Medicare & Medicaid Services
The Honorable Orrin G. Hatch, Chairman, Committee on Finance, U.S. Senate
The Honorable Ron Wyden, Ranking Member, Committee on Finance, U.S. Senate
The Honorable Greg Walden, Chairman, Committee on Energy and Commerce, U.S. House of Representatives
The Honorable Frank Pallone Jr., Ranking Member, Committee on Energy and Commerce, U.S. House of Representatives
The Honorable Michael Burgess, Chairman, Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives
The Honorable Gene Green, Ranking Member, Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives