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July 20, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

RE: CMS 2434–P Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program

Dear Administrator Brooks-LaSure:

The Medicaid and CHIP Payment and Access Commission (MACPAC) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule, Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program on May 26, 2023. MACPAC is a nonpartisan legislative branch agency that provides policy and data analysis and makes recommendations to Congress, the Secretary of the U.S. Department of Health and Human Services, and the states on a wide array of issues affecting Medicaid and the State Children's Health Insurance Program (CHIP).

This proposed rule includes a number of provisions designed to clarify key definitions, increase price transparency, and address drug misclassification under the Medicaid Drug Rebate Program (MDRP). The Commission would like to express its support for the objectives of the proposed rule to ensure the rebates provided under the MDRP are calculated appropriately and collected in a timely manner.

This letter draws on the Commission's work over the years and highlights pertinent recommendations addressed in the proposed rule. In MACPAC's June 2018 *Report to Congress on Medicaid and CHIP*, the Commission recommended that the Secretary of Health and Human Services (the Secretary) should be given additional authority to level intermediate financial sanctions to compel drug manufacturers to submit accurate drug classification data and strengthen enforcement actions (MACPAC 2018). In MACPAC's June 2019 *Report to Congress on Medicaid and CHIP*, the Commission made a recommendation to remove the cap on Medicaid rebates (MACPAC 2019). Both of these recommendations were included in the Medicaid Services Investment and Accountability Act of 2019 (MSIAA, P.L. 116-16) and the American Rescue Plan Act of 2021 (ARP, P.L. 117-2) respectively. As discussed below, the Commission supports efforts in this proposed rule to implement these statutory changes. This letter concludes with technical considerations on the drug price verification survey.



Drug misclassification

The MSIAA provides the Secretary with additional authorities to ensure drug manufacturers comply with MDRP requirements and classify drugs appropriately for purposes of calculating rebates. CMS proposes new paragraphs §§ 447.5109(d) and 447.510(i) to implement these statutory changes into regulation. The proposed rule specifies a process to identify, notify, and correct a manufacturer's drug misclassification and to impose other penalties such as civil monetary penalties or temporary suspension of the drug from the MDRP.

As stated before, the Commission made a recommendation in 2018 to give the Secretary additional authority to address drug misclassifications, which was reflected in the MSIAA provisions (MACPAC 2018). The Commission appreciates CMS's efforts to develop a process to address drug misclassifications with specific steps and timelines in regulations. It is important for drug manufacturers to have clearly defined steps and timelines that address misclassifications and for states to understand how these misclassifications could affect rebate amounts or coverage under the MDRP.

At the time of its recommendation, the Commission considered but did not recommend that CMS have the authority to suspend a misclassified drug from the MDRP (MACPAC 2018). In its deliberations, the Commission determined that the threat to beneficiary access outweighed the benefits of such a measure and that the authority to reclassify a drug or to impose financial penalties would be a more appropriate remedy. The Commission reiterates its concern that a drug's suspension from the MDRP could have harmful effects on beneficiaries who rely on the drug, particularly if that drug is the primary course of treatment with few therapeutic alternatives, and would encourage CMS to seek other remedies such as financial penalties and only suspend a drug in rare instances.

Rebate cap

The proposed rule makes conforming changes to reflect the provision in the ARP to remove the cap on maximum rebate amounts for periods beginning on or after January 1, 2024. The Commission made this recommendation in its June 2019 report (MACPAC 2019). We appreciate CMS making the conforming change prior to the January 1, 2024 start date to eliminate any potential confusion that could have been caused if the statute and regulation were not aligned.

Drug price verification survey

CMS proposes to survey drug manufacturers and wholesalers regarding prices reported under section 1927(b)(3)(A) of the Social Security Act to ensure that Medicaid payments and applicable rebates can be made and that Medicaid payments are economical, efficient, and provide access to care. The collection of this information could assist states in establishing and negotiating payment for certain high-cost prescription drugs. Over the past several years, the Commission has engaged with stakeholders to identify additional tools that could help states manage utilization of and spending for prescription drugs. The Commission generally supports efforts that could help states better understand and negotiate drug prices. We offer a few technical comments on the proposed survey methodology for CMS to consider based on our prior work with Medicaid data.

CMS proposes to exclude certain covered outpatient drugs from the survey based on certain criteria such as a manufacturer's willingness to negotiate further rebates either through a CMS-authorized supplemental rebate or a manufacturer's participation in a CMS drug pricing program or initiative. In §447.510(k)(3)(ii), CMS proposes to exclude a covered outpatient drug for which the manufacturer has negotiated a supplemental rebate with over half of states that results in a total rebate percentage (total statutory and supplemental rebate divided by gross drug spending for the drug) that is greater than the average total rebate percentage across all drugs for states that



cover outpatient drugs on a fee-for-service (FFS) basis as reflected on the most recent CMS-64 financial management report (FMR).

First, the Commission would like to note that a drug with a higher than average rebate percentage is not necessarily reflective of a manufacturer's willingness to negotiate and may be more attributable to price increases over time. In MACPAC's analysis of state drug utilization data and Medicaid unit rebate amounts for fiscal year (FY) 2020, we found that brand drugs received a statutory rebate that was approximately 61.6 percent of gross drug spending. However, this differed greatly between brand drugs that received an inflationary rebate and those that did not. Over 50 percent of brand drugs (as counted at the National Drug Code level) received an inflationary rebate, and on average, these brand drugs had a total statutory rebate of 72.3 percent of gross drug spending compared to 26.9 percent for brand drugs that did not receive an inflationary rebate (MACPAC 2022).

CMS's proposed survey exclusion methodology in §447.510(k)(3)(ii) may largely leave out drugs that have large inflationary rebates due to substantial price increases over time. While these drugs have a higher than average rebate, the inclusion of some of these products in the price verification survey may result in a better understanding of the factors contributing to these increases in price. Furthermore, many high-cost drugs may not have a higher than average rebate. Many high-cost drugs launch at a high price, but do not increase prices substantially over time, so they are likely to have lower inflationary rebates. Additionally, many high-cost drugs are new products with limited or no competition and, thus, have basic rebates that are closer to the minimum rebate of 23.1 percent.

In our analysis, we found that drugs (including generic drugs) under \$1,000 per claim had an average statutory rebate of 56.1 percent of gross drug spending, whereas drugs between \$1,000 and \$10,000 per claim received 52.1 percent in rebates and drugs greater than \$10,000 per claim received 43.8 percent in rebates (MACPAC 2022). If CMS's initial exclusion is primarily focused on drugs whose manufacturer has shown a willingness to negotiate, it may want to consider exclusion based on the extent to which the supplemental rebate increases the total rebate beyond the statutory rebate amount. For example, CMS could consider excluding drugs whose manufacturer has negotiated a supplemental rebate agreement with more than half the states and has a supplemental rebate percentage that is greater than the average supplemental rebate percentage.

Second, CMS has stated that the price verification survey will only include single-source covered outpatient drugs (i.e., brand drugs). The rebate amounts reported on the CMS-64 FMR are aggregated at the state-level across brand and generic drugs. Overall, MACPAC found that total rebates (statutory plus supplemental rebates) reported on the CMS-64 across FFS and managed care were approximately 54.6 percent of gross drug spending reported in the state drug utilization data. Brand drugs receive a substantially higher statutory rebate than generic drugs. In FY 2020, MACPAC calculated that brand drugs received an average statutory rebate of 61.6 percent of gross drug spending while statutory rebates for generic drugs were only 8.6 percent of gross drug spending (MACPAC 2022). By using the aggregated rebate amount as reported on the CMS-64, CMS could exclude some drugs from the survey that have a rebate amount that is less than the average brand drug. CMS could consider excluding drugs from the survey that have a total rebate percentage higher than the average statutory rebate percentage for brand drugs.

Third, MACPAC would like to note the potential for data anomalies within the CMS-64 reports due to the timing of when drug expenditures and rebates are reported as well as prior period adjustments. States are generally able to report drug spending in the quarter during which the drug was dispensed due to the short lag in the payment of drug claims. However, due to the time it takes to collect the drug utilization information and invoice drug manufacturers for the rebate, the rebates collected in any particular quarter are generally attributable to drugs purchased in prior quarters; thus, the gross spending and rebate dollars for any given time period are not necessarily aligned. Changes in covered populations or benefit design (e.g., managed care expansion of



pharmacy carve-in or -out) can create distortions in the data for a particular period because changes will be reflected in gross spending before they are reflected in rebates collected. Furthermore, the CMS-64 net FMR includes spending on services paid during the reporting quarter as well as prior period adjustments, which are increases and decreases made to expenditures previously reported on a prior CMS-64 filing. In our analyses of CMS-64 data, MACPAC has found that prior period adjustments can create large year-to-year variations in spending that primarily reflect the timing of when they are reported. This is particularly true when analyzing spending at the state- or service-level (MACPAC 2020). CMS may want to consider a process for identifying potential data anomalies in the CMS-64 data due to a significant change in a state's program (e.g., recent pharmacy carve-out from managed care) or prior period adjustments.

Thank you for the opportunity to comment on this proposed rule. The Commission appreciates CMS's efforts to improve program integrity and administration within the Medicaid Drug Rebate Program. Please let us know if there is any further information MACPAC can provide you to aid in your consideration of our comments or that would be helpful as you finalize the rule.

Sincerely,



Melanie Bella, MBA
Chair

cc: The Honorable Ron Wyden, Chair, Senate Finance Committee
The Honorable Mike Crapo, Ranking Member, Senate Finance Committee
The Honorable Cathy McMorris Rodgers, Chair, House Energy and Commerce Committee
The Honorable Frank Pallone, Jr., Ranking Member, House Energy and Commerce Committee

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