July 25, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted electronically via regulations.gov

Re: Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program [CMS-2434-P]

Dear Administrator Brooks-LaSure:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to the proposed rule titled "Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program [CMS-2434-P]" published in the Federal Register on May 26, 2023.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP's nearly 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.

BIN/PCN on Medicaid Managed Care Cards (§ 438.3(s)(7))

AMCP supports CMS' proposal to require Medicaid Managed Care Organizations (MCOs) to assign unique Medicaid-specific Beneficiary Identification Numbers (BIN), Processor Control Numbers (PCN), and group number identifiers for inclusion on beneficiary ID cards. This change would enable pharmacies to identify patients as Medicaid beneficiaries to reduce the incidence of 340B duplicate discounts and foregone rebates.

Drug manufacturers have shouldered the financial burden of duplicate discounts without any means of identifying when a 340B drug is dispensed to a Medicaid patient. Although the Medicaid Exclusion File is used in some states to exclude 340B drugs from Medicaid drug

rebate requests and HRSA oversight is available through audits, these approaches have proven insufficient to alleviate the duplicate discount problem.[1]

For these reasons, AMCP applauds CMS' steps toward prevention of duplicate discounts and believes that this simple requirement may help ensure that the most vulnerable patients have access to the drugs they need at a price they can afford.

Drug Cost Transparency in Medicaid Managed Care Contracts (§ 438.3(s)(8))

AMCP generally supports efforts to promote transparency within the health care system but is concerned about the potential for unintended consequences on the competitive marketplace. CMS is proposing that state Medicaid programs require Medicaid MCOs to include provisions in contracts with subcontractors for the delivery or administration of Covered Outpatient Drugs (CODs) that would require reporting of separate amounts related to: (1) the costs for incurred claims; and (2) the administrative costs, fees, and expenses of the contractor.

AMCP believes that the U.S. health care delivery system benefits from a competitive marketplace which provides increased value to patients and payers. Over time, competition has pushed health plans and pharmacy benefit managers (PBMs) to develop utilization management and clinical evaluation tools such as tiered co-payments, prior authorization, and mail-order services. Additionally, competition has continued to foster the adoption of increasingly innovative strategies by plans and PBMs. These newer tools include value-based contracting programs, affordability solutions geared towards certain critical medications, and advanced approaches to rebating and formulary management.

Policies that disincentivize competition restrict the ability of plans, PBMs, and manufacturers to collaborate and innovate best practices concerning the pharmacy benefit. AMCP urges caution regarding the potential to dampen competition while creating an excessive administrative burden for MCOs and their subcontractors. Plans and PBMs should be able to determine the allocation of costs, fees, and expenses among themselves as part of their contractual relationships within the free market. For this reason, AMCP urges caution.

Proposal to Account for Stacking When Determining Best Price (§ 447.505)

AMCP strongly encourages CMS to consider the impact stacking may have on drug market dynamics. CMS proposes to revise § 447.505(d)(3) to clarify that a manufacturer must adjust the best price for a covered outpatient drug for a rebate period if cumulative discounts to best price eligible entities subsequently adjust the price available from the manufacturer for the drug. For example, if a manufacturer provides a discount to a wholesaler, then a rebate to the provider who dispensed the drug unit, and then another rebate to the insurer who covered that drug unit, CMS has concluded that the best price must include all the discounts and rebates associated with the final price.

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[1] GAO Report to Congressional Requesters, 340B Drug Discount Program, Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement, January 2020. Available at https://www.gao.gov/assets/gao-20-212.pdf.
See also, Chary, S. Duplicate Discounts Threaten the 340B Program During COVID-19, Oct 2020. Available at https://blog.petrieflom.law.harvard.edu/2020/10/14/duplicate-discounts-340b-covid19/

AMCP believes that to provide the greatest value to Americans who need prescription drugs, market forces must effectively ensure that manufacturers of similar drugs compete with one another to establish reasonable pricing levels and maintain consumer access to needed therapies. The Medicaid best price provisions were originally intended to ensure the Medicaid program receives the lowest price on CODs but have had the unintended consequence of disincentivizing manufacturers from offering discounts that would then also apply to the nationwide Medicaid market.

Stacking has the potential to amplify this unintended effect by further shifting costs to other payers as manufacturers look to cover their costs in other ways. This artificially inflates drug costs for employers, state and federal employees, health benefits programs, privately insured patients, and health care providers. AMCP urges CMS to exercise caution in implementing changes that may disrupt free market forces.

Transparency of Manufacturer Misclassification (§ 447.509(d)(5))

AMCP advocates for increased transparency within health care to maintain the affordability of the prescription drug benefit. AMCP believes that CMS' proposal to publish an annual report of the CODs identified as misclassified and any steps taken to reclassify the drugs would further this goal. If finalized, the new transparency requirements would provide the public access to information on drugs misclassified in the previous year.

Proposal to Establish a Drug Price Verification Survey Process of Certain Reported CODs (§ 447.510)

AMCP supports CMS' proposal to establish a drug price verification survey. AMCP is a strong proponent of transparency within health care because having complete information allows payers, such as state Medicaid programs, to make informed health care resource decisions.

State Medicaid programs and MCOs currently receive cost data on CODs dispensed through retail pharmacies through the monthly NADAC file. States then use this data to establish reimbursement methodologies for both the ingredient cost and professional dispensing fee components of CODs. If a drug is not traditionally dispensed through retail pharmacies, no such survey data is currently captured. Referencing both the emergence of specialty and high-cost gene therapy drugs, as well as new models for the production and distribution of these drugs, CMS is proposing to use its authority under the MDRP to: (1) identify select drugs subject to price verification; (2) survey manufacturers and wholesalers on a variety of pricing, product, and cost topics; and (3) publicly post the non-proprietary results of the survey. As a goal for this proposed initiative, CMS specifically cites arming state Medicaid programs with drug pricing information to enable them to "better negotiate supplemental rebates."

Conclusion

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with CMS. If you have any questions regarding AMCP's

comments or would like further information, please contact AMCP's Director of Regulatory Affairs, Geni Tunstall, at etunstall@amcp.org or (703) 705-9358.

Sincerely,

Susan A. Cantrell, MHL, RPh, CAE
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