mhpa Medicaid Health Plans of America

July 25, 2023

Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–2434–P,
P.O. Box 8016, Baltimore, MD 21244–8016

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,

On behalf of the Medicaid Health Plans of America (MHPA), we thank you for the opportunity to provide input on the Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program Proposed Rule (CMS–2434–P).

MHPA is the only national trade association with a sole focus on Medicaid, representing more than 130 Medicaid Managed Care Organizations (MCOs) serving more than 52 million Medicaid beneficiaries in 40 states, the District of Columbia and Puerto Rico. MHPA's members include both for-profit and non-profit, national, regional, as well as single-state health plans that compete in the Medicaid market. Nearly three-quarters of all Medicaid beneficiaries receive health care through MCOs, and the Association provides research and advocacy services that support policy solutions to enhance the delivery and coordination of comprehensive, cost-effective, and quality health care for Medicaid beneficiaries.

Below you will find our comments in response to this rule.

Requirement of BIN/PCN Inclusion on Medicaid Managed Care Pharmacy Identification Cards
We applaud the Centers for Medicare & Medicaid Services (CMS) for taking steps to ensure that pharmacists have the information necessary to process claims, including whether a patient is enrolled in a Medicaid managed care plan or if a claim is paid for under the 340B Drug Pricing Program. Adding unique identifiers would make members' Medicaid managed care status distinguishable from the other lines of business offered by the MCO. The identification of a Medicaid member at the point of dispensing can result in the pharmacy placing a code on the prescription so that the claim will be excluded from the Medicaid rebate pool and thus lower the incidence of duplicate discounts.

As the Medicare Part D program has successfully implemented the inclusion of BIN/PCN numbers for pharmacy cards, we believe it would help to lower the incidence of duplicate discounts and increase efficiency within the MDRP while posing little operational impact to MCOs.

MHPA is generally supportive of this provision but would like to share a recommendation to facilitate the implementation of this requirement. Specifically, we recommend that rather than requiring identification (ID) cards to have a unique National Council for Prescription Drug Programs (NCPDP) Processing Bank Identification Number (BIN), unique Processor Control Number (PCN), and unique group number identifier, that CMS instead require that ID cards have a unique BIN, PCN, and group *combination*. We believe that providing some flexibility for this requirement would accomplish CMS' goal of beneficiary ID

cards clearly identifying whether a patient is covered by Medicaid and whether a claim is covered under the 340B Drug Pricing Program.

MHPA also recommends that CMS delay implementation of this requirement by a year to allow time for new cards to be created and distributed to enrollees. Given the current bandwidth constraints at the State and MCO level tied to redeterminations efforts, we believe that a delay in implementation would allow stakeholders the time necessary to implement and communicate this requirement more effectively.

Payment of Claims
We express thanks and appreciation to CMS for its proposed revisions to third-party liability and "pay and chase" policies. Allowing 90 days for third-party liability to be resolved while ensuring that access to care for Medicaid enrollees is not adversely affected will help maintain continuity of care while reducing the administrative burden on stakeholders.

Drug Cost Transparency in Medicaid Managed Care Contracts
We appreciate CMS' efforts to promote transparency in drug costs for the Medicaid program and to ensure accurate calculation of MCOs' Medical Loss Ratios (MLRs). As CMS considers new requirements pertaining to drug cost data collection, we recommend alignment with other payer models, such as the prescription drug data collection requirements for commercial health insurance. Alignment would facilitate the ability of MCOs to provide cost transparency, minimize burden, and would improve the ability of CMS to compare drug costs across delivery systems.

Proposal To Modify the Definition of Covered Outpatient Drug (COD)
We appreciate CMS' interest in increasing clarity regarding "direct reimbursements" and support the proposal to modify the definition of "covered outpatient drug (COD)." This proposed change would help to address situations in which providers incorrectly report or misclassify drugs in the Medicaid Drug Rebate Program (MDRP) – helping to ensure states receive the MDRP rebates to which they are entitled.

Proposal to Account for Stacking When Determining Best Price
We applaud CMS for its proposal to make clear that "manufacturers have to stack all applicable discounts that they offer on a single sale of a COD, including discounts or rebates provided to more than one best price eligible entity," including in instances where "cumulative discounts, rebates, or other arrangements to best price eligible entities subsequently adjust the prices available from the manufacturer."

We support this proposal as it would ensure states are receiving "best price" as intended under MDRP and capturing maximum rebate dollars.

Proposal To Establish a Drug Price Verification Survey Process of Certain Reported CODs
We commend CMS' interest in drug price verification and transparency through data collection by proposing to establish a survey process of certain reported CODs. We support the proposal as it will lead to increased drug price transparency but request increased information on the details of required disclosures.

Federal Financial Participation (FFP): Conditions Relating to Physician-Administered Drugs
We appreciate CMS' commitment to ensuring states receive the COD rebates they are entitled to under the MDRP. States are currently required to provide for the collection and submission of utilization data and coding (such as J-codes and NDC numbers) for a COD that is a single source or a multiple source drug that is a top 20 high dollar volume physician-administered drug on a published list (based on highest dollar

volume dispensed under Medicaid identified by the Secretary) in order for states to secure applicable Medicaid rebates. The proposed regulation would specify to states that they should invoice for rebates for all multiple source physician administered drugs that are CODs, and not limit rebates invoicing the top 20 high dollar volume list to receive federal matching funds.

We support CMS' efforts to align statutory requirements but urge CMS to consider potential burdens these requirements may have on states.

Request for Information on Requiring a Diagnosis on Medicaid Prescriptions

MHPA supports the objective of ensuring that CODs are used for "medically accepted indications," but cautions that there could be significant operational implications and member impacts if this proposal is implemented without adequate flexibility. Requiring a diagnosis code for Medicaid prescriptions creates the potential for administrative error that can cause a claim to be rejected or delay an approval; we believe this administrative burden puts patient access to care at risk by establishing a barrier to needed treatments for Medicaid enrollees. Despite low or no-copayment requirements in state Medicaid programs, medication adherence continues to be a challenge for low-income individuals who may be facing issues that include transportation difficulties or health literacy, or other structural barriers. In addition, as Medicaid enrollees are being redetermined for eligibility for the first time in three years, we believe that interruptions in continuity of coverage could be further exacerbated by the implementation of this policy.

Operationally, this provision would be difficult for Medicaid MCOs to monitor for compliance, as physicians would be responsible for adding codes to prescriptions. In addition, we anticipate that pharmacies could have difficulties validating these codes. If CMS plans to leverage ICD-10 codes to provide diagnosis information, we express reservations and underscore that these codes are not treatment indication code values and could create conflict between details in the medical record and the ICD-10 code submitted on the prescription claim. Issues such as a medical claim having multiple diagnoses could interfere with claims processing systems, and we may see rejections of valid prescriptions due to missing information.

Further, we anticipate issues with this policy related to "off-label" prescriptions, which account for 10 to 20 percent of all prescriptions written.[1] Off-label prescribing is used for populations that are often excluded from clinical trials, such as children, pregnant individuals, the elderly, and psychiatric patients. Physicians have the authority to make off-label prescriptions when conforming to clinical practice standards and when the prescription is in the best interests of the patient on the basis of scientific data supporting the use of the COD in that context.[2] Requiring a diagnosis for Medicaid prescriptions could hamper access to established treatments for some of the most vulnerable populations who are eligible for Medicaid, including children and pregnant individuals. As CMS considers requiring diagnosis codes for Medicaid prescriptions of CODs, we recommend ensuring that the benefits of the proposal outweigh the potential unintended consequences to members, pharmacists, and providers.

[1] American Medical Association Journal of Ethics, "Prescribing "Off-Label": What Should a Physician Disclose". Katrina Furey, MD and Kristen Wilkins, MD. Accessed at https://journalofethics.ama-assn.org/article/prescribing-label-what-should-physician-disclose/2016-06

[2] *Id.*

Once again, thank you for the opportunity to provide comments on this proposed rule. We appreciate the opportunity to share our perspective to address barriers to care in the Medicaid Drug Rebate Program and look forward to continuing to work with CMS and our state partners to make a meaningful difference in the lives of Medicaid beneficiaries.

Please feel free to reach out to me directly at sattanasio@mhpa.org with any questions or should you need any additional information.

Sincerely,

/s/

Shannon Attanasio
Vice President, Government Relations and Advocacy