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July 25, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–2434–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program

Administrator Brooks-LaSure,

The National Community Pharmacists Association (NCPA) writes today to provide feedback on CMS' [proposed rule](#): *Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program*.

NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a \$78.5 billion healthcare marketplace, employ 240,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

Standard Medicaid Managed Care Contract Requirements (§ 438.3(s))

BIN/PCN on Medicaid Managed Care Cards

CMS is proposing to amend § 438.3(s) to require MCOs, PIHPs, and PAHPs that provide coverage of covered outpatient drugs to assign and exclusively use unique Medicaid-specific BIN, PCN, and group number identifiers on all issued Medicaid managed care beneficiary identification cards for pharmacy benefits.

NCPA supports this provision. As CMS stated, with the inclusion of Medicaid-specific BIN/PCN and group numbers on the pharmacy identification cards issued to the enrollees of MCOs, PIHPs and PAHPs, pharmacies would be able to identify patients as Medicaid beneficiaries. This would be helpful to all parties to ensure that Medicaid benefits are applied appropriately. Additionally,

as CMS stated, if Medicaid-specific BIN/PCN and group information were included on the card, the pharmacy could enter this information into its claims processing system which would identify that the beneficiary is enrolled in a Medicaid managed care plan. CMS believes it is important that unique BIN/PCN/group numbers are established for Medicaid managed care plans for several program needs, including facilitating the appropriate identification of cost sharing and ensuring claims are billed and paid for appropriately.

CMS also states that this provision would also help avoid duplicate discounts between Medicaid and the 340B Drug Pricing Program. **NCPA opposes pharmacies being required to identify 340B claims either prospectively or retroactively. Pharmacies submitting a 340B identifier involves high administrative burden and financial risk and should be considered a last resort. NCPA opposes retroactive identification of 340B units by pharmacies, as it is unduly burdensome for pharmacies to be able to comprehensively make these identifications. NCPA has found that the N1 transaction is not feasible as it is not adopted by pharmacy information systems. NCPA supports an alternative solution where Third-Party Administrators provide 340B data to CMS.** For details, see NCPA's comments on 340B claims identification submitted to CMS' *Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments* back in March 2023.¹

Drug Cost Transparency in Medicaid Managed Care Contracts

CMS is proposing that Medicaid managed care plans that subcontract with a pharmacy benefit administrator or pharmacy benefit manager require the subcontractor to provide specific details to the Medicaid managed care plans about the various pharmacy and non-pharmacy (administrative) costs associated with providing the pharmacy benefit, so the managed care plan can appropriately calculate its Medicaid managed care MLR.

Specifically, CMS is proposing to amend § 438.3(s) to require Medicaid MCOs, PIHPs, and PAHPs that provide coverage of covered outpatient drugs (CODs) to structure any contract with any subcontractor for the delivery or administration of the COD benefit require the subcontractor to report separately the amounts related to the incurred claims described in § 438.8(e)(2), such as reimbursement for the CODs, payments for other patient services, and the dispensing or administering providers fees, and subcontractor administrative fees. The proposal would ensure that MLRs reported by MCOs, PIHPs, and PAHPs that use subcontractors in the delivery of COD coverage would be more accurate and transparent. The separate payment requirements would help States and managed care plans better understand whether they are appropriately and efficiently paying for the delivery of CODs, a significant part of which is funded by the Federal Government.

CMS believes this new transparency requirement would assist States and Medicaid managed care plans in complying with § 438.8 and related guidance because subcontractor PBMs would be required to appropriately identify certain costs, so that the managed care plan can appropriately calculate its MLR. In particular with COD spending, the managed care plan would have to

¹ See [comments-cms-part-d-inflation-rebatesL.pdf \(ncpa.org\)](https://www.ncpa.org/wp-content/uploads/2023/03/comments-cms-part-d-inflation-rebatesL.pdf).

separately identify prescription drug and dispensing or administration fee claim costs when calculating the MLR, in contrast to administrative costs. As a result, any payments for costs over and above the cost of the prescription and dispensing fee would be separately identifiable by the managed care plan and cannot be used to inappropriately inflate the MLR which may result in managed care plan capitation rates that are not actuarially sound. **NCPA supports these PBM transparency provisions.**

Additionally, NCPA asks CMS to provide further regulation requiring:

- **A pass-through payment model, where all monies to PBMs (e.g., reimbursements, rebates, etc.) are passed through to the MCO, and PBMs are paid a flat administrative fee. This would eliminate the PBM’s ability to benefit from spread pricing.** NCPA supports current legislation (S. 1038, Drug Price Transparency in Medicaid Act of 2023 / H.R. 3561, the PATIENT Act) that would ban spread pricing in Medicaid.²
- **PBMs to reimburse pharmacies based on a transparent benchmark like National Average Drug Acquisition Cost (NADAC) with a commensurate dispensing fee comparable to the state’s Medicaid fee for service dispensing fee.**
- **The prohibition of PBMs/plans/MCOs from reimbursing non-affiliate pharmacies less than PBM owned or PBM affiliated pharmacies.** NCPA supports current legislation (H.R.2880 - Protecting Patients Against PBM Abuses Act) that contains similar affiliate pharmacy language for Medicare Part D plans.

Proposals Related to State Plan Requirements, Findings, and Assurances (§ 447.518)

In this proposed rule, CMS is proposing to clarify the data requirements that States must submit to establish the adequacy of both the current ingredient cost and the professional dispensing fee reimbursement. Furthermore, CMS is specifying professional dispensing fees cannot simply be determined by a market-based review of what other third-party payers may reimburse for dispensing prescriptions. CMS proposes to clarify in regulatory text that in a State’s periodic review of the rates being paid to pharmacies, the examination of market-based research data used to justify dispensing costs is an inappropriate basis for determining professional dispensing fees.³ **NCPA supports this proposal.**

In 2016, CMS finalized 42 CFR 447.518 that stipulates that “States must provide adequate data such as a State or national survey of retail pharmacy providers or other reliable data other than a survey to support any proposed changes to either or both of the components of the reimbursement methodology.”⁴ CMS further stipulated that “...states have several options when reviewing and adjusting their professional dispensing fee (including

² See [Bipartisan Senate Bill Will Ban PBM Spread Pricing, Pay Pharmacies Appropriately, Protect Taxpayers | NCPA](#).

³ See *Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program*, at 34773. May 26, 2023. Available at: [2023-10934.pdf \(govinfo.gov\)](#).

⁴ See 42 CFR 447.518(d)(1). Available at: [eCFR :: 42 CFR 447.518 -- State plan requirements, findings, and assurances](#).

using a neighboring state’s survey results, conducting their own survey, or using survey data from a prior survey within a reasonable timeframe]).”⁵ However, while rejecting an annual cost of dispensing study,⁶ CMS did not finalize the frequency of the study:

We agree that to the extent that a state is conducting a cost of dispensing study, it should be a transparent, comprehensive, and well-designed tool that addresses a pharmacy provider’s cost to dispense the drug product to a Medicaid beneficiary. States retain the flexibility to set professional dispensing fees, including creating a differential reimbursement per provider delivery type. We disagree that they should be required to use any specific methodology or study to do so, because we believe that states are in the best position to establish fees based on data reflective of the cost of dispensing drugs in their state.⁷

NCPA asks CMS to promulgate further regulations stipulating the baseline frequency for Medicaid programs to conduct cost of dispensing studies. Especially in light of inflation, NCPA advocates that such studies occur no less than every three years. In 2020, NCPA along with National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) and the National Association of Specialty Pharmacy (NASP) conducted a study that revealed that pharmacies' cost of dispensing Medicaid prescriptions exceeds the dispensing fee paid by 46 of 47 states.⁸

Request for Information—Comments on Issues Relating to Requiring a Diagnosis on Medicaid Prescriptions as a Condition for Claims Payment

Under the MDRP, a COD is generally defined as a prescribed drug that is FDA approved and used for a medically accepted indication. While the statute limits the definition of a COD to those products used for “medically accepted indications,” without a diagnosis on a prescription drug claims, CMS stated that it is difficult to determine whether a drug is being used for a medically accepted indication, and if it therefore satisfies the definition of a COD, and is rebate eligible.

CMS is soliciting comments on the possibility and potential impact of proposing a requirement that a patient’s diagnosis be included on a prescription as a condition of receiving Medicaid FFP for that prescription. CMS is soliciting comment on the patient care, clinical, and operational impact of requiring that a patient’s diagnosis be included on a prescription as a condition of a State receiving FFP for that prescription. CMS is particularly interested in understanding any operational implications, privacy related concerns, the burden associated, and how to negate any foreseeable impact on beneficiaries and providers, including what steps would be needed by States to successfully implement a Medicaid requirement for diagnosis on prescriptions.

⁵ See *Medicaid Program; Covered Outpatient Drugs*, page 5331. February 1, 2016. Available at: [2016-01274.pdf \(govinfo.gov\)](#).

⁶ *Id.* at 5202.

⁷ *Id.* at 5311.

⁸ See <https://ncpa.org/newsroom/news-releases/2020/03/02/pharmacy-reimbursement-modernization-needed-report-says>.

NCPA opposes such a requirement, as it would result in great administrative burden to pharmacists. Physicians frequently write off-label prescriptions, which would further complicate such a proposal. This requirement could also result in pharmacists being subject to audits, and would be unnecessarily duplicative given the work of states' drug review boards.

Conclusion

NCPA is committed to working with CMS and other stakeholders on these important matters. If the agency requires further information or has questions, please contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

A handwritten signature in black ink, appearing to read 'Steve Postal', with a long horizontal line extending to the right.

Steve Postal, JD
Director, Policy & Regulatory Affairs
National Community Pharmacists Association