July 25, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services (CMS)
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, Proposed rule [Docket No. CMS–2434–P]

Dear Administrator Brooks-LaSure,

The American Pharmacists Association (APhA) and the National Alliance of State Pharmacy Associations (NASPA) are pleased to submit comments on the "Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program," proposed rule.

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

NASPA, founded in 1927 as the National Council of State Pharmacy Association Executives, is dedicated to enhancing the success of state pharmacy associations in their efforts to advance the profession of pharmacy. NASPA's membership is comprised of state pharmacy associations and over 70 other stakeholder organizations. NASPA promotes leadership, sharing, learning, and policy exchange among its members and pharmacy leaders nationwide.

Overall comments on Medicaid-managed care plan contracts

As a result of the predatory practices of pharmacy benefit managers (PBMs), patients' access to medications from their local pharmacist across the country has declined[1], taxpayer dollars have been funneled into corporate profits[2], and generationally owned community pharmacies have been driven out of business.[3] Recently, a study found that PBM tactics forced Oregon Medicaid to overpay $1.9M on a single drug, where PBMs marked up the drug by 800 percent.[4] Appropriate

[1] Rose J, Krishnamoorth R. Why your neighborhood community pharmacy may close. *The Hill*. Available at https://thehill.com/blogs/congress-blog/healthcare/530477-why-your-neighborhood-community-pharmacy-may-close
[2] 3 Axis Advisors. Analysis of PBM Spread Pricing in New York Medicaid Managed Care. Available at http://www.ncpa.co/pdf/state-advoc/new-york-report.pdf
[3] Callahan C. Mom-and-pop pharmacies struggle to hang on. *Times Union*. Available at https://www.timesunion.com/hudsonvalley/news/article/Mom-and-pop-pharmacies-struggle-to-hang-on-16187714.php
[4] https://oregonpharmacy.org/2022/10/27/oregon-report/

action is necessary to address the misaligned incentives in the PBM industry that prioritize profits over patients.

Robust transparency, independent oversight, and appropriate consequences to disincentivize infractions are vital themes that must be included in Medicaid-managed care plans contracts with PBMs. Transparency is needed to ensure PBM business practices that prioritize profits over patients are minimized. Included within this oversight is the need to prohibit specific PBM practices that can be detrimental to patients. For example, PBMs may attempt to coerce a patient to break their long-standing relationship with their local pharmacist and begin filling medications at another certain mail order, specialty, or retail pharmacy by making it more inconvenient for the patient to access their medications.[5] Numerous studies[6,7,8] have shown that adherence to medications increases when patients are able to fill a 90-day supply. However, despite a prescriber's intention to write a prescription for a 90-day supply and a pharmacist's intention to fill for a 90-day supply, PBMs may only cover a percentage of the days' supply. For example, a PBM may only cover a 30-day supply at a local community pharmacy but would cover a 90-day supply if the patient filled at another mail order, specialty, or retail pharmacy. Not only does this attempt to coerce a patient to sever their relationship with their pharmacist, but if the patient decides to continue filling their medications at their local community pharmacy can decrease their adherence to their medications leading to potentially worse health outcomes for the patient.

Independent oversight of the PBMs is necessary to regularly monitor activities and complete audits as frequently as needed to ensure compliance with state laws and regulations. Authority for this oversight may be granted to either or both an independent organization with no financial ties to the PBM and the state Medicaid program. We would encourage the use of an independent organization to monitor pricing discounts, rebates of any kind, inflationary payments, credits, clawbacks, fees, grants, chargebacks, reimbursements, or other benefits received by the PBM and to share this information with the general public for additional scrutiny. This independent organization should have no financial, governance, or leadership ties to the PBM and should have complete transparency to monitor benefits received by the PBM. Regular reports should be submitted to the state Medicaid program, and the Medicaid Director should have the authority to conduct an audit of the PBM at any time. Prohibition of auditors utilizing extrapolation as a means of payment for the audit recoveries and requiring states to reimburse pharmacies for any overpayments recovered by the states from the Medicaid-managed care organizations must also be an integral part of any Medicaid audit and oversight of PBMs.

States have taken different approaches to increasing the oversight of PBMs. Kentucky[9] and Ohio[10] Medicaid programs both recently moved to a single PBM. California[11] and New York[12] Medicaid programs recently carved-out pharmacy benefits from their managed care programs and transitioned them to fee-for-service. The impact of these programs has been a greater level

[5] PBM ABUSES. National Community Pharmacists Association. Available at https://ncpa.org/sites/default/files/2020-12/pbm-business-practices-one-pagers.pdf
[6] Rymer JA, et al. Difference in Medication Adherence Between Patients Prescribed a 30-Day Versus 90-Day Supply After Acute Myocardial Infarction. Journal of the American Heart Association. Available at https://www.ahajournals.org/doi/10.1161/JAHA.119.016215
[7] Batal, et al. Impact of Prescription Size on Statin Adherence and Cholesterol. BMC Health Services Research. 2007; 7:175.
[8] Steiner, et al. The effect of prescription size on acquisition of maintenance medications. J Gen Intern Med.1993; 8(6):3063-10
[9] Pharmacy Policy Branch. Kentucky Cabinet for Health and Family Services. Available at https://www.chfs.ky.gov/agencies/dms/dpo/ppb/Pages/default.aspx
[10] Single Pharmacy Benefit Manager and Pharmacy Pricing and Audit Consultant. Ohio Medicaid Managed Care. Available at https://managedcare.medicaid.ohio.gov/managed-care/single-pharmacy-benefit-manager
[11] Medi-Cal Rx. California Department of Health Care Services. Available at https://www.dhcs.ca.gov/Pages/AboutUs.aspx
[12] Welcome to the NY Medicaid Pharmacy Program (NYRx). New York State Department of Health. Available at https://www.health.ny.gov/health_care/medicaid/redesign/mrt2/pharmacy_transition/

of transparency and oversight into PBM activities and has resulted in greater consistency and sustainability in the delivery of pharmacy benefits for Medicaid beneficiaries and pharmacies.

Additionally, appropriate consequences to disincentivize infractions are necessary and may be accomplished through monetary fines and/or the termination of licensure of a PBM in the state. For example, if the state Medicaid program suspects a violation in contract, state policy, or federal policy, the Medicaid program should have the authority to fine the PBM and/or terminate their licensure to serve as a PBM in the state.

9. Proposal Regarding Drug Price Verification and Transparency Through Data Collection (88 FR 34238)

While we appreciate the increase in transparency that will be the result of the proposed rule to better understand the level of spread pricing by PBMs in Medicaid-managed care, we feel the proposed rule needs to be improved. Our organizations recommend PBM spread pricing be prohibited in Medicaid-managed care plan contracts. By only increasing transparency, CMS will be aware of the level of spread pricing in Medicaid-managed care programs, but pharmacies will continue to be under-reimbursed, potentially leading to their closure and risk of patients' decreased access to necessary medications. Specifically, our organizations recommend CMS explicitly prohibit spread pricing between Medicaid-managed care plans and PBMs and between PBMs and pharmacies. Scrutiny of spread pricing must also account for effective rate clawbacks that deploy advanced drug pricing mechanics as a means to harvest spread outside the scope of traditional spread audits.[13,14]

10. Proposal To Clarify and Establish Requirements for FFS Pharmacy Reimbursement (88 FR 34238)

We recommend Medicaid-managed care plans structure contracts with PBMs to include consistent, transparent, fair, and sustainable reimbursement rates for medication ingredient costs and dispensing fees. It is necessary to mandate adequate reimbursement for the dispensing of medications to ensure a predictable environment for community pharmacies to operate and minimize the risk of further community pharmacy closure. States have taken many different approaches to ensuring reimbursement rates within state Medicaid fee-for-service and managed care programs are adequate. These approaches include using national benchmarks for ingredient costs, such as the National Average Drug Acquisition Cost (NADAC). Other states have developed their own version of a NADAC survey to provide a state-specific metric for ingredient costs. States have begun using regularly recurring cost-of-dispensing surveys conducted by organizations independent of PBMs to determine adequate dispensing fees. Others have taken additional approaches beyond the cost of a dispensing survey to ensure appropriate reimbursement. For example, Ohio implemented a regularly recurring cost of dispensing survey and a tiered structure based on total pharmacy script volume.[15] This allows for fair and equitable reimbursement for independent, regional, and chain pharmacies.

Overall, our organizations recommend CMS structure Medicaid-managed care plan contracts to include robust transparency, independent oversight, and appropriate consequences to disincentivize infractions by PBMs. Additionally, we recommend that Medicaid-managed care

[13] Rowland D. Ohio launches probe of PBM practice that critics say gouges patients and taxpayers. *The Columbus Dispatch.* Available at https://www.dispatch.com/story/news/2021/12/29/health-care-drug-prices-pharmacy-benefit-manager-pbm-money-maneuver-under-investigation-ohio/9037045002/.

[14] Tepper N. PBM clawbacks sidestep state bans on spread pricing. *Modern Healthcare.* Available at https://www.modernhealthcare.com/payment/pbm-clawbacks-sidestep-state-bans-spread-pricing.

[15] SPBM and PPAC Frequently Asked Questions (FAQs). Ohio Department of Medicaid. Available at https://managedcare.medicaid.ohio.gov/wps/wcm/connect/gov/de1fcc01-2e43-4085-a676-0ec62b3d21f3/SPBM+Provider+FAQ_September+2022.pdf?MOD=AJPERES&CVID=oe0eQNA

plans structure contracts with PBMs include consistent, transparent, fair, and sustainable reimbursement rates for medication ingredient costs and dispensing fees. We encourage CMS to include a timeframe of no less than every 3 years for which the state's cost of dispensing survey be updated.

13. Proposals Related to Managed Care Plan Standard Contract Requirements (88 FR 34238)

Overall, our organizations have several recommendations on requirements within managed care plans standard contracts. These recommendations are focused on coverage of pharmacists' patient care services under the medical benefit, consistency of over-the-counter (OTC) medication coverage, consistency of uniform preferred drug list (UPDL), and other recommendations.

Coverage of pharmacists' patient care services under the medical benefit

There are numerous examples of pharmacists' patient care services being covered under the state's medical assistance program. APhA has identified over 40 state plan amendments (SPAs) that expand coverage of pharmacists' services and are aware of programs in 28 states where a pharmacist's service is covered by Medicaid fee-for-service. Services are being reimbursed under the medical benefit using Healthcare Common Procedure Coding System Level I and Level II codes similar to those used by other health care professionals (physicians, advanced practice registered nurses, physician assistants, etc.) providing outpatient services, in settings such as pharmacies, offices, homes, walk-in retail health clinics, federally qualified health centers, rural health clinics, skilled nursing facilities, assisted living facilities, or other places of service.

The scope of reimbursable services under Medicaid is variable from state-to-state. Services include, but are not limited to, acute disease state management, chronic disease state management, diabetes self-management training services, hormonal contraceptive services, medication management services, services related to dispensing and education on opioid antagonists, test and treat for minor ailment services (influenza, Group A Streptococcus Pharyngitis, COVID-19, etc.), tobacco cessation services, transitions of care services, and travel medication services.

In order to implement these programs, state medical assistance programs are applying to the United States Department of Health and Human Services for amendments to their state Medicaid plan and requesting any necessary Medicaid waiver to implement programs to reimburse pharmacists for their services. For example, state Medicaid programs can submit emergency or regular state plan amendments (SPAs) to add pharmacists as "Other Licensed Practitioners," allowing reimbursement of the necessary "services" required for a patient "service," such as pharmacist-prescribing under the medical benefit. For example, pharmacists in Nevada recently were granted the authority to prescribe HIV pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) through a statewide protocol, and the state Medicaid program submitted a SPA to allow pharmacists to bill for services associated with the prescribing of HIV PrEP and PEP. In Nevada, pharmacists are able to bill Medicaid using a broad range of codes, including, but not limited to 99202-99205 and 99211-99215.[16]

Although many state Medicaid programs have begun covering pharmacists' patient care services under the medical benefit, there is a lack of consistency in the establishment of programs, especially in Medicaid-managed care programs. We recommend CMS issue guidance to the state Medicaid programs encouraging submission of state plan amendments (SPAs) to add

[16] Provider Type 91 Billing Guide. Nevada Medicaid. Available at https://www.medicaid.nv.gov/Downloads/provider/NV_BillingGuidelines_PT91.pdf

pharmacists as "Other Licensed Practitioners," allowing reimbursement of services with the pharmacists' state scope of practice. Additionally, we recommend that Medicaid-managed care plans contracts include the coverage of pharmacists' patient care services. Pharmacists should be paid under the medical benefit using comparable billing codes another health care professional would use for providing a comparable service and should be paid in parity with other comparable health care professionals.

Consistency of OTC medication coverage

There is a lack of consistent coverage of OTC medications by state Medicaid programs that are prescribed by pharmacists. For example, pharmacists in every state[17] can either prescribe naloxone themselves or dispense naloxone without a prescription in accordance with a protocol, standing order, or other process. With Naloxone moving to OTC,[18] there is concern that many patients, especially Medicaid beneficiaries will not be able to afford naloxone by paying out of pocket. Given the high accessibility of pharmacist-provided naloxone, there is concern that naloxone furnished by a pharmacist without a prescription will not be covered by state Medicaid programs. There are examples of state Medicaid programs covering OTC medications that are furnished by pharmacists. For example, Massachusetts Medicaid requires coverage of OTC emergency contraceptives when dispensed by a pharmacist without a prescription.[19] As pharmacists' authority to prescribe OTC medications continues to expand, it is necessary to ensure coverage of these needed medications for patients. Accordingly, our organizations recommend CMS require Medicaid-managed care plans include coverage for OTC medications prescribed, furnished, or dispensed without a prescription by a pharmacist.

Consistency of UPDL

States have transitioned to a UPDL for fee-for-service (FFS) and managed care beneficiaries for a variety of reasons, including that "it reduces disruptions in therapy when a member moves from one plan to another… encourages the use of the most cost-effective drugs within a PDL drug class"[20] and, "simplifies pharmacy benefits for prescribers and pharmacies".[21] Despite the benefits of a UPDL, over 60% of states with managed care do not have a unified UPDL.[22] We recommend Medicaid-managed care plans structure include a uniform preferred drug list consistent amongst all beneficiary classes and consistent with the state's UPDL for fee-for-service. It is imperative, however, that generic drugs be included or allowed as first-line therapy for patients because of the higher costs to pharmacies of many brand drugs listed on the UPDL.

Standard contract requirements (§ 438.3)

We support the provision that requires Medicaid-managed care plans and their PBMs to assign and exclusively use unique Medicaid-specific Beneficiary Identification Number (BIN), Processor Control Number (PCN), and group number identifiers for all Medicaid-managed care beneficiary identification cards for pharmacy benefits, beginning no later than the State's next rating period for the applicable Medicaid managed care contract. We are opposed to any requirement for pharmacies to identify 340B claims as pharmacy transaction/information systems are not capable of this type of transaction both as prospective or retrospective claims.

[17] Pharmacist Prescribing: Naloxone. *NASPA*. Published January 17, 2019. Available at https://naspa.us/resource/naloxone-access-community-pharmacies/
[18] FDA Approves First Over-the-Counter Naloxone Nasal Spray. *FDA*. Published March 29, 2023. Available at https://www.fda.gov/news-events/press-announcements/fda-approves-first-over-counter-naloxone-nasal-spray
[19] Coursolle A, McCaman. Coverage of Over-the-Counter Drugs in Medicaid. National Health Law Program. Available at https://healthlaw.org/wp-content/uploads/2019/12/OTC-Drugs-in-Medicaid-FINAL.pdf
[20] Frequently Asked Questions (FAQs) for Providers Regarding the Uniform Preferred Drug List. Minnesota Department of Human Services. Available at https://mn.gov/dhs/assets/pdl-faq-providers_tcm1053-378520.pdf
[21] Ibid
[22] State Medicaid Preferred Drug Lists. KFF. Available at https://www.kff.org/other/state-indicator/medicaid-preferred-drug-lists/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

Thank you for the opportunity to provide comments on the Proposed rule. Please contact APhA at mmurphy@aphanet.org and NASPA at jcover@naspa.us if you have any questions or require additional information.

Sincerely,

Michael Baxter
Acting Head of Government Affairs
American Pharmacists Association

Joni Cover
Vice President of Strategic Initiatives
National Alliance of State Pharmacy Associations