NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

November 15, 2022

Sent via Email: scott.mcanally@tn.gov.

Mr. Scott McAnally,
Director of Insurance
Tennessee Department of Commerce and Insurance (TDCI)
500 James Robertson Parkway
Nashville, TN 37243

RE: Proposed Emergency Rules Regarding Pharmacy Benefit Managers- Public Chapter 1070

Dear Director McAnally:

On behalf of our member pharmacies providing accessible, quality, and equitable care services in Tennessee, the National Association of Chain Drug Stores (NACDS) thanks the Tennessee Department of Commerce and Insurance (TDCI) for the opportunity to provide comments on the topic of pharmacy reimbursement practices by pharmacy benefit managers (PBMs).

Enforcement of Pro-Pharmacy Provisions

NACDS applauds TDCI for recognizing the need to enforce pro-pharmacy regulations that not only serve to reform and provide transparency into harmful PBM practices but also serve to advance a measurable and meaningful positive impact on pharmacy operations and reimbursement allowing pharmacists to better meet the needs of the patients they serve. Regarding the amendments included in chapter 1070, NACDS supports policies that would adopt processes for pharmacies to appeal unfair and inadequate reimbursement for prescription drugs. Furthermore, NACDS supports provisions establishing and granting oversight authority to the Commissioner over the PBM appeal process and provisions that would prohibit a PBM from shifting the cost of services related to an appeal to the pharmacy regardless of the outcome. However, with the support of those provisions, NACDS seeks clarity on the scope of application of such provisions that may lead to compliance issues and unintended liabilities to pharmacies and ultimately impact the enforceability of these regulations.

As written, *Section 0780-01-??-03(7)* states that "this rule shall not apply to a PBM that meets the requirements of T.C.A. § 56-7-3206(d) by utilizing a reimbursement methodology that is identical to the methodology provided for in the state plan for medical assistance approved by the federal Centers for Medicare and Medicaid Services." While it is our understanding that the reimbursement structure identified and approved by CMS is intended to ensure that pharmacies are not reimbursed below the cost to acquire and dispense prescription drugs, the above language could be interpreted to mean that such provisions do not apply to all PBMs and could serve as an unintended compliance loophole.

In addition to the provisions above, NACDS also has concerns with the language included in *Section 0780-01-??-04* regarding information pharmacies are to submit to the PBM upon filing an initial appeal. More specifically, as written the current language requires pharmacies to provide PBMs with "a copy of the invoice(s) showing the pharmacy's purchase price for the drug or medical product or device at issue, along with all discounts, price concessions, rebates, or other reductions, excluding cash discounts, received as of the date of the filing of the initial appeal by the pharmacy." Additionally, the language states that "if the pharmacy receives any additional discounts, price concessions, rebates, or other reductions, excluding cash discounts, during the pendency of an initial appeal, the

pharmacy shall inform the PBM of the additional discount, price concession, rebate, or other reduction, excluding a cash discount."

TDCI should be mindful that drug purchasing is complex, and it does involve a variety of discounts, rebates, and other pricing concessions. However, because a massive number of drug purchasing transactions occur each year, discounts can lag behind the actual drug purchase and may be received months later. In addition to the complex nature of reporting, several technical issues cause concern with this proposal. For example, discounts, rebates, and price concessions may be related to performance contracts that take place over a longer period and cannot be applied to patient transactions for a particular period. Furthermore, some discounts, rebates, and price concessions may be due to purchases of multiple products and may not be easily applied to particular products at a specific point in time that coincides with the invoice being provided. Lastly, it is important to note that discounts, rebates, and price concessions available to some pharmacies may not be available to others, and therefore including this information in the appeal review process may be harmful to pharmacies unable to obtain these discounts, rebates, and price concessions and thus inappropriate to include in the decision-making process. Considering the high level of difficulty in reporting these items at any given time, we strongly urge TCDI to reconsider the inclusion of such information in the appeals process. Additionally, while the current proposed rules include language that states "failure of a pharmacy to provide this information shall not constitute grounds to deny an initial appeal" we believe added protections should also be in place to prohibit PBMs from prematurely or unjustly basing appeals decisions due to the inability of pharmacies to provide this information.

PBM Market Power

As TDCI moves to establish transparency in PBM practices, it is essential to keep top of mind that PBMs exert tremendous market power that negatively impacts patients and the pharmacies that serve them. This is because prescriptions filled by patients who are paying cash without any form of insurance or discount card account for only about 3% of the total volume of prescriptions.[1] While approximately 91% of prescriptions filled have a payment component coming from Medicare Part D, Medicaid, or a commercial insurance plan, these plans are ordinarily administered by PBMs. The top three PBMs manage about 80% of the volume.[2] The top six PBMs and plans manage about 96% of the volume.[3] Five of those six PBMs are owned by large national health insurers. This business environment makes it very difficult for pharmacies to negotiate equitable business practices and transparency because the PBMs and health insurers have more commercial market power and leverage in the relationship due to their size and scale.

Retail pharmacies are in crisis, facing unsustainable financial pressures as they are increasingly reimbursed by payers below the cost of buying and dispensing prescription drugs. Dire financial pressures have forced an alarming number of pharmacies to shut their doors. Payers have increasingly reduced reimbursements; in many cases, pharmacies dispense prescriptions below cost. In addition to constant reductions in reimbursement, retroactive fees and claw backs, often occur weeks or months after a transaction closes, when a PBM decides to recoup a portion of the pharmacy's reimbursement further decreasing the amount pharmacies are paid for dispensing prescription drugs. These fees have made the economic viability of community pharmacies increasingly difficult, due to the unpredictability of reimbursement and the increased damage to bottom lines.

A study commissioned by the PBMs' own trade association, the Pharmaceutical Care Management Association (PCMA), recognizes that community pharmacies, and particularly chain pharmacies, are in trouble.[4] PCMA concludes

[1] Source: IQVIA, National Prescription Audit & RxInsight, June 2022; Approximately 5.4% of patients use a discount card to assist with payment.
[2] https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html
[3] *Id.*
[4] See https://www.pcmanet.org/the-independent-pharmacy-marketplace-is-stable/

over the last ten years (2012-2022) the total number of chain pharmacies decreased by 5.2% and decreased by 6.7% over the last five years (2017-2022).[5] PCMA's chart from the study shows an accelerating decline in chain pharmacies since 2017.[6] While PCMA does not suggest why chains are closing pharmacies, in a recent Supreme Court filing, PCMA agreed it is "undisputed" that "reimbursements below cost are approximately 10% of prescriptions filled."[7]

The epidemic of pharmacy closures is reducing access to vital healthcare services, especially in rural areas where options are already limited. Recent polling by Morning Consult confirmed that patients heavily rely on retail pharmacies among all healthcare destinations.[8] However, patients' access to retail pharmacies is increasingly threatened as more pharmacies go out of business.

PBM Reimbursement Practices are Widespread

The harmful effects of PBM reimbursement practices have been well-documented by other states that have conducted audits of PBMs. In August 2021, the Delaware State Auditor concluded that "[b]y restricting more and more patients to mail order only pharmacies, PBMs are limiting access to medications for [patients]."[9] In 2018, a similar audit report in Ohio found the impacts of "reductions in pharmacy reimbursement on access to care, particularly in rural communities."[10] Similarly, audit reports in other states have recognized the dangerous nature of PBM reimbursement practices and have recommended increased oversight of PBMs. A Maryland audit report concluded that "[t]he [PBM] spread pricing model tends to obscure the amount of remuneration retained by PBMs and makes it difficult for state agencies administering the Medicaid benefit to determine if the amount of PBM remuneration is a reasonable expense to be borne by a Medicaid program."[11] A need for greater PBM oversight was also found by an audit report of a PBM's compliance with a Louisiana state contract to administer prescription drug benefits for state employees, retirees, and their dependents.[12]

PBM Reimbursement Practices Harm Patients

Harmful practices utilized by PBMs not only harm pharmacies, but these practices also increase patient costs and shift costs to the government. The impact of higher cost-sharing for beneficiaries not only increases out-of-pocket costs for prescription drugs but also negatively impacts medication adherence, leading to the increased total cost of care and poorer health outcomes.

Medication non-adherence—that is, patients not taking their medications as prescribed by their healthcare provider—contributes to $100-290 billion in unnecessary healthcare expenditures every year as a result of increased hospitalizations and other avoidable, expensive medical services.[13-15] A systematic literature review of 79 studies conducted in 2018 revealed the adjusted total cost of non-adherence across multiple disease groups ranged from $949 to $52,341.[16] A 2017 white paper found that the direct medical costs and consequences related to not taking

[5] *Id.*
[6] *Id.*
[7] *Rutledge v. Pharmaceutical Care Management Association*, 18-540, 1 App. 341 (*petition granted* Jan. 10, 2020) (referring to the joint appendix in the case now pending before the Supreme Court of the United States).
[8] A poll of adults conducted March 4-6, 2022, by Morning Consult and commissioned by NACDS found that retail pharmacies received the highest ratings for ease of access among the destinations tested. Of note, 79 percent of those surveyed support pharmacists helping patients prevent chronic diseases.
[9] *See:* https://auditor.delaware.gov/wp-content/uploads/sites/40/2021/08/PBM-Survey-Report-Final.pdf
[10] *See:* https://audits.ohioauditor.gov/Reports/AuditReports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf
[11] *See:* https://health.maryland.gov/mmcp/SiteAssets/Pages/Reports-and-Publications/hb589PBMauditappealsJCRfinal12-19%20(1).pdf
[12] *See:* https://app.lla.la.gov/PublicReports.nsf/3631E09F3B442E468625839900683DB6/$FILE/0001BB0A.pdf
[13] Rosenbaum L, Shrank WH; "Taking Our Medicine - Improving Adherence in the Accountability Era;" *New England Journal of Medicine*; Aug. 22, 2013
[14] Network for Excellence in Health Innovation; "Bend the Curve: A Health Care Leader's Guide to High Value Health Care;" 2011. https://www.nehi.net/writable/publication_files/file/health_care_leaders_guide_final.pdf
[15] The NCPIE Coalition; "Enhancing Prescription Medicine Adherence: A National Action Plan;" 2007. http://www.bemedwise.org/docs/enhancingprescriptionmedicineadherence.pdf
[16] Cutler RL, et al; "Economic Impact of Medication Non-Adherence by Disease Groups: A Systematic Review;" *BMJ Open* 2018;8:e016982. doi:10.1136/bmjopen-2017-016982 https://bmjopen.bmj.com/content/bmjopen/8/1/e016982.full.pdf

medication as prescribed is estimated to be 7 to 13 percent of national health spending annually – approximately $250 billion to $460 billion in 2017, translated to a potential cost to taxpayers of $6 trillion over 10 years.[17] And a 2016 cost-benefit analysis concluded that between one and two-thirds of medicine-related hospitalizations are caused by poor adherence. Improving adherence could result in annual per-person savings ranging from $1,000 to $7,000, depending on the disease state.[18] Multiple, credible sources have drawn the same conclusion: medication non-adherence is a costly, preventable problem that dramatically affects the total cost of care.

Conclusion

NACDS appreciates the opportunity to provide our comments on pharmacy reimbursement practices by PBMs. For questions or further discussion, please contact NACDS' Christie Boutte, Senior Vice President, Reimbursement, Innovation, & Advocacy at cboutte@nacds.org.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' over 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit NACDS.org.

[17] "A Treatable Problem: Addressing Medication Nonadherence by Reforming Government Barriers to Care Coordination;" *Prescriptions for a Healthy America*; October 2017. https://static1.squarespace.com/static/589912df1b10e39bd04eb3ab/t/59f0e439edaed84e6822d9bd/1508959306380/P4HA+WhitePaper+E-DigitalFinal+1017.pdf

[18] Patterson JA, et al; "Cost-Benefit of Appointment-based Medication Synchronization in Community Pharmacies;" *American Journal of Managed Care;* 2016. https://www.ajmc.com/journals/issue/2016/2016-vol22-n9/cost-benefit-of-appointment-based-medication-synchronization-in-community-pharmacies