



November 15, 2022

[submitted electronically via: scott.mcanally@tn.gov]

Scott McAnally
Director of Insurance
Tennessee Department of Commerce & Insurance
500 James Robertson Pkwy, Nashville, TN 37243

Re: PBM Appeals Rule Draft

Dear Director McAnally:

The American Pharmacists Association (APhA) would like to express our sincere gratitude on behalf of our pharmacist members and their patients for the leadership of Governor Lee in signing into law Senate Bill (SB) 2458 (McNally) / House Bill (HB) 2661 (Sexton) earlier this year to increase transparency and regulation of the pharmacy benefit manager (PBM) industry. APhA recognizes that appropriate implementation of this legislation is vital to ensure patients continue to have access to services provided by their pharmacist and to lifesaving medications at their local community pharmacy. In addition to supporting comments from the Tennessee Pharmacists Association, APhA appreciates the opportunity to provide feedback on the Tennessee Department of Commerce & Insurance's (TDCI) request for comment to make certain the implementation aligns with the full intent of the law.

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. In Tennessee, APhA represents pharmacists and students that practice in numerous settings and provide care to many of your constituents. As the voice of pharmacy, APhA leads the profession and equips members for their role as the medication expert in team-based, patient-centered care. APhA inspires, innovates, and creates opportunities for members and pharmacists worldwide to optimize medication use and health for all.

As a result of the predatory practices of pharmacy benefit managers (PBMs), patients' access to medications from their local pharmacist across the country has declined¹, taxpayer dollars have been funneled into corporate profits², and generationally owned pharmacies have been driven out of business.³ Appropriate government intervention is necessary to address the misaligned incentives in the PBM industry that prioritize profits over patients. We would encourage your department to consider the following comments related to the proposed PBM appeals rules:

Within the rule entitled *Actions During and After an Initial Appeal*, we are concerned with the term "reasonable effort" included in 0780-01-??.04(5)(a)1 and 0780-01-??.04(5)(a)3. Without defining "reasonable effort," this grants too great of flexibility to PBMs to determine from appeal to appeal what is reasonable and what is not. The motivation for the signing of SB2458/HB2661 into law was a lack of government oversight that allowed PBMs to manipulate portions of the drug supply chain for their own profit and at the expense of patients and pharmacies. Without clear and explicit expectations in law and regulation PBMs will likely continue this manipulation. We urge TDCI to include clear expectations of PBMs throughout this rule package that does not allow for misinterpretation by PBMs. Regarding the example of "reasonable effort," if this term cannot be defined, we recommend that a timely review process be established by TDCI to ensure that the Department's intent of a "reasonable effort" is being followed by the PBM.

Another section of this rule that could be misinterpreted is 0780-01-??.04(10). As written, a PBM could interpret that it could not assess costs to a pharmacy for an initial appeal but could assess costs for any appeal not meeting the definition included in 0780-01-??.02(2)(d). We are concerned that subsequent appeals would not be included in this definition and that a PBM could interpret 0780-01-??.04(10) and assess costs that would hinder pharmacies from appealing. This loophole would undermine the intent of SB2458/HB2661 and the work of TDCI to create a system of oversight and appeals process for pharmacies. We recommend TDCI expand the definition and term of initial appeal in 0780-01-??.02(2)(d) to include initial and subsequent appeals and reflect these changes throughout the rule package.

Thank you again to Governor Lee and your department for your work to prioritize patients' access to health care services and medications. We urge your department and the Commissioner, or a designated representative use your full authority to conduct financial examinations, compliance audits, and investigate complaints of each PBM as often as is deemed necessary. We are confident that with the appropriate implementation of this law, Tennessee will be seen as a leader of transparency in the drug supply chain. If you have any questions or require additional

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>

information, please don't hesitate to contact E. Michael Murphy, PharmD, MBA, APhA Advisor for State Government Affairs by email at mmurphy@aphanet.org.

Sincerely,



E. Michael Murphy, PharmD, MBA
Advisor for State Government Affairs
American Pharmacists Association

cc: The Honorable Governor Bill Lee
The Honorable Carter Lawrence, Commissioner, Commerce & Insurance
Anthony Pudlo, PharmD, MBA, Executive Director, Tennessee Pharmacists Association