June 1, 2023

The Honorable TK Keen
Chair, Pharmacy Benefit Manager Regulatory Issues (B) Subgroup
National Association of Insurance Commissioners
444 North Capitol Street NW, Suite 700
Washington, DC 20001

RE: COMMENTS ON DRAFT PBM WHITE PAPER

Dear Chair Keen and members of the PBM Regulatory Issues (B) Subgroup:

With the support of the undersigned organizations, the National Community Pharmacists Association (NCPA) appreciates the opportunity to provide written comments on the draft white paper titled "Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation." NCPA has been supportive of the white paper process as a means to delve into pharmacy benefit managers' (PBMs') role as middlemen in the drug supply chain and their impact on drug formulary creation, consumer access to community pharmacy services, and drug pricing. With the feedback we share below, we believe a strengthened final version of the white paper can help the nation's insurance commissioners and their staff to better understand the role of PBMs and put them in a better position to enforce existing or future laws to protect consumers from certain PBM practices and conflicts of interest.

Characterization of Relationships Among Key Players in Pharmaceutical Ecosystem

We appreciate the structure of the white paper to include description of the key players in the pharmaceutical ecosystem. While we recognize the need to be balanced in these descriptions, we believe the white paper does not adequately characterize the asymmetrical relationship between PBMs and community independent pharmacies on the distribution chain. In the Vertical Integration and Consolidation section, the white paper correctly points to the competitive disadvantage independent pharmacies face compared to PBM-affiliated pharmacies when it comes to contracting. We believe it is important for policymakers to also recognize the broader challenges of a small business attempting to negotiate terms with Fortune 10 companies. For all practical purposes, such contracts are "take it or leave it." With vertical integration both upstream and downstream, there is a need to level the playing field between community pharmacies and PBM-affiliated pharmacies to protect patients from paying too much at the counter and to address conflicts of interests among vertically integrated companies. The vertical integration of PBMs into monoliths with an affiliated upstream insurance provider and downstream group purchasing organizations, mail-order, specialty, and retail pharmacies has only increased the incentives for PBMs to disfavor independent pharmacies and steer patients to their own affiliated pharmacies[1]. This

[1] Vertical relationships among insurers, PBMs, GPOs, pharamcies and other providers https://ncpa.org/sites/default/files/2023-03/verical-bus-chart.pdf

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asymmetrical relationship is fundamental to understanding the need to regulate and enforce PBMs and should be reflected in the white paper.

Key Jurisprudence: Greater Emphasis Needed on *PCMA v. Wehbi*

The white paper understandably spends considerable time and attention to legal issues, both in Section C (Enforcement and Federal Preemption Issues) and Section G (Key Jurisprudence). However, we believe the draft overlooks key issues and insights from the *Wehbi* case and overemphasizes implications from the *Mulready* case. District courts do not create precedent; one district court is not binding on another. The Eighth Circuit's decision in *Wehbi* is binding on all district courts within the Eighth Circuit. Meanwhile, the Tenth Circuit could one day overrule the district court's decision in *Mulready,* as recent arguments have underscored. We believe the white paper draft would be improved by focusing on the *Wehbi* case rather than the *Mulready* case in Section C.

We wish to address a point, on page 12, that "the authority of the states to regulate MA or Medicare Part D plans is significantly limited." We do not believe that is what is meant by either the *Wehbi* ruling or the Centers for Medicare and Medicaid Services (CMS). Rather, states have authority to regulate Part D plans in areas where Congress and CMS have failed to enact standards, or where a state law might frustrate federal policy. The outcome in *Wehbi* alone proves that state authority is not significantly limited. There, the Eighth Circuit upheld a variety of state-law regulations even as applied to Part D plans.

Key Jurisprudence: Additional Relevant Cases

We suggest the white paper include discussion of additional relevant court cases such as *PCMA v. District of Columbia* and *PCMA v. Rowe*. As currently drafted, the white paper's summary focuses on the regulation of a PBM's pharmacy-facing function. As you may know, PBMs have a plan-facing function as well. In the *District of Columbia* and *Rowe* cases, federal appellate courts explored the authority of states to regulate this aspect of a PBM's business model. With the D.C. Circuit invalidating D.C.'s law, whereas the First Circuit upheld Maine's—the two courts also split on rationale in an important area. Whereas the D.C. Circuit treated the regulation of a PBM as a regulation of an ERISA plan itself, the First Circuit expressly rejected that argument, emphasizing that PBMs are not ERISA fiduciaries, and as a result, their regulation does not give rise to ERISA preemption.

Uniform PBM Regulation and Enforcement in States Silent on ERISA

As a practical matter, states are continuing to preempt ERISA plans from PBM oversight and regulation in spite of legal rulings such as *Rutledge* and *Wehbi*. If state law is silent on ERISA, we believe NAIC members should be enforcing the law, especially as it pertains to price, rate and cost regulation. We recognize the implications stated on page 12 regarding the *Rutledge* case that regulation not be applied differently to ERISA and non-ERISA plans. We also acknowledge that select states expressly mention ERISA preemption in their statutes. That being the case, we recommend NAIC track state laws with and without ERISA

distinction and that the white paper highlight the imperative to enforce PBM regulations in states with statutes silent on ERISA.

Enforcement: Made Possible by Authority, Expertise, and Resources

We believe other practical aspects of PBM enforcement are ommitted from the draft white paper. From its nearly twenty years of legislative engagement to address the egegrious business practices of PBMs, NCPA has observed numerous hard fought laws not achieving their potential and intended effect. One key factor is the lack of enforcement provisions within state laws. Accordingly, states are increasingly revisiting statutes to add enforcement authority, often to the Office of the Insurance Commissioner. We appreciate the larger role NAIC members are beginning to play in these states and believes these best practices should be detailed in the white paper.

The white paper also misses an opportunity to point out that PBM-relevant expertise and resources are needed in state insurance departments to enforce PBM laws. The contractual practices of PBMs are not the same as the typical risk-based insurance policy topics of expertise. It is essential for departments to train or hire personnel who can oversee, review reporting, and/or audit PBMs as appropriate per state law.

There is also considerable variation among states in their preparedness to receive complaints from pharmacists, pharmacies, and patients in an online format appropriate for the subject matter. Independent pharmacists are more likely to submit complaints when they believe the department is equipped to receive, understand, and act upon them. Several state insurance departments have created and implemented PBM-specific complaint forms on their websites. These complaint forms are designed to better capture information related to PBM violations than standard consumer complaint forms. We recommend the creation of a standardized state-based system form for PBM complaints that will enable NAIC and its members to analyze and enforce regulation. In sum, we believe the white paper can be strengthened with practical information and best practices about enforcement.

Feedback to the Recommendations

We support nearly all the draft's recommendations for future engagement, offering the following feedback on select topics.

Recommendation #1: Model Guidelines to Address PBM Regulation

In collaboration with the undersigned organizations, NCPA supported and actively engaged NAIC's process to develop a PBM model for licensing and registration and was disappointed that it failed to be adopted. Presuming an expanded model could be adopted, we support the concept of model guidelines to address PBM regulation. We stand ready to provide insight and expertise to such a process.

Recommendation #5: Database of Contracting Provisions

We support the creation and maintenance of a nationwide database of contracting provisions. We urge NAIC to actively engage independent pharmacy stakeholders in the process to select relevant and impactful contract provisions. Having seen new concerns emerge since NAIC's previous model effort, it is important this database can accept new provisions for tracking as they arise.

Recommendation #6: Dialogue with Federal Agencies

We recognize the value of coordination between state and federal government on matters of public policy through dialogue and collaboration. We support this recommendation provided that it does not slow or replace the current process of honing appropriate and effective state-level regulation of PBMs. States are leading the way on PBM reform and this process must not be slowed.

Recommendation #7: Current Listing of PBM Laws, Regulations, and Case Law

We support the creation and maintenance of a current list of PBM laws, regulations, and case law. Per our comments in this letter to include additional case law, independent pharmacy stakeholders bring important insight and perspective to the discourse. We urge NAIC to engage and/or consult independent pharmacy stakeholders in the construction of such a list. Similar to the above recommendation, it is important this tracking be a living document and able to capture emerging issues.

Thank you for the opportunity to provide these comments. NCPA and the undersigned organizations appreciate NAIC's continued engagement of issues related to PBM regulation and believes NAIC's best contributions are yet to come. A final white paper strengthened by our feedback can propel public policy that improves care for patients and the independent community pharmacies that serve them. If you have any questions, please don't hesitate to contact Joel Kurzman at (703) 600-1186 or joel.kurzman@ncpa.org.

Sincerely,

National Community Pharmacists Association
AIDS Healthcare Foundation
Alabama Pharmacy Association
Alaska Pharmacists Association
AlliantRx
American Pharmacies
American Pharmacy Cooperative, Inc
Arizona Pharmacy Association
Aspire Health Pharmacy Services
Association of Community Pharmacists

California Pharmacists Association
CARE Pharmacies
Coalition of State Rheumatology Organizations
Colorado Pharmacists Society
Connecticut Pharmacists Association
Delaware Pharmacists Association
Federation of Pharmacy Networks
Florida Pharmacy Association
Fruth Pharmacy
Garden State Pharmacy Owners
Georgia Pharmacy Association
GRX Holdings, LLC
Hi-School Pharmacy Services LLC
Idaho State Pharmacy Association
Illinois Pharmacists Association
Independent Pharmacy Alliance
Independent Pharmacy Cooperative
Indiana Pharmacy Association
Iowa Pharmacy Association
Kansas Pharmacists Association
Kentucky Independent Pharmacists Association
Kentucky Pharmacists Association
Keystone Pharmacy Purchasing Alliance
Lewis Drug
Louisiana Independent Pharmacies Association
Louisiana Pharmacists Association
Louisiana Wholesale Drug
Maine Pharmacy Association
Maryland Pharmacists Association
Massachusetts Independent Pharmacists Association
Massachusetts Pharmacists Association
Michigan Pharmacists Association
Minnesota Pharmacists Association
Mississippi Independent Pharmacies Association
Missouri Pharmacy Association
Montana Pharmacy Association
National Alliance of State Pharmacy Associations
Nebraska Pharmacists Association
Nevada Pharmacy Alliance
New Mexico Pharmacists Association
New Mexico Pharmacy Business Council
New Jersey Pharmacists Association

North Carolina Mutual Drug
North Dakota Pharmacists Association
Omega Pharmacy Group
Oregon State Pharmacy Association
Osborn Drugs
PARD
Pennsylvania Pharmacists Association
Pharmacy Owners Alliance
Pharmacy Society of Wisconsin
PPSC
RestoreRx
RxPlus
Sav-Mor Pharmacy Services
South Carolina Pharmacy Association
South Dakota Pharmacists Association
Tennessee Pharmacists Association
Texas Pharmacy Association
Texas Pharmacy Business Council
Utah Pharmacy Association
Value Drug
Value Specialty Pharmacy
Vermont Pharmacists Association
Virginia Pharmacy Association
Washington D.C. Pharmacy Association
Washington State Pharmacy Association
West Virginia Independent Pharmacy Association
WSPC