

September 15, 2023

Members of the Regulatory Framework Task Force:

Thank you for the continued opportunity to provide perspective about the draft PBM white paper. Below please find a summary of our previously submitted comments, which were co-signed by 78 other organizations. Although we believe the white paper could always be perfected, we appreciate the PBM Regulatory Issues Subgroup's hard work and lengthy process to date. We respectfully ask you to adopt the document as currently drafted keeping in mind our feedback below.

Characterization of relationships among key players in the pharmaceutical ecosystem

- White paper does not accurately characterize the asymmetrical relationship between PBMs and community independent pharmacies. How can a small business realistically negotiate contract terms with Fortune 10 companies?
- Vertical integration both upstream and downstream: affiliated upstream insurance provider and downstream group purchasing organizations, mail-order, specialty, and retail pharmacies. Increased incentives for steering patients to affiliated pharmacies¹.

Uniform PBM regulation and enforcement in states without ERISA exemption

- We acknowledge implications stated on page 12 of the draft white paper regarding *Rutledge* that regulation must not be applied differently to ERISA and non-ERISA plans.
- We acknowledge some states expressly mention ERISA exemption in their statutes. NAIC should track state laws as they pertain to expressly mentioning ERISA exemption.
- If state law is silent on ERISA exemption, NAIC members should apply and enforce the law equally to all health plans and PBMs as it pertains to price, rate, and cost regulation per court rulings such as *Rutledge* and *Wehbi*.

Enforcement: Made possible by authority, expertise, and resources

- White paper does not recognize that PBM-relevant expertise and resources are needed in state insurance departments to enforce PBM laws: to train, hire personnel to oversee, review reporting, and/or audit PBMs as appropriate per state law.

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

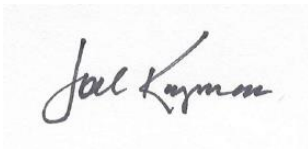
- White paper does not provide a model PBM enforcement scheme or best practices for Departments of Insurance and their Commissioners to enforce existing laws and regulations.
- NAIC should recommend a standardized state-based system form with electronic standards for PBM complaints that will enable NAIC and its members to collect and analyze online complaints and to enforce regulations.

Feedback on recommendations

- General support for all recommendations, provided community independent pharmacy stakeholders are engaged and at the table.
- Recommendation #1 (Model Guidelines to Address PBM Regulation): any model language should include a model enforcement scheme, including structure for audits, fines, suspensions, and discontinuation.
- Recommendation #6 (Dialogue with Federal Agencies): we support, provided that it does not slow or replace the current process of honing state-level regulation of PBMs. States are leading the way on PBM reform and this process must not be slowed.

NCPA and its 78 co-signing organizations appreciate NAIC's continued engagement of issues related to PBM regulation and believes NAIC's best contributions are yet to come. If you have any questions, please don't hesitate to contact me at (703) 600-1186 or joel.kurzman@ncpa.org.

Sincerely,

A handwritten signature in black ink that reads "Joel Kurzman". The signature is written in a cursive style and is positioned above a light gray rectangular background.

Joel Kurzman
Director, State Government Affairs