June 6, 2023

Members of the PBM Regulatory Issues (B) Subgroup
National Association of Insurance Commissioners
444 North Capitol Street NW, Suite 700
Washington, DC 20001

Attn: Jolie Matthews, Senior Health Policy Advisor and Counsel
Via Email: Jmatthews@naic.org

Dear Ms. Matthews:

The National Association of Benefit and Insurance Professionals (NABIP), which was previously known as the National Association of Health Underwriters (NAHU), appreciates the significant work the PBM Regulatory Issues (B) Subgroup has completed in developing the “Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation” white paper. As an association of health insurance agents, brokers, and consultants, our members regularly help business and individual health insurance consumers navigate pharmacy costs and payment issues.

NABIP has an active Prescription Drug working group, which reviewed the draft white paper in detail. Overall, we found the paper a fair and factual account of PBM regulation and related ongoing policy issues. However, we have some specific suggestions and comments on sections of the document, which are presented below.

**Section B – Key Players in the Drug Pricing Ecosystem**

This section outlines almost all key players in the drug pricing system, but NABIP members believe a crucial player is missing. Group health plan sponsors play a vital role in this process, particularly when it comes to self-funded plans. Self-funded group plan sponsors are not only payors but also select and contract with their PBM, determining which services the PBM will provide for their plan. Pricing, rebates, and transparency are essential issues for sponsors of self-insured plans. Even fully insured group plan sponsors consider this part of their carrier contracting process. While PBM services are generally integrated with the fully insured plan, which provides a health plan with pharmacy services is known to the plan sponsor when shopping for coverage options and affects the selection process. The cost and management of pharmacy benefits are crucial for all group health plan sponsors, regardless of plan funding structure.

NABIP suggests adding group plan sponsors as key players, with perhaps a designation noting the differences between those groups offering participants fully
insured coverage versus those offering self-funded or level-funded plans. In addition, in the subsection labeled Pharmacy Benefit Chain, we suggest adding language under the PBMs and Payors heading noting the differences between a health insurance carrier as a payor and a self-funded group plan sponsor, as well as the differences between those group plans that elect to carve out their PBM services and those who choose integrated services, which then affects both transparency to group and rebate distribution.

Section C – Enforcement and Federal Preemption Issues

This section provides an excellent factual overview of the current legal issues concerning preemption. As an association with a long history of support for the preemptive authority of ERISA, we appreciate the balanced approach of the draft paper. The subsections concerning Medicare Part D and Medicaid and the potential state-based authority to regulate PBMs as they relate to those two programs are similarly factual. However, NABIP members believe that all these subsections would benefit from more detail and greater explanations of the unique roles PBMs play in each marketplace. Adding this information would help inform state policymakers considering their options regarding state-based regulation. Such individuals will need to understand the functional responsibilities of PBMs when it comes to Medicare and Medicaid and the commercial marketplace, including the differences in those responsibilities by market segment, when assessing the need for state action and crafting effective policy solutions.

Section D – Functional Issues

In subsection one, titled Formulary Design, NABIP members who specialize in Medicare suggest the addition of a sentence explaining the Medicare Part D rule that requires the inclusion of at least two drugs per therapeutic class.

Regarding subsection three, Pricing and Contracting Practices, we suggest adding additional definitional information and explanatory text regarding average wholesale price, maximum allowable cost pricing, and the differences between them.

One functional issue that the white paper currently does not address, but our Pharmacy Issues working group members suggest you consider including the role that PBMs play in conducting utilization management of pharmacy benefits for health insurers and group health plan sponsors, including making medical necessity determinations, overseeing the prior authorization process, and managing step therapy and other means of access to prescription drugs by plan participants.

A second functional issue that NABIP suggests including is the role of manufacturer assistance in the pharmacy benefit management process. Some concerns in this area are currently being litigated in Johnson & Johnson Healthcare Systems v. Save
On SP, LLC. Another example of how this functional issue has been considered by both federal regulators and state lawmakers concerns co-payment assistance and how it may or may not be applied by a PBM on behalf of a health plan sponsor toward a participant's deductible and out-of-pocket limits.

**Subsection H – Recommendations**

NABIP appreciates the thoughtful recommendations for potential future action by the PBM Regulatory Issues subgroup. Our association is particularly interested in increasing the transparency of PBM contracts regarding price and the possible role states might play in this area without delving into the areas of actual price control and fee-setting. We suggest the subgroup consider potential targeted amendments to Model 22 and would welcome the chance to provide the working group with input and partnership in this specific policy area.

We truly appreciate the opportunity to comment on this draft whitepaper and your willingness to consider the views of all stakeholders. If you need additional information or have any questions, please do not hesitate to contact me at (202) 595-0639 or jtrautwein@nahu.org.

Sincerely,

Janet Stokes Trautwein
Executive Vice President and CEO
National Association of Health Underwriters