

September 13, 2023

The Honorable Sharon Clark
Commissioner, Kentucky Department of Insurance
Chair, 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 Commissioner Clark:

The National Association of Benefit and Insurance Professionals (NABIP), which was previously known as the National Association of Health Underwriters (NAHU), provided comments to the PBM Regulatory Issues (B) Subgroup in June regarding its draft white paper titled, “Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation.” NABIP has an active Prescription Drug working group, which reviewed the draft white paper in detail. Overall, we found the paper to be a very fair and factual account of PBM regulation and related ongoing policy issues. However, we did have some specific suggestions for improvement that were not included in the latest draft paper. As per your request, we have summarized them below.

Section B – Key Players in the Drug Pricing Ecosystem

1. As per NABIP’s initial suggestion, the revised version of the paper includes the addition of Employers/Unions/Taft Hartley Plans as key players. However, we believe this text should be enhanced to show 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. Ideally these differences would be reflected in the paper’s distribution chain graphic.

Section C – Enforcement and Federal Preemption Issues

2. Adding more detail to the subsections addressing Medicaid and Medicare to explain the unique roles PBMs play in each of these public programs, so that readers understand the differences in functional responsibilities of PBMs when it comes to Medicare and Medicaid and the commercial marketplace.

Section D – Functional Issues

3. In subsection one, titled Formulary Design, the addition of a sentence explaining the Medicare Part D rule that requires the inclusion of at least two drugs per therapeutic class.
- 4.
5. In subsection three, we suggest adding additional definitional information and explanatory text regarding average wholesale price and maximum allowable cost pricing, as well as the



- differences between them. While both MAC and AWP pricing are mentioned elsewhere, we suggest adding a paragraph addressing both common pricing methodologies together.
6. We suggest including the role that PBMs play in conducting utilization management of pharmacy benefits for health insurers and group health plan sponsors.
 - 7.
 8. We suggest including 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 issue is 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.

We truly appreciate the opportunity to comment on this draft white paper and your willingness to consider the views of all stakeholders. If you need any additional information or have any questions, please do not hesitate to contact me at (703) 496-0796 or jessica@forwardhealthconsulting.com.

Sincerely,

Jessica F. Waltman
Regulatory Consultant
National Association of Benefits and Insurance Professionals