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July 27, 2023

Mr. TK Keen
Chair, PBM Regulatory Issues (B) Subgroup
National Association of Insurance Commissioners
444 North Capitol Street NW, Suite 700
Washington, DC 20001-1512

Forwarded via email: Jolie H. Matthews

RE: AHIP Comments on NAIC PBM White Paper Draft – Rereleased July 23

Dear Mr. Keen,

On behalf of AHIP and our member plans, we would like to voice our concerns with the pending draft of the PBM white paper (paper) re-released on July 23, 2023, and the related review process.

Background: In 2019, the NAIC established the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup (Subgroup) and developed their charge to consider the development of a new NAIC model to establish a licensing or registration process for PBMs. When the draft model was not able to gain consensus and pass through the Executive Plenary, the Subgroup changed their charge in 2021 to develop a white paper to analyze all the various supply chain entities' roles in the provision of prescription drugs and examine state regulatory approaches to PBM business practices.

Subgroup's Process: The paper was drafted by multiple authors and released by the Subgroup on April 16, with public comments due June 1. The paper was then updated with authors deciding which comments to incorporate and released on July 23. Although the Subgroup indicated that stakeholders would be given "sufficient time to allow everyone to review it before the meeting" the revised 40-page paper was released with only 3 ½ days for stakeholders to review changes for a potential vote on July 27.

AHIP's Objections: AHIP has consistently raised three major issues with the Subgroup's paper. Those issues are:

1. The paper must be revised to fulfill the Subgroup's stated and agreed to charges. The paper as currently drafted continues to fall short of expanding the focus beyond PBMs to discuss the role of payors, wholesalers, PSAOs, etc.
2. The paper must be revised to remove non-objective, biased perspective. There are several sections of the paper that provide only one viewpoint. A white paper should provide regulators and interested readers a fact-based, balanced, and non-biased approach to the issues.
3. The paper must be revised to synthesize and streamline sections.

Per AHIP's review of the version released July 23 we remain deeply concerned with the extent of bias and opinion included in many sections of the paper.

Major Concerns With Revised Paper: There are several sections that continue to provide only one perspective, presented as undisputed fact – even after AHIP shared numerous academic and unbiased sources that provide a different perspective. Two of the sources cited often are presentations to the committee that do not contain the type of academic, peer-reviewed research that one would expect NAIC to point to as the basis for such a paper. Following, are examples of the most notable components of the

paper which should raise questions by Subgroup members about whether this paper meets NAIC's standards of presenting a neutral, balanced, and fact-based discussion of the issues:

1. **Spread pricing:** On page 11, spread pricing is aptly defined as "spread pricing, also known as a risk mitigation pricing model, the payor will either not pay or pay a reduced administration fee and the PBM will retain certain risk related to the difference between the price paid by the customer and the price paid to the pharmacy." However, on page 19, spread pricing is defined as "Spread pricing is the practice of a PBM charging a plan sponsor a higher amount for a drug than they will reimburse the pharmacy and **pocketing the difference**. Pharmacy pricing is complex, and the process is not transparent. Plan sponsors are often unaware of the difference between the amount they are billed and the pharmacy reimbursement." AHIP raised this flag citing the biased and inflammatory language in the latter definition and recommended that page 19 refer back to the earlier definition on page 11, which is a more neutral and fact-based explanation of the practice.

Plan sponsors have the ability to choose (or allow for their contracted health insurance providers to decide) whether they want to contract with their PBM vendors utilizing a spread pricing model or administrative fee model. Each has pros and cons and payors can choose the option that best fits their needs and the needs of their enrollees. **Using a term like "pocketing the difference" is a biased description intended to convince the reader to oppose the practice rather than providing a factual and neutral discussion of differing viewpoints.**

2. **MAC transparency:** As stated in example 1, "pocketing the difference" was also used in defining MAC transparency on page 19. The paper states, "PBMs may sometimes use multiple MAC lists and **pocketing the spread between the two**. For example, PBMs might use a very low MAC list to reimburse pharmacies but a higher list when charging plan sponsors." Most states currently have MAC laws in place to ensure that such practices do not occur. Yet the paper continues to include this scenario without our suggested addition to provide more context about how state laws have changed since the paper's cited source over five years ago in June 2018.
3. **Rebates:** On page 10, the paper claims rebates "create a market dynamic that may force up the "list" price of drugs by increasing the potential to generate "spread" profit." Not only does the cited source provide **no data to support this supposition, but multiple studies have been submitted to demonstrate this assertion is not true**. In fact, one of our cited sources (the US House Oversight & Reform Committee's Drug Pricing Investigation) explicitly stated "this data, which has never before been shared with the public, undermines industry (drug manufacturers) claims that price increases are primarily due to increasing rebates and discounts paid to pharmacy benefit managers." And yet, the unsubstantiated claim about rebates driving higher list prices remains and no additional context was added.

On page 19, the paper notes "Rebates may provide incentive for a PBM to eliminate a less expensive, comparable medication from a formulary. Pharmaceutical manufacturers claim that these rebates are meant to be shared with plan sponsors or passed on to consumers in the form of lower drug prices. However, PBMs regularly keep a share of the rebates before passing the rest through to the plan sponsor." As part of a health plan's contract with their PBM vendor, they will negotiate and determine what percentage – if any – the PBM is allowed to keep as compensation for its services. This context should have been added to the paper to provide the full explanation of how rebates are shared.

Further, on page 17, the paper states, “it is possible the PBM keeps the entire rebate with no direct benefit to the plan sponsor or the consumer.” also citing Dr. Sood. The cited sources provide no evidence that this practice is occurring today. It is prejudicial, misleading, and **unjustifiable to include a hypothetical concept in this paper.**

4. **PBM Practices:** Page 18 states that the integration of health plans, PBMs, and pharmacies, enables PBMs to “**engage in contracting practices that may be detrimental to consumers and other market participants**” and on page 20 “A PBM-pharmacy affiliation creates several incentives for PBMs to act against the best interests of the consumer.” again citing Dr. Sood.

Continuing with the myopic view of PBMs, the paper continues to state on page 21, “An affiliation with a pharmacy may also incentivize a PBM to do the following, which are all contrary to the best interests of consumers:

- Perform fewer generic substitutions;
- Switch patients to higher-cost therapeutic alternatives (“therapeutic interchange”); or,
- Repackage drugs in a manner that could lead to increased costs to plan sponsors, while maximizing revenue for the PBM (“package size pricing”).”

None of these accusations include data or evidence to show they are happening, and the mere inclusion of the word “may” does not negate the negative opinion the paper continues to espouse about the PBM industry. The opposing perspective is that integration has allowed given companies the negotiating leverage to finally push back against drug manufacturers’ abusive pricing tactics; however, that viewpoint is not included in the paper.

5. **DOI Licensing:** Page 23 starts a descriptive listing of the licensure requirements of various entities involved in the pricing of drugs. Health insurance providers are listed as the first entity with 2 sentences describing our involvement, while all other entities are described in full. While AHIP understands that regulators already are fully aware of carrier licensure parameters, the paper is intended to be used as an educational resource for those not as familiar with the drug industry. AHIP’s redlines provided a short but comprehensive list of those requirements, none of which were included. By not providing a more balanced perspective of insurers oversight, the paper continues the discourse that there is little oversight on carriers’ operations.

In addition to the bias illustrated above, various ERISA sections would have benefited from additional context and clarifications on the status of cases as well as highlighting the importance of, and updates to, NAIC’s ERISA handbook of which the Subgroup received a presentation in 2022.

AHIP believes in NAIC’s mission and role in bringing together all stakeholders to allow for a discourse that produces the best end product for consumers. **We urge Subgroup members to reevaluate the biased, unsubstantiated accusations and request further analyses of the paper.** The preferences included in the current draft jeopardize the credibility of an NAIC resource, which should inform, educate, and provide factual information to its audience.

While AHIP remains concerned about the direction of the paper, we are grateful for NAIC’s continued focus on high-price drugs as you appreciate and understand their impact to your constituency and our customers. We hope to continue working together to find solutions to address this critical issue within the health care market.

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For further information or continued dialogue, please contact me khathaway@ahip.org or 202.870.4468.
Thank you very much for your consideration.

Sincerely,

A handwritten signature in black ink that reads "Kris Hathaway". The signature is written in a cursive style with a large, looping "H" and a long tail on the "y".

Kris Hathaway
Vice President, State Affairs
AHIP

cc Commissioner Sharon P. Clark
Chair, Regulatory Framework (B) Task Force
National Association of Insurance Commissioners

America's Health Insurance (AHIP) is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to market-based solutions and public-private partnerships that make health care better and coverage more affordable and accessible for everyone. Visit www.ahip.org to learn how working together, we are Guiding Greater Health.