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September 15, 2023

Commissioner Sharon P. Clark
Chair, Regulatory Framework (B) Task Force
National Association of Insurance Commissioners
444 North Capitol Street NW, Suite 700
Washington, DC 20001-1512

Forwarded via email: Jolie H. Matthews

RE: AHIP's Previously Submitted Comments on NAIC PBM White Paper Draft (7.23.23 version)

Dear Commissioner Clark,

We greatly appreciate the opportunity to resubmit a condensed version of AHIP's comments to the NAIC PBM White Paper ("Paper"; 7.23.2023 version) as accepted by the Regulatory Framework Committee during the NAIC summer meeting. Our comments provided below, as requested, are abbreviated, focusing on those issues that remain unaddressed. AHIP's full set of comments are available at: July 27 comments; June 1 comments.

Remove Bias. The Paper still includes several sections that reflect only one perspective. This one-sided perspective is presented as undisputed fact even after AHIP shared numerous academic and impartial sources that provide a different perspective. Once again, we ask that either both viewpoints are presented, or the Paper only include factual statements for which evidence can be cited.

1. **Spread Pricing** & **MAC Transparency:** Using a term like "pocketing the difference/spread" is a biased description intended to convince the reader to oppose the practice rather than providing a factual and neutral discussion of the payment methodology. Recommendation 1 and 2 includes redlines necessary to remove this bias terminology from the Paper.

   Language: Spread pricing – page 20 (clean version)
   Spread pricing: ~~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.~~

   Instead, we urge you to use the more neutral definition already in the Paper on page 12 (clean version)

   Spread pricing: 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. This arrangement provides the payor with the assurance of a set price.

Language: MAC transparency – page 19 (clean version)
MAC transparency: A maximum allowable cost (MAC) list is a ~~list~~ tool that establishes a competitive unit price ~~includes the maximum amount~~ that a ~~plan~~ PBM will pay for certain drugs.[1] Most states have passed MAC laws that require PBMs to be transparent about what sources they use to create their MAC lists. ~~MAC lists are often generated by the PBM. There is no standardization in the industry as to the criteria for the inclusion of drugs on MAC lists or for the methodology as to how the maximum price is determined, changed or updated. 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.~~

2. **Rebates:** As part of a health plan's contract with their PBM vendor, they will negotiate and determine what percentage of the rebates received – if any – the PBM is allowed to keep as compensation for its services. No data supports the statements included in the Paper that follow. AHIP has repeatedly submitted sources that illustrate the contrary is true, and provided balanced language; however, these incorrect and biased claims remain. Further background is on page 2 of AHIP's July 27 comments which are included.

   Language: Pharmaceutical manufacturer and PBM*:* page 10 (clean version)
   Pharmaceutical manufacturers set list prices for their prescription drugs to have a maximum impact on revenue. The PBM then negotiates rebates with the pharmaceutical manufacturers~~,~~ to lower the cost of those drugs; ~~and~~ rebates are typically based on volume. PBMs can offer manufacturers higher volume, and thus command higher rebates, by putting a manufacture's drug on the PBM's formulary and/or in a formulary's less expensive cost sharing tier. ~~Rebates create a market dynamic that may force up the "list" price of drugs by increasing the potential to generate "spread" profit.~~

   Language: Rebates: page 18 (clean version)
   ~~The existence of rebates alone is not a problem. However, the PBM's ability to retain a percentage of the rebate creates a concern as they are also commonly in charge of formulary design. These two factors give PBMs a financial incentive to prioritize drugs in the formulary based on the highest rebate instead of the lowest total cost to the plan sponsor or consumer. This could result in plan sponsors and consumers paying a higher cost for prescription drugs than is necessary, resulting in higher prescription drug coverage costs.~~ Rebates are paid throughout the year and then trued up between the PBM and the payor at the conclusion of the contracted year and reported within their medical loss ratio filings. Most state employee plans and Medicaid contracts establish a preferred drug list (PDL) which allows them to negotiate supplemental rebates for favorable placement on the PDL.

3. **Vertical Integration and Consolidation.** The following section claims that a PBM-pharmacy affiliation drives higher costs, but none of the accusations below cite any data or evidence to show they are happening**.** The opposing perspective is that integration has given companies the negotiating leverage to finally push back against drug manufacturers' abusive pricing tactics; however, that viewpoint is not included in the Paper. Once again, we ask that either both

viewpoints are presented, or the Paper only include factual statements for which evidence can be cited.

Language: Vertical Integration and Consolidation – page 21 (clean version).
~~A PBM-pharmacy affiliation creates several incentives for PBMs to act against the best interests of the consumer. PBMs have been found inserting language into pharmacy benefit contracts that requires~~ Benefit designs sometimes requires enrollees to use PBM-owned mail pharmacy services for long-term (90 days or longer) "maintenance" medications. This may eliminate ~~contractual requirement effectively eliminates~~ any competition to fill these prescriptions, however, in many cases, mail order pharmacies are less expensive and more convenient for enrollees who prefer to receive prescriptions at their homes. Employers sometimes prefer these benefit designs to help control the cost of providing coverage to their employees. ~~allowing the pharmacy to charge higher prices to the consumer. 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").~~

Make Necessary Technical Updates. The Paper must be updated to reflect the current state of the law and the Subgroup's stated charges.

1. **Update Legal Sections;** On August 15, 2023, the U.S. Court of Appeals for the Tenth Circuit issued a decision in *PCMA v. Mulready*, No. 22-6074 (10th Cir. 2023), finding that certain provisions of Oklahoma state law governing how PBMs operate are preempted under both ERISA and the Medicare Part D statute. The case reverses an earlier decision by the district court upholding those same provisions.

   The 10th Circuit Court reversed the District's court's view of the Supreme Court's earlier *Rutledge* decision largely excluded PBMs from ERISA preemption. The court found that certain PBM-related network restrictions are preempted under federal law because they "govern a central matter of plan administration" by either directing or forbidding an element of plan structure or benefit design.

   In considering the Oklahoma law's application to PBMs providing services to Part D plans, the court found that Medicare Part D statute's preemption provision is "broad", "sweeping", and "akin to field preemption." Accordingly, the court concluded that the provision "precludes States from regulating Part D plans except for licensing and plan solvency." This reading reverses the approach that Medicare Part D preemption only exists if there is an overlapping or on-point federal standard. The *Mulready* decision by the 10th Circuit follows a First Circuit decision in *Medicaid & Medicare Advantage Prods. Ass'n of P.R., Inc. v. Hernández*, 58 F.4th 5, 11 (1st Cir. 2023), in affirming how and when Medicare Part D preempts state law.

   The Paper references the earlier *Mulready* decision:
   - On page 14, the ERISA section mentions the court's decision in the context of *Rutledge*.
   - On pages 14-15, Mulready is discussed in the context of Part D.
   - On pages 34-35, there is a full summary of the *Mulready* decision.

- These discussions must be either updated or deleted because they no longer represent the current state of the law in that Circuit.

- Members of the PBM Subgroup discussed on July 27 including language prefacing the pages listed above that legal proceedings were not yet resolved. Language, such as "The court cases discussed in the following section may not be resolved and encourage further review of the current legal environment."

2. **Remove Recommendations**. The PBM Subgroup had specific three charges for the Paper, and they are to: 1) analyze the role of supply chain entities of the drug cycle chain, 2) identify regulatory approaches, and 3) discuss challenges of implementations. The recommendations should be deleted given the Subgroup was not charged with identifying recommendations as part of the Paper. In addition, the supply chain entities were briefly outlined in the Paper but their roles within the drug pricing environment were not detailed, comprehensive, or consistent with the level of review of PBMs, which is just one entity of the supply chain. This remains inconsistent with the unanimously agreed to charges.

While AHIP remains concerned about the direction of the Paper, we are grateful for NAIC's continued focus on high-price drugs set by drug manufacturers. This is important to ensure impactful reform and relief to individuals, families, employers, and taxpayers. For further information or continued dialogue, please contact me khathaway@ahip.org or 202.870.4468. Thank you very much for your consideration.

Sincerely,

Kris Hathaway

Kris Hathaway
Vice President, State Affairs
AHIP

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.

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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.

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

Sincerely,

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.