June 1, 2023

The Honorable TK Keen, Chair
Pharmacy Benefit Manager Regulatory Issues (B) Subgroup
National Association of Insurance Commissioners
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Washington, DC 20001
EMAIL: JMatthews@naic.org

SENT VIA EMAIL

Re: *Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* a/k/a the NAIC's PBM White Paper

Dear Chair Keen:

I write on behalf of the Pharmaceutical Care Management Association ("PCMA") to express our concerns with the draft white paper titled, "Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation" (hereinafter referred to as the "White Paper").

PCMA is a national trade association representing pharmacy benefit managers ("PBMs"). PCMA member companies administer drug benefits for more than 275 million Americans, who have health coverage through employer-sponsored health plans, commercial health insurance plans, union plans, Medicare Part D plans, managed Medicaid plans, state employee health plans, and others. PBMs use a variety of benefit management tools to help these plans provide high quality, cost-effective prescription drug coverage to plan beneficiaries.

PCMA believes the White Paper, as presently drafted is seriously flawed and should not be adopted or at a minimum should include an appendix to highlight alternative perspectives. PCMA reached this conclusion, as set forth in more detail below, because we believe the White Paper:

- Does not adhere to the charges adopted by the NAIC's PBM Regulatory Issues (B) Subgroup;
- Reads like a biased advocacy piece rather than an objective source of information and guidance;
- Is not appropriately sourced;
- Includes many unsupported claims;
- Relies on biased information;
- Contains numerous factual errors; and
- Was developed with a lack of process, as well as a lack of transparency.

The White Paper does not adhere to the specific charges adopted by the Subgroup

The PBM Subgroup failed to adhere to the charges and required elements approved by the Regulatory Framework (B) Task Force in developing the content in the White Paper.

The first charge for the Subgroup was to "analyze and assess the role of pharmacy benefit managers (PBMs), Pharmacy Services Administrative Organizations (PSAOs), and other supply chain entities play in the provision of prescription drug benefits." Except for brief and insufficient definitions of PSAOs and some of the other entities in the prescription drug supply chain, the White Paper does little to address the vital role entities other than PBMs play in the delivery of prescription drug benefits and the overall cost of prescription drugs. Additionally, the White Paper is rife with conjecture and subjective language when describing the critical role and value PBMs bring to patients and payers.

The second charge for the Subgroup to include in the White Paper was to "identify, examine and describe current and emerging state regulatory approaches to PBM business practices, such as price transparency and reporting requirement, rebating and spread pricing, including the implications of the *Rutledge vs. Pharmaceutical Care Management Association (PCMA)* decision on such business practices." While the White Paper lists some state laws and federal legislation relative to PBMs or other entities, it does not include any examination of such laws or regulations or an assessment of whether any of the PBM laws have resulted in lower or higher costs or better quality of care for patients and payers.

The third charge for the Subgroup to consider when drafting the White Paper was to "discuss what challenges, if any, the states have encountered in implementing such laws and/or regulations." The White Paper does not address this issue. Perhaps it does not fit the narrative to write about PBM compliance with state laws and regulations and as previously mentioned, no state law or regulations has resulted in lower costs for patients or payers.

The White Paper does not serve as an objective source of information and guidance

As background, following the failure of the PBM Model Act in late-2021, the PBM Subgroup elected to move forward with the development of this White Paper. The intent was to draft a document that would be an authoritative guide to state insurance commissioners and their staffs regarding prescription drug supply chain. Merriam-Webster defines "White Paper" as:

1. *A government report on any subject; and/or*
2. *A detailed or authoritative report.*[1]

This draft White Paper fails under both definitions. At no time was this White Paper ever intended to be a completely biased advocacy document. It was never intended to negatively focus on a single entity of the pharmaceutical supply chain, let alone private industry. Unfortunately, as further outlined below, the agenda of this White Paper is clear. And it is neither a detailed nor authoritative report. It is a completely biased and careless drafted advocacy document.

The White Paper is Not Properly Sourced

There is a plethora of publicly available and widely accepted material regarding PBMs and the overall pharmaceutical supply chain that the blatant failure to cite most of it in the White Paper poses a number of questions. First, was it always the intent to avoid any of this material?

[1] Merriam-Webster Dictionary. (http://www.merriam-webster.com/dictionary/white%20paper).

Second, why were the presentations (already questionable quality as a source) cited only those with an anti-PBM bias? And third, was this White Paper reverse-engineered to support a biased conclusion, causing the drafters to cherry-pick poor quality citations that align with their views?

Below are some examples of generally accepted and widely known public resources that the drafters of the White Paper excluded from consideration. In doing so, this White Paper presents a biased narrative in which the ends justify the means.

- **Congressional Budget Office (CBO):** *Prescription Drugs: Spending, Use, and Prices*
  - This is a major 2022 report released on the prescription drug supply chain by the CBO.
  - To provide an industry perspective, here is a blog post that provides some additional context: http://www.pcmanet.org/cbo-report-on-prescription-drug-trends/

- **Government Accountability Office (GAO):** *Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization*
  - The GAO undertook a comprehensive look at how PBMs operate in the Medicare Part D program. Much of this information could inform the White Paper and how PBMs operate in the commercial market.

- **Lawson Robert Burns:** *The Healthcare Value Chain: Demystifying the Role of GPOs and PBMs, Dark Territory: Lifting The Veil On GPOs and PBMs*
  - Excerpt: "The remarkable finding here is that these intermediaries [PBMs] may nevertheless serve the public's welfare by controlling the rise in health care costs."

- **Casey Mulligan:** *The Value of Pharmacy Benefit Management*
  - Excerpt: PBMs create $145 billion in value to society annually. PBMs improve patient health outcomes, creating medical benefit savings ($40 billion in annual savings), encourage generic drug use ($16 billion), accelerate the pace of new drug development ($6 billion), create pharmacy networks ($5 billion), decrease tax distortions (reduce the amount of money the government spends on health insurance subsidies; $47 billion), negotiate rebates from manufacturers ($51 billion), and facilitate mail-order pharmacy ($3 billion).

- **Health Evaluations:** Pharmacy Services Administrative Organizations (PSAOs) and Their Little-Known Connections to Independent Pharmacies
  - Excerpt: "The primary service that PSAOs perform for their members is collective negotiation of the contract terms with PBMs."

Leaving references and citations to this research out of the draft White Paper is especially egregious.

Further, the supply chain diagram on page eight of the White Paper is from PCMA's commissioned research on PSAOs. The drafters of the White Paper cherry-picked a singular

graphic from PCMA research without bothering to cite to the broader research the graphic references, as it does not fit the agenda of the White Paper.

The White Paper includes numerous unsupported claims

A White Paper should include factually correct statements with proper citations for claims that are not widely accepted or understood. This White Paper fails to follow this standard and includes a substantial number of unsupported claims. Below are a few examples that illustrate this failure.

Federal preemption
Regarding health plans organized under the federal Employee Retirement Income Security Act ("ERISA") of 1974, the White Paper states:

> *It remains unclear how much authority states may exercise over PBM pharmacy networks and other elements of PBM administration.*

It does not remain unclear. The U.S. Supreme Court's decision in *Rutledge* was very narrow and allows for state regulation of reimbursement in maximum allowable cost ("MAC") appeals. This is the result of a narrow case on reimbursement having to do with Arkansas Act 900. Thus, the Supreme Court did not deviate from 50 years of ERISA jurisprudence.

Formulary design
Regarding formulary design, page 15 states:

> *The PBM will look at acceptable drugs that have been determined "clinically equivalent" and negotiate for the highest rebate and include these drugs in the formulary.*

Many drugs are placed on a formulary, not just those with high rebates. For example, generic drugs account for at least 90% of all prescriptions filled each year.[2] In other words, there are multiple factors that determine what drugs are added to formularies and at what placement. Additionally, at the end of the day, a health plan sponsor decides what drugs to cover. This includes generic drugs, which have no rebates. PBMs may make recommendations and provide expertise in this space but do not make a final decision. This whole section of the White Paper appears to erroneously connect PBMs to plan design. Plan design is determined by the health plan.

Rebates
Page 16 of the White Paper makes a number of claims about rebates that are not only unsupported, but untrue. In the commercial market, over 90% of rebates are passed through to clients, see PEW. Moreover, PBMs leverage competition to negotiate rebates, which create drug savings for their clients – see CBO *Prescription Drugs: Spending, Use, and Prices*

As previously mentioned, employers, health plans, and other clients of PBMs have the ability to choose what kind of contract structure they choose for their PBM. For example, the widely-read

[2] U.S. Food & Drug Administration. Office of Generic Drugs 2022 Annual Report. Mar, 1, 2023. Available at: (http://www.fda.gov/drugs/generic-drugs/office-generic-drugs-2022-annual-report).

blog, Drug Channels[3], regularly publishes data on the proportion of employers that choose rebate retention, rebate pass-through, or other arrangements.

A widely-known report from the GAO states that the vast majority of rebates in Medicare Part D get passed on to plans sponsors.[4] Furthermore, as previously cited, we know from PEW that over 90% of rebates in the commercial market get passed to plans. It begs the question, why did drafters of the White Paper ignore all of this high-quality and widely-known research?

Rebates are used to keep premiums low and make drug benefits more generous.

According to the CBO, "The health plan, in turn, shares most of the rebate with its enrollees in the form of lower premiums or more generous benefits on its insurance coverage." Put another way, rebates are just one source of funding for a plan. Indeed, if rebates are prohibited, then underwriting has to make up the difference in premiums.

On page 17, the White Paper states,

> *Rebates may provide incentive for a PBM to eliminate a less expensive, comparable medication from a formulary*.

This statement appears to have been drafted by someone who has no understanding of PBMs or the overall pharmaceutical supply chain. PBMs incentivize generics when they provide a lower net cost to the plan, which is part of the reason why 90% of all prescriptions filled being generics, *see* Mulligan.

The White Paper relies on biased information

The White Paper relies extensively on three main sources – Sood, Horvath, and Oestreicher – who made presentations to the PBM Subgroup at different points over the past few years. These presentations are slide-decks posted on the PBM Subgroup's website. However, they are not widely known, nor generally accepted sources. Nor do they contain readily verifiable supporting information. They also contain instances of contradictory claims and statistics. Therefore, there is no way for an individual reading the White Paper to properly evaluate the quality of these sources and the claims made with their alleged support.

Importantly, Dr. Casey Mulligan also made a presentation to the PBM Subgroup on October 24, 2022, yet his presentation is nowhere to be found in the White Paper. In fact, his name is the only one missing from the list of presenters on page 35 of the White Paper. This is a glaring absence and oversight. Dr. Mulligan is a member of the Economics Department at the University of Chicago. Additionally, he previously served on the National Council of Economic Advisers. The complete exclusion of Dr. Mulligan is stunning, and his work directly calls into question the objectivity and validity of the White Paper.

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[3] Adam Fein. Drug Channels: *Solving the Mystery of Employer-PBM Rebate Pass Through (rerun)*. May 3, 2016. Available at: (http://www.drugchannels.net/2016/05/solving-mystery-of-employer-pbm-rebate.html) and Fein. Drug Channels: *Employers Are Absorbing Even More Manufacturer Rebates from Their PBMs. March* 12, 2019. Available at: (http://www.drugchannels.net/2019/03/employers-are-absorbing-even-more.html).

[4] U.S. GAO. Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization. 2019. Available at: (http://www.gao.gov/products/gao-19-498).

As outlined above, there is no lack of high-quality, free, and publicly available research that the drafters of this White Paper did not utilize. One example of a flaw in the literature cited in the draft White Paper exists on page nine. Here, the claim is that rebates drive up list prices for drugs. To support the claim, the drafters cited a 2019 Sood presentation to the Subgroup. This claim has been refuted in the publicly available resources listed in this letter. Further, citing a presentation and its corresponding slide-deck as support for this claim is one example of the drafters not adhering to the level of rigor that a white paper, as is commonly understood and defined, demands.

The White Paper contains many factual errors

This White Paper contains multiple false statements. Those false statements take the form of unsupported claims, opinions, and in the case of one specific example from page nine, something that is a blatant deception and/or ignorance.

On page nine, the White Paper states:

> *Rebates create a market dynamic that may force up the "list" price of drugs by increasing the potential to generate "spread" profit.*

This statement is simply incorrect and illogical. Rebates do not drive "spread." And there is no scenario where they would. Moreover, the citation for this statement is a presentation to the PBM Subgroup, given by Dr. Neeraj Sood. To include a citation to a presentation given to a Subgroup of the NAIC rather than rigorous and widely available and cited research is a stain on this draft White Paper.

Additional false or misleading statements can be found on a variety of topics throughout the White Paper; for example: point-of-sale rebates (pg. 16), gag clauses (pg. 17), copay clawbacks (pg. 17), MAC lists (pg. 17), spread pricing (pg. 17), pharmacy audits (pg. 18), pharmacy networks (pg. 19), and government regulation and oversight of PBMs (pg. 19). No reputable White Paper would make a false statement, even one that is contained in a presentation; there is so much easily available research.[5] Again, a White Paper must be a reputable document that contains exhaustive, rigorous, and legitimate research.

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[5] Some potential research that offers either an unbiased point of view, or function as a counterweight to all of the anti-PBM citations included in the White Paper are listed below.

U.S. Health & Human Services Office of the Inspector General:
Rebates for Brand-Name Drugs in Part D Substantially Reduced the Growth in Spending from 2011 to 2015
"If manufacturers increased rebates at the same rate as reimbursement increased, we would expect that unit rebates would account for the same percentage of unit reimbursement for individual drugs. However, we found that percentage declined at the median from 2011 to 2015." (In other words, prices go up, but rebates fluctuate, suggesting that rebates do not drive prices up.)

Matrix Global Advisors (MGA):
Understanding Drug Rebates and Their Role in Promoting Competition
"While there is a lack of evidence that rebates increase list prices, as well as evidence to the contrary, this misconception persists."

PCMA:
Data Shows That Manufacturer Drug Price Increases Are Unrelated to PBM Negotiated Rebates
" Increasing list prices are not correlated with changes in prescription drug rebates. The R2 = 0.0003 shown with the blue regression line indicates no statistical correlation."
Rebuttal Of USC Schaeffer's "The Association Between Drug Rebates and List Prices"

PBM Subgroup lack of process & transparency

Throughout 2022, there were small pieces of information distributed by the PBM Subgroup, usually verbally via Subgroup member comments, regarding progress with the White Paper.

Then in August 2022, the NAIC held its Summer Meeting in Portland, Oregon. It was at this meeting PCMA learned that the intent of the PBM Subgroup was to expose a draft White Paper for comments, sometime in Fall 2022. However, no stakeholder input would be allowed on the White Paper until it was ready for public exposure.

Finally, on December 15, 2022, the PBM Subgroup exposed what it deemed a "rough draft" of its White Paper. This document contained a gratuitous amount of spelling and grammatical errors. It was unformatted, with font types and styles lacking uniformity. Moreover, it had a lack of citations for what appeared to be content directly copied from different anti-PBM websites and/or blogs. And it was a document not worthy of comment.

After learning at the NAIC 2022 Fall/Winter Meeting in Tampa, Florida, that there would be an actual draft version of the White Paper forthcoming for public comment, PCMA and its member companies decided to save our comments for that time. And now that our industry waited for an additional four months for an actual draft White Paper to comment on, we generally hold the same view that we did for the "rough draft."

The PBM White Paper made public on April 17, 2023, is not a White Paper as is generally understood and is not worthy of public dissemination by the NAIC. Rather, it is a blatantly biased document that does not follow the charges given to the Subgroup, makes no attempt to be unbiased and authoritative, correct on the facts, nor engender support among stakeholders on a solution to any problem that the White Paper's advocates indicate requires attention by state insurance commissioners and their staffs. Those regulators and their staffs are the audience for any final version of this document.

Due to the aforementioned issues with the draft of the White Paper, PCMA and its member companies respectfully request that the PBM Subgroup do not move forward with the adoption of the White Paper. And should the Subgroup decide to move forward with some sort of finalization of the White Paper, then we respectfully request that our comments be included as an addendum to the White Paper to show the multitude of concerns that a large segment of stakeholders have with it.

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As a closing note, it must again be stated that the content of the NAIC"s PBM White Paper fails to achieve the standard definition and general understanding of an actual "white paper." It fails this standard because of its brazen bias and its inability to cite real academic sources that are widely known and/or available. Because of this, it should be concerning to NAIC membership more broadly, that in a May 11 letter from the NAIC to the U.S. Federal Trade Commission

"Contrary to the white paper's suggestion, statistical analysis of the top brand drugs in Medicare Part D has found no correlation (R^2=0.002) between rising list prices set by drug manufacturers and the change in rebate levels that they negotiate with PBMs over the 2014-2019 period— a broader time period than that examined by the USC Schaeffer white paper."

("FTC"), this White Paper is referenced as a document in development for the purposes of state regulation of PBMs. If this White Paper moves forward without substantial changes—involving a complete restructuring and the removal of biased content and inclusion of input from all stakeholders—the NAIC will undermine the objectivity of its "white paper" and its own credibility as a fair and unbiased standard setting organization for the industry.

Sincerely,

Peter Fjelstad

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