



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
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 Clark:

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.

Lastly, there was no charge that the PBM (B) Subgroup offer recommendations as part of the PBM White Paper. A "white paper" is supposed to be an educational document. It is not supposed to be a biased advocacy document with recommendations. By including recommendations, this White Paper is further delegitimized. And without significant changes to

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the White Paper, the NAIC is risking its reputation as an unbiased resource for state regulators and their staffs.

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

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.”

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.”

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 fails on all these charges.

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.

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. Was it always the intent to avoid any of this material? And 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?

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

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



includes a substantial number of unsupported claims. Below is one blatant example to illustrate this failure – specific to the federal preemption section of the White Paper.

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.

Moreover, a recent decision for the U.S. Court of Appeals for the Tenth Circuit recently clarified the question of federal preemption. In a unanimous decision on the *Mulready* case, the Court sustained a challenge to four provisions of a misguided Oklahoma state law by finding them to be preempted under federal ERISA law, as well as the federal Medicare Part D program. The Court explicitly stated:

- Federal law preempts state laws that “relate to” covered benefit plans, including state laws that directly regulate plan design;
- The provider network is a crucial component of an employer-sponsored health plan’s benefit design;
- The challenged provisions of Oklahoma law are preempted according to these principles;
- Allowing this kind of state regulation of network design would erode the protections of federal preemption and threaten the nationwide benefits enjoyed by millions of Americans.

Beyond the problems with the White Paper’s section on federal preemption, there are various problems with its sections on formulary design, as well as rebates.

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 39 of the White Paper. The complete

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exclusion of Dr. Mulligan is stunning, and his work directly calls into question the objectivity and validity of the White Paper.

The White Paper contains many factual errors

This White Paper contains multiple false statements. Those false statements take the form of unsupported claims and/or opinions. On page 11, the current version of 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. There are many such errors throughout the White Paper.

PBM Subgroup lack of process & transparency

Throughout 2022 and 2023, there were small pieces of information distributed by the PBM Subgroup, usually verbally via Subgroup member comments, regarding progress with the White Paper. Ultimately, the White Paper was drafted in closed sessions with no public input rather than a few solicitations for feedback within specific timeframes.

Due to the aforementioned issues, PCMA and its member companies respectfully request that the Regulatory Framework (B) Task Force do not move forward with the adoption of the White Paper. However, should the Task Force 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.

Finally, it should be concerning to NAIC membership more broadly, that in a May 11, 2023, letter from the NAIC to the U.S. Federal Trade Commission (“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,

A handwritten signature in blue ink that reads "Peter Fjelstad".

Peter Fjelstad, Director, State Legal & Regulatory Affairs, PCMA

CC: Jolie Matthews, Senior Health and Life Policy Counsel, NAIC

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