December 3, 2025

Ms. Joylynn Fix, Chair
Ms. Susan Jennette, Co-Vice Chair
Ms. Ashley Scott, Co-Vice Chair
PBM (D) Working Group
NAIC
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Washington, DC 20001-1512
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SENT VIA EMAIL

RE: PCMA comments on PBM Licensure and Regulation Guideline Document

Dear Chair Fix and Co-Vice Chairs Jennette and Scott:

On behalf of our member companies, the Pharmaceutical Care Management Association ("PCMA")[1] appreciates the opportunity to provide feedback on the National Association of Insurance Commissioners' ("NAIC") draft of a proposed Pharmacy Benefit Manager ("PBM") Licensure and Regulation Guidelines for Regulators document ("Draft"). We understand the goal of this Draft is to provide regulators with guidance on PBM licensure and basic regulatory procedures and we have no objections to that goal.

However, we are concerned that the Draft goes far beyond guidance and attempts to set policy standards for states. Many of the provisions in the Draft are substantive in nature and necessitate statutory authority for promulgation of rules and regulations. Therefore, this is not appropriate for any NAIC guidance document.

In our reading of the Draft, many of the requirements appear to be much closer in character to a model law, which is described by the NAIC as "proposed insurance laws drafted by the NAIC to promote uniformity among the states."[2] The PBM (D) Working Group ("Working Group") was charged to develop PBM licensing and registration standards aligned to state and federal requirements to support uniformity in the licensure process, not to develop a model law. The guideline document (i.e., the Draft) should be amended accordingly to help states with overall licensure while deferring to their state laws for critical items such as definitions, operational expectations, and compliance targets.

What is more, the NAIC previously attempted to pass a PBM model law via the proper NAIC committee process in 2021. Noteworthy is that this PBM model law failed to be adopted by the entirety of the NAIC December 2021. Thus, PCMA and its members companies are concerned that this Draft incorporates the failed model's language throughout and is a guidance document in name only.

[1] For background, PCMA is the national trade association representing PBMs. PCMA's PBM member companies administer drug benefits for more than 289 million Americans, who have health insurance through employer-sponsored health plans, commercial health plans, union plans, Medicare Part D plans, managed Medicaid plans, state employee health plans, and others.
[2] NAIC Library. *NAIC Model Laws 101: What are model laws?* Available here: (http://content.naic.org/sites/default/files/topic-model-laws-101.pdf).

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With all that said, PCMA and its member companies offer the comments below, to help the Working Group achieve its goal of developing licensing guidance for state regulators.

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Specific Requests for Changes

- **Section 2. Purpose**: The purpose of the Draft is to provide a foundation of standards to assist state departments of insurance ("DOIs") in licensing PBMs. The language in that section is not appropriate for any guidance document as powers for licensure, oversight of solvency, providing for the commissioner's authority and proscription of fines will already be outlined in the state's existing statute. This section should acknowledge those already enumerated powers and simply note that its purpose is to provide a framework for licensure of the PBM entity.

- **Section 3. Definitions**: Remove the section on definitions as they are unnecessary as every state has definitions in their insurance code that defines key terms (i.e., "health carrier," "health plan," "PBM," "pharmacy," etc.) and the addition of new defined terms may inadvertently lead to conflicts with state or federal law. Additionally, definitions related to market conduct exams or investigatory powers are also delineated and defined in insurance codes in each state.

  As noted above, a simple "drafting note" in the guidance that acknowledges the state's definitions for purposes of licensure and oversight is all that is needed. And the inclusion of terms such as "health benefit plan," may lead a state to erroneously believe it has regulatory authority over self-funded health plans, which it generally does not. Finally, a term such as "claims processing center," is unfamiliar. PCMA and its members have not seen the term defined in state law, and therefore, we respectfully request that it be deleted.

- **Section 4. Applicability**: Clarify that the applicability of the Draft should only be effective for health benefit plan contracts and services as delineated in statute. As you know, each state DOI's regulatory authority is governed by state and federal law, along with legal precedent. If a state has questions as to its authority, the guidance should remind the DOI to refer to the state and federal law and jurisprudence, as well as consult the NAIC's ERISA Handbook for additional, general guidelines.

  Furthermore, this section should be updated with a "drafting note" to address the timing of applicable standards. For example, as a condition of licensure, any contract that is *issued, renewed, recredentialed, amended, or extended* ***on or after*** the date the PBM receives its license to do business in this state should comply with the state's relevant licensing and regulation requirements in effect as of the time of licensure. This is consistent with many states' laws applicable to other regulated entities, which often avoid requiring a change to the terms of an in-effect contract prior to the contract's renewal and/or expiration.

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- **Section 5. Licensing Requirement**: Since this is not a model law, the guidelines here need to be limited to licensure and basic DOI requirements tied to licensure. Many of the provisions in this section are substantive in nature, are not tied to licensure, and would need statutory authority for a regulator to promulgate rules or demand compliance as part of a licensure process. We recommend all non-licensure substantive provisions be deleted, including the following:
    - Remove the reference to reporting requirement from subsection B given such requirements and elements of reporting would require statutory authority.
    - Delete Subsection F (3)(a) as this requirement is not tied to licensure and statutory authority is needed for the state to require the provision. Some states have requirements on "steering" or "point of service" rebates, but most do not. This is a policy issue that should not be included in licensure requirements.
    - Delete Subsection G (1), (2) & (3) as these requirements are not tied to licensure and statutory authority is needed for the state to require the provisions. Similar to above, most states do not have a payment mandate nor reporting mandate related to National Average Drug Acquisition Cost ("NADAC") payment standards.
    - Delete Subsection 4 (a), (b), (c), & (d) as these requirements are not tied to licensure and statutory authority is needed for the state to require the provisions. Network adequacy standards as well as pharmacy contracting standards must be delineated by state law and not under licensure guidelines. In addition, NADAC reports are public, with the NADAC reference files being freely available on the Medicaid.gov website and Data.Medicaid.gov. These resources are updated regularly and contain the calculated average prices for prescription drugs, making them accessible to the public, including healthcare providers, policymakers, and the public.

- **Section 6. Gag Clauses and Other Pharmacy Benefit Manager Prohibited Practices**: While gag clauses are generally not permitted, this section includes additional provisions that relate to contractual standards between a PBM and their contracted network. Any requirements relating to pharmacy contracts should follow the state law and not assume that all states have these provisions in place. A "drafting note" that advises a state to review any statutory requirements relating to agreements between PBMs and their contracted network is all that is needed here. And provisions E (1) and (2) within this section both pertain to plan enrollee cost-sharing. Thus, they are directly related to plan benefit design, which is not under the purview of the PBM. Rather, the plan sponsor makes such decisions.

- **Section 7 Enforcement**: we suggest the following clarifications:
    - Clarify in B (2) that the information sought by the Commissioner or designee must be relevant to PBM services that are the subject of state regulatory authority.
    - Remove the reference in B (3) to the Model law on Examinations (#390) which applies to financial exams of insurers as this is not relevant for any guidance document on PBM licensure and regulation.
    - Clarify the scope of regulatory examination authority to activities conducted within the state's jurisdiction.

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- Provide operational guidance for multi-state health plans to ensure compliance without excessive audits or conflicting requirements.

We respectfully request that the Working Group revise the Draft to ensure it functions as a true guidance document, rather than a model law. To assist in this effort, below we offer the following overview of standards that should be included, as well as policy issues that should be excluded, to maintain the Draft's intended purpose.

Standards Appropriate for Inclusion

- **General purpose**: The guidelines should establish a foundational framework for PBM licensing and registration standards.
- **Reference to State Law:** Include a drafting note advising states to rely on their existing PBM statutes for definitions, applicability, and scope.
- **Licensure or Registration Requirements:** Limit requirements to those consistent with other licensed entities and prevailing state laws, such as:
  - Standard application information;
  - Renewal procedures;
  - Process for license disapproval or revocation; and
  - Recordkeeping standards during and after licensure.
- **Regulatory Oversight:** Affirm the general authority of state insurance regulators to examine books and records relevant to PBM services subject to state insurance regulation.
- **Introduce materiality thresholds:** The guidance should specify when licensure may be refused, consistent with other licensed entities and prevailing state laws. For example, licensure may only be refused for material violations, not minor infractions.
- Clearly **outline an appeals process** for PBMs to contest licensure refusals, ensuring fair treatment and due process that complies with the state's administrative disputes statutes and procedures.
- **Limit officer attestation** to PBM activity rather than plan activity.
- **Limit renewal and reporting requirements** to PBM activities and plans subject to the state's regulatory authority.
- Where possible, recommend insurance departments **access data (such as NADAC) directly from federal or public sources**, rather than requiring PBMs to furnish it.

Policy Issues That Should Be Excluded

- **Data Calls and Reporting:** Exclude requirements for data calls, reporting, or examination standards beyond those generally applicable to other regulated entities.
- **Network Adequacy:** Exclude network adequacy requirements, as these are typically addressed in separate statutory provisions applicable to health insurance issuers that a PBM supports.

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- **Pharmacy Contracting or Reimbursement Requirements:** Exclude requirements related to pharmacy contracting or reimbursement, which are matters of state law and policy, not licensure.
- **Expansion of NAIC Policy:** Avoid including any provisions that would establish NAIC policy beyond general licensing and registration standards.
- **Pharmacy Accreditation**: Exclude requirements that would prohibit or restrict pharmacy accreditation standards for PBMs and/or health plans/carriers, as this issue exceeds requirements for state licensure.

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Again, PCMA and its member companies look forward not only to your response, but also to collaborating with you on all the aforementioned necessary revisions to the Draft. We appreciate the opportunity to provide comments.

And, PCMA and its member companies look to working with the NAIC on revisions to the Draft, as well as subsequent drafts of the PBM Licensure and Regulation Guideline Document.

Please do not hesitate to contact me with any questions or for further discussion.

Sincerely,

Peter Fjelstad

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