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November 21, 2025

Ms. Jolie Matthews

Submitted via electronic mail: jmatthews@naic.org

RE: NAIC Prescription Drug Coverage (B) Working Group Draft Pharmacy Benefit Manager Licensure and Regulation Guidelines for Regulators

Dear Ms. Matthews,

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), we commend the National Association of Insurance Commissioners (NAIC) for its sustained focus on strengthening accountability for pharmacy benefit managers (PBMs). Your work to advance coherent, enforceable standards is critical to ensuring PBMs operate transparently and in the best interests of patients and plan sponsors. PhRMA appreciates the opportunity to provide comments on the draft "Pharmacy Benefit Manager Licensure and Regulation Guidelines for Regulators" (Regulation Guidelines).

PhRMA represents the nation's leading innovative biopharmaceutical research companies dedicated to developing medicines that transform lives and create a healthier world. Together, we fight for solutions that ensure patients can access and afford treatments that prevent, treat, and cure disease. Over the past decade, PhRMA member companies have invested more than $850 billion in the search for new therapies, supporting nearly five million U.S. jobs.

PBMs play a decisive yet largely unseen role in determining coverage, pricing for plan sponsors, and costs for patients at the pharmacy counter. Without clear and enforceable licensure and transparency requirements, the opaque practices by PBMs (such as spread pricing, undisclosed fees, and retained rebates and other price concessions) can divert savings from patients and plan sponsors and increase out-of-pocket costs for patients.

PhRMA strongly supports:

- PBM licensure and registration backed by real oversight tools;
- Robust transparency of fees and network arrangements;
- Clear prohibitions on spread pricing;
- Standardized reporting to regulators; and
- Policies that require negotiated savings to be passed through at the point of sale to see lower out-of-pocket costs for patients.

These pragmatic steps, increasingly embraced by states, will bring sunlight and accountability to PBM operations.

NAIC's Regulation Guidelines are a necessary foundation to bring clarity and standardization to regulation of the PBM industry. The proposed draft of the Regulation Guidelines offers a solid base for that foundation. PhRMA provides below for your consideration suggestions regarding definitions, applicability, and transparency that we believe will further strengthen the intent of the regulations.

Definition Considerations

Recommendation: PhRMA recommends expanding the definition of "other prescription drug or device services" to encompass a full range of PBM business activities.

Rationale: The amendments clarify the service types and names of services that PBMs and/or their related and affiliated entities perform on behalf of PBMs' clients to help ensure that relevant PBM activities are captured within the regulations.

Amendment: Section 3: Definitions: "Other prescription drug or device services": insert new language

G. "Other prescription drug or device services" means services other than claims processing services, provided directly or indirectly, whether in connection with or separate from claims processing services, including, but not limited to:

(1) Negotiating the price of prescription drugs, including negotiating and contracting for direct or indirect rebates, discounts, other price concessions, or other financial incentives and arrangements with drug companies;

(2) Disbursing or distributing rebates;

(3) Managing or participating in incentive programs or arrangements for pharmacist services;

(4) Negotiating or entering into contractual arrangements with pharmacists or pharmacies, or both;

(5) Developing and maintaining formularies;

(6) Designing or managing any aspect(s) of prescription benefit programs including but not limited to, the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to the prescription drug benefit, controlling the cost of covered prescription drugs, managing or providing data relating to the prescription benefit programs, or the provisions of services related thereto; or

(7) Advertising or promoting services.

Applicability Considerations

Recommendation: PhRMA recommends language similar to that within New York Insurance Law, which makes PBMs responsible for the actions of their subcontractors, affiliates, and other downstream entities when those entities are acting on behalf of the PBM.

NY Ins. Law Section 2911(c) states, "The pharmacy benefit manager shall be responsible for the actions of any subcontractor, affiliate, subsidiary, or other individual or entity who violates any provision of this article in performance of any pharmacy benefit management services for the pharmacy benefit manager whether or not the pharmacy benefit manager was aware of, or sanctioned, the conduct."

Rationale: By making a PBM responsible for the actions of entities related to and affiliated with the PBM that act on behalf of the PBM, the suggested amendment helps to close a potential loophole that PBMs may try to exploit to evade accountability.

Amendment: Section 4: Applicability: Insert new applicability requirement: Create new Section 4(D)

Transparency Considerations

Recommendation: To complement and strengthen the existing reporting requirements for license renewal included in the Regulation Guidelines, PhRMA recommends including data elements similar to that enacted in Pennsylvania's "Pharmacy Audit Integrity and Transparency Act – Omnibus Amendments: Act of Jul. 17, 2024, P.L. 852, No. 77" ("Act 77").[i]

Section 7 of Act 77 requires PBMs to submit annual transparency reports to the state insurance department detailing prior-year data for each health insurer client. Reports must include aggregate rebates, aggregate administrative fees received from manufacturers, aggregate retained rebates not passed through to plans, rebate percentage ranges, and any differences in reimbursement between affiliated and non-affiliated pharmacies.

Rationale: Requiring a more comprehensive data will allow states to gain more insight into the financial flows within PBM business activities and brings much-needed accountability by PBMs for the role they play in the rising costs to plan sponsors and out-of-pocket expenses for patients.

Amendment: Section 5: Licensing: Insert new reporting section for renewal: new G(4) subsection

Final Thoughts

States across the country have moved to license PBMs, increase reporting, restrict the use of spread pricing, and require greater transparency into rebates and price concessions. Uniform NAIC Regulation Guidelines for regulators will raise the floor, reduce fragmentation in regulation, and provide regulators with tools to help ensure that PBMs are held accountable to the states they operate in and the patients and clients they serve.

PhRMA applauds the NAIC's commitment to advancing a modern, enforceable framework that holds PBMs accountable. Licensure with real oversight, transparent and auditable reporting, and strong enforcement mechanisms are pragmatic steps that will improve accountability and fairness across the industry. We stand ready to support the Working Group and staff as you refine model provisions, data standards, and implementation guidance.

Thank you for your consideration and for your leadership in protecting consumers.

Sincerely,

Charise Richard
Sr. Director, State Policy
PhRMA

[i] https://www.palegis.us/statutes/unconsolidated/law-information/view-statute?sessind=0&actnum=77&txttype=htm&sessyr=2024