September 1, 2020

The Honorable Andrew Stolfi
The Honorable TK Keen
Chair, Pharmacy Benefit Manager Regulatory Issues (B) Subgroup
National Association of Insurance Commissioners
444 North Capitol Street NW, Suite 700
Washington, DC 20001

**RE: EXPLANATION OF AMENDMENTS TO "[STATE] PHARMACY BENEFIT MANAGER LICENSURE AND REGULATION MODEL ACT"**

Dear Chair Stolfi and Chair Keen,

The National Community Pharmacists Association and the 74 signatories below appreciate the opportunity to provide written comments on the proposed "[State] Pharmacy Benefit Manager Licensure and Regulation Model Act" ("Draft"), which would empower state insurance commissioners to regulate and license pharmacy benefit managers (PBMs) doing business in their states. This model act is a step towards greater oversight of a massive, largely unregulated industry.

We applaud the Subgroup's efforts to regulate PBM practices and conflicts of interest that PBMs use to enrich themselves to the detriment of patients, payers, and community pharmacies. In pursuit of that goal, we request you strengthen the Draft by including the following amendments as shown in the attached document.

**Section 3. Definitions**

Amendment #1 removes the provision that exempts certain health plans, namely federally regulated plans, from the definition of "covered entity."[1] These exemptions are unnecessary, because the Draft contains a provision clarifying that nothing in the Draft is intended to conflict with federal law.[2] By removing the exemption, the Draft will authorize each insurance commissioner to regulate health plans and their PBMs to the full extent allowed under federal law.

Amendment #2 moves, but does not change, the definition of "pharmacy benefit manager affiliate" to the "Definitions" section.[3]

**Section 5. Licensing Requirement**

Amendment #3 adds a provision requiring the insurance commissioner to adopt a PBM license application fee that is based on the department's reasonable costs in administering the laws.[4] This

[1] Section (3)(C)(2).
[2] Section (4)(C).
[3] Section (3)(K).
[4] Section (5)(D).


100 Daingerfield Road
Alexandria, VA 22314-2888
(703) 683-8200 PHONE
(703) 683-3619 FAX

provision will ensure that the department can enforce the Draft's provisions in the public's best interest while minimizing the cost to the public.

**Section 6. Prohibited PBM Practices**

Amendment #4 changes the section title to "Prohibited PBM Practices" from "Gag Clauses Prohibited." Gag clauses are only one practice utilized by PBMs that serve their interests at the expense of enrollees, and the Draft should be amended to prohibit additional self-serving PBM practices.

Amendment #5 clarifies that a PBM may not prohibit or otherwise prevent pharmacists from discussing PBM practices with government officials for public policy purposes. To protect patients, pharmacies, and payers from self-serving PBM practices, policymakers must know how those practices work. Given their direct contact with patients, pharmacists are well-situated to provide that information to policymakers, and "gag clauses" should not prevent pharmacists from helping policymakers make decisions in the public's best interest.

Amendments #6 and #7 adds provisions protecting patient choice from PBM conflicts of interest.[5] Specifically, the provisions would prohibit a PBM from preventing an enrollee from utilizing the network pharmacy of his/her choice, refusing to contract with a pharmacy that is willing to meet the terms and conditions of network participation, mandating that an enrollee use a mail-order pharmacy, and steering an enrollee to a pharmacy that is a PBM-affiliated pharmacy. Too often, a PBM will usurp a patient's ability to make his/her own healthcare decisions by mandating or steering a patient to a specific pharmacy, often one owned or otherwise affiliated with the PBM. Not only do such practices remove a patient's autonomy, they often cost the patient and plan more. One study in Florida found PBMs steer patients with high-cost, high-profit prescriptions to affiliated pharmacies, and "when it comes to dispensing brand name drugs, MCO/PBM-affiliated pharmacies are making 18x to 109x more profit over the cost of the drugs than the typical community pharmacy."[6] This amendment would ensure patients are free to make healthcare decisions that are in their best interest, instead of the PBM's best interest. Provisions such as these have been implemented in states nationwide; twenty-eight states currently have laws protecting patients from mandated mail-order provisions, and twenty-seven states protect a patient's right to utilize any pharmacy that is willing to meet the terms and conditions for network participation.

Amendment #8 would protect payers by requiring PBMs to be fiduciaries of the covered entities they serve.[7] The conflicts of interest mentioned above that serve PBM interests at patients' expense also cost payers significant amounts. Although PBMs claim to cut costs for payers, they are typically under no legal or contractual obligation to do so. And practices such as spread pricing

[5] Section (5)(E) and (F).
[6] 3 Axis Advisors, *Sunshine in the Black Box of Pharmacy Benefits Management: Florida Medicaid Pharmacy Claims Analysis* 126 (Jan. 27, 2020).
[7] Section (5)(G).

and patient-steering force payers to hand additional dollars to PBMs. Requiring PBMs to act as fiduciaries would prevent these costly conflicts of interest.

Amendment #9 would ensure pharmacies have the opportunity to correct errors found during the course of a pharmacy audit.[8] Pharmacists understand that audits are a necessary practice to identify fraud, abuse, and wasteful spending, and they are not opposed to appropriate audits to identify such issues. Current PBM audits of pharmacies, however, are often used as an additional revenue source for the PBM. PBMs routinely target community pharmacies and recoup vast sums of money for nothing more than technical clerical errors where the correct medication was appropriately dispensed, and no financial harm was incurred. One issue is that pharmacy audits often occur after the period during which a pharmacy can reverse and rebill a claim. In that scenario, if an audit turns up an error, the pharmacy does not have the opportunity to correct the mistake. Allowing the PBM to reach back into the distant past to challenge previously adjudicated claims places the pharmacy at a distinct financial disadvantage, and this amendment would ensure the pharmacy has the opportunity to correct any mistakes that are found. Forty-two states currently have laws addressing pharmacy audit procedures, and this provision, modeled on a Maryland statute,[9] would further strengthen those laws.

**Section 7. Enforcement**

Amendment #10 would strengthen the insurance commissioner's enforcement authority by allowing the commissioner to sanction violations of the Draft's provisions.[10] This authority will ensure the commissioner can compel compliance with the law.

**Section 8. Regulations**

Amendment #11 would extend the commissioner's rulemaking authority to include reconciliations and remittance procedures, as well as rebates.[11] PBMs derive revenue from almost every player in the drug supply chain, including pharmacies and manufacturers. This revenue is often, but not exclusively, in the form of rebates. This amendment would allow the commissioner to address more PBM revenue streams and bring more transparency to the flow of prescription drug dollars.

Amendment #12 would reinforce the idea that healthcare decisions should be made by healthcare professionals and not PBMs or insurance companies.[12]

Amendment #13 would add retroactive adjudication/transaction fees to the list of prohibited "clawbacks."[13] This provision prohibiting clawbacks will lower patient out-of-pocket costs. When a PBM has reimbursed a pharmacy for filling a prescription, it is not uncommon for the PBM to

[8] Section (5)(H).
[9] H.B. 1273 (Md. 2020).
[10] Section (7)(A)
[11] Section (8)(B)(4).
[12] Section (8)(B)(5).
[13] Section (8)(B)(12).

claw back a portion of the reimbursement days, weeks, or even months later. However, a patient's cost share amount is tied to the initial reimbursement. Therefore, when there is a retroactive clawback, the true reimbursement amount is lower than the initial reimbursement. This means that a patient's cost share is based on an arbitrarily inflated figure. By prohibiting retroactive clawbacks, the Draft will ensure a patient's cost share reflects the true cost of their healthcare services. Over 17 states have already taken action to save patients money by addressing these retroactive clawbacks.

**Conclusion**

We commend the Subgroup's efforts to promote, preserve, and protect the public health, safety, and welfare by establishing common sense standards and criteria for the regulation and licensure of PBMs. We thank you for the opportunity to provide these comments. If you have any questions about the information provided in this letter, please contact Matthew Magner at (703) 600-1186 or matthew.magner@ncpa.org.

Sincerely,

National Community Pharmacists Association
AIDS Healthcare Foundation
Alabama Pharmacy Association
Alaska Pharmacists Association
Alliance for Transparent and Affordable Prescriptions
AlliantRx
American Associated Pharmacies
American Pharmacies
American Pharmacy Cooperative, Inc.
American Pharmacy Services Corporation
Arete Pharmacy Network
Arizona Pharmacy Association
Arkansas Pharmacists Association
California Pharmacists Association
CARE Pharmacies Cooperative, Inc.
Colegio de Farmacéuticos de Puerto Rico
Colorado Pharmacists Society
Connecticut Pharmacists Association
Dakota Drug, Inc
Delaware Pharmacists Society
Federation of Pharmacy Networks
Florida Pharmacy Association
Georgia Pharmacy Association
Good Neighbor Pharmacy/Elevate Provider Network
Idaho State Pharmacy Association
Illinois Pharmacists Association
Independent Pharmacy Alliance
Independent Pharmacy Cooperative
Iowa Pharmacy Association
Kansas Pharmacists Association
Kentucky Pharmacists Association
Keystone Pharmacy Purchasing Alliance
Louisiana Independent Pharmacies Association
Louisiana Pharmacists Association
Louisiana Wholesale Drug Co., Inc.
Massachusetts Independent Pharmacists Association
Massachusetts Pharmacists Association

Michigan Pharmacists Association
Minnesota Pharmacists Association
Mississippi Pharmacists Association
Missouri Pharmacy Association
Montana Pharmacy Association
National Alliance of State Pharmacy Associations
Nebraska Pharmacists Association
New Hampshire Pharmacists Association
New Jersey Pharmacists Association
New Mexico Pharmacists Association
New Mexico Pharmacy Business Council
North Carolina Association of Pharmacists
North Dakota Pharmacists Association
Northeast Pharmacy Service Corp.
Ohio Pharmacists Association
Oklahoma Pharmacists Association
Oregon State Pharmacy Association
Osborn Drugs
PARD, an Association of Community Pharmacies
Pennsylvania Pharmacists Association
Pharmacists Society of the State of New York
Pharmacists United for Truth and Transparency
Pharmacy Providers of Oklahoma (PPOk)
Pharmacy Society of Wisconsin
PPSC
QualityCare Pharmacies
Sav-Mor Drug Stores, Inc
Smith Drug Company
South Carolina Pharmacy Association
South Dakota Pharmacists Association
Tennessee Pharmacists Association
Texas Pharmacy Association
Texas Pharmacy Business Council
Value Drug Company
Virginia Pharmacists Association
Washington State Pharmacy Association
West Virginia Pharmacists Association
WSPC “Well-Served Pharmacy Community”