



September 1, 2020

The Honorable Andrew R. Stolfi
Chairman – Chair PBM Regulatory Issues (B) Subgroup
Members of the PBM Regulatory Issues (B) Subgroup

Delivered via email to Jolie Matthews @ jmatthews@naic.org

Re: Proposed Draft of the Pharmacy Benefit Manager and Regulation Model Act

Dear Chair Stolfi and Subgroup Members:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to provide the attached comments on the proposed draft of the Pharmacy Benefit Manager (PBM) Licensure and Regulation Model Act (Model) the PBM Regulatory Issues (B) Subgroup (Subgroup) exposed for comments on July 16, 2020.

PCMA is the national association representing America's PBMs, which administer prescription drug plans and operate specialty pharmacies for more than 270 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program (FEHBP), and the exchanges established by the Affordable Care Act (ACA).

We believe the Model exceeds the Subgroup's original stated goal of drafting PBM licensure and gag clause legislation. This proposed Model as written is highly unlikely to meet the NAIC's threshold rule for adoption. The so-called "Walter Bell rule" requires not only a three-quarter's majority, but also a vote for the model is a commitment to introduce the model in the state.

Section 6, Gag Clause, goes well beyond the federal gag clause mandate, encourages pharmacists to opine on issues on which they have no knowledge and is a considerable departure from what many states have already adopted.

Additionally, Section 8.B., Regulations, is extremely problematic. This section does not reflect the deliberative process of the NAIC nor the stated purpose of this model regulation. Much of the language reflects a delegation of legislative authority and contains no standards. In some cases, it is duplicative, addressing issues covered in other model acts including the NAIC's Health Carrier Prescription Drug Benefit Management Model Act and the Health Benefit Plan Network Access and Adequacy Model Act. We believe the issues contained in this Section would be more appropriately addressed separately from the model.

PCMA recommends the following specific amendments to the Model:

Section 2. Purpose

PCMA recommends adding language to Section 2A to include gag clause and recommends striking Section 2B.



A. This Act establishes the standards and criteria for the licensure and regulation of pharmacy benefit managers providing claims processing services or other prescription drug or device services for health benefit plans and prevents PBMs from requiring gag clauses in pharmacy contracts.

B. ~~The purpose of this Act is to:~~

- ~~(1) Promote, preserve, and protect the public health, safety and welfare through effective regulation and licensure of pharmacy benefit managers;~~
- ~~(2) Promote the solvency of the commercial health insurance industry, the regulation of which is reserved to the states by the McCarran-Ferguson Act (15 U.S.C. §§ 1011–1015), as well as provide for consumer savings, and fairness in prescription drug benefits;~~
- ~~(3) Provide for powers and duties of the commissioner; and~~
- ~~(4) Prescribe penalties and fines for violations of this Act.~~

We believe these suggested language changes more clearly define the stated goal and intent of the Model and eliminate unrelated, redundant, and misleading language.

Section 6. Gag Clauses Prohibited

PCMA recommends aligning the Section 6. Gag Clause language to the federal law requirement in order to meet the threshold requirement for state adoption and to more accurately reflect PBM contracting with network pharmacies.

A. In any participation contract between a pharmacy benefit manager and ~~pharmacists or a pharmacies~~ pharmacy providing prescription drug coverage for health benefit plans, no pharmacy ~~or pharmacist~~ may be prohibited, restricted or penalized ~~in any way~~ from disclosing to any a covered person ~~any healthcare information that the pharmacy or pharmacist deems appropriate regarding:~~

- ~~(1) The nature of treatment, risks or alternative thereto;~~
- ~~(2) The availability of alternate therapies, consultations, or tests;~~
- ~~(3) The decision of utilization reviewers or similar persons to authorize or deny services;~~
- ~~(4) The process that is used to authorize or deny healthcare services or benefits; or~~
- ~~(5) Information on financial incentives and structures used by the insurer.~~



- ~~B.—— A pharmacy or pharmacist may provide to a covered person (1) information regarding the covered person’s total cost for pharmacist services for a prescription drug, out-of-pocket cost under the plan or coverage with respect to acquisition of the drug and the amount an individual would pay for acquisition of the drug without using any health plan or health insurance coverage; and~~
- ~~C.—— A pharmacy benefit manager may not prohibit a pharmacy or pharmacist from discussing (2) information regarding the total cost for pharmacist services for a prescription drug or from selling a more affordable alternative to the covered person if a more affordable alternative is available.~~
- ~~D-B.~~ A pharmacy benefit manager contract with a participating pharmacist or pharmacy may not prohibit, restrict, or limit disclosure of information to the commissioner, law enforcement or state and federal governmental officials investigating or examining a complaint or conducting a review of a pharmacy benefit manager's compliance with the requirements under this Act.

PCMA supports a health plan enrollee always being offered and paying the lowest price available for prescription drugs at the pharmacy counter. We suggest the preceding language changes in the Model for the following reasons:

- Section 6 goes far beyond ensuring an enrollee will always pay the lesser of a co-payment or what a pharmacy charges as the usual and customary amount to a person without insurance.
- It wrongly includes language on PBM contracts with pharmacists. PBMs do not contract with network pharmacists for pharmacy services - they contract with pharmacies.
- The Section requires PBMs to allow pharmacists to discuss with plan enrollees' information the pharmacy does not have or that is more appropriately available to the enrollee in the health plan evidence of benefits.
- It runs afoul of the federal gag clause mandate.
- Thirty-six states have already enacted gag clause mandates. The majority of these laws follow the federal parameters.

In 2018, to ensure patients always paid the lowest price available, the Congress passed two bills: S.2553, *The Know the Lowest Price Act*, and S.2554, *The Patient Right to Know Drug Prices Act*. Below is the language included in the federal law:

Federal Gag Rule: SEC. 2729. Information on prescription drugs.

“(a) In general. A group health plan or a health insurance issuer offering group or individual health insurance coverage shall:

“(1) not restrict, directly or indirectly, any pharmacy that dispenses a prescription drug to an enrollee in the plan or coverage from informing (or penalize such pharmacy for informing) an enrollee of any differential between the enrollee's out-



of-pocket cost under the plan or coverage with respect to acquisition of the drug and the amount an individual would pay for acquisition of the drug without using any health plan or health insurance coverage; and

“(2) ensure that any entity that provides pharmacy benefits management services under a contract with any such health plan or health insurance coverage does not, with respect to such plan or coverage, restrict, directly or indirectly, a pharmacy that dispenses a prescription drug from informing (or penalize such pharmacy for informing) an enrollee of any differential between the enrollee’s out-of-pocket cost under the plan or coverage with respect to acquisition of the drug and the amount an individual would pay for acquisition of the drug without using any health plan or health insurance coverage.

“(b) Definition.—For purposes of this section, the term ‘out-of-pocket cost’, with respect to acquisition of a drug, means the amount to be paid by the enrollee under the plan or coverage, including any cost-sharing (including any deductible, copayment, or coinsurance) and, as determined by the Secretary, any other expenditure.”

Section 8.B. Regulations

PCMA believes the issues contained in Section 8.B. would be more appropriately addressed separately from the Model and therefore recommends the following changes to the language in this Section.

A. The commissioner may adopt regulations regulating pharmacy benefit managers that are not inconsistent with this Act.

B. ~~The regulations adopted pursuant to Subsection A may include but are not limited to the following:~~

~~———— (1) Pharmacy benefit manager network adequacy;~~

~~———— (2) Prohibited market conduct practices;~~

~~———— (3) Data reporting requirements under state price-gouging laws;~~

~~———— (4) Rebates;~~

~~———— (5) Prohibitions and limitations on the corporate practice of medicine (CPOM);~~

~~———— (6) Compensation;~~

~~(7) Procedures for pharmacy audits conducted by or on behalf of a pharmacy benefit manager;~~

~~———— (8) Medical loss ratio (MLR) compliance;~~

- ~~—————(9)———Affiliate information-sharing;~~
- ~~(10)———Lists of health benefit plans administered by a pharmacy benefit manager in this state;~~
- ~~(11)———Reimbursement lists or payment methodology used by pharmacy benefit managers;~~
- ~~—————(12)———Clawbacks prohibited. A pharmacy benefit manager or representative of a pharmacy benefit manager may not make or permit any reduction of payment for pharmacist services by a pharmacy benefit manager or a covered entity directly or indirectly to a pharmacy under a reconciliation process to an effective rate of reimbursement, including but not limited to, generic effective rates, brand effective rates, direct and indirect remuneration fees or any other reduction or aggregate reduction of payment;~~
- ~~—————(13)———Affiliate compensation.~~
 - ~~—————(a)———“Pharmacy benefit manager affiliate” means a pharmacy or pharmacist that directly or indirectly, through one (1) or more intermediaries owns or controls, is owned or controlled by, or is under common ownership or control with a pharmacy benefit manager.~~
 - ~~—————(b)———A pharmacy benefit manager may not reimburse a pharmacy or pharmacist in the state an amount less than the amount that the pharmacy benefit manager reimburses a pharmacy benefit manager affiliate for providing the same pharmacist services; and~~
- ~~—————(14)———Spread pricing prohibited.~~
 - ~~—————(a)———“Spread pricing” means the model of prescription drug pricing in which the pharmacy benefit manager charges a health benefit plan a contracted price for prescription drugs, and the contracted price for the prescription drugs differs from the amount the pharmacy benefit manager directly or indirectly pays the pharmacist or pharmacy for pharmacist services.~~
 - ~~—————(b)———A pharmacy benefit manager is prohibited from conducting spread pricing in this state.~~

Drafting Note: Subsection B lists options for a state to consider in adopting regulations to implement the provisions of this Act. Not every option listed will be appropriate for every state.



We look forward to working with the Subgroup on a Model that would meet the original mandate for PBM licensure and gag clause legislation.

Sincerely,

A handwritten signature in black ink, appearing to read "Lauren".

Lauren Rowley
Senior Vice President

Cc: Jolie Matthews

DRAFT