

## FROM THE NAIC CONSUMER REPRESENTATIVES

September 1, 2020

Mr. Andrew S. Stolfi and Mr. TK Keen  
Oregon Department of Consumer and Business Services  
c/o National Association of Insurance Commissioners  
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Ms. Jolie H. Matthews  
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### **RE: Consumer Representatives' Recommendations for Pharmacy Benefit Manager Licensure and Regulation Model Act**

Dear Mr. Stolfi, Mr. Keen, and Ms. Matthews:

On behalf of the undersigned Consumer Representatives to the National Association of Insurance Commissioners (NAIC), we appreciate the opportunity to provide recommendations and comments to the NAIC's proposed Pharmacy Benefit Manager Licensure and Regulation Model Act. Pharmacy benefits managers (PBMs) play a critical role in the drug pricing, access, and delivery system. As such, their actions have a profound impact on consumer access and affordability. We appreciate the NAIC's attention to the regulation of PBMs and have provided redline comments to the draft model. We would like to highlight the following areas included in our redline edits:

#### **Section 1 (Purpose)**

We believe "transparency" should be added to the purpose section as well as to substantive provisions.

#### **Section 2 (Definitions)**

We propose adding definitions for "cost sharing" and "rebates" in keeping with other suggested additions to the model that reference these terms. We also recommend deleting the section describing what "covered entities" are not. These exceptions are unnecessary and/or covered in other subsections (i.e., Section 4 (C) "Nothing in this Act is intended or shall be construed to conflict with existing relevant federal law").

#### **Section 5 (Licensing Requirement)**

In keeping with our proposed language in the enforcement section, we are proposing additional provisions in this section to allow regulators to refuse to issue a license in situations where a PBM has been subject to sanctions under another state's PBM law. We also believe there should be a penalty provision for doing business without a license.

#### **Section 6 (Gag Clauses Prohibited)**

We appreciate the prohibition of gag clauses. Inclusion of this section reflects legislation already in place in the majority of states as well as federal legislation. However, we are concerned that this section leaves out important consumer affordability protections. We have included two additional subsections in our redline

version that prohibit a consumer from being charged more for a drug when using insurance than she would be charged without insurance and requiring amounts paid in this situation to be attributable to the plan's deductible and out-of-pocket maximum.<sup>1</sup>

### **Section 7 (Enforcement)**

We believe stronger provisions are necessary to ensure that the protections included in the model law are enforced. We have included several suggestions for monetary penalties in line with other state PBM laws. Penalty provisions are necessary to give meaning to the language in section two ("Purpose") prescribing "penalties and fines for violations of this Act."<sup>2</sup>

### **Section 8 (Regulations)**

While we appreciate the need to balance the variability in state approaches to PBM legislation, we are concerned that the list of optional regulations is confusing and provides little teeth to important consumer protections. We are also concerned that the model law language itself does not support the substantive regulatory action included in section 8. Therefore, we are suggesting the following topics be added to the substantive sections of the law.

### **Additional Section (Transparency)**

The nation's drug pricing, access, and delivery system is at best complex and at worst deliberately opaque. While there is an important competitive business need to protect proprietary information, this must be balanced with strong transparency requirements, a goal that several states have codified in their own PBM laws. We believe a section requiring aggregate data reporting from PBMs to regulators should be added to the substance of the model law, with specific provisions on the types of data that must be submitted annually to the insurance commissioner.<sup>3</sup>

### **Additional Section (Business Practices)**

Ensuring that PBMs have a legal duty to act in good faith and in the best interest of a health plan or other third party with whom the PBM has a contractual obligation is critical to promote sound business practices and to prevent activities that will raise the overall costs of prescription drugs and harm consumers. We have included a new substantive section, including imposing a fiduciary duty on PBMs in their contracts with health plans and other third parties.<sup>4</sup>

### **Additional Section (Prescription Drug Benefit Management)**

The NAIC Health Carrier Prescription Drug Benefit Management Model Law (#22) includes provisions governing plan benefit design, pharmacy and therapeutics committees and other activities that are often carried out by PBMs. While Model 22 does not directly regulate the activities of PBMs, it requires issuers to ensure compliance of any third party acting as the "designee" of the issuer. A drafting note in Section 4:

*The reference to "designee" in Section 4 is intended to be construed broadly to apply to a person or entity the health carrier contracts with to perform, or carry out on its behalf, specified activities required under this Act or applicable regulations, such as pharmacy benefit manager (PBM). Section 10 of this Act provides that the health carrier is responsible for monitoring all of activities carried out by, or on behalf, of the health carrier by a designee that the health carrier has contracted with to perform that activity and ensuring that the designee is complying with the requirements of this Act and any applicable regulations related to that activity. If a state has enacted or intends to enact a specific law or regulation*

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<sup>1</sup> See Kentucky PBM law for example of these two provisions, KY Rev Stat § 304.9-053 (2017).

<sup>2</sup> See Connecticut PBM law, CT Public Act No. 18-41 (2018).

<sup>3</sup> See Washington PBM law, RCW 74.09.215 and Connecticut PBM law, CT Public Act No. 18-41 (2018).

<sup>4</sup> See Nevada PBM law, NRS 439.915 (2017).

*directly regulating certain persons or entities that may be designees under this Act, such as PBMs, those states should review the provisions of this Act, such as Section 10 of this Act, to determine whether any provisions of this Act should be modified or clarified to encompass such persons or entities in light of that law or regulation.*

To ensure consistency of the consumer protections, we believe the PBM model should cross-reference Model 22 and/or the state's prescription drug management law.

For any questions, please contact Amy Killelea ([akillelea@nastad.org](mailto:akillelea@nastad.org)).

Sincerely,

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Comments are being requested on this draft by Tuesday, Sept. 1, 2020. Comments should be sent by email only to Jolie Matthews at [jmatthews@naic.org](mailto:jmatthews@naic.org).

## [STATE] PHARMACY BENEFIT MANAGER LICENSURE AND REGULATION MODEL ACT

### Table of Contents

Section 1.	Short Title
Section 2.	Purpose
Section 3.	Definitions
Section 4.	Applicability
Section 5.	Licensing Requirement
Section 6.	Gag Clauses Prohibited
Section 7.	Enforcement
Section 8.	Regulations
Section 9.	Severability
Section 10.	Effective Date

### Section 1. Short Title

This Act shall be known and may be cited as the [State] Pharmacy Benefit Manager Licensure and Regulation Act.

### Section 2. Purpose

- 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.
- 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)
  - ~~(3)~~ (3) ~~Provide, as well as provide~~ for consumer savings, transparency and fairness in prescription drug benefits;
  - ~~(4)~~ (4) Provide for powers and duties of the commissioner; and
  - ~~(5)~~ (5) Prescribe penalties and fines for violations of this Act.

### Section 3. Definitions

For purposes of this Act:

- A. “Claims processing services” means the administrative services performed in connection with the processing and adjudicating of claims relating to pharmacist services that include:
  - (1) Receiving payments for pharmacist services;
  - (2) Making payments to pharmacists or pharmacies for pharmacist services; or
  - (3) Both paragraphs (1) and (2).

B. “Commissioner” means the insurance commissioner of this state.

**Drafting Note:** Use the title of the chief insurance regulatory official wherever the term “commissioner” appears.

~~C.~~ C. “Cost sharing” means the amount paid by a covered person as required under the covered person’s health benefit plan at the point of sale.

~~DE.~~ DE. (1) “Covered entity” means:

- (a) A nonprofit hospital or medical service corporation, health insurer, health benefit plan or health maintenance organization;
- (b) A health program administered by a department or a state in the capacity of a provider of health coverage; or
- (c) An employer, a labor union or other group of persons organized in the state that provides health coverage to covered individuals who are employed or reside in the state.

~~(2) “Covered entity” does not include:~~

~~(a) A self-funded plan that is exempt from state regulation pursuant to federal law;~~

~~(b) A plan issued for coverage for federal employees; or~~

~~(c) A health benefit plan that provides coverage only for accidental injury, specified disease, hospital indemnity, Medicare supplement, disability income, long term care or other limited benefit health insurance policies and contracts.~~

~~ED.~~ ED. “Covered person” means a member, policyholder, subscriber, enrollee, beneficiary, dependent or other individual participating in a health benefit plan.

~~FE.~~ FE. “Health benefit plan” means a policy, contract, certificate or agreement entered into, offered or issued by a health carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of [physical, mental or behavioral] health care services.

~~GF.~~ GF. “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 rebates, discounts 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 prescription benefit programs; or
- (7) Advertising or promoting services.

~~HG.~~ HG. “Pharmacist” means an individual licensed as a pharmacist by the [state] Board of Pharmacy.

**H.** “Pharmacist services” means products, goods, and services or any combination of products, goods and services, provided as a part of the practice of pharmacy.

**J.** “Pharmacy” means the place licensed by the [state] Board of Pharmacy in which drugs, chemicals, medicines, prescriptions and poisons are compounded, dispensed or sold at retail.

**K.** (1) “Pharmacy benefit manager” means a person, business or entity, including a wholly or partially owned or controlled subsidiary of a pharmacy benefit manager, that provides claims processing services or other prescription drug or device services, or both, to covered persons who are residents of this state, for health benefit plans.

(2) “Pharmacy benefit manager” does not include:

(a) A health care facility licensed in this state;

(b) A health care professional licensed in this state; or

(c) A consultant who only provides advice as to the selection or performance of a pharmacy benefit manager.

**L.** “Rebates” means all price concessions paid by a manufacturer to a Pharmacy Benefit Manager or health carrier, including rebates, discounts, and other price concessions that are based on actual or estimated utilization of a prescription drug.

#### **Section 4. Applicability**

A. This Act shall apply to a contract or health benefit plan issued, renewed, recredentialed, amended or extended on or after the effective date of this Act, including any covered entity that offers pharmacy benefits through a third party.

**Drafting Note:** States may want to consider adding language to Subsection A above or Section 10—Effective Date providing additional time for pharmacy benefit managers to come into compliance with the requirements of this Act.

B. As a condition of licensure, any contract in existence on the date the pharmacy benefit manager receives its license to do business in this state shall comply with the requirements of this Act.

C. Nothing in this Act is intended or shall be construed to conflict with existing relevant federal law.

#### **Section 5. Licensing Requirement**

A. A person may not establish or operate as a pharmacy benefit manager in this state for health benefit plans without first obtaining a license from the commissioner under this Act.

B. The commissioner may adopt regulations establishing the licensing application, financial and reporting requirements for pharmacy benefit managers under this Act.

**Drafting Note:** States that are restricted in their rulemaking to only what is prescribed in statute may want to consider including in this section specific financial standards required for a person or organization to obtain a license to operate as a pharmacy benefit manager in this state.

C. A person applying for a pharmacy benefit manager license shall submit an application for licensure in the form and manner prescribed by the commissioner.

**Drafting Note:** States may want to consider reviewing their third party administrator statute if a state wishes to specify what documents must be provided to the commissioner to obtain a pharmacy benefit manager license in the state.

D. A person submitting an application for a pharmacy benefit manager license shall include with the application

a non-refundable application fee of \$[X].

- E. The commissioner may refuse to issue a license if the commissioner determines that the applicant or any individual responsible for the conduct of affairs of the applicant is not competent, trustworthy, financially responsible or of good personal and business reputation, ~~or~~ has had an insurance or other certificate of authority or license denied or revoked for cause by any jurisdiction, or has been subject to penalties under another state's pharmacy benefits manager statute or regulation.
- F. (1) Unless surrendered, suspended or revoked by the commissioner, a license issued under this section shall remain valid as long as the pharmacy benefit manager continues to do business in this state and remains in compliance with the provisions of this act and any applicable rules and regulations, including the payment of an annual license renewal fee of \$[X] and completion of a renewal application on a form prescribed by the commissioner.  
(2) Such renewal fee and application shall be received by the commissioner on or before [x] days prior to the anniversary of the effective date of the pharmacy benefit manager's initial or most recent license.
- G. If a pharmacy benefits manager acts without obtaining a license pursuant to this section, the pharmacy benefits manager is subject to a fine of \$5,000 per day for the period the pharmacy benefits manager is found to be in violation.

## **Section 6. Gag Clauses Prohibited**

- A. In any participation contracts between a pharmacy benefit manager and pharmacists or pharmacies 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 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 information regarding the covered person's total cost for pharmacist services for a prescription drug.
- C. A pharmacy benefit manager may not prohibit a pharmacy or pharmacist from discussing 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. 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.
- E. A pharmacy benefit manager may not require a covered person purchasing a prescription drug to pay a cost-sharing amount greater than the amount the insured would pay for the drug if he or she were to purchase the drug without coverage under a health benefit plan.
- F. Any amount paid by a covered person under subsection (E) of this section shall be attributable toward any deductible or annual out-of-pocket maximums under the covered person's health benefit plan

## Section 7. Enforcement

- A. The commissioner shall enforce compliance with the requirements of this Act.
- B. (1) The commissioner may examine or audit the books and records of a pharmacy benefit manager providing claims processing services or other prescription drug or device services for a health benefit plan to determine compliance with this Act.
- C. The commissioner shall require a pharmacy benefit manager to submit a report for the preceding calendar year stating that the pharmacy benefit manager is in compliance with the requirements of the act.
- D. The commissioner may impose a penalty of not more than seven thousand five hundred dollars on a pharmacy benefits manager for each violation of this law.

**Drafting Note:** States may want to consider including a reference to the cost of examinations in the *Model Law on Examinations* (#390).

- (2) The information or data acquired during an examination under paragraph (1) is:
  - (a) Considered proprietary and confidential;
  - (b) Not subject to the [Freedom of Information Act] of this state;
  - (c) Not subject to subpoena; and
  - (d) Not subject to discovery or admissible in evidence in any private civil action.

## Section 8. Transparency

- A. Annually, a pharmacy benefit manager must provide the commissioner the following information from the previous calendar year:
  - (1) the aggregate dollar amount of all discounts, including the total dollar amount and percentage discount, and all rebates received from a manufacturer for drugs on the pharmacy benefit manager's formularies;
  - (2) the aggregate dollar amount of all discounts and rebates that are retained by the PBM for drugs on the PBM's formularies;
  - (3) actual total reimbursement amounts the pharmacy benefit manager pays retail pharmacies after all direct and indirect administrative and other fees that have been retrospectively charged to the pharmacies are applied;
  - (4) the negotiated price health plans pay the pharmacy benefit manager for drugs on the pharmacy benefit manager's formularies;
  - (5) the amount, terms, and conditions relating to copayments, reimbursement options, and other payments or fees associated with a prescription drug benefit plan;
  - (6) any ownership interest the pharmacy benefit manager has in a pharmacy or health plan with which it conducts business;
- B. All information submitted to the commissioner pursuant to this section shall be exempt from disclosure under the Freedom of Information Act, except to the extent such information is included on an aggregated basis in the report required by subsection (C) of this section. The commissioner shall not disclose information submitted pursuant to

this section in a manner that is likely to compromise the financial, competitive or proprietary nature of such information.

- C. The commissioner shall submit an annual report to the committee(s) of jurisdiction within General Assembly having cognizance of matters relating to insurance. The report shall contain (1) an aggregation of the information submitted to the commissioner pursuant to this section for the immediately preceding calendar year, and (2) such other information as the commissioner, in the commissioner's discretion, deems relevant for the purposes of this section.

## **Section 9. Business Practices**

A. A pharmacy benefit manager has a fiduciary duty to a to a third party with which the pharmacy benefit manager has entered into a contract to manage the pharmacy benefits plan of the third party client and shall discharge that duty in accordance with the provisions of state and federal law.

B. A pharmacy benefit manager shall perform its duties with care, skill, prudence, diligence, and professionalism.

C. A pharmacy benefit manager shall notify a health carrier client in writing of any activity, policy, or practice of the pharmacy benefit manager that directly or indirectly presents any conflict of interest with the duties imposed in this section.

## **Section 10 Prescription Drug Benefit Management**

- A. As "designees" of health plans, pharmacy benefits managers must comply with state laws governing prescription drug management, including formulary design, non-discrimination, transparency, and notice requirements.

**Drafting note:** States may want to consider inserting specific reference to the state law governing prescription drug benefit management. The NAIC *Health Carrier Prescription Drug Benefit Management Model Law* (#22) includes provisions governing plan benefit design, pharmacy and therapeutics committees, formulary change notice requirements, and other activities that are often carried out by pharmacy benefit managers acting as the designee of the issuer. States should consider cross-referencing the state's prescription drug management law with specific reference to any additional legal requirements pharmacy benefits managers have with regard to any activity covered by the prescription drug management law carried out by the pharmacy benefit manager on behalf of an issuer.

## **Section 118. Regulations**

- 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.

**Section 129. Severability**

If any provision of this Act, or the application of the provision to any person or circumstance shall be held invalid, the remainder of this Act, and the application of the provision to persons or circumstances other than those to which it is held invalid, shall not be affected.

**Section 1310. Effective Date**

This Act shall be effective [insert date]. A person doing business in this state as a pharmacy benefit manager on or before the effective date of this Act shall have [six (6)] months following [insert date that the Act is effective] to come into compliance with the requirements of this Act.