Dear Jolie:

Hope you are doing well and staying safe. Attached, please find the American Medical Association’s (AMA) suggested changes to the National Association of Insurance Commissioner’s (NAIC) Pharmacy Benefit Manager Licensure and Regulation Model Act (July 6, 2020 draft). We appreciate the opportunity to submit these comments and are looking forward to engaging with you and the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup on this initiative.

Our edits focus on several broad issues including improving transparency of pharmacy benefit managers (PBMs) practices, establishing a PBM’s fiduciary duty to insurers or employers, creating measurable requirements for compliance with this act through regulation, and strengthening insurance commissioners’ enforcement authority.

We see drafting this model bill to be an important and timely effort for NAIC, as we regularly hear concerns from physician about the practices and policies of PBMs. Moreover, as patients shoulder more and more of the costs of their health care, we think there are important efficiencies, and hopefully patient savings, that can be found in stronger and more targeted regulation of PBM practices.

Please feel free to reach out with any questions or concerns, and we look forward to the coming discussions.

Take care,
Emily Carroll and Daniel Blaney-Koen
[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) Provide for consumer savings, transparency and fairness in prescription drug benefits;

   (4) Provide for powers and duties of the commissioner; and

   (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. “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.

D. (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)

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

F. “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.

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 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.

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

I. “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. “Rebate” means a discount or concession, which affects the price of a prescription drug, that a pharmaceutical
manufacturer directly provides to a (i) health carrier for a prescription drug manufactured by the
pharmaceutical manufacturer, or (ii) pharmacy benefits manager after the manager processes a claim from a
pharmacy or a pharmacist for a prescription drug manufactured by the pharmaceutical manufacturer.

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, 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. The Commissioner may suspend, revoke, or place on probation a Pharmacy Benefit Manager license under any of the following circumstances:

(1) The Pharmacy Benefit Manager has engaged in fraudulent activity that constitutes a violation of state or federal law:

(2) The Commissions received consumer complains that justify an action under this section to protect the safety and interests of consumers;

(3) The Pharmacy Benefit Manager fails to pay an application fee for the license; or

(4) The Pharmacy Benefit Manager fails to comply with a requirement set forth in this section.

H. 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.

I. A pharmacy benefits manager's license may not be sold or transferred to a nonaffiliated or otherwise unrelated party. A pharmacy benefits manager may not contract or subcontract any of its negotiated formulary services to any unlicensed nonaffiliated business entity.

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.

New Section. Prohibition against Interference with the Patient-Physician Relationship.
A. A pharmacy benefit manager shall be prohibited from implementing or carrying out any policy that interferes with a pharmacist licensed in this state from carrying out his or her corresponding responsibility under the federal Controlled Substances Act.
B. A pharmacy benefit manager shall, prior to implementing a policy that limits or otherwise places a restriction on the quantity or dosage of a prescription for a controlled substance, or the means of dispensing a prescription for a controlled substance, shall be required to submit the policy to the [state medical board, state pharmacy board and any other appropriate regulatory board charged with regulating health care professionals] for review prior to implementation.
   a. The [regulatory board(s)] shall cooperatively review the policy to determine whether it comports with state law and regulation.
   b. The [regulatory board(s)] shall publish a coordinated opinion as to its findings within six months of the date that the policy was submitted for review.
   c. The pharmacy, pharmacy benefit manager or covered entity shall not be permitted to implement, continue or enforce its policy prior to the issuance of the findings as required under this section.
   d. Any policy that the [regulatory board] determines interferes with the practice of medicine, pharmacy, or other licensed health care profession shall be declared null and void.
C. A pharmacy benefit manager that has its own, or acts to carry out, a policy that limits or otherwise places a restriction on the quantity or dosage of a prescription for a controlled substance, or the means of dispensing a prescription for a controlled substance, shall immediately suspend the policy, and within 30 days of this Act going into effect, be required to submit the policy to the state medical board, state pharmacy board [and any other appropriate regulatory board charged with regulating health care professionals] for review as required under Section B of this Act.
D. Unless the U.S. Drug Enforcement Administration, state medical, nursing or other health care professional licensing board has rendered a final decision limiting, suspending or terminating a duly licensed health care professional’s authority to prescribe controlled substances, a pharmacy benefit manager shall be prohibited from limiting, suspending or terminating the health care professional’s authority to prescribe controlled substances.
E. Nothing in this Act shall be construed as preventing an individually licensed pharmacist from exercising his or her corresponding responsibility as required under state and federal law.

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.

(2) All pharmacy benefit files and records shall be subject to examination by the Commissioner or by duly appointed designees. The Commissioner, authorized employees and examiners shall have access to any of a pharmacy benefit manager’s files and records that may relate to a particular complaint under investigation or to an inquiry or examination by the Insurance Department.

(3) Every officer, director, employee or agent of the pharmacy benefit manager, upon receipt of any inquiry from the Commissioner shall, within thirty (30) days from the date the inquiry is sent, furnish the Commissioner with an adequate response to the inquiry.
(4) When making an examination under this section, the Commissioner may retain subject matter experts, attorneys, appraisers, independent actuaries, independent certified public accountants or an accounting firm or individual holding a permit to practice public accounting, certified financial examiners or other professionals and specialists as examiners, the cost of which shall be borne by the PBM which is the subject of the examination.

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.

E. The Commissioner shall provide for the receiving and processing of individual complaints alleging violations of the provisions of this Act.

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 each drug on the pharmacy benefit manager’s formularies;

(2) the aggregate dollar amount of all discounts and rebates that are retained by the pharmacy benefit manager for each drug on the PBM's formularies;

(3) actual total reimbursement amounts for each drug 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 each drug 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. Report from the commissioner

1) 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 (b) of this section. The commissioner shall not disclose information submitted pursuant to this section in a manner that (1) is likely to compromise the financial, competitive or proprietary nature of such information, or (2) would enable a third party to identify a health care plan, health carrier, pharmacy benefits manager, pharmaceutical manufacturer, or the value of a rebate provided for a particular outpatient prescription drug or therapeutic class of outpatient prescription drugs.

2) Not later than March 1, 202[ ], and annually thereafter, the commissioner shall submit a 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. Not later than February 1, 202[ ], and annually thereafter, the commissioner shall provide each pharmacy benefits manager and any third party affected by submission of a report required by this subsection with a written notice describing the content of the report.

3) 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 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.

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 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 10. Regulations

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

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

(1) Pharmacy benefit manager network adequacy requirements, including, but limited to;

   (a) An individual's choice of in-network provider may include a retail pharmacy or a mail-order pharmacy. A health insurer or pharmacy benefit manager shall not restrict such choice.

   (b) Such health insurer or pharmacy benefit manager shall not require or incentivize using any discounts in cost-sharing or a reduction in copay or the number of copays to individuals to receive prescription drugs from an individual's choice of in-network pharmacy.

(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 11. 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 12. 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.