

Comments are being requested on this draft. Comments should be sent by email only to Jolie Matthews at 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 and Other Pharmacy Benefit Manager Prohibited Practices
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), 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.

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. “Covered person” means a member, policyholder, subscriber, enrollee, beneficiary, dependent or other individual participating in a health benefit plan.
- D. “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.
- E. “Health carrier” means an entity subject to the insurance laws and regulations of this state, or subject to the jurisdiction of the commissioner, that contracts or offers to contract or enters into an agreement to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services, including a sickness and accident insurance company, a health insurance company, a health maintenance organization, a hospital and health service corporation, or any other entity providing a plan of health insurance, health benefits, or health care services.

Drafting Note: States that license health maintenance organizations pursuant to statutes other than the insurance statutes and regulations, such as the public health laws, will want to reference the applicable statutes instead of, or in addition to, the insurance laws and regulations.

- F. “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.
- G. “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.
- I. “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.
- J.
 - (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;

- (c) A consultant who only provides advice as to the selection or performance of a pharmacy benefit manager; or
- (d) A health carrier to the extent that it performs any claims processing and other prescription drug or device services exclusively for its enrollees.

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 health carrier that performs claims processing or other prescription drug or device services 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 or renew 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 been found to have violated the insurance laws of this state or any other jurisdiction, or has had an insurance or other certificate of authority or license denied or revoked for cause by any jurisdiction.
- 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.

Section 6. Gag Clauses and Other Pharmacy Benefit Manager Prohibited Practices

- 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 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.

- C. 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, provided that:
 - (1) The recipient of the information represents it has the authority, to the extent provided by state or federal law, to maintain proprietary information as confidential; and
 - (2) Prior to disclosure of information designated as confidential the pharmacist or pharmacy:
 - (a) Marks as confidential any document in which the information appears; or
 - (b) Requests confidential treatment for any oral communication of the information.

- D. A pharmacy benefit manager may not terminate the contract of or penalize a pharmacist or pharmacy due to pharmacist or pharmacy:
 - (1) Disclosing information about pharmacy benefit manager practices, except for information determined to be a trade secret, as determined by state law or the commissioner; or
 - (2) Sharing any portion of the pharmacy benefit manager contract with the commissioner pursuant to a complaint or a query regarding whether the contract is in compliance with this Act.

- E.
 - (1) A pharmacy benefit manager may not require a covered person purchasing a covered prescription drug to pay an amount greater than the lesser of the covered person’s cost-sharing amount under the terms of the health benefit plan or the amount the covered person would pay for the drug if the covered person were paying the cash price.
 - (2) Any amount paid by a covered person under paragraph (1) of this subsection shall be attributable toward any deductible or, to the extent consistent with section 2707 of the Public Health Service Act, the 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.

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

Drafting Note: States may want to consider incorporating their existing market conduct examination statutes into this Act rather than relying on the examination authority provided under this section.

- (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.
- C. The commissioner may use any document or information provided pursuant to Section 6C of this Act or Section 6D of this Act in the performance of the commissioner's duties to determine compliance with this Act.
- D. The commissioner may impose a penalty on a pharmacy benefit manager or the health carrier with which it is contracted, or both, for a violation of this Act. The penalty may not exceed [insert appropriate state penalty] per entity for each violation of this Act.

Drafting Note: If an appeals process is not otherwise provided, a state should consider adding such a provision to this section.

Section 8. Regulations

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

Drafting Note: This Act is primarily intended to establish licensing standards for pharmacy benefit managers (PBMs). A number of states have enacted statutes or made suggestions that extend into the regulation of pharmacy benefit manager business practices. The provisions below, which are followed by citations to state law where applicable, provide topic areas that states pursuing this Act may wish to consider in their proposed legislation:

- (1) PBM network adequacy (see provisions in the *Health Carrier Prescription Drug Benefit Management Model Act* (#22))
- (2) Prohibited market conduct practices (South Carolina Code §38-71-2230(A)(1). MD. ANN. CODE §15-1642, and Oregon Rev. Stat. §§ 735.534 through 735.552).
- (3) Data reporting requirements under state price-gouging laws;
- (4) Rebates (Texas Insurance Code §1369.502 and MD. ANN. CODE §15-1624);
- (5) Prohibitions and limitations on the corporate practice of medicine (CPOM);
- (6) Compensation (N.J.S.A. 17B:27F-8 (New Jersey));
- (7) Procedures for pharmacy audits conducted by or on behalf of a PBM (40 PA. CONS. STAT. §§ 4511-4514, MD. ANN. CODE §15-1629, and Oregon Rev. Stat. §§735.540 through 735.552);
- (8) Medical loss ratio (MLR) compliance;
- (9) Affiliate information-sharing;

- (10) Lists of health benefit plans administered by a PBM in this state (New Hampshire Rev Stat § 402-N:6)
- (11) Reimbursement lists or payment methodology used by PBMs (Kansas Rev Stat §§ 40-3829 - 40-3830, 24-A Maine Rev. Stat. Ann. Chapter 56-C, Colo. Rev Stat. § 25-37-103.5, MD. ANN. CODE §15-1628.1 and §15-1628.2, and Oregon Rev. Stat. §735.534 and §735.536);
- (12) Prohibiting clawbacks (Ala. Code § 27-45A-5, MD. ANN. CODE §15-1628.3, N.J.S.A. 17B:27-7 (New Jersey), and Oregon Rev. Stat. §735.534);
- (13) Affiliate compensation (Colo. Rev. Stat. § 10-16-122.3);
- (14) Prohibiting spread pricing (LA. REV. STAT. ANN § 22:1867); and
- (15) Transparency provisions (Texas Insurance Code § 1369.502; and 24-A Maine Rev. Stat. Ann. Chapter 56-C).

Section 9. 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 10. 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.

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