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National Council of Insurance Legislators (NCOIL)

Pharmacy Benefits Manager Licensure and Regulation Model Act

**Sponsored by Sen. Jason Rapert (AR)*

**To be discussed and considered during the Health, Long Term Care and Health Retirement Issues Committee on December 8, 2018*

Please note that the Sponsor, Sen. Jason Rapert (AR), reserves the right to make sponsor's amendments to the Model between now and the December 8, 2018 meeting of the Health, Long Term Care and Health Retirement Issues Committee

Table of Contents

Section 1.	Title
Section 2.	Purpose
Section 3.	Definitions
Section 4.	License to do business – Annual statement – Assessment
Section 5.	Gag Clauses Prohibited
Section 6.	Enforcement
Section 7.	Rules
Section 8.	Applicability
Section 9.	Severability Clause
Section 10.	Effective Date

Section 1. Title

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

Section 2. Purpose

(a) This Act establishes the standards and criteria for the regulation and licensure of pharmacy benefits 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 benefits 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 benefits.
- (3) Provide for powers and duties of the Insurance Commissioner, the State Insurance Department; 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 subdivisions (a)(1) and (2) of this section.
- (b) "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 without limitation:
 - (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 formularies;
 - (6) Designing prescription benefit programs; or

- (7) Advertising or promoting services.
- (c) "Pharmacist" means an individual licensed as a pharmacist by the State Board of Pharmacy.
- (d) "Pharmacist services" means products, goods, and services, or any combination of products, goods, and services, provided as a part of the practice of pharmacy.
- (e) "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.
- (f) (1) "Pharmacy benefits manager" means a person, business, or entity, including a wholly or partially owned or controlled subsidiary of a pharmacy benefits manager, that provides claims processing services or other prescription drug or device services, or both, for health benefit plans.
- (2) "Pharmacy benefits manager" does not include any:
- (i) Healthcare facility licensed in [this State];
 - (ii) Healthcare professional licensed in [this State];
 - (iii) Consultant who only provides advice as to the selection or performance of a pharmacy benefits manager; or

Section 4. License to do business – Annual statement – Assessment

- (a) (1) A person or organization shall not establish or operate as a pharmacy benefits manager in this State for health benefit plans without obtaining a license from the Insurance Commissioner under this Act.
- (2) The commissioner shall prescribe the application for a license to operate in this State as a pharmacy benefits manager and may charge application fees and renewal fees as established by rule.
- (b) The commissioner shall issue rules establishing the licensing, fees, application, financial standards, and reporting requirements of pharmacy benefits managers under this Act and not inconsistent herewith.

Section 5. Gag clauses prohibited

Drafting Note: In addition to the Model language set forth below, States seeking to enact “gag clause” legislation may look to Federal law for guidance. Specifically, S.2553 – The Know the Lowest Price Act of 2018” – and S. 2554 – The Patient Right Know Drug Prices Act.”

- (a) In any participation contracts between pharmacy benefits managers 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 the nature of treatment, risks, or alternatives thereto, the availability of alternate therapies, consultations, or tests, the decision of utilization reviewers or similar persons to authorize or deny services, the process that is used to authorize or deny healthcare services or benefits, or information on financial incentives and structures used by the insurer.
- (b) A pharmacy or pharmacist may provide to an insured information regarding the insured's total cost for pharmacist services for a prescription drug.
- (c) A pharmacy or pharmacist shall not be proscribed by a pharmacy benefits manager from discussing information regarding the total cost for pharmacist services for a prescription drug or from selling a more affordable alternative to the insured if a more affordable alternative is available.
- (d) A pharmacy benefits manager contract with a participating pharmacist or pharmacy shall not prohibit, restrict, or limit disclosure of information to the Insurance Commissioner, law enforcement, or state and federal governmental officials investigating or examining a complaint or conducting a review of a pharmacy benefits manager's compliance with the requirements under this Act.

Section 6. Enforcement

- (a) The Insurance Commissioner shall enforce this Act.
- (b) (1) The commissioner may examine or audit the books and records of a pharmacy benefits manager providing claims processing services or other prescription drug or device services for a health benefit plan to determine if the pharmacy benefits manager is in compliance with this Act.
 - (2) The information or data acquired during an examination under subdivision (b)(1) of this section is:
 - (A) Considered proprietary and confidential; and
 - (B) Not subject to the [Freedom of Information Act]¹ of this State

¹ DRAFTING NOTE: State FOIAs have different names in different states, often called Open Records Acts, Public Records Act, Public Records Law, etc. and thus the specific title used in this subsection needs to be tailored accordingly.

Section 7. Rules

- (a) The Insurance Commissioner may adopt rules regulating pharmacy benefits managers that are not inconsistent with this Act.
- (b) Rules adopted under this Act shall set penalties or fines, including without limitation monetary fines, suspension of licensure, and revocation of licensure for violations of this Act and rules adopted under this Act.

***Drafting Note:** Although Section 7(a) expressly authorizes rules not inconsistent with this Act, as opposed to those merely implementing it, states may also wish to consider providing the Insurance Commissioner with specific guidance to adopt regulations relating to:*

- (1) Pharmacy benefits 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)²*
- (6) Compensation;*
- (7) Procedures for pharmacy audits conducted by or on behalf of a pharmacy benefits manager;*
- (8) Medical loss ratio (MLR) abuses;*
- (9) Affiliate information sharing;*
- (10) Lists of health benefit plans administered by a pharmacy benefits manager in this state.*

Section 8. Applicability

- (a) This Act is applicable to a contract or health benefit plan issued, renewed, recredentialled, amended, or extended on and after _____.

² Commissioners may wish to evaluate whether PBMs disregarding of physicians' prescribing practices and substituting their (PBMs') own judgment through the use of mandated step therapy constitutes the practice of medicine

- (b) A contract existing on the date of licensure of the pharmacy benefits manager shall comply with the requirements of this Act as a condition of licensure for the pharmacy benefits manager.
- (c) This Act is not applicable to self-funded health benefit plans, as they do not constitute the business of insurance; thus, the regulation of such self-funded plans is not specifically reserved to this State and the several States by the McCarran-Ferguson Act of 1945, 15 U.S.C. §§ 1011 – 1015.

****Drafting Note:** *To resolve disputes between pharmacies and pharmacy benefit managers over reimbursements for drugs, states may wish to consider implementing an independent dispute resolution program, which would appear as Section 9. NCOIL suggests the following language***

Section 9. Independent Dispute Resolution

(a) A program of Independent Dispute Resolution (IDR) for disputes between pharmacies and pharmacy benefit managers over reimbursements for drugs shall be established and administered by the National Council of Insurance Legislators (NCOIL).

(1) NCOIL shall develop forms and procedures for the implementation and administration of the IDR program.

(2) NCOIL may charge the parties participating in the IDR program such fees as necessary to cover its costs of implementation and administration.

(3) NCOIL shall maintain a list of qualified reviewers.

(b) The sole issue to be considered and determined in an IDR proceeding is the reasonable amount that a pharmacy should be reimbursed by the pharmacy benefit manager for the drug or drugs purchased by the pharmacy.

(c) To be eligible to serve as an independent reviewer, an individual must be knowledgeable and experienced in applicable principles of contract and insurance law and the healthcare and pharmaceutical industries generally.

(1) In approving an individual as an independent reviewer, NCOIL shall ensure that the individual does not have a conflict of interest that would adversely impact the individual's independence and impartiality in rendering a decision in an IDR proceeding.

(d) Either party to an IDR proceeding may request an oral hearing.

(1) If no oral hearing is requested, the independent reviewer shall set a date for the submission of all information to be considered by the independent reviewer.

(2) Each party to the IDR shall submit a “binding award amount”; the independent reviewer must choose one party’s or the other’s “binding award amount” based on which amount the independent reviewer determines to be closest to the reasonable amount for reimbursement, with no deviation.

(3) If an oral hearing is requested, the independent reviewer may make procedural rulings.

(4) There shall be no discovery in IDR proceedings.

(5) The independent reviewer shall issue his or her written decision within ten (10) days of submission or hearing.

(e) Unless otherwise agreed by the parties, each party shall:

(1) Bear its own attorney fees and costs; and

(2) Equally bear all fees and costs of the independent reviewer.

(f) The decision of the independent reviewer is final and shall be binding on the parties. The prevailing party may seek enforcement of the independent reviewer’s decision in any court of competent jurisdiction.

Section 9. Severability Clause

If any provision of this act or the application of this act to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of this act which can be given effect without the invalid provision or application, and to this end, the provisions of this act are declared severable.

Section 10. Effective Date

This Act is effective immediately.