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A new model

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.

[STATE] PHARMACY BENEFIT MANAGER LICENSURE AND REGULATION MODEL ACT

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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 benefitplans.

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. (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~~ 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.

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

E. "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.

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; or

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

K. "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.

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 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]~~ established through regulation by the commissioner. Any fee adopted by the commissioner under this section must be based on the department's reasonable costs in administering this Act..

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.

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~~ Prohibited PBM 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 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, penalize, 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, or gathering information for public policy purposes.

E. Patient choice: a pharmacy benefit manager may not:

(1) Prohibit or limit any person who is a participant or beneficiary of the policy or plan from selecting a pharmacy or pharmacist of his choice who has agreed to participate in the plan according to the terms offered by the insurer;

(2) Deny a pharmacy or pharmacist the right to participate as a contract provider under the policy or plan if the pharmacy or pharmacist agrees to provide pharmacy services, including but not limited to prescription drugs, that meet the terms and requirements set forth by the insurer under the policy or plan and agrees to the terms of reimbursement set forth by the insurer;

(3) Impose upon a beneficiary of pharmacy services under a health benefit plan any copayment, fee or any other condition that is not equally imposed upon all beneficiaries in the same benefit category, class or copayment level under the health benefit plan when receiving services from a contract provider;

(4) Impose a monetary advantage, incentive or penalty under a health benefit plan that would affect or influence a beneficiary's choice among those pharmacies or pharmacists who have agreed to participate in the plan according to the terms offered by the insurer.

(5) Require a beneficiary, as a condition of payment or reimbursement, to purchase pharmacy

services, including prescription drugs, exclusively through a mail-order pharmacy or pharmacy benefit manager affiliate; or

(6) Impose upon a beneficiary any copayment, amount of reimbursement, number of days of a drug supply for which reimbursement will be allowed, or any other payment, restriction, limitation, or condition relating to purchasing pharmacy services from any pharmacy, including prescription drugs, that is more costly or more restrictive than that which would be imposed upon the beneficiary if such services were purchased from a mail-order pharmacy, a pharmacy benefit manager affiliate or any other pharmacy that is willing to provide the same services or products for the same cost and copayment as any mail order service.

F. Patient steering and data privacy protection:

(1) A pharmacy benefits manager or any pharmacy benefits manager affiliate shall not:

- Refer a covered person to a mail order pharmacy or any other pharmacy benefit manager affiliate.
- Utilize a covered person's pharmacy service data collected pursuant to the provision of claims processing services for the purpose referring the covered person to a mail order pharmacy or any other pharmacy benefit manager affiliate.

(2) For purposes of this subsection 'refer' means:

- Ordering a covered person to a pharmacy either orally or in writing, including online messaging;
- Offering or implementing plan designs that require covered persons to utilize pharmacy benefit manager affiliate, or that increase plan or patient costs, including requiring covered persons to pay the full cost for a prescription when covered persons choose not to use a pharmacy benefit manager affiliate; or
- Person-specific advertising, marketing, direct written, electronic or verbal communication, promotion or other solicitation of a pharmacy by an affiliate or pharmacy benefit manager as a result of an arrangement or agreement with the pharmacy's affiliate.

G. Fiduciary responsibility: A pharmacy benefits manager is a fiduciary to a covered entity and shall:

(1) Discharge that duty in accordance with the provisions of federal and/or state law.

(2) Notify the covered entity in writing of any activity, policy or practice of the pharmacy benefits manager that directly or indirectly presents any conflict of interest and inability to comply with the duties imposed by this subsection; but in no event does such notification exempt the pharmacy benefits manager from compliance with all other sections of this chapter.

(3) Disclose all direct or indirect payments related to the dispensation of prescription drugs or classes or brands of drugs to the covered entity.

H. Audit procedures:

(1) A contract between a pharmacy or pharmacist and a pharmacy benefits manager must contain a provision allowing, during the course of a pharmacy audit conducted by or on behalf of a pharmacy benefit manager, a pharmacy or pharmacist to withdraw and resubmit a claim within 30 days after:

- The preliminary written audit report is delivered if the pharmacy or pharmacist does not request an internal appeal; or
- The conclusion of the internal audit appeals process if the pharmacy or pharmacist requests an internal audit appeal.

(2) To the extent that an audit results in the identification of any clerical or record-keeping errors (such as typographical errors, scrivener's errors, or computer errors) in a required document or record, the pharmacy shall not be subject to recoupment of funds by the PBM unless—the PBM can provide proof of intent to commit fraud or such error results in actual financial harm to the PBM, a health plan managed by the PBM, or a consumer.

(3) For purposes of this subsection, "audit" means any physical on site, remote electronic or concurrent review of a pharmacist service submitted to the pharmacy benefit manager or pharmacy benefit

manager affiliate by a pharmacists or pharmacy for payment.

Section 7. Enforcement

A. The commissioner shall enforce compliance with the requirements of this Act. The commissioner may assess fines, impose civil penalties, and suspend or revoke a license for a violation of 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).

(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. Regulations

A. The commissioner ~~may~~ shall 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, reconciliation, and remittance procedures;

(5) ~~Prohibitions~~ Coverage and formulary determinations that implicate 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, transaction or adjudication 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 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.