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National Council of Insurance Legislators (NCOIL)

Pharmacy Benefits Manager Licensure and Regulation Model Act

Sponsored by Sen. Jason Rapert (AR)
Discussion Draft as of May 8, 2018

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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) Provide for powers and duties of the Insurance Commissioner, the State Insurance Department; and

(3) 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) (1) "Health benefit plan" means any individual, blanket, or group plan, policy, or contract for healthcare services issued or delivered by a healthcare insurer in this state.

(2) “Health benefit plan” does not include:

(i) Accidental-only plans;

(ii) Specified disease plans;

(iii) Disability income plans;

(iv) Plans that provide only for indemnity for hospital confinement;

(v) Long-term care only plans that do not include pharmacy benefits;

(vi) Other limited-benefit health insurance policies or plans; or

(vii) Health benefit plans provided under the Workers’ Compensation Laws of this State

(viii) Health benefit plans that are self-funded and specifically exempted from regulation by this State by The Employee Retirement Income Security Act of 1974 (ERISA)

(c) "Healthcare insurer" means an insurance company, a health maintenance organization, or a hospital and medical service corporation.

(d) “Independent pharmacy” means a pharmacy that is not in any way affiliated with a pharmacy benefits manager.

(e) “Maximum Allowable Cost List” means a listing of drugs used by a pharmacy benefits manager setting the maximum allowable cost on which reimbursement to a pharmacy or pharmacist may be used.

(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 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.

(g) “Pharmaceutical wholesaler” means a person or entity that sells and distributes prescription pharmaceutical products, including without limitation a full line of brand-name, generic, and over-the-counter pharmaceuticals, and that offers regular and private delivery to a pharmacy

(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) “Pharmacy acquisition cost” means the amount that a pharmaceutical wholesaler charges for a pharmaceutical product as listed on the pharmacy’s invoice.

(l) (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

(iv) Entity that provides claims processing services or other prescription drug or device services for the fee-for-service [State]Medicaid Program only in that capacity.

(m) "Pharmacy benefits 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 benefits manager.

(n) “Pharmacy benefits manager network” means a network of pharmacists or pharmacies that are offered by an agreement or insurance contract to provide pharmacist services for health benefit plans.

(o) "Pharmacy benefits plan or program" means a plan or program that pays for, reimburses, covers the cost of, or otherwise provides for pharmacist services under a health benefit plan.

(p) "Pharmacy services administrative organization" means an organization that helps independent pharmacies and pharmacy benefits managers, or third-party payers achieve administrative efficiencies, including contracting and payment efficiencies.

(q) (1) "Rebate" means a discount or other price concession based on utilization of a prescription drug that is paid by a manufacturer or third party, directly or indirectly, to a pharmacy benefits manager, pharmacy services administrative organization, or pharmacy after a claim has been processed and paid at a pharmacy.

(2) "Rebate" includes without limitation incentives, disbursements, and reasonable estimates of a volume-based discount.

(r) "Third party" means a person, business, or entity other than a pharmacy benefits manager that is not an enrollee or insured in a health benefit plan.

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) (1) 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. Pharmacy Benefit Manager Network Adequacy

A pharmacy benefits manager shall provide:

(a) (1) A reasonably adequate and accessible pharmacy benefits manager network for the provision of prescription drugs for a health benefit plan that shall provide for convenient patient access to pharmacies within a reasonable distance from a patient's residence.

(2) A mail-order pharmacy shall not be included in the calculations determining pharmacy benefits manager network adequacy; and

(b) A pharmacy benefits manager network adequacy report describing the pharmacy benefits manager network and the pharmacy benefits manager network's accessibility in this state in the time and manner required by rule issued by the State Insurance Department.

Section 6. Compensation – Prohibited Practices

(a) (1) The Insurance Commissioner may review and approve the compensation program of a pharmacy benefits manager with a health benefit plan to ensure that the reimbursement for pharmacist services paid to a pharmacist or pharmacy is fair and reasonable to provide an adequate pharmacy benefits manager network for a health benefit plan under the standards issued by rule of the State Insurance Department.

(2) All information and data acquired during the review under subdivision (a)(1) of this section is:

(A) Considered proprietary and confidential; and

(B) Not subject to the [Freedom of Information Act][1] of this State.

(b) A pharmacy benefits manager or representative of a pharmacy benefits manager shall not:

(1) Cause or knowingly permit the use of any advertisement, promotion, solicitation, representation, proposal, or offer that is untrue, deceptive, or misleading;

(2) Unless reviewed and approved by the commissioner, charge a pharmacist or pharmacy a fee related to the adjudication of a claim, including without limitation a fee for:

(A) The receipt and processing of a pharmacy claim;

(B) The development or management of claims processing services in a pharmacy benefits manager network; or

(C) Participation in a pharmacy benefits manager network;

(3) Unless reviewed and approved by the commissioner in coordination with the State Board of Pharmacy, require pharmacy accreditation standards or certification requirements inconsistent with, more stringent than, or in addition to requirements of the board;

(4) (A) Reimburse an independent pharmacy or pharmacist in the state an amount less than the amount that the pharmacy benefits manager reimburses a pharmacy benefits manager affiliate for providing the same pharmacist services.

(B) The amount shall be calculated on a per-unit basis using the same generic product identifier or generic code number; or

(5) Do any combination of the actions listed in subdivisions (b)(1)-(4) of this section.

(c) A claim for pharmacist services shall not be retroactively denied or reduced after adjudication of the claim, unless:

(1) The original claim was submitted fraudulently;

(2) The original claim payment was incorrect because the pharmacy or pharmacist had already been paid for the pharmacist services; or

(3) The pharmacist services were not properly rendered by the pharmacy or pharmacist.

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[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.

(d) Termination of a pharmacy or pharmacist from a pharmacy benefits manager network shall not release the pharmacy benefits manager from the obligation to make any payment due to the pharmacy or pharmacist for pharmacist services properly rendered.

(e) The commissioner may issue a rule establishing prohibited practices of pharmacy benefits managers providing claims processing services or other prescription drug or device services for health benefit plans.

Section 7. Gag clauses prohibited

(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 8. 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][2] of this State

Section 9. Rules

(a) (1) The Insurance Commissioner may adopt rules regulating pharmacy benefits managers that are not inconsistent with this Act.

(2) Rules that the commissioner may adopt under this Act include without limitation rules relating to:

(A) Licensing;

(B) Application fees;

(C) Financial solvency requirements;

(D) Pharmacy benefits manager network adequacy;

(E) Prohibited market conduct practices;

(F) Data reporting requirements under State price-gouging laws

(G) Compliance and enforcement requirements under State laws concerning Maximum Allowable Cost Lists;

(H) Rebates;

(I) Prohibitions and limitations on the corporate practice of medicine (CPOM)[3];

(J) Compensation; and

(K) Lists of health benefit plans administered by a pharmacy benefits manager in this state.

(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

[2] 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.

[3] DRAFTING NOTE: 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.

Act and rules adopted under this Act.

Section 10. Applicability

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

(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 health benefit plans that are self-funded and specifically exempted from regulation by this State by The Employee Retirement Income Security Act of 1974 (ERISA).

Section 11. Annual Report

(a)(1) Unless otherwise required more frequently by the Insurance Commissioner, a pharmacy benefits manager shall file an annual report with the commissioner pursuant to the timing, format, and requirements issued by rule of the State Insurance Department.

(2) The annual report shall contain information regarding:

(i) when seeking payment or reimbursement for pharmacist services provided in connection with a pharmacy benefits plan or program or reporting expenditures for pharmacist services provided in connection with a pharmacy benefits plan or program, a pharmacy benefits manager shall itemize by individual claim:

(1) The amount actually paid or to be paid to the pharmacy or pharmacist for the pharmacist services;

(2) The identity of the pharmacy or pharmacist actually paid or to be paid; and

(3) The prescription number or other identifier of the pharmacist services.

(b) The annual report shall be considered proprietary and confidential and not subject to the [Freedom of Information Act][4] of this State.

Section 12. Maximum Allowable Cost Lists

(a) Before a pharmacy benefits manager places or continues a particular drug on a Maximum Allowable Cost List, the drug:

[4] 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.

(1) Shall be listed as therapeutically equivalent and pharmaceutically equivalent "A" or "B" rated in the United States Food and Drug Administration's most recent version of the "Orange Book" or "Green Book" or has an NR or NA rating by Medi-span, Gold Standard, or a similar rating by a nationally recognized reference;

(2) Shall be available for purchase by each pharmacy in the state from national or regional wholesalers operating in this State; and

(3) Shall not be obsolete.

(b) A pharmacy benefits manager shall:

(1) Provide access to its Maximum Allowable Cost List to each pharmacy subject to the Maximum Allowable Cost List;

(2) Update its Maximum Allowable Cost List on a timely basis, but in no event longer than seven (7) calendar days from an increase of ten percent (10%) or more in the pharmacy acquisition cost from sixty percent (60%) or more of the pharmaceutical wholesalers doing business in the state or a change in the methodology on which the Maximum Allowable Cost List is based or in the value of a variable involved in the methodology;

(3) Provide a process for each pharmacy subject to the Maximum Allowable Cost List to receive prompt notification of an update to the Maximum Allowable Cost List; and

(4) (A) (i) Provide a reasonable administrative appeal procedure to allow pharmacies to challenge maximum allowable costs and reimbursements made under a maximum allowable cost for a specific drug or drugs as:

(a) Not meeting the requirements of this section; or

(b) Being below the pharmacy acquisition cost.

(ii) The reasonable administrative appeal procedure shall include the following:

(a) A dedicated telephone number and email address or website for the purpose of submitting administrative appeals;

(b) The ability to submit an administrative appeal directly to the pharmacy benefits manager regarding the pharmacy benefits plan or program or through a pharmacy service administrative organization; and

(c) No less than seven (7) business days to file an administrative appeal.

(B) The pharmacy benefits manager shall respond to the challenge under subdivision (c)(4)(A) of this section within seven (7) business days after receipt of the challenge.

(C) If a challenge is under subdivision (c)(4)(A) of this section, the pharmacy benefits manager shall within seven (7) business days after receipt of the challenge either:

(i) If the appeal is upheld:

(a) Make the change in the maximum allowable cost;

(b) Permit the challenging pharmacy or pharmacist to reverse and rebill the claim in question;

(c) Provide the National Drug Code number that the increase or change is based on to the pharmacy or pharmacist; and

(d) Make the change under subdivision (c)(4)(C)(i)(a) of this section effective for each similarly situated pharmacy as defined by the payor subject to the Maximum Allowable Cost List;

(ii) If the appeal is denied, provide the challenging pharmacy or pharmacist the National Drug Code number and the name of the national or regional pharmaceutical wholesalers operating in this State that have the drug currently in stock at a price below the Maximum Allowable Cost List; or

(iii) If the National Drug Code number provided by the pharmacy benefits manager is not available below the pharmacy acquisition cost from the pharmaceutical wholesaler from whom the pharmacy or pharmacist purchases the majority of prescription drugs for resale, then the pharmacy benefits manager shall adjust the Maximum Allowable Cost List above the challenging pharmacy's pharmacy acquisition cost and permit the pharmacy to reverse and rebill each claim affected by the inability to procure the drug at a cost that is equal to or less than the previously challenged maximum allowable cost.

(c) (1) A pharmacy benefits manager shall not reimburse a pharmacy or pharmacist in the state an amount less than the amount that the pharmacy benefits manager reimburses a pharmacy benefits manager affiliate for providing the same pharmacist services.

(2) The amount shall be calculated on a per unit basis based on the same generic product identifier or generic code number.

(d) A pharmacy or pharmacist may decline to provide the pharmacist services to a patient or pharmacy benefits manager if, as a result of a Maximum Allowable Cost List, a pharmacy or pharmacist is to be paid less than the pharmacy acquisition cost of the pharmacy providing pharmacist services.

(e) (1) This section does not apply to a Maximum Allowable Cost List maintained by the State Medicaid Program or the Employee Benefits Division.

(2) This section shall apply to the pharmacy benefits manager employed by the State Medicaid Program or the Employee Benefits Division if, at any time, the State Medicaid Program or the Employee Benefits Division engages the services of a pharmacy benefits manager to maintain a Maximum Allowable Cost List.

(f) A violation of this section is a deceptive and unconscionable trade practice under the [State] Deceptive Trade Practices Act, a prohibited practice under this Act, and the [State] Trade Practices Act.

Section 13. 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 14. Effective Date

This Act is effective immediately.