Atlantic Corporate Center
2317 Route 34, Suite 2B
Manasquan, NJ 08736
732-201-4133
CHIEF EXECUTIVE OFFICER: Thomas B. Considine

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

Table of Contents

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; or

(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) “Health care facility” has the meaning given that term in [state law].

(d) “Health care service contractor” has the meaning given that term in [state law].

(e) "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.~~

(f) (1) “Manufacture” means:

(i) The production, preparation, propagation, compounding, conversion or processing of a drug, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; and

(ii) The packaging or repackaging of a drug or labeling or relabeling of a drug container.

(2) “Manufacture” does not include the preparation or compounding of a drug by an individual for the individual’s own use or the preparation, compounding, packaging or labeling of a drug:

(i) By a health care practitioner incidental to administering or dispensing a drug in the course of professional practice;

(ii) By a health care practitioner or at the practitioner’s authorization and supervision for the purpose of or incidental to research, teaching or chemical analysis activities and not for sale;

(iii) By a health care service contractor for dispensing to a subscriber or delivery to a health care facility or outpatient clinic owned or operated by the health care service con- tractor or an affiliate of the health care service contractor;

(iv) By a centralized repackaging operation for distribution to subscribers of health care service contractors or to pharmacies, health care facilities or outpatient clinics operated by or affiliated with a health care service contractor; or

(v) By a health care facility for dispensing to a patient or other person.

(g) “Manufacturer” means a company or a person that manufactures a prescription drug that is sold in this state.

(~~e~~h) “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.

(i) “New prescription drug” has the meaning prescribed by the [department] by rule.

(~~f~~j) "~~Other prescription drug or device services~~Pharmacy benefits management" 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) The reimbursement of prescription drugs at a negotiated contracted rate for dispensation with the State of [State] to covered individuals;

(2) The administration or management of prescription drug benefits provided by a health plan for the benefit of covered individuals; and

(3) The administration of pharmacy benefits, including:

(~~1~~i) Negotiating rebates, discounts, or other financial incentives and arrangements with drug companies;

(ii) Claims processing;

~~(2) Disbursing or distributing rebates;~~

~~(3) Managing or participating in incentive programs or arrangements for pharmacist services;~~

(~~4~~iii) Negotiating or entering into contractual arrangements with pharmacists or pharmacies, or both;

(~~5~~iv) Developing formularies; or

(v) Managing a retail pharmacy network.

~~(6) Designing prescription benefit programs; or~~

~~(7) Advertising or promoting services.~~

(k) “Patient assistance program” means a program that a manufacturer offers to the general public in which a consumer may reduce the consumer’s out-of-pocket costs for prescription drugs by using coupons or discount cards, receiving copayment assistance or by other means.

(~~g~~l) “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~~m) "Pharmacist" means an individual licensed as a pharmacist by the State Board of Pharmacy.

(~~i~~n) "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~~o) "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~~p) (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 pharmacy benefits management services ~~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~~.~~; or

(v) Health benefit plans as defined in Section 3(b).

~~(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.~~

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

(~~or~~) "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.

(~~ps~~) "Pharmacy services administrative organization" means an organization that contracts with pharmacies and pharmacy benefits managers or third-party payers for administrative purposes~~helps independent pharmacies and pharmacy benefits managers, or third-party payers achieve administrative efficiencies,~~ including, but not limited to, 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.~~

(~~rt~~) "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.

(u) “Prescription drug” means a drug that must:

(1) Under federal law, be labeled “Caution: Federal law prohibits dispensing without prescription” prior to being dispensed or delivered; or

(2) Under any applicable federal or state law or regulation, be dispensed only by prescription or restricted to use only by health care practitioners.

(v) “Price” means the wholesale acquisition cost as defined in 42 U.S.C. 1395w-3a(C)(6)(B).

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

(a) No person or entity shall administer the medication or device portion of pharmacy benefits coverage provided by a covered entity or otherwise act as a pharmacy benefits manager in this state unless the person or entity has obtained licensure through the [insurance commissioner].

(b) To obtain licensure as a pharmacy benefits manager, the person or entity must demonstrate to the department that the person or entity:

(1) Is authorized to transact business in this state;

(2) Is financially responsible, as determined by the department; and

(3) Has not had a prior license to be a pharmacy benefits manager denied or revoked by the department within five (5) years of the date on which licensure is sought.

(c) (1) In addition to the showing required by subsection (a), a person or entity seeking licensure as a pharmacy benefits manager shall also provide the following information to the department:

(A) The person or entity's name, address, telephone number, email address, and website address; and

(B) If the licensure is sought for an entity, the name, address, telephone number, and email address for a contact person.

(2) Any material changes in the information described in this subsection (c) shall be filed with the [department] within thirty (30) days of the change.

(d) A person or entity licensed as a pharmacy benefits manager shall seek renewal of its license biennially as prescribed by regulation.

(e) (1) Any person or entity seeking licensure as a pharmacy benefits manager shall pay a fee in the amount of one hundred dollars ($100) to the [department] to obtain the license. Any person or entity seeking renewal of a license as a pharmacy benefits manager shall pay a fee in the mount of fifty dollars ($50) to renew the license.

(2) All fees paid pursuant to this section shall be used by the department for purposes of administering this section.

(f) (1) Failure to obtain licensure or renew a license pursuant to this section while acting as a pharmacy benefits manager in this state shall constitute a violation of this section and shall be punishable by a fine of not less than one hundred dollars ($100) and not to exceed five hundred dollars ($500).

(2) Any person assessed a fine pursuant to this section or denied a license or renewal of a license may appeal the fine or denial pursuant to [state administrative procedures act].All fees paid pursuant to this section shall be used by the department for purposes of administering this section.

~~(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~~5. ~~Compensation~~ Contracting Requirements – Prohibited Practices

(a) Every contract between a pharmacy benefit manager and a pharmacist, pharmacy or pharmacy service administrative organization shall be mutually agreed upon and outline the terms and conditions for the provision of pharmacy services.

~~(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, c~~Charge a pharmacist or pharmacy a fee related to the adjudication of a claim, unless such fee is set out in the contract ~~including without limitation a fee for:~~.

(c) A contract between a pharmacy benefits manager and a pharmacy or pharmacy service administrative organization shall outline the terms for auditing of claims and retroactively adjusting such claims payment as appropriate pursuant to [State Pharmacy Audit Law].

~~(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;~~

~~[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.~~

~~(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.~~

(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~~ 6. Gag clauses prohibited

(a) A pharmacy benefits manager may not:

(1) Prohibit a pharmacist or pharmacy from providing an insured individual information on the amount of the insured's cost share for such insured's prescription drug and the clinical efficacy of a more affordable alternative drug if one is available. Neither a pharmacy nor a pharmacist shall be penalized by a pharmacy benefits manager for disclosing such information to an insured or for selling to an insured a more affordable alternative if one is available; or

(2) Charge or collect from an insured a copayment that exceeds the total submitted charges by the network pharmacy.[2]

(b) For purposes of subsection (a)(1) of this section, the more affordable alternative drug does not include a price that is reduced due to a copay assistance program, drug manufacturer coupon, product voucher, or other reduction in the individual's cost sharing.

~~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.~~

[2] DRAFTING NOTE: States wishing to consider alternative language may wish to consider the following for subsection (a)(2): (2) Charge or collect from an insured a copayment for a prescription drug at the point of sale in an amount that exceeds the lesser of: (1) the contracted copayment amount, or (2) the amount an individual would pay for a prescription if that individual were paying cash.

~~(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~~7. 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][3] of this State~~

Section ~~9~~8. Rules

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

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

~~(A) Licensing;~~

~~(B) Application fees;~~

---

[3] ~~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.~~

~~(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)[4];~~

~~(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 Act and rules adopted under this Act.

Section ~~10~~9. Applicability

(a) This Act is applicable to a contract or health benefit plan issued or ~~,~~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~~b) 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) or for prescription drug coverage pursuant to Title I (Medicare Prescription Drug Benefit) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 or Title 18 of the Social Security Act.~~.~~

(c) This Act shall not apply to Excepted Benefits as those terms are defined in 45 C.F.R. Sections 146.145(c)(2) through (c)(5).

Section ~~11~~10. ~~Annual Report~~Reporting Requirements

---

[4] ~~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.~~

(a) (1) 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 to demonstrate compliance with sections (5) and (6) of this Act.

~~(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~~2) The annual report shall be considered proprietary and confidential and not subject to the [Freedom of Information Act][5] of this State.

(b) No later than [date], a manufacturer shall report the information described in subsection (c) of this section to the [department] regarding each prescription drug for which:

(1) The price was $100 or more for a one-month supply or for a course of treatment lasting less than one month; and

(2) There was a net increase of 10 percent or more in the price of the prescription drug described in paragraph (1) of this subsection over the course of the previous calendar year.

(c) For each prescription drug described in subsection (b) of this section, a manufacturer shall report to the [department], in the form and manner prescribed by the [department]:

[5] ~~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) The name and price of the prescription drug and the net increase, expressed as a percentage, in the price of the drug over the course of the previous calendar year;

(2) The length of time the prescription drug has been on the market;

(3) The factors that contributed to the price increase, including a statement regarding whether a change or improvement in the drug necessitates the price increase. If so, the manufacturer shall describe the change or improvement;

(4) The name of any generic version of the prescription drug available on the market;

(5) The research and development costs associated with the prescription drug that were paid using public funds;

(6) The direct costs incurred by the manufacturer:

(A) To manufacture the prescription drug;

(B) To market the prescription drug;

(C) To distribute the prescription drug; and

(D) For ongoing safety and effectiveness research associated with the prescription drug;

(7) The total sales revenue for the prescription drug during the previous calendar year;

(8) The manufacturer's profit attributable to the prescription drug during the previous calendar year;

(9) The introductory price of the prescription drug when it was approved for marketing by the United States Food and Drug Administration and the net yearly increase, by calendar year, in the price of the prescription drug during the previous five years;

(10) The 10 highest prices paid for the prescription drug during the previous calendar year in any country other than the United States;

(11) Any other information that the manufacturer deems relevant to the price increase described in subsection (b)(2) of this section; and

(12) The documentation necessary to support the information reported under this subsection.

(d) The [department] may use any prescription drug price information the [department] deems appropriate to verify that manufacturers have properly reported price increases as required by subsections (b) and (c) of this section.

(e) A manufacturer shall accompany the report provided under subsection (b) of this section with the following information about each patient assistance program offered by the manufacturer to consumers residing in this state for the prescription drugs described in subsection (b) of this section:

(1) The number of consumers who participated in the program;

(2) The total value of the coupons, discounts, copayment assistance or other reduction in costs provided to consumers in this state who participated in the program;

(3) For each drug, the number of refills that qualify for the program, if applicable;

(4) If the program expires after a specified period of time, the period of time that the program is available to each consumer; and

(5) The eligibility criteria for the program and how eligibility is verified for accuracy.

(f) Beginning [date], 30 days or less after a manufacturer introduces a new prescription drug for sale in the United States at a price that exceeds the threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program, the manufacturer shall notify the [department], in the form and manner prescribed by the [department], of all the following information:

(1) A description of the marketing used in the introduction of the new prescription drug;

(2) The methodology used to establish the price of the new prescription drug;

(3) Whether the United States Food and Drug Administration granted the new prescription drug a breakthrough therapy designation or a priority review;

(4) If the new prescription drug was not developed by the manufacturer, the date of and the price paid for acquisition of the new prescription drug by the manufacturer;

(5) The manufacturer's estimate of the average number of patients who will be prescribed the new prescription drug each month; and

(6) The research and development costs associated with the new prescription drug that were paid using public funds.

(g) (1) After receiving the report or information described in subsections (b), (c), (e) or (f) of this section, the [department] may make a written request to the manufacturer for supporting documentation or additional information concerning the report. The [department] shall prescribe by rule the periods:

(A)Following the receipt of the report or information during which the [department] may request additional information; and

(B) Following a request by the [department] for additional information during which a manufacturer may respond to the request.

(2) The [department] may extend the period prescribed under paragraph (1)(B) of this subsection, as necessary, on a case-by-case basis.

(h) A manufacturer may be subject to a civil penalty, as provided in subsection (n) of this section for:

(1) Failing to submit timely reports or notices as required by this section;

(2) Failing to provide information required under this section;

(3) Failing to respond in a timely manner to a written request by the [department] for additional information under subsection (g) of this section; or

(4) Providing inaccurate or incomplete information under this section.

(i) Except as provided in subsection (j) of this section, the [department] shall post to its website all of the following information:

(1) A list of the prescription drugs reported under subsection (b) of this section and the manufacturers of those prescription drugs;

(2) Information reported to the [department] under subsections (c) and (e) to (g) of this section; and

(3) Written requests by the [department] for additional information under subsection (g) of this section.

(j) (1) The [department] may not post to its website any information described in subsection (i) of this section if:

(A) The information is conditionally exempt from disclosure under [state law] as a trade secret; and

(B) The public interest does not require disclosure of the information.

(2) If the [department] withholds any information from public disclosure pursuant to this subsection, the [department] shall post to its website a report describing the nature of the information and the [department]'s basis for withholding the information from disclosure.

(3) A person may petition the Attorney General, as provided in [state law], to review a decision by the [department] to withhold information pursuant to this subsection.

(k) The [department] shall make available to consumers, online and by telephone, a process for consumers to notify the [department] about an increase in the price of a prescription drug.

(l) The [department] may adopt rules as necessary for carrying out the provisions of this section, including but not limited to rules establishing fees to be paid by manufacturers to be used solely to pay the costs of the [department] in carrying out the provisions of this section.

(m) No later than December 15 of each year, the [department] shall compile and report the information collected by the [department] under this section to the interim committees of the [legislature] related to health. The report shall include recommendations for legislative changes, if any, to contain the cost of prescription drugs and reduce the impact of price increases on consumers, the [Department of Corrections], the [Public Employees' Benefit Board], the [Oregon Health Authority], the [Department of Human Services], the [Oregon Educators Benefit Board] and health insurance premiums in the commercial market.

(n) A manufacturer that fails to report or provide information as required by subsection (b) of this section may be subject to a civil penalty as provided in this section.

(o)The [insurance department] shall adopt a schedule of penalties, not to exceed $10,000 per day of violation, based on the severity of each violation.

(p) The [department] shall impose civil penalties under this section as provided in [state law].

(q) The [department] may remit or mitigate civil penalties under this section upon terms and conditions the department considers proper and consistent with the public health and safety.

(r) Civil penalties collected under this section shall be paid over to the [State Treasurer] and deposited in the [General Fund] to be made available for general governmental expenses.

(s) An insurer shall include with any filing under [state law] the following information regarding drugs reimbursed by the insurer under policies or certificates issued in this state:

(1) The 25 most frequently prescribed drugs;

(2) The 25 most costly drugs as a portion of total annual spending;

(3) The 25 drugs that have caused the greatest increase in total plan spending from one year to the next; and

(4) The impact of the costs of prescription drugs on premium rates.

(t) The [insurance department] shall conduct a public hearing annually on prescription drug prices, information reported to the [department] under subsection (b) of this section and information described in subsection (s) of this section.

(u) The [department] shall regularly update the interim committees of the [legislature] related to health on the information described in subsection (s) of this section.

(v) Subsection (s) of this section applies to an insurer that issues policies or certificates of health insurance for sale in this state that include a prescription drug benefit.

Section 12. Maximum Allowable Cost Lists

A contract between a health insurer and a pharmacy benefits manager must require that the pharmacy benefits manager:

(a) Update maximum allowable cost pricing information at least every 7 calendar days;

and

(b) Maintain a process that will, in a timely manner, eliminate drugs from maximum allowable cost lists or modify drug prices to remain consistent with changes in pricing data used in formulating maximum allowable cost prices and product availability.

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

~~(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~~12. 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~~13. Effective Date

This Act is effective immediately.

[*DRAFTING NOTE: States may wish to include separate language clarifying that rulemaking authority begins upon the effective date of the legislation, while the effective date for licensure and other provisions are effective at a later date to accommodate rulemaking*]