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Bruce
3/17/16

CS FOR SENATE BILL NO. 175()

IN THE LEGISLATURE OF THE STATE OF ALASKA

TWENTY-NINTH LEGISLATURE - SECOND SESSION

BY

**Offered:
Referred:**

Sponsor(s): SENATOR GIESSEL BY REQUEST

A BILL

FOR AN ACT ENTITLED

1 **"An Act relating to the registration and duties of pharmacy benefits managers; relating**
2 **to procedures, guidelines, and enforcement mechanisms for pharmacy audits; relating to**
3 **the cost of multi-source generic drugs and insurance reimbursement procedures;**
4 **relating to the duties of the director of the division of insurance; and providing for an**
5 **effective date."**

6 **BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:**

7 *** Section 1.** AS 21.27 is amended by adding new sections to read:

8 **Article 10. Pharmacy Benefits Managers.**

9 **Sec. 21.27.901. Registration of pharmacy benefits managers; scope of**
10 **business practice.** (a) A person may not conduct business in the state as a pharmacy
11 benefits manager unless the person is registered with the director as a third-party
12 administrator under AS 21.27.630.

13 (b) A pharmacy benefits manager registered under AS 21.27.630 may

(1) contract with an insurer to administer or manage pharmacy benefits provided by an insurer for a covered person, including claims processing services for and audits of payments for prescription drugs and medical devices and supplies;

(2) contract with network pharmacies;

(3) set the cost of multi-source generic drugs under AS 21.27.945; and

(4) adjudicate appeals related to multi-source generic drug reimbursement.

Sec. 21.27.905. Renewal of registration. (a) A pharmacy benefits manager shall biannually renew a registration with the director.

(b) To renew a registration under this section, a pharmacy benefits manager shall pay a renewal fee established by the director. The director shall set the amount of the renewal fee to allow the renewal and oversight activities of the division to be self-supporting.

Sec. 21.27.910. Pharmacy audit procedural requirements. (a) When a pharmacy benefits manager conducts an audit of the records of a pharmacy, the period covered by the audit of a claim may not exceed two years from the date that the claim was submitted to or adjudicated by the pharmacy benefits manager, whichever is earlier. Except as required under AS 21.36.495, a claim submitted to or adjudicated by a pharmacy benefits manager does not accrue interest during the audit period.

(b) A pharmacy benefits manager conducting an on-site audit shall give the pharmacy written notice of at least 10 business days before conducting an initial audit.

(c) A pharmacy benefits manager may not conduct

(1) an audit during the first seven calendar days of any month unless agreed to by the pharmacy;

(2) more than one on-site audit of a pharmacy within a 12-month period; or

(3) on-site audits of more than 250 separate prescriptions at one pharmacy within a 12-month period unless fraud by the pharmacy or an employee of the pharmacy is alleged.

(d) If an audit involves clinical or professional judgment, the individual conducting the audit must

(1) be a pharmacist who is licensed and in good standing under AS 08.80; or

(2) conduct the audit in consultation with a pharmacist who is licensed and in good standing under AS 08.80.

(e) A pharmacy, in responding to an audit, may use

(1) verifiable statements or records, including medication administration records of a nursing home, assisted living facility, hospital, physician, or other authorized practitioner, to validate the pharmacy record;

(2) a legal prescription to validate claims in connection with prescriptions, refills, or changes in prescriptions, including medication administration records, prescriptions transmitted by facsimile, electronic prescriptions, or documented telephone calls from the prescriber or the prescriber's agent.

(f) A pharmacy benefits manager shall audit each pharmacy under the same standards and parameters as other similarly situated pharmacies in a network pharmacy contract in this state.

Sec. 21.27.915. Overpayment or underpayment. (a) When a pharmacy benefits manager conducts an audit of a pharmacy, the pharmacy benefits manager shall base a finding of overpayment or underpayment by the pharmacy on the actual overpayment or underpayment and not on a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs, except as provided in (b) of this section.

(b) A pharmacy benefits manager may resolve a finding of overpayment or underpayment by entering into a settlement agreement with the pharmacy. The settlement agreement

(1) must comply with the requirements of AS 21.36.125; and

(2) may be based on a statistically justifiable projection method.

(c) A pharmacy benefits manager may not include the dispensing fee amount in a finding of an overpayment unless

(1) a prescription was not actually dispensed;

(2) the prescriber denied authorization;

(3) the prescription dispensed was a medication error by the pharmacy;

or

(4) the identified overpayment is solely based on an extra dispensing fee.

Sec. 21.27.920. Recoupment. (a) When a pharmacy benefits manager conducts an audit of a pharmacy, the pharmacy benefits manager shall base the recoupment of overpayments on the actual overpayment of the claim, except as provided in AS 21.27.915(b).

(b) A pharmacy benefits manager conducting an audit of a pharmacy may not

(1) use extrapolation in calculating recoupments or penalties for audits, unless required by state or federal contracts;

(2) assess a charge-back, recoupment, or other penalty against a pharmacy solely because a prescription is mailed or delivered at the request of a patient; or

(3) receive payment

(A) based on a percentage of the amount recovered; or

(B) for errors that have no actual financial harm to the patient or medical plan.

Sec. 21.27.925. Pharmacy audit reports. (a) A pharmacy benefits manager shall deliver a preliminary audit report to the pharmacy audited within 60 days after the conclusion of the audit.

(b) A pharmacy benefits manager shall allow the pharmacy at least 30 days following receipt of the preliminary audit report to provide documentation to the pharmacy benefits manager to address a discrepancy found in the audit. A pharmacy benefits manager may grant a reasonable extension upon request by the pharmacy.

(c) A pharmacy benefits manager shall deliver a final audit report to the pharmacy within 120 days after receipt of the preliminary audit report, settlement agreement, or final appeal, whichever is latest.

Sec. 21.27.930. Pharmacy audit appeal; future repayment. (a) A pharmacy benefits manager conducting an audit shall establish a written appeals process.

(b) Recoupment of disputed funds or repayment of funds to the pharmacy benefits manager by the pharmacy, if permitted by contract, shall occur, to the extent

demonstrated or documented in the pharmacy audit findings, after final internal disposition of the audit, including the appeals process. If the identified discrepancy for an individual audit exceeds \$15,000, future payments to the pharmacy may be withheld pending finalization of the audit.

(c) A pharmacy benefits manager may not assess against a pharmacy a charge-back, recoupment, or other penalty until the pharmacy benefits manager's appeals process has been exhausted and the final report or settlement agreement issued.

Sec. 21.27.935. Fraudulent activity. When a pharmacy benefits manager conducts an audit of a pharmacy, the pharmacy benefits manager may not consider unintentional clerical or record-keeping errors, including typographical errors, writer's errors, or computer errors regarding a required document or record, to be fraudulent activity. In this section, "fraudulent activity" means an intentional act of theft, deception, misrepresentation, or concealment committed by the pharmacy.

Sec. 21.27.940. Pharmacy audits; restrictions. The requirements of AS 21.27.901 - 21.27.955 do not apply to an audit

(1) in which suspected fraudulent activity or other intentional or wilful misrepresentation is evidenced by a physical review, a review of claims data, a statement, or another investigative method; or

(2) of claims paid for under the medical assistance program under AS 47.07.

Sec. 21.27.945. Drug pricing list; procedural requirements. (a) A pharmacy benefits manager shall

(1) make available to each network pharmacy at the beginning of the term of the network pharmacy's contract, and upon renewal of the contract, the methodology and sources used to determine the drug pricing list;

(2) provide a telephone number at which a network pharmacy may contact an employee of a pharmacy benefits manager to discuss the pharmacy's appeal;

(3) provide a process for a network pharmacy to have ready access to the list specific to that pharmacy;

(4) review and update applicable list information at least once every

seven business days to reflect modification of list pricing;

(5) update list prices within one business day after a significant price update or modification provided by the pharmacy benefits manager's national drug database provider; and

(6) ensure that dispensing fees are not included in the calculation of the list pricing.

(b) When establishing a list, the pharmacy benefits manager shall use

(1) the most up-to-date pricing data to calculate reimbursement to a network pharmacy for drugs subject to list prices;

(2) multi-source generic drugs that are sold or marketed in the state during the list period.

Sec. 21.27.950. Multi-source generic drug appeal. (a) A pharmacy benefits manager shall establish a process by which a network pharmacy, or a network pharmacy's contracting agent, may appeal the reimbursement for a multi-source generic drug. A pharmacy benefits manager shall resolve an appeal from a network pharmacy within 10 calendar days after the network pharmacy or the contracting agent submits the appeal.

(b) A network pharmacy, or a network pharmacy's contracting agent, may appeal a reimbursement from a pharmacy benefits manager for a multi-source generic drug if the reimbursement for the drug is less than the amount that the network pharmacy can purchase from two or more of its contracted suppliers.

(c) A pharmacy benefits manager shall grant a network pharmacy's appeal if an equivalent multi-source generic drug is not available at a price at or below the pharmacy benefits manager's list price from at least one of the network pharmacy's contracted wholesalers who operate in the state. If an appeal is granted, the pharmacy benefits manager shall adjust the reimbursement of the network pharmacy to equal the network pharmacy acquisition cost for each paid claim included in the appeal.

(d) If the pharmacy benefits manager denies a network pharmacy's appeal, the pharmacy benefits manager shall provide the network pharmacy with the

(1) reason for the denial;

(2) national drug code of an equivalent multi-source generic drug that

has been purchased by another network pharmacy located in the state at a price that is equal to or less than the pharmacy benefits manager's list price within seven days after the network pharmacy appeals the claim; and

(3) name of a pharmaceutical wholesaler who operates in the state in which the drug may be acquired by the challenging network pharmacy.

(e) A network pharmacy may request a hearing under AS 21.06.170 - 21.06.240 for an adverse decision from a pharmacy benefits manager within 30 calendar days after receiving the decision. The parties may present all relevant information to the director for the director's review.

(f) The director shall enter an order that

(1) grants the network pharmacy's appeal and directs the pharmacy benefits manager to make an adjustment to the disputed claim;

(2) denies the network pharmacy's appeal; or

(3) directs other actions considered fair and equitable.

Sec. 21.27.955. Definitions. In AS 21.27.901 - 21.27.955,

(1) "audit" means an official examination and verification of accounts and records;

(2) "board" means the Board of Pharmacy;

(3) "claim" means a request from a pharmacy or pharmacist to be reimbursed for the cost of filling or refilling a prescription for a drug or for providing a medical supply or device;

(4) "extrapolation" means the practice of inferring a frequency or dollar amount of overpayments, underpayments, invalid claims, or other errors on any portion of claims submitted, based on the frequency or dollar amount of overpayments, underpayments, invalid claims, or other errors actually measured in a sample of claims;

(5) "list" means the list of multi-source generic drugs for which a predetermined reimbursement amount has been established such as a maximum allowable cost or maximum allowable cost list or any other list of prices used by a pharmacy benefits manager;

(6) "multi-source generic drug" means any covered outpatient

prescription drug that the United States Food and Drug Administration has determined is pharmaceutically equivalent or bioequivalent to the originator or name brand drug and for which there are at least two drug products that are rated as therapeutically equivalent under the United States Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations";

(7) "network pharmacy" means a pharmacy that provides covered health care services or supplies to an insured or a member under a contract with a network plan to act as a participating provider;

(8) "pharmacy" has the meaning given in AS 08.80.480;

(9) "pharmacy acquisition cost" means the amount that a pharmaceutical wholesaler or distributor charges for a pharmaceutical product as listed on the pharmacy's invoice;

(10) "pharmacy benefits manager" means a person that contracts with a pharmacy on behalf of an insurer to process claims or pay pharmacies for prescription drugs or medical devices and supplies or provide network management for pharmacies;

(11) "recoupment" means the amount that a pharmacy must remit to a pharmacy benefits manager when the pharmacy benefits manager has determined that an overpayment to the pharmacy has occurred.

* **Sec. 2.** The uncodified law of the State of Alaska is amended by adding a new section to read:

APPLICABILITY. (a) This Act applies to audits of pharmacies conducted by pharmacy benefits managers and contracts with pharmacy benefits managers entered into on or after the effective date of sec. 1 of this Act.

(b) In this section, "pharmacy" and "pharmacy benefits manager" have the meanings given in AS 21.27.955, added by sec. 1 of this Act.

* **Sec. 3.** The uncodified law of the State of Alaska is amended by adding a new section to read:

TRANSITIONAL PROVISIONS: REGULATIONS. The division of insurance may adopt regulations necessary to implement the changes made by this Act. The regulations take effect under AS 44.62 (Administrative Procedure Act), but not before the effective date of the

1 law implemented by the regulation.

2 * **Sec. 4.** The uncodified law of the State of Alaska is amended by adding a new section to
3 read:

4 REVISOR'S INSTRUCTIONS. The revisor of statutes is requested to renumber
5 AS 21.27.900 as AS 21.27.990. The revisor of statutes is requested to change "AS 21.27.900"
6 to "AS 21.27.990" in AS 21.36.475(c)(2) and (4) and AS 21.97.900(26).

7 * **Sec. 5.** Section 3 of this Act takes effect immediately under AS 01.10.070(c).

8 * **Sec. 6.** Except as provided in sec. 5 of this Act, this Act takes effect July 1, 2017.