Enrolled
House Bill 2123

Introduced and printed pursuant to House Rule 12.00. Presession filed (at the request of House Interim Committee on Health Care)

CHAPTER .....

AN ACT

Relating to prescription drugs.

Be It Enacted by the People of the State of Oregon:

SECTION 1. Sections 2 to 11 of this 2013 Act are added to and made a part of the Insurance Code.

SECTION 2. As used in sections 2 to 11 of this 2013 Act:

(1) "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 service.

(2) "Insurer" has the meaning given that term in ORS 731.106.

(3) "Pharmacist" has the meaning given that term in ORS 689.005.

(4) "Pharmacy" has the meaning given that term in ORS 689.005.

(5)(a) "Pharmacy benefit manager" means a person that contracts with pharmacies on behalf of an insurer, a third party administrator or the Oregon Prescription Drug Program established in ORS 414.312 to:

(A) Process claims for prescription drugs or medical supplies or provide retail network management for pharmacies or pharmacists;

(B) Pay pharmacies or pharmacists for prescription drugs or medical supplies; or

(C) Negotiate rebates with manufacturers for drugs paid for or procured as described in this paragraph.

(b) "Pharmacy benefit manager" does not include a health care service contractor as defined in ORS 750.005.

(6) "Third party administrator" means a person licensed under ORS 744.702.

SECTION 3. (1) To conduct business in this state, a pharmacy benefit manager must register with the Department of Consumer and Business Services and annually renew the registration.

(2) To register under this section, a pharmacy benefit manager must:

(a) Submit an application to the department on a form prescribed by the department by rule.

(b) Pay a registration fee, not to exceed $50, adopted by the department by rule.

(3) To renew a registration under this section, a pharmacy benefit manager must pay a renewal fee, not to exceed $50, adopted by the department by rule.

(4) The department shall deposit all moneys collected under this section into the Consumer and Business Services Fund created in ORS 705.145.

SECTION 4. As used in sections 4 to 10 of this 2013 Act:

(1) "Audit" means an on-site or remote review of the records of a pharmacy by or on behalf of an entity.

(2) "Clerical error" means a minor error:

(a) In the keeping, recording or transcribing of records or documents or in the handling of electronic or hard copies of correspondence;

(b) That does not result in financial harm to an entity; and

(c) That does not involve dispensing an incorrect dose, amount or type of medication or dispensing a prescription drug to the wrong person.

(3) "Entity" includes:

(a) A pharmacy benefit manager;

(b) An insurer;

(c) A third party administrator;

(d) A state agency; or

(e) A person that represents or is employed by one of the entities described in this subsection.

(4) "Fraud" means knowingly and willfully executing or attempting to execute a scheme, in connection with the delivery of or payment for health care benefits, items or services, that uses false or misleading pretenses, representations or promises to obtain any money or property owned by or under the custody or control of any person.

SECTION 5. An entity that audits claims or an independent third party that contracts with an entity to audit claims:

(1) Must establish, in writing, a procedure for a pharmacy to appeal the entity's findings with respect to a claim and must provide a pharmacy with a notice regarding the procedure, in writing or electronically, prior to conducting an audit of the pharmacy's claims;

(2) May not conduct an audit of a claim more than 24 months after the date the claim was adjudicated by the entity;

(3) Must give at least 15 days' advance written notice of an on-site audit to the pharmacy or corporate headquarters of the pharmacy;

(4) May not conduct an on-site audit during the first five days of any month without the pharmacy's consent;

(5) Must conduct the audit in consultation with a pharmacist who is licensed by this or another state if the audit involves clinical or professional judgment;

(6) May not conduct an on-site audit of more than 250 unique prescriptions of a pharmacy in any 12-month period except in cases of alleged fraud;

(7) May not conduct more than one on-site audit of a pharmacy in any 12-month period;

(8) Must audit each pharmacy under the same standards and parameters that the entity uses to audit other similarly situated pharmacies;

(9) Must pay any outstanding claims of a pharmacy no more than 45 days after the earlier of the date all appeals are concluded or the date a final report is issued under section 9 (3) of this 2013 Act;

(10) May not include dispensing fees or interest in the amount of any overpayment assessed on a claim unless the overpaid claim was for a prescription that was not filled correctly;

(11) May not recoup costs associated with:

(a) Clerical errors; or

(b) Other errors that do not result in financial harm to the entity or a consumer; and

(12) May not charge a pharmacy for a denied or disputed claim until the audit and the appeals procedure established under subsection (1) of this section are final.

SECTION 6. An entity's finding that a claim was incorrectly presented or paid must be based on identified transactions and not based on probability sampling, extrapolation or other

means that project an error using the number of patients served who have a similar diagnosis or the number of similar prescriptions or refills for similar drugs.

SECTION 7. An entity that contracts with an independent third party to conduct audits may not:

(1) Agree to compensate the independent third party based on a percentage of the amount of overpayments recovered; or

(2) Disclose information obtained during an audit except to the contracting entity, the pharmacy subject to the audit or the holder of the policy or certificate of insurance that paid the claim.

SECTION 8. For purposes of sections 4 to 10 of this 2013 Act, an entity, or an independent third party that contracts with an entity to conduct audits, must allow as evidence of validation of a claim:

(1) An electronic or physical copy of a prescription that complies with ORS chapter 689 if the prescribed drug was, within 14 days of the dispensing date:

(a) Picked up by the patient or the patient's designee;

(b) Delivered by the pharmacy to the patient; or

(c) Sent by the pharmacy to the patient using the United States Postal Service or other common carrier;

(2) Point of sale electronic register data showing purchase of the prescribed drug, medical supply or service by the patient or the patient's designee; or

(3) Electronic records, including electronic beneficiary signature logs, electronically scanned and stored patient records maintained at or accessible to the audited pharmacy's central operations and any other reasonably clear and accurate electronic documentation that corresponds to a claim.

SECTION 9. (1)(a) After conducting an audit, an entity must provide the pharmacy that is the subject of the audit with a preliminary report of the audit. The preliminary report must be received by the pharmacy no later than 45 days after the date on which the audit was completed and must be sent:

(A) By mail or common carrier with a return receipt requested; or

(B) Electronically with electronic receipt confirmation.

(b) An entity shall provide a pharmacy receiving a preliminary report under this subsection no fewer than 45 days after receiving the report to contest the report or any findings in the report in accordance with the appeals procedure established under section 5 (1) of this 2013 Act and to provide additional documentation in support of the claim. The entity shall consider a reasonable request for an extension of time to submit documentation to contest the report or any findings in the report.

(2) If an audit results in the dispute or denial of a claim, the entity conducting the audit shall allow the pharmacy to resubmit the claim using any commercially reasonable method, including facsimile, mail or electronic mail.

(3) An entity must provide a pharmacy that is the subject of an audit with a final report of the audit no later than 60 days after the later of the date the preliminary report was received or the date the pharmacy contested the report using the appeals procedure established under section 5 (1) of this 2013 Act. The final report must include a final accounting of all moneys to be recovered by the entity.

(4) Recoupment of disputed funds from a pharmacy by an entity or repayment of funds to an entity by a pharmacy, unless otherwise agreed to by the entity and the pharmacy, shall occur after the audit and the appeals procedure established under section 5 (1) of this 2013 Act are final. If the identified discrepancy for an individual audit exceeds $40,000, any future payments to the pharmacy may be withheld by the entity until the audit and the appeals procedure established under section 5 (1) of this 2013 Act are final.

SECTION 10. Sections 4 to 10 of this 2013 Act do not:

(1) Preclude an entity from instituting an action for fraud against a pharmacy;

(2) Apply to an audit of pharmacy records when fraud or other intentional and willful misrepresentation is evidenced by physical review, review of claims data or statements or other investigative methods; or

(3) Apply to a state agency that is conducting audits or a person that has contracted with a state agency to conduct audits of pharmacy records for prescription drugs paid for by the state medical assistance program.

SECTION 11. (1) As used in this section:

(a) "List" means the list of drugs for which maximum allowable costs have been established.

(b) "Maximum allowable cost" means the maximum amount that a pharmacy benefit manager will reimburse a pharmacy for the cost of a drug.

(c) "Multiple source drug" means a therapeutically equivalent drug that is available from at least two manufacturers.

(d) "Network pharmacy" means a retail drug outlet registered under ORS 689.305 that contracts with a pharmacy benefit manager.

(e) "Therapeutically equivalent" has the meaning given that term in ORS 689.515.

(2) A pharmacy benefit manager:

(a) May not place a drug on a list unless there are at least two therapeutically equivalent, multiple source drugs, or at least one generic drug available from only one manufacturer, generally available for purchase by network pharmacies from national or regional wholesalers.

(b) Shall ensure that all drugs on a list are generally available for purchase by pharmacies in this state from national or regional wholesalers.

(c) Shall ensure that all drugs on a list are not obsolete.

(d) Shall make available to each network pharmacy at the beginning of the term of a contract, and upon renewal of a contract, the sources utilized to determine the maximum allowable cost pricing of the pharmacy benefit manager.

(e) Shall make a list available to a network pharmacy upon request in a format that is readily accessible to and usable by the network pharmacy.

(f) Shall update each list maintained by the pharmacy benefit manager every seven business days and make the updated lists, including all changes in the price of drugs, available to network pharmacies in a readily accessible and usable format.

(g) Shall ensure that dispensing fees are not included in the calculation of maximum allowable cost.

(3) A pharmacy benefit manager must establish a process by which a network pharmacy may appeal its reimbursement for a drug subject to maximum allowable cost pricing. A network pharmacy may appeal a maximum allowable cost if the reimbursement for the drug is less than the net amount that the network pharmacy paid to the supplier of the drug. An appeal requested under this section must be completed within 30 calendar days of the pharmacy making the claim for which appeal has been requested.

(4) A pharmacy benefit manager must provide as part of the appeals process established under subsection (3) of this section:

(a) A telephone number at which a network pharmacy may contact the pharmacy benefit manager and speak with an individual who is responsible for processing appeals;

(b) A final response to an appeal of a maximum allowable cost within seven business days; and

(c) If the appeal is denied, the reason for the denial and the national drug code of a drug that may be purchased by similarly situated pharmacies at a price that is equal to or less than the maximum allowable cost.

(5)(a) If an appeal is upheld under this section, the pharmacy benefit manager shall make an adjustment on the date that the pharmacy benefit manager makes the determination. The

pharmacy benefit manager shall make the adjustment effective for all similarly situated pharmacies in this state that are within the network.

(b) If the request for an adjustment has come from a critical access pharmacy, as defined by the Oregon Health Authority by rule for purposes related to the Oregon Prescription Drug Program, the adjustment approved under paragraph (a) of this subsection shall apply only to critical access pharmacies.

(6) This section does not apply to the state medical assistance program.

SECTION 12. The amendments to section 11 of this 2013 Act by section 13 of this 2013 Act become operative on January 1, 2015.

SECTION 13. Section 11 of this 2013 Act is amended to read:

Sec. 11. (1) As used in this section:

(a) "List" means the list of drugs for which maximum allowable costs have been established.

(b) "Maximum allowable cost" means the maximum amount that a pharmacy benefit manager will reimburse a pharmacy for the cost of a drug.

(c) "Multiple source drug" means a therapeutically equivalent drug that is available from at least two manufacturers.

(d) "Network pharmacy" means a retail drug outlet registered under ORS 689.305 that contracts with a pharmacy benefit manager.

(e) "Therapeutically equivalent" has the meaning given that term in ORS 689.515.

(2) A pharmacy benefit manager:

(a) May not place a drug on a list unless there are at least two therapeutically equivalent, multiple source drugs, or at least one generic drug available from only one manufacturer, generally available for purchase by network pharmacies from national or regional wholesalers.

(b) Shall ensure that all drugs on a list are generally available for purchase by pharmacies in this state from national or regional wholesalers.

(c) Shall ensure that all drugs on a list are not obsolete.

(d) Shall make available to each network pharmacy at the beginning of the term of a contract, and upon renewal of a contract, the sources utilized to determine the maximum allowable cost pricing of the pharmacy benefit manager.

(e) Shall make a list available to a network pharmacy upon request in a format that is readily accessible to and usable by the network pharmacy.

(f) Shall update each list maintained by the pharmacy benefit manager every seven business days and make the updated lists, including all changes in the price of drugs, available to network pharmacies in a readily accessible and usable format.

(g) Shall ensure that dispensing fees are not included in the calculation of maximum allowable cost.

(3) A pharmacy benefit manager must establish a process by which a network pharmacy may appeal its reimbursement for a drug subject to maximum allowable cost pricing. A network pharmacy may appeal a maximum allowable cost if the reimbursement for the drug is less than the net amount that the network pharmacy paid to the supplier of the drug. An appeal requested under this section must be completed within 30 calendar days of the pharmacy making the claim for which appeal has been requested.

(4) A pharmacy benefit manager must provide as part of the appeals process established under subsection (3) of this section:

(a) A telephone number at which a network pharmacy may contact the pharmacy benefit manager and speak with an individual who is responsible for processing appeals;

(b) A final response to an appeal of a maximum allowable cost within seven business days; and

(c) If the appeal is denied, the reason for the denial and the national drug code of a drug that may be purchased by similarly situated pharmacies at a price that is equal to or less than the maximum allowable cost.

(5)(a) If an appeal is upheld under this section, the pharmacy benefit manager shall make an adjustment [*on the date that the pharmacy benefit manager makes the determination. The pharmacy*

benefit manager shall make the adjustment effective for all similarly situated pharmacies in this state that are within the network.] **for the pharmacy that requested the appeal from the date of initial adjudication forward.**

(b) If the request for an adjustment has come from a critical access pharmacy, as defined by the Oregon Health Authority by rule for purposes related to the Oregon Prescription Drug Program, the adjustment approved under paragraph (a) of this subsection shall apply only to critical access pharmacies.

(6) This section does not apply to the state medical assistance program.

SECTION 14. (1) Section 11 of this 2013 Act applies to contracts between pharmacies and pharmacy benefit managers that are entered into, renewed or extended on or after the effective date of this 2013 Act.

(2) The amendments to section 11 of this 2013 Act by section 13 of this 2013 Act apply to contracts between pharmacies and pharmacy benefit managers that are entered into, renewed or extended on or after the operative date specified in section 12 of this 2013 Act.

Passed by House June 18, 2013

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Ramona J. Line, Chief Clerk of House

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Tina Kotek, Speaker of House

Passed by Senate June 25, 2013

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Peter Courtney, President of Senate

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John Kitzhaber, Governor

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Kate Brown, Secretary of State