Senate Bill 608

Sponsored by Senator CAMPOS (Presession filed.)

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure **as introduced.**

Prohibits insurers offering policies or certificates of health insurance and pharmacy benefit managers from requiring claim for reimbursement of prescription drug to include modifier or other indicator that drug is 340B drug.

Requires Oregon Health Authority to adopt dispensing fee to be paid to pharmacies and pharmacists dispensing prescription drugs to medical assistance recipients. Sets minimum dispensing fee at \$______.

Takes effect on 91st day following adjournment sine die.

1 A BILL FOR AN ACT

Relating to prescription drugs; amending ORS 414.325, 735.530, 735.534 and 743A.062; and prescribing an effective date.

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

- 5 **SECTION 1.** ORS 735.530 is amended to read:
- 6 735.530. As used in ORS 735.530 to 735.552:
 - (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) "Enrollee" means an individual who has enrolled for coverage in a health benefit plan for which a pharmacy benefit manager has contracted with the insurer to reimburse claims submitted by pharmacies or pharmacists for the costs of drugs prescribed for the individual.
 - (3) "Health benefit plan" has the meaning given that term in ORS 743B.005.
- 13 (4) "Insurer" has the meaning given that term in ORS 731.106.
- 14 (5) "Long term care pharmacy" means a pharmacy for which the primary business is to serve 15 a:
 - (a) Licensed long term care facility, as defined in ORS 442.015;
- 17 (b) Licensed residential facility, as defined in ORS 443.400; or
 - (c) Licensed adult foster home, as defined in ORS 443.705.
- 19 (6) "Mail order pharmacy" means a pharmacy for which the primary business is to receive pre-20 scriptions by mail, telephone or electronic transmission and dispense drugs to patients through the 21 use of the United States Postal Service, a package delivery service or home delivery.
- 22 (7) "Network pharmacy" means a pharmacy that contracts with a pharmacy benefit manager.
- 23 (8) "Pharmacist" has the meaning given that term in ORS 689.005.
- 24 (9) "Pharmacy" includes:
- 25 (a) A pharmacy as defined in ORS 689.005;
- 26 (b) A long term care pharmacy; and
- 27 (c) An entity that provides or oversees administrative services for two or more pharmacies.
- 28 (10) "Pharmacy benefit" means the payment for or reimbursement of an enrollee's cost for pre-

NOTE: Matter in **boldfaced** type in an amended section is new; matter [*italic and bracketed*] is existing law to be omitted. New sections are in **boldfaced** type.

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- (11)(a) "Pharmacy benefit manager" means a person that contracts with pharmacies on behalf of an insurer offering a health benefit plan, 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
- 8 (C) Negotiate rebates with manufacturers for drugs paid for or procured as described in this paragraph.
- 10 (b) "Pharmacy benefit manager" does not include a health care service contractor as defined in ORS 750.005.
 - (12) "Specialty drug" means a drug that:
 - (a) Is subject to restricted distribution by the United States Food and Drug Administration; or
 - (b) Requires special handling, provider coordination or patient education that cannot be provided by a retail pharmacy.
 - (13) "Specialty pharmacy" means a pharmacy capable of meeting the requirements applicable to specialty drugs.
 - (14) "Third party administrator" means a person licensed under ORS 744.702.
 - (15) "340B drug" means a covered drug that is subject to the cap on amounts required to be paid in 42 U.S.C. 256b(a)(1) and that is dispensed by a 340B pharmacy.
 - [(15)] (16) "340B pharmacy" means a pharmacy that is authorized to purchase drugs at a discount under 42 U.S.C. 256b.
 - **SECTION 2.** ORS 735.534 is amended to read:
- 24 735.534. (1) As used in this section:
 - (a)(A) "Generally available for purchase" means a drug is available for purchase in this state by a pharmacy from a national or regional wholesaler at the time a claim for reimbursement is submitted by a network pharmacy.
 - (B) A drug is not "generally available for purchase" if the drug:
 - (i) May be dispensed only in a hospital or inpatient care facility;
 - (ii) Is unavailable due to a shortage of the product or an ingredient;
 - (iii) Is available to a pharmacy at a price that is at or below the maximum allowable cost only if purchased in substantial quantities that are inconsistent with the business needs of a pharmacy;
 - (iv) Is sold at a discount due to a short expiration date on the drug; or
 - (v) Is the subject of an active or pending recall.
 - (b) "List" means the list of drugs for which maximum allowable costs have been established.
- 36 (c) "Maximum allowable cost" means the maximum amount that a pharmacy benefit manager 37 will reimburse a pharmacy for the cost of a drug.
 - (d) "Multiple source drug" means a therapeutically equivalent drug that is available from at least two manufacturers.
 - (e) "Therapeutically equivalent" has the meaning given that term in ORS 689.515.
 - (2) A pharmacy benefit manager registered under ORS 735.532:
- 42 (a) May not place a drug on a list unless there are at least two multiple source drugs, or at least 43 one generic drug generally available for purchase.
 - (b) Shall ensure that all drugs on a list are generally available for purchase.
- 45 (c) Shall ensure that no drug on a list is 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 specific authoritative industry sources, other than proprietary sources, the pharmacy benefit manager uses to determine the maximum allowable cost set by the pharmacy benefit manager.
 - (e) Shall make a list available to a network pharmacy upon request in a format that:
- (A) Is electronic;

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- (B) Is computer accessible and searchable;
- (C) Identifies all drugs for which maximum allowable costs have been established; and
- (D) For each drug specifies:
- 10 (i) The national drug code; and
- 11 (ii) The maximum allowable cost.
 - (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 the format described in paragraph (e) of this subsection.
 - (g) Shall ensure that dispensing fees are not included in the calculation of maximum allowable cost.
 - (h) May not reimburse a 340B pharmacy differently than any other network pharmacy based on its status as a 340B pharmacy or require a claim for reimbursement of a prescription drug to include a modifier or other indicator that the drug is a 340B drug unless:
 - (A) The claim is for payment, directly or indirectly, by the state medical assistance program; or
 - (B) The modifier or other indicator is required by law to prevent a duplicate discount or rebate.
 - (i) May not retroactively deny or reduce a claim for reimbursement of the cost of services after the claim has been adjudicated by the pharmacy benefit manager unless the:
 - (A) Adjudicated claim was submitted fraudulently;
 - (B) Pharmacy benefit manager's payment on the adjudicated claim was incorrect because the pharmacy or pharmacist had already been paid for the services;
 - (C) Services were improperly rendered by the pharmacy or pharmacist; or
 - (D) Pharmacy or pharmacist agrees to the denial or reduction prior to the pharmacy benefit manager notifying the pharmacy or pharmacist that the claim has been denied or reduced.
 - (3) Subsection (2)(i) of this section may not be construed to limit pharmacy claim audits under ORS 735.540 to 735.552.
 - (4) 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. The process must allow a network pharmacy a period of no less than 60 days after a claim is reimbursed in which to file the appeal. 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.
 - (5) A pharmacy benefit manager shall allow a network pharmacy to submit the documentation in support of its appeal on paper or electronically and may not:
 - (a) Refuse to accept an appeal submitted by a person authorized to act on behalf of the network pharmacy;
 - (b) Refuse to adjudicate an appeal for the reason that the appeal is submitted along with other

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- (c) Impose requirements or establish procedures that have the effect of unduly obstructing or delaying an appeal.
- (6) A pharmacy benefit manager must provide as part of the appeals process established under subsection (4) 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.
 - (7)(a) If an appeal is upheld under this section, the pharmacy benefit manager shall:
- (A) Make an adjustment for the pharmacy that requested the appeal from the date of initial adjudication forward; and
- (B) Allow the pharmacy to reverse the claim and resubmit an adjusted claim without any additional charges.
- (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.
 - (8) This section does not apply to the state medical assistance program.
- (9) The Department of Consumer and Business Services may adopt rules to carry out the provisions of this section.
 - SECTION 3. ORS 743A.062 is amended to read:
 - 743A.062. (1) As used in this section[,]:
- (a) "Medical assistance program" means the state program that provides medical assistance as defined in ORS 414.025.
- (b) "340B drug" means a covered drug dispensed by a covered entity, as those terms are defined in 42 U.S.C. 256b, that is subject to the cap on amounts required to be paid in 42 U.S.C. 256b(a)(1).
- (2) [An insurance policy or] A policy or certificate of health insurance or other contract providing [coverage] for the reimbursement of the cost of a prescription drug to a resident of this state may not:
- (a) Exclude coverage of the drug for a particular indication solely on the grounds that the indication has not been approved by the United States Food and Drug Administration if the Health Evidence Review Commission established under ORS 414.688 or the Pharmacy and Therapeutics Committee established under ORS 414.353 determines that the drug is recognized as effective for the treatment of that indication:
 - (A) In publications that the commission or the committee determines to be equivalent to:
- (i) The American Hospital Formulary Service drug information;
- 41 (ii) "Drug Facts and Comparisons" (Lippincott-Raven Publishers);
 - (iii) The United States Pharmacopoeia drug information; or
- 43 (iv) Other publications that have been identified by the United States Secretary of Health and 44 Human Services as authoritative;
 - (B) In the majority of relevant peer-reviewed medical literature; or

- (C) By the United States Secretary of Health and Human Services; or
- (b) For an insured who is enrolled in the medical assistance program:
- (A) Except as provided in subsection (3) of this section, require a prescription for the drug to be filled or refilled at a mail order pharmacy; or
 - (B) Require a prescription for the drug to be filled or refilled at a pharmacy that is not a local pharmacy enrolled in the medical assistance program.
 - (c) Require a claim for reimbursement of the prescription drug to include a modifier or other indicator that the drug is a 340B drug unless:
 - (A) The claim is for payment, directly or indirectly, by the medical assistance program; or
- (B) The modifier or other indicator is required by law to prevent a duplicate discount or rebate.
- (3) Subsection (2)(b)(A) of this section does not prohibit an insurer from requiring a medical assistance recipient to fill or refill a prescription for a specialty drug at a mail order pharmacy that is a specialty pharmacy.
- (4) Required coverage of a prescription drug under this section shall include coverage for medically necessary services associated with the administration of that drug.
- (5) Nothing in this section requires coverage for any prescription drug if the United States Food and Drug Administration has determined use of the drug to be contraindicated.
- (6) Nothing in this section requires coverage for experimental drugs not approved for any indication by the United States Food and Drug Administration.
 - (7) This section is exempt from ORS 743A.001.
 - SECTION 4. ORS 414.325 is amended to read:
 - 414.325. (1) As used in this section:

- (a) "Legend drug" means any drug requiring a prescription by a practitioner, as defined in ORS 689.005.
- (b) "Urgent medical condition" means a medical condition that arises suddenly, is not lifethreatening and requires prompt treatment to avoid the development of more serious medical problems.
- (2) A licensed practitioner may prescribe such drugs under this chapter as the practitioner in the exercise of professional judgment considers appropriate for the diagnosis or treatment of the patient in the practitioner's care and within the scope of practice. Prescriptions shall be dispensed in the generic form pursuant to ORS 689.515 and pursuant to rules of the Oregon Health Authority unless the practitioner prescribes otherwise and an exception is granted by the authority.
- (3) Except as provided in subsections (4) and (5) of this section, the authority shall place no limit on the type of legend drug that may be prescribed by a practitioner, but the authority shall pay only for drugs in the generic form unless an exception has been granted by the authority.
- (4) Notwithstanding subsection (3) of this section, an exception must be applied for and granted before the authority is required to pay for minor tranquilizers and amphetamines and amphetamine derivatives, as defined by rule of the authority.
- (5)(a) Notwithstanding subsections (1) to (4) of this section and except as provided in paragraph (b) of this subsection, the authority is authorized to:
- (A) Withhold payment for a legend drug when federal financial participation is not available; and
- (B) Require prior authorization of payment for drugs that the authority has determined should

- 1 be limited to those conditions generally recognized as appropriate by the medical profession.
 - (b) The authority may not require prior authorization for therapeutic classes of nonsedating antihistamines and nasal inhalers, as defined by rule by the authority, when prescribed by an allergist for treatment of any of the following conditions, as described by the Health Evidence Review Commission on the funded portion of its prioritized list of services:
 - (A) Asthma;
- 7 (B) Sinusitis;

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- 8 (C) Rhinitis; or
- (D) Allergies.
- 10 (6) The authority shall pay a rural health clinic for a legend drug prescribed and dispensed un-11 der this chapter by a licensed practitioner at the rural health clinic for an urgent medical condition 12 if:
 - (a) There is not a pharmacy within 15 miles of the clinic;
 - (b) The prescription is dispensed for a patient outside of the normal business hours of any pharmacy within 15 miles of the clinic; or
 - (c) No pharmacy within 15 miles of the clinic dispenses legend drugs under this chapter.
 - (7) Notwithstanding ORS 414.334, the authority may conduct prospective drug utilization review in accordance with ORS 414.351 to 414.414.
 - (8) Notwithstanding subsection (3) of this section, the authority may pay a pharmacy for a particular brand name drug rather than the generic version of the drug after notifying the pharmacy that the cost of the particular brand name drug, after receiving discounted prices and rebates, is equal to or less than the cost of the generic version of the drug.
 - (9)(a) Within 180 days after the United States patent expires on an immunosuppressant drug used in connection with an organ transplant, the authority shall determine whether the drug is a narrow therapeutic index drug.
 - (b) As used in this subsection, "narrow therapeutic index drug" means a drug that has a narrow range in blood concentrations between efficacy and toxicity and requires therapeutic drug concentration or pharmacodynamic monitoring.
 - (10) The authority shall adopt by rule a dispensing fee to be paid to pharmacies and pharmacists enrolled in the medical assistance program for each dispensing of a prescription drug to a recipient of medical assistance. The fee may not be less than \$_____.
 - **SECTION 5.** ORS 414.325, as amended by section 3, chapter 628, Oregon Laws 2021, is amended to read:
 - 414.325. (1) As used in this section:
 - (a) "Legend drug" means any drug requiring a prescription by a practitioner, as defined in ORS 689.005.
 - (b) "Urgent medical condition" means a medical condition that arises suddenly, is not lifethreatening and requires prompt treatment to avoid the development of more serious medical problems.
 - (2) A licensed practitioner may prescribe such drugs under this chapter as the practitioner in the exercise of professional judgment considers appropriate for the diagnosis or treatment of the patient in the practitioner's care and within the scope of practice. Prescriptions shall be dispensed in the generic form pursuant to ORS 689.515 and pursuant to rules of the Oregon Health Authority unless the practitioner prescribes otherwise and an exception is granted by the authority.
 - (3) Except as provided in subsections (4) and (5) of this section, the authority shall place no limit

- on the type of legend drug that may be prescribed by a practitioner, but the authority shall pay only for drugs in the generic form unless an exception has been granted by the authority.
- (4) Notwithstanding subsection (3) of this section, an exception must be applied for and granted before the authority is required to pay for minor tranquilizers and amphetamines and amphetamine derivatives, as defined by rule of the authority.
 - (5)(a) Notwithstanding subsections (1) to (4) of this section and except as provided in paragraph (b) of this subsection, the authority is authorized to:
- 8 (A) Withhold payment for a legend drug when federal financial participation is not available; 9 and
- 10 (B) Require prior authorization of payment for drugs that the authority has determined should 11 be limited to those conditions generally recognized as appropriate by the medical profession.
 - (b) The authority may not require prior authorization for:
 - (A) Therapeutic classes of nonsedating antihistamines and nasal inhalers, as defined by rule by the authority, when prescribed by an allergist for treatment of any of the following conditions, as described by the Health Evidence Review Commission on the funded portion of its prioritized list of services:
 - (i) Asthma;
 - (ii) Sinusitis;
- 19 (iii) Rhinitis; or
- 20 (iv) Allergies

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- (B) Any mental health drug prescribed for a medical assistance recipient if:
- (i) The claims history available to the authority shows that the recipient has been in a course of treatment with the drug during the preceding 365-day period; or
 - (ii) The prescriber specifies on the prescription "dispense as written" or includes the notation "D.A.W." or words of similar meaning.
 - (6) The authority shall pay a rural health clinic for a legend drug prescribed and dispensed under this chapter by a licensed practitioner at the rural health clinic for an urgent medical condition if:
 - (a) There is not a pharmacy within 15 miles of the clinic;
 - (b) The prescription is dispensed for a patient outside of the normal business hours of any pharmacy within 15 miles of the clinic; or
 - (c) No pharmacy within 15 miles of the clinic dispenses legend drugs under this chapter.
 - (7) Notwithstanding ORS 414.334, the authority may conduct prospective drug utilization review in accordance with ORS 414.351 to 414.414.
 - (8) Notwithstanding subsection (3) of this section, the authority may pay a pharmacy for a particular brand name drug rather than the generic version of the drug after notifying the pharmacy that the cost of the particular brand name drug, after receiving discounted prices and rebates, is equal to or less than the cost of the generic version of the drug.
 - (9)(a) Within 180 days after the United States patent expires on an immunosuppressant drug used in connection with an organ transplant, the authority shall determine whether the drug is a narrow therapeutic index drug.
 - (b) As used in this subsection, "narrow therapeutic index drug" means a drug that has a narrow range in blood concentrations between efficacy and toxicity and requires therapeutic drug concentration or pharmacodynamic monitoring.
 - (10) The authority shall adopt by rule a dispensing fee to be paid to pharmacies and

pharmacists enrolled in the medical assistance program for each dispensing of a prescription
drug to a recipient of medical assistance. The fee may not be less than \$______.

SECTION 6. This 2023 Act takes effect on the 91st day after the date on which the 2023
regular session of the Eighty-second Legislative Assembly adjourns sine die.