A-Engrossed
House Bill 3409

Ordered by the House May 1
Including House Amendments dated May 1

Sponsored by COMMITTEE ON RULES (at the request of Representative Ben Bowman)

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. The statement includes a measure digest written in compliance with applicable readability standards.

Digest: Makes rules for some insurers and PBMs about 340B drugs. (Flesch Readability Score: 61.3).

[*Digest: The Act tells OHA to study health care. (Flesch Readability Score: 92.9).*]

[*Requires the Oregon Health Authority to study health care. Directs the authority to submit findings to the interim committees of the Legislative Assembly related to health not later than September 15, 2026.*]

[*Sunsets on January 2, 2027.*]

Allows insurers offering policies or certificates of health insurance and pharmacy benefit managers to require that a claim for reimbursement of a prescription drug include a modifier or other indicator that the drug is a 340B drug unless certain requirements are met.

Takes effect on the 91st day following adjournment sine die.

A BILL FOR AN ACT

Relating to health care; amending ORS 735.530, 735.534 and 743A.062; and prescribing an effective date.

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

SECTION 1. ORS 735.530, as amended by section 3, chapter 87, Oregon Laws 2024, is amended to read:

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.

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

(5) "Long term care pharmacy" means a pharmacy for which the primary business is to serve a:

(a) Licensed long term care facility, as defined in ORS 442.015;

(b) Licensed residential facility, as defined in ORS 443.400; or

(c) Licensed adult foster home, as defined in ORS 443.705.

(6) "Mail order pharmacy" means a pharmacy for which the primary business is to receive prescriptions by mail, telephone or electronic transmission and dispense drugs to patients through the use of the United States Postal Service, a package delivery service or home delivery.

(7) "Network pharmacy" means a pharmacy that contracts with a pharmacy benefit manager.

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.

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

(9) "Pharmacy" includes:

(a) A pharmacy as defined in ORS 689.005;

(b) A long term care pharmacy; and

(c) An entity that provides or oversees administrative services for two or more pharmacies.

(10) "Pharmacy benefit" means the payment for or reimbursement of an enrollee's cost for prescription drugs.

(11)(a) "Pharmacy benefit manager" means a person that contracts with pharmacies on behalf of an insurer, coordinated care organizations as defined in ORS 414.025 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;

(C) Negotiate rebates, discounts or other financial incentives or arrangements with manufacturers for drugs paid for or procured as described in this paragraph;

(D) Receive payments for pharmacy services;

(E) Disburse or distribute rebates;

(F) Manage or participate in incentive programs or arrangements with manufacturers of drugs;

(G) Negotiate or enter into contracts with pharmacies;

(H) Develop formularies;

(I) Design pharmacy benefit programs; or

(J) Advertise or promote pharmacy services.

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

(12) "Pharmacy services" means the provision of products, goods or services in the course of the practice of pharmacy.

(13) "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.

(14) "Specialty pharmacy" means a pharmacy capable of meeting the requirements applicable to specialty drugs.

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

(16) "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 at a 340B pharmacy.

[*(16)*] **(17)** "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, as amended by section 6, chapter 87, Oregon Laws 2024, is amended to read:

735.534. (1) As used in this section:

(a) "Conflict of interest" means:

(A) Present employment, ownership or control by a covered entity, pharmaceutical manufacturer, pharmacy benefit manager or health benefit plan as defined in ORS 743B.005; or

(B) Third party employment, ownership or control by a covered entity, pharmaceutical

manufacturer, pharmacy benefit manager or health benefit plan as defined in ORS 743B.005.

(b) "Covered entity" means a covered entity as defined in 42 U.S.C. 256b(a)(4)(A) and (C) to (G).

[*(a)(A)*] **(c)(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)*] **(d)** "List" means the list of drugs for which maximum allowable costs have been established.

[*(c)*] **(e)** "Maximum allowable cost" means the maximum amount that a pharmacy benefit manager will reimburse a pharmacy for the cost of a drug.

[*(d)*] **(f)** "Multiple source drug" means a therapeutically equivalent drug that is available from at least two manufacturers.

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

(2) A pharmacy benefit manager licensed under ORS 735.532:

(a) May not place a drug on a list unless there are at least two multiple source drugs, or at least one generic drug generally available for purchase.

(b) Shall ensure that all drugs on a list are generally available for purchase.

(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;

(B) Is computer accessible and searchable;

(C) Identifies all drugs for which maximum allowable costs have been established; and

(D) For each drug specifies:

(i) The national drug code; and

(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.

(i) Shall comply with the provisions of ORS 743A.062.

(j) May not retroactively deny or reduce payment on 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 had already been paid for the services;

(C) Services were improperly rendered by the pharmacy in violation of state or federal law; or

(D) Payment was incorrect due to an error that the pharmacy and pharmacy benefit manager agree was a clerical error.

(k) May not impose a fee on a pharmacy after the point of sale.

(L) Shall provide notice to a pharmacy of any claim for reimbursement of the cost of a prescription drug that is denied or reduced. The notice shall identify the specific disaggregated claim that was denied or reduced and a detailed explanation for why the specific claim was denied or reduced.

(m) May require a covered entity to submit a claim for reimbursement of a prescription drug that includes a modifier or other indicator that the drug is a 340B drug unless:

(A) The covered entity has submitted 340B drug data to a third party clearinghouse of the covered entity's choosing that:

(i) Requests and receives claim data, including pharmacy claims, from covered entities;

(ii) Ensures that claim data submissions by covered entities are complete and accurate;

(iii) Provides manufacturers with validation of a 340B drug that includes requested claim information submitted by a covered entity and allows pharmaceutical manufacturers to identify units of a 340B drug that may be subject to a rebate or discount under a voluntary rebate or discount arrangement and to verify invoices;

(iv) Allows payers, health benefit plans, and pharmacy benefit managers to access only the validated 340B drug claim information that is necessary to verify rebate payments while ensuring data integrity and privacy;

(v) Allows a covered entity the option of submitting claim data on an aggregated retrospective basis that does not require the application of modifiers on individual claims or point-of-sale identification;

(vi) Does not disclose confidential information other than as permitted to perform the purposes of this paragraph;

(vii) Does not collect pricing information regarding drugs that are not 340B drugs;

(viii) Does not sell or otherwise generate revenue by licensing or making available the data described in this section; and

(ix) Does not have a conflict of interest;

(B) The modifier or other indicator is not required by law to prevent a duplicate discount or rebate; or

(C) The claim is not for payment, directly or indirectly, by the state medical assistance program.

(3) Subsection (2)(j) of this section may not be construed to limit pharmacy claim audits under ORS 735.540 to 735.552.

(4) Nothing in subsection (2)(m) of this section requires a pharmacy benefit manager to participate in or subscribe to a clearinghouse.

[*(4)*] **(5)** 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)*] **(6)** 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 claims that are denied; or

(c) Impose requirements or establish procedures that have the effect of unduly obstructing or delaying an appeal.

[*(6)*] **(7)** A pharmacy benefit manager must provide as part of the appeals process established under subsection [*(4)*] **(5)** 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 the reimbursement for a drug 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)*] **(8)(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)*] **(9)** A pharmacy may file a complaint with the Department of Consumer and Business Services to contest a finding of a pharmacy benefit manager in response to an appeal under subsection [*(4)*] **(5)** of this section or a pharmacy benefit manager's failure to comply with the provisions of this section.

[*(9)*] **(10)** The Department of Consumer and Business Services may adopt rules to carry out the provisions of this section.

SECTION 3. ORS 743A.062, as amended by section 11, chapter 87, Oregon Laws 2024, is amended to read:

743A.062. (1) As used in this section:

(a) "Conflict of interest" means:

(A) Present employment, ownership or control by a covered entity, pharmaceutical manufacturer, pharmacy benefit manager or health benefit plan as defined in ORS 743B.005; or

(B) Third party employment, ownership or control by a covered entity, pharmaceutical manufacturer, pharmacy benefit manager or health benefit plan as defined in ORS 743B.005.

(b) "Covered entity" means a covered entity as defined in 42 U.S.C. 256b(a)(4)(A) and (C) to (G).

[*(a)*] **(c)** "Medical assistance program" means the state program that provides medical assistance as defined in ORS 414.025.

[*(b)*] **(d)** "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) A policy or certificate of health insurance or other contract providing for the reimbursement of the cost of a prescription drug to a resident of this state [*may not*]:

(a) **May not** 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;

(ii) "Drug Facts and Comparisons" (Lippincott-Raven Publishers);

(iii) The United States Pharmacopoeia drug information; or

(iv) Other publications that have been identified by the United States Secretary of Health and 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;

(b) For an insured who is enrolled in the medical assistance program:

(A) Except as provided in subsection (3) of this section, **may not** require a prescription for the drug to be filled or refilled at a mail order pharmacy; or

(B) **May not** 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) **May not** discriminate in the reimbursement of a prescription for 340B drugs from other prescription drugs;

(d) **May not** assess a fee, chargeback, clawback or other adjustment for the dispensing of a 340B drug;

(e) **May not** exclude a pharmacy from a pharmacy network on the basis that the pharmacy dispenses a 340B drug;

(f) **May not** restrict the methods by which a 340B drug may be dispensed or delivered; [*or*]

(g) **May not** restrict the number of pharmacies within a pharmacy network that may dispense or deliver 340B drugs**; or**

(h) May require a covered entity to submit a claim for reimbursement of a prescription drug that includes a modifier or other indicator that the drug is a 340B drug unless:

(A) The covered entity has submitted 340B drug data to a third party clearinghouse of the covered entity's choosing that:

(i) Requests and receives claim data, including pharmacy claims, from covered entities;

(ii) Ensures that claim data submissions by covered entities are complete and accurate;

(iii) Provides manufacturers with validation of a 340B drug that includes requested claim information submitted by a covered entity and allows pharmaceutical manufacturers to identify units of a 340B drug that may be subject to a rebate or discount under a voluntary

rebate or discount arrangement and to verify invoices;

(iv) Allows payers, health benefit plans, and pharmacy benefit managers to access only the validated 340B drug claim information that is necessary to verify rebate payments while ensuring data integrity and privacy;

(v) Allows a covered entity the option of submitting claim data on an aggregated retrospective basis that does not require the application of modifiers on individual claims or point-of-sale identification;

(vi) Does not disclose confidential information other than as permitted to perform the purposes of this paragraph;

(vii) Does not collect pricing information regarding drugs that are not 340B drugs;

(viii) Does not sell or otherwise generate revenue by licensing or making available the data described in this section; and

(ix) Does not have a conflict of interest;

(B) The modifier or other indicator is not required by law to prevent a duplicate discount or rebate; or

(C) The claim is not for payment, directly or indirectly, by the state medical assistance program.

(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) Nothing in subsection (2)(h) of this section requires a pharmacy benefit manager to participate in or subscribe to a clearinghouse.

[*(4)*] **(5)** Required coverage of a prescription drug under this section shall include coverage for medically necessary services associated with the administration of that drug.

[*(5)*] **(6)** 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)*] **(7)** Nothing in this section requires coverage for experimental drugs not approved for any indication by the United States Food and Drug Administration.

[*(7)*] **(8)** Notwithstanding ORS 750.055 (1)(h), this section does not apply to a health maintenance organization as defined in ORS 750.005.

[*(8)*] **(9)** This section is exempt from ORS 743A.001.

SECTION 4. This 2025 Act takes effect on the 91st day after the date on which the 2025 regular session of the Eighty-third Legislative Assembly adjourns sine die.
