## B-Engrossed House Bill 2185

Ordered by the Senate May 31 Including House Amendments dated April 12 and Senate Amendments dated May 31

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

## **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.

Imposes new requirements on pharmacy benefit managers registered in this state.

1	A BILL FOR AN ACT
2	Relating to pharmacy benefit managers; creating new provisions; and amending ORS 735.530 and
3	735.534.
4	Be It Enacted by the People of the State of Oregon:
5	SECTION 1 Section 2 of this 2019 Act is added to and made a part of ORS 735 530 to

SECTION 1. Section 2 of this 2019 Act is added to and made a part of ORS 735.530 to 735.552.

<u>SECTION 2.</u> (1) As used in this section, "out-of-pocket cost" means the amount paid by an enrollee under the enrollee's coverage, including deductibles, copayments, coinsurance or other expenses as prescribed by the Department of Consumer and Business Services by rule.

- (2) A pharmacy benefit manager registered under ORS 735.532:
- (a) May not require an enrollee to fill or refill prescriptions at a mail order pharmacy.
- (b) May require an enrollee to fill or refill a prescription for a specialty drug at a specialty pharmacy.
- (c) Shall allow an enrollee who is residing in a long term care facility to fill or refill a prescription at a pharmacy that contracts with the long term care facility to dispense drugs for the residents of the facility if:
  - (A) The contracted pharmacy is legally authorized to dispense; or
  - (B) The pharmacist at the pharmacy is properly trained to dispense.
- (d)(A) Except for a specialty pharmacy as provided in paragraph (b) of this subsection, shall allow a network pharmacy to mail, ship or deliver prescription drugs to its patients.
- (B) May not require a patient signature as proof of delivery of a mailed or shipped prescription drug if the network pharmacy maintains a mailing or shipping log signed by a representative of the pharmacy or maintains each notification of delivery provided by the United States Postal Service or a package delivery service.
- (C) Is not required to reimburse a delivery fee charged by a pharmacy for a delivery described in subparagraph (A) of this paragraph unless the fee is specified in the contract between the pharmacy benefit manager and the pharmacy.
  - (e) May not penalize a network pharmacy for or otherwise directly or indirectly prevent

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a network pharmacy from informing an enrollee of the difference between the out-of-pocket cost to the enrollee to purchase a prescription drug using the enrollee's pharmacy benefit and the pharmacy's retail price for the prescription drug.

(3) The Department of Consumer and Business Services shall adopt rules to carry out the provisions of this section.

**SECTION 3.** ORS 735.530 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 is a beneficiary under a policy or certificate of health insurance, a multiple employer welfare arrangement or a health care service contract or is covered by a self-insured health benefit plan for which a pharmacy benefit manager reimburses claims submitted by pharmacies or pharmacists for the costs of prescription drugs.
- (3) "Health care service contract" means the coverage offered by a health care service contractor as defined in ORS 750.005.
  - [(2)] (4) "Insurer" has the meaning given that term in ORS 731.106.
- (5) "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.
- (6) "Multiple employer welfare arrangement" has the meaning given that term in ORS 750.301.
- (7) "Network pharmacy" means a retail drug outlet registered under ORS 689.305 that contracts with a pharmacy benefit manager.
  - [(3)] (8) "Pharmacist" has the meaning given that term in ORS 689.005.
- [(4)] (9) "Pharmacy" includes:
- (a) A pharmacy as defined in ORS 689.005; and
  - (b) 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.
- [(5)(a)] (11)(a) "Pharmacy benefit manager" means a person that contracts with pharmacies or pharmacists on behalf of an insurer, a third party administrator, a multiple employer welfare arrangement, a health care service contractor, as defined in ORS 750.005, a person offering a self-insured health benefit plan 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 pharmacies;
  - (B) Pay pharmacies or pharmacists for prescription drugs or medical supplies; or
- 40 (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.
    - (12) "Specialty drug" means a drug that meets two or more of the following criteria:
    - (a) A drug that cannot be routinely dispensed at a majority of local retail drug outlets,

as defined in ORS 689.005.

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- (b) A drug that is designated by the United States Food and Drug Administration as a drug for a rare disease or condition under 21 U.S.C. 360bb.
  - (c) A drug that requires:
  - (A) A difficult or unusual method of delivery to a patient;
- 6 (B) The pharmacy or pharmacist to manage the patient's adherence to the drug regimen; 7 and
  - (C) The pharmacy or pharmacist to provide therapeutic support to the patient prior to or following the administration of the drug.
- 10 (13) "Specialty pharmacy" means a pharmacy capable of meeting the requirements ap-11 plicable to specialty drugs.
  - [(6)] (14) "Third party administrator" means a person licensed under ORS 744.702.
  - (15) "340B pharmacy" means a pharmacy that is authorized to purchase drugs at a discount under 42 U.S.C. 256b.
    - **SECTION 4.** ORS 735.534 is amended to read:
- 16 735.534. (1) As used in this section:
  - (a)(A) "Generally available for purchase" means a drug is available for purchase by similarly situated pharmacies 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) Is dispensed by an institutional drug outlet, as defined in ORS 689.005;
  - (ii) Is available at a price that is at or below the maximum allowable cost only if purchased in quantities that materially exceed the dispensing needs of similarly situated pharmacies;
  - (iii) Is available at a price that is at or below the maximum allowable cost only if purchased at a discount due to a short expiration date on the drug; or
    - (iv) Is the subject of a recall notice.
  - [(a)] (b) "List" means the list of drugs for which maximum allowable costs have been established.
  - [(b)] (c) "Maximum allowable cost" means the maximum amount that a pharmacy benefit manager will reimburse a pharmacy for the cost of a drug.
  - [(c)] (d) "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) "Similarly situated pharmacies" means pharmacies that:
    - (A) Are located in this state;
  - (B) Are similar in size and in the same type of trade, such as independent, retail chain, supermarket, mass merchandiser, mail order or specialty; and
  - (C) Have contracted with a pharmacy benefit manager on the same terms.
- 41 [(e)] (f) "Therapeutically equivalent" has the meaning given that term in ORS 689.515.
  - (2) A pharmacy benefit manager registered under ORS 735.532:
  - (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 **generally** available **for purchase** [from only one manufacturer, generally available for purchase by network pharmacies from national or regional

1 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] no drug on a list [are not] 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 [sources utilized] specific authoritative industry sources, other than proprietary sources, the pharmacy benefit manager uses to determine the maximum allowable cost [pricing of] set by 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.]:
  - (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;
    - (ii) The maximum allowable cost; and
    - (iii) The date and time when the maximum allowable cost goes into effect.
    - (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] 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 for dispensing a prescription drug at a rate that is lower than the rate paid to other network pharmacies for dispensing the prescription drug.
    - (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.
    - [(3)] (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. 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] the reimbursement paid by the pharmacy benefit manager if the reimbursement is less than the pharmacy's net cost of the drug as reflected on the invoice from the supplier of the drug. The process must allow a pharmacy no less than 60 days after the claim is reimbursed to file the appeal.

- (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 acting on behalf of the network pharmacy;
- (b) Refuse to accept an appeal for the reason that the appeal is submitted along with other claims or appeals; or
- (c) Impose requirements or establish procedures that have the effect of unduly obstructing or delaying an appeal.
- [(4)] (6) A pharmacy benefit manager must provide as part of the appeals process established under subsection [(3)] (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[,]:

- (A) The reason for the denial and the national drug code of a multiple source drug or generic drug that may be purchased by similarly situated pharmacies at a price that is [equal to or less than] at or below the maximum allowable cost.
- (B) If the reason for the denial is that the drug was generally available for purchase at a price that was at or below the maximum allowable cost, the location where the drug was available at that price when the claim for reimbursement was submitted by the network pharmacy.
- [(5)(a)] (7)(a) If an appeal is upheld under this section, the pharmacy benefit manager shall [make an adjustment for the pharmacy that requested the appeal from the date of initial adjudication forward]:
  - (A) Reimburse the network pharmacy's claim as submitted;
- (B) Allow the network pharmacy to submit an adjusted claim and reimburse the adjusted claim without any additional charges; and
- (C) For all subsequent claims for reimbursement of the cost of the drug submitted by the network pharmacy and all similarly situated pharmacies under the same ownership as the network pharmacy, pay the pharmacy's net cost for the drug as reflected on the invoice from the supplier of the drug.
- (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)] (8) This section does not apply to the state medical assistance program.
- (9) The Department of Consumer and Business Services shall adopt rules to carry out the provisions of this section.
- SECTION 5. Section 2 of this 2019 Act and the amendments to ORS 735.530 and 735.534 by sections 3 and 4 of this 2019 Act apply to pharmacy benefits and to contracts between pharmacies or pharmacists and pharmacy benefit managers entered into, renewed or extended on or after the effective date of this 2019 Act.