

# D R A F T

## SUMMARY

Digest: The Act requires PBMs to be licensed and changes the definition of a PBM. The Act changes how drug stores can appeal the amounts that a PBM pays the drug store for drugs sold by the drug store. The Act changes the way PBMs can audit drug stores. The Act requires PBMs to report certain information each year to DCBS. The Act requires health insurance policies to allow the individuals covered by the policies to choose their own drug store or druggist. The Act requires insurers that offer health insurance to contract with any drug store that is willing to agree to the terms of the insurance contract. The Act makes changes to the way 340B drugs are covered by insurance. (Flesch Readability Score: 67.4).

Requires pharmacy benefit managers to be licensed by the Department of Consumer and Business Services beginning January 1, 2025. Modifies the definition of “pharmacy benefit manager” and imposes new requirements on pharmacy benefit managers. Modifies the procedures for a pharmacy to appeal the payment made by a pharmacy benefit manager on a claim for reimbursement. Restricts audits of pharmacy claims for reimbursement.

Requires pharmacy benefit managers to report specified information to the department on an annual basis.

Requires policies or certificates of health insurance and contracts providing for the reimbursement of the cost of prescription drugs to allow a policyholder, certificate holder and beneficiary to select a pharmacy or pharmacist for filling prescriptions and for prescription renewals. Requires policies, certificates and contracts to contract with any pharmacy or pharmacist willing to abide by the terms and conditions of the policy, certificate or contract. Imposes new requirements with respect to the insurance coverage of 340B drugs.

Declares an emergency, effective on passage.

## A BILL FOR AN ACT

1

2 Relating to pharmacy benefits; creating new provisions; amending ORS

3 646A.694, 735.530, 735.532, 735.533, 735.534, 735.536, 735.537, 735.540, 735.542

1 and 743A.062; and declaring an emergency.

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

3 **SECTION 1. Sections 2 and 3 of this 2024 Act are added to and made**  
4 **a part of ORS 735.530 to 735.552.**

5 **SECTION 2. (1) As used in this section, “pharmacy services admin-**  
6 **istrative organization” means an entity that:**

7 **(a) Contracts with a pharmacy to act as the pharmacy’s agent with**  
8 **respect to matters involving a pharmacy benefit manager, third party**  
9 **payer or other entity, including by negotiating, executing or adminis-**  
10 **tering contracts with the pharmacy benefit manager, third party payer**  
11 **or other entity; and**

12 **(b) Provides administrative services to pharmacies.**

13 **(2) Upon the request of the Department of Consumer and Business**  
14 **Services, a pharmacy benefit manager shall submit to the department**  
15 **the pharmacy benefit manager’s contracts and amendments to con-**  
16 **tracts with pharmacies or pharmacy services administrative organiza-**  
17 **tions and the pharmacy benefit manager’s provider manuals.**

18 **(3) Contracts, contract amendments and provider manuals submit-**  
19 **ted to the department under this section are exempt from disclosure**  
20 **under ORS 192.311 to 192.478.**

21 **SECTION 3. Nothing in ORS 735.530 to 735.552 regulates health**  
22 **benefit plans, as defined in ORS 743B.005.**

23 **SECTION 4. (1) No later than December 31, 2025, the Oregon Health**  
24 **Authority, in consultation with the Prescription Drug Affordability**  
25 **Board, shall establish by rule dispensing fees to be paid by pharmacy**  
26 **benefit managers under ORS 735.534 (2)(j) for prescription drugs that**  
27 **are not covered by the medical assistance program.**

28 **(2) Until the authority has adopted a dispensing fee by rule, the**  
29 **dispensing fee paid by a pharmacy benefit manager under ORS 735.534**  
30 **(2)(j) for the dispensing of a prescription drug that is not covered by**  
31 **the medical assistance program may be no less than \$10.**

1       **SECTION 5.** ORS 735.530 is amended to read:

2       735.530. As used in ORS 735.530 to 735.552:

3       (1) “Claim” means a request from a pharmacy or pharmacist to be reim-  
4       bursed for the cost of filling or refilling a prescription for a drug or for  
5       providing a medical supply or service.

6       (2) “Enrollee” means an individual who has enrolled for coverage in a  
7       health benefit plan for which a pharmacy benefit manager has contracted  
8       with the insurer to reimburse claims submitted by pharmacies or pharmacists  
9       for the costs of drugs prescribed for the individual.

10       (3) “Health benefit plan” has the meaning given that term in ORS  
11       743B.005.

12       (4) “Insurer” has the meaning given that term in ORS 731.106.

13       (5) “Long term care pharmacy” means a pharmacy for which the primary  
14       business is to serve a:

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

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

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

18       (6) “Mail order pharmacy” means a pharmacy for which the primary  
19       business is to receive prescriptions by mail, telephone or electronic trans-  
20       mission and dispense drugs to patients through the use of the United States  
21       Postal Service, a package delivery service or home delivery.

22       (7) “Network pharmacy” means a pharmacy that contracts with a phar-  
23       macy benefit manager.

24       (8) “Pharmacist” has the meaning given that term in ORS 689.005.

25       (9) “Pharmacy” includes:

26       (a) A pharmacy as defined in ORS 689.005;

27       (b) A long term care pharmacy; and

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

30       (10) “Pharmacy benefit” means the payment for or reimbursement of an  
31       enrollee’s cost for prescription drugs.

1 (11)(a) “Pharmacy benefit manager” means a person that contracts with  
2 pharmacies on behalf of [*an insurer offering a health benefit plan, a third*  
3 *party administrator*] **an insurer, entities that accept risk, third-party**  
4 **payers of claims, coordinated care organizations as defined in ORS**  
5 **414.025, an employer who is self-insured** or the Oregon Prescription Drug  
6 Program established in ORS 414.312 to:

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

9 (B) Pay pharmacies or pharmacists for prescription drugs or medical  
10 supplies; [*or*]

11 (C) Negotiate rebates, **discounts or other financial incentives or ar-**  
12 **rangements** with manufacturers for drugs paid for or procured as described  
13 in this paragraph;

14 (D) **Receive payments for pharmacy services;**

15 (E) **Disburse or distribute rebates;**

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

18 (G) **Negotiate or enter into contracts with pharmacies;**

19 (H) **Develop formularies;**

20 (I) **Design pharmacy benefit programs; or**

21 (J) **Advertise or promote pharmacy services.**

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

24 (12) **“Pharmacy services” means the provision of products, goods**  
25 **or services in the course of the practice of pharmacy.**

26 [(12)] (13) “Specialty drug” means a drug that:

27 (a) Is subject to restricted distribution by the United States Food and  
28 Drug Administration; or

29 (b) Requires special handling, provider coordination or patient education  
30 that cannot be provided by a retail pharmacy.

31 [(13)] (14) “Specialty pharmacy” means a pharmacy capable of meeting the

1 requirements applicable to specialty drugs.

2 [(14)] (15) “Third party administrator” means a person licensed under ORS  
3 744.702.

4 [(15)] (16) “340B pharmacy” means a pharmacy that is authorized to pur-  
5 chase drugs at a discount under 42 U.S.C. 256b.

6 **SECTION 6.** ORS 735.532 is amended to read:

7 735.532. [(1) *To conduct business in this state, a pharmacy benefit manager*  
8 *must register with the Department of Consumer and Business Services and*  
9 *annually renew the registration.*]

10 [(2) *To register under this section, a pharmacy benefit manager must:*]

11 (1) **A person may not transact business or purport to transact**  
12 **business in this state as a pharmacy benefit manager unless the per-**  
13 **son has a license to transact business as a pharmacy benefit manager**  
14 **issued by the Department of Consumer and Business Services.**

15 (2) **To obtain a license under this section, a person must:**

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

18 (b) Pay a [*registration*] fee in an amount adopted by the department by  
19 rule.

20 (3) **A license to transact business as a pharmacy benefit manager**  
21 **must be renewed every 12 months.** To renew a [*registration*] **license** under  
22 this [*section*] **subsection**, a pharmacy benefit manager must pay a renewal  
23 fee in an amount adopted by the department by rule.

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

26 (5) Any fee adopted by the department under this section must be [*based*  
27 *on*] **sufficient to pay** the department’s reasonable costs in administering  
28 ORS 735.530 to 735.552.

29 **SECTION 7.** ORS 735.533 is amended to read:

30 735.533. (1) In accordance with ORS chapter 183, the Department of Con-  
31 sumer and Business Services may deny an application for [*registration*] **a li-**

1 **cense to transact business** as a pharmacy benefit manager or **deny** an  
2 application for renewal of a [*registration*] **license to transact business** as  
3 a pharmacy benefit manager, and may suspend or revoke a [*registration*] a  
4 **license to transact business** as a pharmacy benefit manager, if the de-  
5 partment finds that an applicant or [*registrant*] **licensee**:

6 (a) Falsified an application for [*registration*] **a license** or for the renewal  
7 of a [*registration*] **license** or engaged in any dishonest act in relation to the  
8 application;

9 (b) Engaged in dishonesty, fraud or gross negligence in the conduct of  
10 business as a pharmacy benefit manager;

11 (c) Engaged in conduct that resulted in a conviction of a felony under the  
12 laws of any state or of the United States, to the extent that such conduct  
13 may be considered under ORS 670.280;

14 (d) Was convicted under the laws of any state or of the United States of  
15 any crime of which an essential element is dishonesty or fraud;

16 (e) Had a certificate of authority or authority to conduct business as a  
17 pharmacy benefit manager denied, revoked or suspended in another state;

18 (f) Failed to pay a civil penalty imposed by final order of the department  
19 or to comply with the terms of suspension set by the department;

20 (g) Failed to meet the terms of a consent decree approved by a court of  
21 competent jurisdiction in this state, or a consent order made between the  
22 department and the pharmacy benefit manager;

23 (h) Refused to be examined or to produce accounts, records or files for  
24 examination, including the refusal by any officer of the applicant or [*regis-*  
25 *trant*] **licensee** to give information with respect to the affairs of the phar-  
26 macy benefit manager, or refused to perform any other legal obligation with  
27 respect to an examination by the department; or

28 (i) Violated any [*rule or order of the department or any*] provision of the  
29 Insurance Code, **any rule adopted by the department pursuant to the**  
30 **Insurance Code or any order of the department.**

31 (2) The department may prescribe by rule a procedure by which a phar-

1 macy or an entity acting on behalf of a pharmacy may file a complaint with  
2 the department alleging that a pharmacy benefit manager has engaged in  
3 conduct [*described in this section*] **in violation of ORS 735.530 to 735.552.**  
4 The department may restrict the right of a pharmacy or entity to file a  
5 complaint only to the extent necessary to prevent abuse of the complaint  
6 process.

7 **SECTION 8.** ORS 735.534 is amended to read:

8 735.534. (1) As used in this section:

9 (a)(A) “Generally available for purchase” means a drug is available for  
10 purchase in this state by a pharmacy from a national or regional wholesaler  
11 at the time a claim for reimbursement is submitted by a network pharmacy.

12 (B) A drug is not “generally available for purchase” if the drug:

13 (i) May be dispensed only in a hospital or inpatient care facility;

14 (ii) Is unavailable due to a shortage of the product or an ingredient;

15 (iii) Is available to a pharmacy at a price that is at or below the maxi-  
16 mum allowable cost only if purchased in substantial quantities that are in-  
17 consistent with the business needs of a pharmacy;

18 (iv) Is sold at a discount due to a short expiration date on the drug; or

19 (v) Is the subject of an active or pending recall.

20 (b) “List” means the list of drugs for which maximum allowable costs  
21 have been established.

22 (c) “Maximum allowable cost” means the maximum amount that a phar-  
23 macy benefit manager will reimburse a pharmacy for the cost of a drug.

24 (d) “Multiple source drug” means a therapeutically equivalent drug that  
25 is available from at least two manufacturers.

26 (e) “Therapeutically equivalent” has the meaning given that term in ORS  
27 689.515.

28 (2) A pharmacy benefit manager [*registered*] **licensed** under ORS 735.532:

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

31 (b) Shall ensure that all drugs on a list are generally available for pur-

1 chase.

2 (c) Shall ensure that no drug on a list is obsolete.

3 (d) Shall make available to each network pharmacy at the beginning of  
4 the term of a contract, and upon renewal of a contract, the specific author-  
5 itative industry sources, other than proprietary sources, the pharmacy bene-  
6 fit manager uses to determine the maximum allowable cost set by the  
7 pharmacy benefit manager.

8 (e) Shall make a list available to a network pharmacy upon request in a  
9 format that:

10 (A) Is electronic;

11 (B) Is computer accessible and searchable;

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

14 (D) For each drug specifies:

15 (i) The national drug code; and

16 (ii) The maximum allowable cost.

17 (f) Shall update each list maintained by the pharmacy benefit manager  
18 every seven business days and make the updated lists, including all changes  
19 in the price of drugs, available to network pharmacies in the format de-  
20 scribed in paragraph (e) of this subsection.

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

23 (h) May not reimburse a 340B pharmacy differently than any other net-  
24 work pharmacy based on its status as a 340B pharmacy.

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

26 **(j) Shall pay a professional dispensing fee in an amount no less than**  
27 **the dispensing fee established by the Oregon Health Authority by rule**  
28 **to a:**

29 **(A) Critical access pharmacy; and**

30 **(B) A pharmacy, other than a pharmacy that caters primarily to**  
31 **veterinary customers, that has nine or fewer locations under common**



1 **ownership in this state.**

2 [(i)] **(k)** May not retroactively deny or reduce payment on a claim for  
3 reimbursement of the cost of services after the claim has been adjudicated  
4 by the pharmacy benefit manager unless the:

5 (A) Adjudicated claim was submitted fraudulently;

6 (B) Pharmacy benefit manager's payment on the adjudicated claim was  
7 incorrect because the pharmacy had already been paid for the services;

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

10 [(D) *Pharmacy agrees to the denial or reduction prior to the pharmacy*  
11 *benefit manager notifying the pharmacy that the claim has been denied or re-*  
12 *duced; or]*

13 [(E)] **(D)** [*The*] Payment was incorrect due to an error that the pharmacy  
14 and pharmacy benefit manager agree was a clerical error.

15 [(j)] **(L)** May not impose a fee on a pharmacy after the point of sale.

16 [(k)] **(m)** Shall provide notice to a pharmacy of any claim for reimburse-  
17 ment of the cost of a prescription drug that is denied or reduced. The notice  
18 shall identify the specific disaggregated claim that was denied or reduced  
19 and a detailed explanation for why the specific claim was denied or reduced.

20 (3) Subsection [(2)(i)] **(2)(k)** of this section may not be construed to limit  
21 pharmacy claim audits under ORS 735.540 to 735.552.

22 (4) A pharmacy benefit manager must establish a process by which a  
23 network pharmacy may appeal its reimbursement for a drug [*subject to max-*  
24 *imum allowable cost pricing*]. A network pharmacy may appeal [*a maximum*  
25 *allowable cost if*] the reimbursement for the drug **if the reimbursement** is  
26 less than the [*net amount that the network pharmacy paid to the supplier of*  
27 *the drug*] **dispensing fee described in subsection (2)(j) of this section.**  
28 The process must allow a network pharmacy a period of no less than 60 days  
29 after a claim is reimbursed in which to file the appeal. An appeal requested  
30 under this section must be completed within 30 calendar days of the phar-  
31 macy making the claim for which appeal has been requested.

1 (5) A pharmacy benefit manager shall allow a network pharmacy to sub-  
2 mit the documentation in support of its appeal on paper or electronically and  
3 may not:

4 (a) Refuse to accept an appeal submitted by a person authorized to act  
5 on behalf of the network pharmacy;

6 (b) Refuse to adjudicate an appeal for the reason that the appeal is sub-  
7 mitted along with other claims that are denied; or

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

10 (6) A pharmacy benefit manager must provide as part of the appeals pro-  
11 cess established under subsection (4) of this section:

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

15 (b) A final response to an appeal of [*a maximum allowable cost*] **the re-**  
16 **imbursement for a drug** within seven business days; and

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

20 (7)(a) If an appeal is upheld under this section, the pharmacy benefit  
21 manager shall:

22 (A) Make an adjustment for the pharmacy that requested the appeal from  
23 the date of initial adjudication forward; and

24 (B) Allow the pharmacy to reverse the claim and resubmit an adjusted  
25 claim without any additional charges.

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

31 [(8) *This section does not apply to the state medical assistance program.*]

1       **(8) A pharmacy may file a complaint with the Department of Con-**  
2 **sumer and Business Services to contest a finding of a pharmacy ben-**  
3 **efit manager in response to an appeal under subsection (4) of this**  
4 **section or a pharmacy benefit manager’s failure to comply with the**  
5 **provisions of this section.**

6       (9) The Department of Consumer and Business Services may adopt rules  
7 to carry out the provisions of this section.

8       **SECTION 9.** ORS 735.536 is amended to read:

9       735.536. (1) As used in this section, “out-of-pocket cost” means the amount  
10 paid by an enrollee under the enrollee’s coverage, including deductibles,  
11 copayments, coinsurance or other expenses as prescribed by the Department  
12 of Consumer and Business Services by rule.

13       (2) A pharmacy benefit manager [*registered*] **licensed** under ORS 735.532:

14       (a) May not require a prescription to be filled or refilled by a mail order  
15 pharmacy as a condition for reimbursing the cost of the drug.

16       (b) Except as provided in paragraph (c) of this subsection, may require a  
17 prescription for a specialty drug to be filled or refilled at a specialty phar-  
18 macy as a condition for the reimbursement of the cost of a drug.

19       (c) Shall reimburse the cost of a specialty drug that is filled or refilled  
20 at a network pharmacy that is a long term care pharmacy.

21       (d)(A) Shall allow a network pharmacy to mail, ship or deliver pre-  
22 scription drugs to its patients as an ancillary service.

23       (B) Is not required to reimburse a delivery fee charged by a pharmacy for  
24 a delivery described in subparagraph (A) of this paragraph unless the fee is  
25 specified in the contract between the pharmacy benefit manager and the  
26 pharmacy.

27       (e) May not require a patient signature as proof of delivery of a mailed  
28 or shipped prescription drug if the network pharmacy:

29       (A)(i) Maintains a mailing or shipping log signed by a representative of  
30 the pharmacy; or

31       (ii) Maintains each notification of delivery provided by the United States

1 Postal Service or a package delivery service; and

2 (B) Is responsible for the cost of mailing, shipping or delivering a re-  
3 placement for a drug that was mailed or shipped but not received by the  
4 enrollee.

5 (f) May not penalize a network pharmacy **by imposing charges or fees,**  
6 **requiring contract amendments, canceling or terminating contracts**  
7 **or demanding recoupment or otherwise retaliate against a network**  
8 **pharmacy for:** [*or otherwise directly or indirectly prevent a network pharmacy*  
9 *from*]

10 (A) Informing an enrollee of the difference between the out-of-pocket cost  
11 to the enrollee to purchase a prescription drug using the enrollee's pharmacy  
12 benefit and the pharmacy's usual and customary charge for the prescription  
13 drug[.];

14 (B) **Filing an appeal;**

15 (C) **Filing a complaint against the pharmacy benefit manager with**  
16 **the Department of Consumer and Business Services;**

17 (D) **Engaging in the legislative process; or**

18 (E) **Challenging the pharmacy benefit manager's practices or**  
19 **agreements.**

20 (g) **May not charge a fee to a pharmacy for submitting claims or**  
21 **for the adjudication of claims.**

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

24 **SECTION 10.** ORS 735.537 is amended to read:

25 735.537. (1) As used in this section:

26 (a) **“Administrative fee” means the administrative and service fees**  
27 **charged by pharmacy benefit managers to manufacturers and carriers**  
28 **that are typically a percentage of the list price of a prescription drug.**

29 [(a)] (b) “Carrier” has the meaning given that term in ORS 743B.005.

30 [(b)] (c) “Manufacturer” has the meaning given that term in ORS  
31 646A.689.

1 [(c)] (d) “Prescription drug” has the meaning given that term in ORS  
2 646A.689.

3 (e) **“Spread pricing” means the difference between the amount an**  
4 **insurer pays a pharmacy benefit manager and the amount that the**  
5 **pharmacy benefit manager reimburses a pharmacy for a beneficiary’s**  
6 **prescription.**

7 (2) Not later than June 1 of each calendar year, a pharmacy benefit  
8 manager [*registered*] **licensed** under ORS 735.532 shall file a report with the  
9 Department of Consumer and Business Services. The report must contain,  
10 for the immediately preceding calendar year[,]:

11 (a) The aggregated dollar amount of rebates, fees, price protection pay-  
12 ments and any other payments the pharmacy benefit manager received from  
13 manufacturers:

14 [(a)] (A) Related to managing the pharmacy benefits for carriers issuing  
15 health benefit plans in this state; and

16 [(b)] (B) That were:

17 [(A)] (i) Passed on to carriers issuing health benefit plans in this state  
18 or enrollees at the point of sale of a prescription drug in this state; or

19 [(B)] (ii) Retained as revenue by the pharmacy benefit manager.

20 (b) **The total dispensing fees paid to the pharmacy benefit manager**  
21 **and to pharmacies.**

22 (c) **The total administrative fees obtained and retained from man-**  
23 **ufacturers and carriers.**

24 (d) **Moneys obtained through spread pricing, pay-for-performance**  
25 **or similar means.**

26 (e) **Deidentified claims data.**

27 (3) The report described in subsection (2) of this section may not disclose:

28 (a) The identity of a carrier or an enrollee;

29 (b) The price charged for a specific prescription drug or class of drugs;

30 or

31 (c) The amount of any rebate or fee provided for a specific prescription

1 drug or class of prescription drugs.

2 (4) Information submitted to the department under this section is confi-  
3 dential and not subject to disclosure except as provided in subsection (5) of  
4 this section and ORS 705.137.

5 (5) Not later than October 1 of each calendar year, the department shall  
6 publish on the department's website the aggregated data from all reports  
7 filed by pharmacy benefit managers under this section for the preceding  
8 calendar year. The department shall publish the data in a manner that does  
9 not disclose confidential information of pharmacy benefit managers.

10 **SECTION 11.** ORS 735.540 is amended to read:

11 735.540. As used in ORS 735.540 to 735.552:

12 (1) "Audit" means an on-site or remote review of the records of a phar-  
13 macy, **or a request for records from a pharmacy for the purpose of an**  
14 **audit**, by or on behalf of an entity.

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

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

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

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

21 (3) "Entity" includes:

22 (a) A pharmacy benefit manager;

23 (b) An insurer;

24 (c) A third party administrator;

25 (d) A state agency; or

26 (e) A person that represents or is employed by one of the entities de-  
27 scribed in this subsection.

28 (4) "Fraud" means knowingly and willfully executing or attempting to  
29 execute a scheme, in connection with the delivery of or payment for health  
30 care benefits, items or services, that uses false or misleading pretenses, re-  
31 presentations or promises to obtain any money or property owned by or un-

1 der the custody or control of any person.

2 **SECTION 12.** ORS 735.542 is amended to read:

3 735.542. An entity that audits claims or an independent third party that  
4 contracts with an entity to audit claims:

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

9 **(2) Must submit requests for records from a pharmacy for the pur-**  
10 **pose of an audit by:**

11 **(a) Electronic mail; and**

12 **(b) Facsimile or certified mail;**

13 [(2)] **(3)** May not conduct an audit of a claim more than [24] **12** months  
14 after the date the claim was adjudicated by the entity;

15 [(3)] **(4)** Must give at least 15 days' advance written notice of an on-site  
16 audit to the pharmacy or corporate headquarters of the pharmacy **by elec-**  
17 **tronic mail;**

18 [(4)] **(5)** May not conduct an on-site audit during the first five days of any  
19 month without the pharmacy's consent;

20 [(5)] **(6)** Must conduct the audit in consultation with a pharmacist who  
21 is licensed by this or another state if the audit involves clinical or profes-  
22 sional judgment;

23 [(6)] **(7)(a)** May not [*conduct an on-site*] audit, [*of more than 250 unique*  
24 *prescriptions of a pharmacy*] in any 12-month period [*except in cases of alleged*  
25 *fraud;*], **more than:**

26 **(A) 250 unique prescriptions during an on-site audit; or**

27 **(B) 250 unique prescriptions through a remote audit.**

28 **(b) The limits on the number of drugs that may be audited de-**  
29 **scribed in paragraph (a) of this subsection do not include an audit**  
30 **conducted by a pharmacy benefit manager resulting from a reasonable**  
31 **suspicion by the pharmacy benefit manager of fraud, waste or abuse**

1 **supported by preliminary evidence that the pharmacy benefit manager**  
2 **produces for the pharmacy.**

3 [(7)] (8) May not conduct more than one on-site audit of a pharmacy in  
4 any 12-month period;

5 **(9) Must give a pharmacy at least 30 days to respond to an audit;**

6 [(8)] (10) Must audit each pharmacy under the same standards and pa-  
7 rameters that the entity uses to audit other similarly situated pharmacies;

8 [(9)] (11) Must pay any outstanding claims of a pharmacy no more than  
9 45 days after the earlier of the date all appeals are concluded or the date a  
10 final report is issued under ORS 735.550 (3);

11 [(10)] (12) May not include dispensing fees or interest in the amount of  
12 any overpayment assessed on a claim unless the overpaid claim was for a  
13 prescription that was not filled correctly;

14 [(11)] (13) May not recoup costs associated with:

15 (a) Clerical errors; or

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

18 [(12)] (14) May not charge a pharmacy for a denied or disputed claim until  
19 the audit and the appeals procedure established under subsection (1) of this  
20 section are final.

21 **SECTION 13.** ORS 743A.062 is amended to read:

22 743A.062. (1) As used in this section[,]:

23 (a) “Medical assistance program” means the state program that provides  
24 medical assistance as defined in ORS 414.025.

25 (b) “**340B drug**” means a covered drug dispensed by a covered entity,  
26 as those terms are defined in 42 U.S.C. 256b, that is subject to the cap  
27 on amounts required to be paid in 42 U.S.C. 256b(a)(1).

28 (2) [*An insurance policy or*] **A policy or certificate of health insurance**  
29 **or other** contract providing [*coverage for*] **for the reimbursement of the**  
30 **cost of** a prescription drug to a resident of this state [*may not*]:

31 (a) **May not** exclude coverage of the drug for a particular indication



1 solely on the grounds that the indication has not been approved by the  
2 United States Food and Drug Administration if the Health Evidence Review  
3 Commission established under ORS 414.688 or the Pharmacy and  
4 Therapeutics Committee established under ORS 414.353 determines that the  
5 drug is recognized as effective for the treatment of that indication:

6 (A) In publications that the commission or the committee determines to  
7 be equivalent to:

8 (i) The American Hospital Formulary Service drug information;

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

10 (iii) The United States Pharmacopoeia drug information; or

11 (iv) Other publications that have been identified by the United States  
12 Secretary of Health and Human Services as authoritative;

13 (B) In the majority of relevant peer-reviewed medical literature; or

14 (C) By the United States Secretary of Health and Human Services; [or]

15 (b) For an insured who is enrolled in the medical assistance program,  
16 **may not:**

17 (A) Except as provided in subsection (3) of this section, require a pre-  
18 scription for the drug to be filled or refilled at a mail order pharmacy; or

19 (B) Require a prescription for the drug to be filled or refilled at a phar-  
20 macy that is not a local pharmacy enrolled in the medical assistance  
21 program[.];

22 **(c) Must permit the policyholder, certificate holder or beneficiary,**  
23 **at the time of issuance, amendment or renewal, to select a licensed**  
24 **pharmacy or licensed pharmacist for the dispensing of prescription**  
25 **drugs reimbursed by the policy, certificate or contract;**

26 **(d) May not deny a pharmacy or pharmacist licensed in this state**  
27 **the opportunity to participate as a preferred provider or a contracting**  
28 **provider under the same terms and conditions applicable to all other**  
29 **preferred or contracting providers if the pharmacy or pharmacist**  
30 **agrees to the terms and conditions;**

31 **(e) May not discriminate in the reimbursement of a prescription for**

1 **340B drugs from other prescription drugs;**

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

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

6 (h) **May not restrict the methods by which a 340B drug may be**  
7 **dispensed or delivered; or**

8 (i) **May not restrict the number of pharmacies within a pharmacy**  
9 **network that may dispense or deliver 340B drugs.**

10 (3) Subsection (2)(b)(A) of this section does not prohibit an insurer from  
11 requiring a medical assistance recipient to fill or refill a prescription for a  
12 specialty drug at a mail order pharmacy that is a specialty pharmacy.

13 (4) Required coverage of a prescription drug under this section shall in-  
14 clude coverage for medically necessary services associated with the admin-  
15 istration of that drug.

16 (5) Nothing in this section requires coverage for any prescription drug if  
17 the United States Food and Drug Administration has determined use of the  
18 drug to be contraindicated.

19 (6) Nothing in this section requires coverage for experimental drugs not  
20 approved for any indication by the United States Food and Drug Adminis-  
21 tration.

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

24 [(7)] (8) This section is exempt from ORS 743A.001.

25 **SECTION 14.** ORS 646A.694 is amended to read:

26 646A.694. (1) The Department of Consumer and Business Services shall  
27 provide to the Prescription Drug Affordability Board each calendar quarter  
28 a list of prescription drugs included in reports submitted to the department  
29 under ORS 646A.689 (2) and (6), a list of drugs included in reports submitted  
30 to the department under ORS 646A.683 and 743.025 and a list of insulin drugs  
31 marketed in this state during the previous calendar year. Each calendar

1 year, the board shall identify nine drugs and at least one insulin product  
2 from the lists provided under this subsection that the board determines may  
3 create affordability challenges for health care systems or high out-of-pocket  
4 costs for patients in this state based on criteria adopted by the board by rule,  
5 including but not limited to:

6 (a) Whether the prescription drug has led to health inequities in commu-  
7 nities of color;

8 (b) The number of residents in this state prescribed the prescription drug;

9 (c) The price for the prescription drug sold in this state;

10 (d) The estimated average monetary price concession, discount or rebate  
11 the manufacturer provides to health insurance plans in this state or is ex-  
12 pected to provide to health insurance plans in this state, expressed as a  
13 percentage of the price for the prescription drug under review;

14 (e) The estimated total amount of the price concession, discount or rebate  
15 the manufacturer provides to each pharmacy benefit manager [*registered*] **li-**  
16 **censed** in this state for the prescription drug under review, expressed as a  
17 percentage of the prices;

18 (f) The estimated price for therapeutic alternatives to the drug that are  
19 sold in this state;

20 (g) The estimated average price concession, discount or rebate the man-  
21 ufacturer provides or is expected to provide to health insurance plans and  
22 pharmacy benefit managers in this state for therapeutic alternatives;

23 (h) The estimated costs to health insurance plans based on patient use  
24 of the drug consistent with the labeling approved by the United States Food  
25 and Drug Administration and recognized standard medical practice;

26 (i) The impact on patient access to the drug considering standard pre-  
27 scription drug benefit designs in health insurance plans offered in this state;

28 (j) The relative financial impacts to health, medical or social services  
29 costs as can be quantified and compared to the costs of existing therapeutic  
30 alternatives;

31 (k) The estimated average patient copayment or other cost-sharing for the

1 prescription drug in this state;

2 (L) Any information a manufacturer chooses to provide; and

3 (m) Any other factors as determined by the board in rules adopted by the  
4 board.

5 (2) A drug that is designated by the Secretary of the United States Food  
6 and Drug Administration, under 21 U.S.C. 360bb, as a drug for a rare disease  
7 or condition is not subject to review under subsection (1) of this section.

8 (3) The board shall accept testimony from patients and caregivers affected  
9 by a condition or disease that is treated by a prescription drug under review  
10 by the board and from individuals with scientific or medical training with  
11 respect to the disease or condition.

12 (4)(a) If the board considers the cost-effectiveness of a prescription drug  
13 in criteria adopted by the board under subsection (1) of this section, the  
14 board may not use quality-adjusted life-years, or similar formulas that take  
15 into account a patient's age or severity of illness or disability, to identify  
16 subpopulations for which a prescription drug would be less cost-effective. For  
17 any prescription drug that extends life, the board's analysis of cost-  
18 effectiveness must weigh the value of the quality of life equally for all pa-  
19 tients, regardless of the patients' age or severity of illness or disability.

20 (b) As used in this subsection:

21 (A) "Health utility" means a measure of the degree to which having a  
22 particular form of disease or disability or having particular functional limi-  
23 tations negatively impacts the quality of life as compared to a state of per-  
24 fect health, expressed as a number between zero and one.

25 (B) "Quality-adjusted life-year" is the product of a health utility multi-  
26 plied by the extra months or years of life that a patient might gain as a re-  
27 sult of a treatment.

28 (5) To the extent practicable, the board shall access pricing information  
29 for prescription drugs by:

30 (a) Accessing pricing information collected by the department under ORS  
31 646A.689 and 743.025;

1 (b) Accessing data reported to the Oregon Health Authority under ORS  
2 442.373;

3 (c) Entering into a memorandum of understanding with another state to  
4 which manufacturers already report pricing information; and

5 (d) Accessing other publicly available pricing information.

6 (6) The information used to conduct an affordability review may include  
7 any document and research related to the introductory price or price in-  
8 crease of a prescription drug, including life cycle management, net average  
9 price in this state, market competition and context, projected revenue and  
10 the estimated value or cost-effectiveness of the prescription drug.

11 (7) The department and the board shall keep strictly confidential any in-  
12 formation collected, used or relied upon for the review conducted under this  
13 section if the information is:

14 (a) Information submitted to the department by a manufacturer under  
15 ORS 646A.689; and

16 (b) Confidential, proprietary or a trade secret as defined in ORS 192.345.

17 **SECTION 15. No later than January 1, 2025, the Department of**  
18 **Consumer and Business Services shall hire at least one additional**  
19 **full-time employee to assist in the regulation of pharmacy benefit**  
20 **managers under ORS 735.530 to 735.552.**

21 **SECTION 16. The amendments to ORS 735.534, 735.536, 735.540 and**  
22 **735.542 by sections 8, 9, 11 and 12 of this 2024 Act apply to contracts**  
23 **between pharmacies and pharmacy benefit managers that are entered**  
24 **into, renewed, extended or automatically renewed on or after January**  
25 **1, 2025.**

26 **SECTION 17. (1) Sections 2 and 3 of this 2024 Act and the amend-**  
27 **ments to ORS 646A.694, 735.530, 735.532, 735.533, 735.534, 735.536, 735.537,**  
28 **735.540, 735.542 and 743A.062 by sections 5 to 14 of this 2024 Act become**  
29 **operative on January 1, 2025.**

30 **(2) The Department of Consumer and Business Services shall take**  
31 **all steps necessary before January 1, 2025, to carry out the amend-**

1 ments to ORS 735.532 and 735.533 by sections 6 and 7 of this 2024 Act  
2 on and after January 1, 2025.

3 **SECTION 18.** Notwithstanding any other law limiting expenditures,  
4 the amount of \$\_\_\_\_\_ is established for the biennium ending June  
5 30, 2025, as the maximum limit for payment of expenses from fees,  
6 moneys or other revenues, including Miscellaneous Receipts, but ex-  
7 cluding lottery funds and federal funds, collected or received by the  
8 Department of Consumer and Business Services for the purpose of  
9 carrying out sections 2 to 4 and 15 of this 2024 Act and the amend-  
10 ments to ORS 646A.694, 735.530, 735.532, 735.533, 735.534, 735.536, 735.537,  
11 735.540, 735.542 and 743A.062 by sections 5 to 14 of this 2024 Act.

12 **SECTION 19.** Section 15 of this 2024 Act is repealed on January 2,  
13 2025.

14 **SECTION 20.** This 2024 Act being necessary for the immediate  
15 preservation of the public peace, health and safety, an emergency is  
16 declared to exist, and this 2024 Act takes effect on its passage.

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