

House Bill 3013

Sponsored by Representative NATHANSON; Representatives DEXTER, GOODWIN, LEVY B, MORGAN, NOSSE, Senators DEMBROW, FINDLEY, HANSELL, PATTERSON, THATCHER (Pre-session 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**.

Requires pharmacy benefit managers to be licensed by Department of Consumer and Business Services beginning January 1, 2024, and imposes new requirements on pharmacy benefit managers.

Requires policies or certificates of health insurance and contracts providing for reimbursement of cost of prescription drugs to allow policyholder, certificate holder and beneficiary to select pharmacy or pharmacist for filling prescriptions and prescription renewals, to contract with any pharmacy or pharmacist willing to abide by terms and conditions of policy, certificate or contract. Prohibits, subject to exceptions, requirement for claim for reimbursement of prescription drug to include indicator that drug is 340B drug.

Appropriates moneys from General Fund to Department of Consumer and Business Services for purpose of employment assistance in regulation of pharmacy benefit managers.

Declares emergency, effective on passage.

A BILL FOR AN ACT

1
2 Relating to pharmacy benefits; creating new provisions; amending ORS 646A.694, 735.530, 735.532,
3 735.533, 735.534, 735.536, 735.540, 735.542 and 743A.062; and declaring an emergency.

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:

7 (1) "Claim" means a request from a pharmacy or pharmacist to be reimbursed for the cost of
8 filling or refilling a prescription for a drug or for providing a medical supply or service.

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

12 (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:

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

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

18 (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) **"Oregon Average Actual Acquisition Cost" means the rate established by the Oregon**
24 **Health Authority, in accordance with 42 C.F.R. 447.518, that represents the average invoice**
25 **amounts for individual drug products based on surveys conducted by or on behalf of the au-**

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.

thority of pharmacies that participate in the state medical assistance program.

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

[(9)] (10) “Pharmacy” includes:

(a) A pharmacy as defined in ORS 689.005;

(b) A pharmacist as defined in ORS 689.005;

[(b)] (c) A long term care pharmacy; and

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

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

[(11)(a)] (12)(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

(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)] (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.

[(13)] (14) “Specialty pharmacy” means a pharmacy capable of meeting the requirements applicable to specialty drugs.

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

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

(17) “Wholesale acquisition cost” has the meaning given that term in 42 U.S.C. 1395w-3a(c)(6)(B).

SECTION 2. ORS 735.532 is amended to read:

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

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

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

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

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

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

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

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

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

3 **SECTION 3.** ORS 735.533 is amended to read:

4 735.533. (1) In accordance with ORS chapter 183, the Department of Consumer and Business
 5 Services may deny an application for *[registration]* **a license to transact business** as a pharmacy
 6 benefit manager or **deny** an application for renewal of a *[registration]* **license to transact business**
 7 as a pharmacy benefit manager, and may suspend or revoke a *[registration]* **a license to transact**
 8 **business** as a pharmacy benefit manager, if the department finds that an applicant or *[registrant]*
 9 **licensee:**

10 (a) Falsified an application for *[registration]* **a license** or for the renewal of a *[registration]* **li-**
 11 **cence** or engaged in any dishonest act in relation to the application;

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

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

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

18 (e) Had a certificate of authority or authority to conduct business as a pharmacy benefit man-
 19 ager denied, revoked or suspended in another state;

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

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

24 (h) Refused to be examined or to produce accounts, records or files for examination, including
 25 the refusal by any officer of the applicant or *[registrant]* **licensee** to give information with respect
 26 to the affairs of the pharmacy 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 Insurance Code, **any**
 29 **rule adopted by the department pursuant to the Insurance Code or any order of the depart-**
 30 **ment.**

31 (2) The department may prescribe by rule a procedure by which a pharmacy or an entity acting
 32 on behalf of a pharmacy may file a complaint with the department alleging that a pharmacy benefit
 33 manager has engaged in conduct *[described in this section]* **in violation of ORS 735.530 to 735.552.**
 34 The department may restrict the right of a pharmacy or entity to file a complaint only to the extent
 35 necessary to prevent abuse of the complaint process.

36 **SECTION 4.** ORS 735.534 is amended to read:

37 735.534. (1) As used in this section:

38 (a)(A) "Generally available for purchase" means a drug is available for purchase in this state
 39 by a pharmacy from a national or regional wholesaler at the time a claim for reimbursement is
 40 submitted by a network pharmacy.

41 (B) A drug is not "generally available for purchase" if the drug:

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

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

44 (iii) Is available to a pharmacy at a price that is at or below the maximum allowable cost only
 45 if purchased in substantial quantities that are inconsistent with the business needs of a pharmacy;

- 1 (iv) Is sold at a discount due to a short expiration date on the drug; or
 2 (v) Is the subject of an active or pending recall.
- 3 (b) "List" means the list of drugs for which maximum allowable costs have been established.
- 4 (c) "Maximum allowable cost" means the maximum amount that a pharmacy benefit manager
 5 will reimburse a pharmacy for the cost of a drug.
- 6 (d) "Multiple source drug" means a therapeutically equivalent drug that is available from at
 7 least two manufacturers.
- 8 (e) "Therapeutically equivalent" has the meaning given that term in ORS 689.515.
- 9 (2) A pharmacy benefit manager [*registered*] **licensed** under ORS 735.532:
- 10 (a) May not place a drug on a list unless there are at least two multiple source drugs, or at least
 11 one generic drug generally available for purchase.
- 12 (b) Shall ensure that all drugs on a list are generally available for purchase.
- 13 (c) Shall ensure that no drug on a list is obsolete.
- 14 (d) Shall make available to each network pharmacy at the beginning of the term of a contract,
 15 and upon renewal of a contract, the specific authoritative industry sources, other than proprietary
 16 sources, the pharmacy benefit manager uses to determine the maximum allowable cost set by the
 17 pharmacy benefit manager.
- 18 (e) Shall make a list available to a network pharmacy upon request in a format that:
- 19 (A) Is electronic;
- 20 (B) Is computer accessible and searchable;
- 21 (C) Identifies all drugs for which maximum allowable costs have been established; and
- 22 (D) For each drug specifies:
- 23 (i) The national drug code; and
- 24 (ii) The maximum allowable cost.
- 25 (f) Shall update each list maintained by the pharmacy benefit manager every seven business days
 26 and make the updated lists, including all changes in the price of drugs, available to network phar-
 27 macies in the format described in paragraph (e) of this subsection.
- 28 (g) Shall ensure that dispensing fees are not included in the calculation of maximum allowable
 29 cost.
- 30 (h) May not reimburse a 340B pharmacy differently than any other network pharmacy based on
 31 its status as a 340B pharmacy.
- 32 (i) **Shall pay a solo network pharmacy or a network pharmacy chain with fewer than 100**
 33 **locations, a professional dispensing fee in an amount no less than the dispensing fee estab-**
 34 **lished by the Oregon Health Authority, in accordance with 42 C.F.R. 447.518, and reimburse**
 35 **the cost of the ingredients of the drug in an amount that is the lesser of, but in no event less**
 36 **than the fee-for-service rate paid by the authority in the medical assistance program:**
- 37 (A) **The pharmacy's usual charge to the public for the drug; and**
- 38 (B)(i) **The Oregon Average Actual Acquisition Cost;**
- 39 (ii) **If the drug is not listed on the Oregon Average Actual Acquisition Cost, the National**
 40 **Average Drug Acquisition Cost published by the Centers for Medicare and Medicaid Services;**
 41 **or**
- 42 (iii) **If the drug is not listed on the Oregon Average Actual Acquisition Cost or the Na-**
 43 **tional Average Drug Acquisition Cost, the wholesale acquisition cost.**
- 44 [(i)] (j) May not retroactively deny or reduce a claim for reimbursement of the cost of services
 45 after the claim has been adjudicated by the pharmacy benefit manager unless the:

1 (A) Adjudicated claim was submitted fraudulently;

2 (B) Pharmacy benefit manager's payment on the adjudicated claim was incorrect because the
3 pharmacy [or *pharmacist*] had already been paid for the services; **or**

4 (C) Services were [*improperly*] rendered by the pharmacy [*or pharmacist*] **in violation of state**
5 **or federal law**]; *or*]

6 [(D) *Pharmacy or pharmacist agrees to the denial or reduction prior to the pharmacy benefit*
7 *manager notifying the pharmacy or pharmacist that the claim has been denied or reduced*].

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

10 [(4) *A pharmacy benefit manager must establish a process by which a network pharmacy may ap-*
11 *peal its reimbursement for a drug subject to maximum allowable cost pricing. A network pharmacy*
12 *may appeal a maximum allowable cost if the reimbursement for the drug is less than the net amount*
13 *that the network pharmacy paid to the supplier of the drug. The process must allow a network phar-*
14 *macy a period of no less than 60 days after a claim is reimbursed in which to file the appeal. An appeal*
15 *requested under this section must be completed within 30 calendar days of the pharmacy making the*
16 *claim for which appeal has been requested.*]

17 [(5) *A pharmacy benefit manager shall allow a network pharmacy to submit the documentation in*
18 *support of its appeal on paper or electronically and may not:*]

19 [(a) *Refuse to accept an appeal submitted by a person authorized to act on behalf of the network*
20 *pharmacy;*]

21 [(b) *Refuse to adjudicate an appeal for the reason that the appeal is submitted along with other*
22 *claims that are denied; or*]

23 [(c) *Impose requirements or establish procedures that have the effect of unduly obstructing or de-*
24 *laying an appeal.*]

25 [(6) *A pharmacy benefit manager must provide as part of the appeals process established under*
26 *subsection (4) of this section:*]

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

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

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

33 **(4) A pharmacy may appeal to the Department of Consumer and Business Services, in the**
34 **manner prescribed by the department, a pharmacy benefit manager's payment of a claim**
35 **that fails to meet the requirements of this section and may not be required to first appeal**
36 **the payment through the pharmacy benefit manager.**

37 [(7)(a)] **(5)(a)** If [*an appeal is upheld under this section*] **the department issues an order in**
38 **favor of the pharmacy under subsection (4) of this section**, the pharmacy benefit manager shall:

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

41 (B) Allow the pharmacy to reverse the claim and resubmit an adjusted claim without any addi-
42 tional charges.

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

1 pharmacies.

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

3 [(9)] (6) The Department of Consumer and Business Services may adopt rules to carry out the
4 provisions of this section.

5 **SECTION 5.** ORS 735.536 is amended to read:

6 735.536. (1) As used in this section, “out-of-pocket cost” means the amount paid by an enrollee
7 under the enrollee’s coverage, including deductibles, copayments, coinsurance or other expenses as
8 prescribed by the Department of Consumer and Business Services by rule.

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

10 (a) May not require a prescription to be filled or refilled by a mail order pharmacy as a condi-
11 tion for reimbursing the cost of the drug.

12 (b) Except as provided in paragraph (c) of this subsection, may require a prescription for a
13 specialty drug to be filled or refilled at a specialty pharmacy as a condition for the reimbursement
14 of the cost of a drug.

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

17 (d)(A) Shall allow a network pharmacy to mail, ship or deliver prescription drugs to its patients
18 as an ancillary service.

19 (B) Is not required to reimburse a delivery fee charged by a pharmacy for a delivery described
20 in subparagraph (A) of this paragraph unless the fee is specified in the contract between the phar-
21 macy benefit manager and the pharmacy.

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

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

25 (ii) Maintains each notification of delivery provided by the United States Postal Service or a
26 package delivery service; and

27 (B) Is responsible for the cost of mailing, shipping or delivering a replacement for a drug that
28 was mailed or shipped but not received by the enrollee.

29 (f) May not penalize a network pharmacy **by imposing charges or fees, requiring contract**
30 **amendments, canceling or terminating contracts or demanding recoupment or otherwise re-**
31 **taliate against a network pharmacy** for [*or otherwise directly or indirectly prevent a network*
32 *pharmacy from*]:

33 (A) Informing an enrollee of the difference between the out-of-pocket cost to the enrollee to
34 purchase a prescription drug using the enrollee’s pharmacy benefit and the pharmacy’s usual and
35 customary charge for the prescription drug[.];

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

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

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

40 (E) **Challenging the pharmacy benefit manager’s practices or agreements.**

41 (g) **Charge a fee to a pharmacy for submitting claims or for the adjudication of claims.**

42 (3) The Department of Consumer and Business Services may adopt rules to carry out the pro-
43 visions of this section.

44 **SECTION 6.** ORS 735.540 is amended to read:

45 735.540. As used in ORS 735.540 to 735.552:

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

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

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

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

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

9 (3) "Entity" includes:

10 (a) A pharmacy benefit manager;

11 (b) An insurer;

12 (c) A third party administrator;

13 (d) A state agency; or

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

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

19 **SECTION 7.** ORS 735.542 is amended to read:

20 735.542. An entity that audits claims or an independent third party that contracts with an entity
 21 to audit claims:

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

25 **(2) Must submit a request to a pharmacy for a record for the purpose of an audit by:**

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

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

28 [(2)] (3) May not conduct an audit of a claim more than [24] **six** months after the date the claim
 29 was adjudicated by the entity;

30 [(3)] (4) Must give at least 15 days' advance written notice of an [*on-site*] audit to the pharmacy
 31 or corporate headquarters of the pharmacy **by electronic mail;**

32 [(4)] (5) May not conduct an on-site audit during the first five days of any month without the
 33 pharmacy's consent;

34 [(5)] (6) Must conduct the audit in consultation with a pharmacist who is licensed by this or
 35 another state if the audit involves clinical or professional judgment;

36 [(6)] (7) May not conduct an [*on-site*] audit of more than [250] **100** unique prescriptions of a
 37 pharmacy in any [*12-month period except in cases of alleged fraud*] **six-month period except as**
 38 **prescribed by the Department of Consumer and Business Services by rule;**

39 [(7)] (8) May not conduct more than one [*on-site*] audit of a pharmacy in any [*12-month*] **six-**
 40 **month** period;

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

42 [(8)] (10) Must audit each pharmacy under the same standards and parameters that the entity
 43 uses to audit other similarly situated pharmacies;

44 [(9)] (11) Must pay any outstanding claims of a pharmacy no more than 45 days after the earlier
 45 of the date all appeals are concluded or the date a final report is issued under ORS 735.550 (3);

1 [(10)] (12) May not include dispensing fees or interest in the amount of any overpayment as-
 2 sessed on a claim unless the overpaid claim was for a prescription that was not filled correctly;

3 [(11)] (13) May not recoup costs associated with:

4 (a) Clerical errors; or

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

6 [(12)] (14) May not charge a pharmacy for a denied or disputed claim until the audit and the
 7 appeals procedure established under subsection (1) of this section are final.

8 **SECTION 8.** ORS 743A.062 is amended to read:

9 743A.062. (1) As used in this section[.];

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

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

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

18 (a) **May not** exclude coverage of the drug for a particular indication solely on the grounds that
 19 the indication has not been approved by the United States Food and Drug Administration if the
 20 Health Evidence Review Commission established under ORS 414.688 or the Pharmacy and
 21 Therapeutics Committee established under ORS 414.353 determines that the drug is recognized as
 22 effective for the treatment of that indication:

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

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

25 (ii) “Drug Facts and Comparisons” (Lippincott-Raven Publishers);

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

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

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

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

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

32 (A) Except as provided in subsection (3) of this section, require a prescription for the drug to
 33 be filled or refilled at a mail order pharmacy; or

34 (B) Require a prescription for the drug to be filled or refilled at a pharmacy that is not a local
 35 pharmacy enrolled in the medical assistance program[.];

36 (c) **Must permit the policyholder, certificate holder or beneficiary, at the time of issu-**
 37 **ance, amendment or renewal, to select a licensed pharmacy or licensed pharmacist for the**
 38 **dispensing of prescription drugs reimbursed by the policy, certificate or contract;**

39 (d) **May not deny a pharmacy or pharmacist licensed in this state the opportunity to**
 40 **participate as a preferred provider or a contracting provider, under the same terms and**
 41 **conditions applicable to all other preferred or contracting providers if the pharmacy or**
 42 **pharmacist agrees to the terms and conditions; or**

43 (e) **May not require a claim for reimbursement of a prescription drug to include a modi-**
 44 **fier or other indicator that the drug is a 340B drug unless:**

45 (A) **The claim is for a direct payment from the medical assistance program; or**

(B) It 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 9. ORS 646A.694 is amended to read:

646A.694. (1) The Department of Consumer and Business Services shall provide to the Prescription Drug Affordability Board each calendar quarter a list of prescription drugs included in reports submitted to the department under ORS 646A.689 (2) and (6), a list of drugs included in reports submitted to the department under ORS 743.025 and a list of insulin drugs marketed in this state during the previous calendar year. Each calendar year, the board shall identify nine drugs and at least one insulin product from the lists provided under this subsection that the board determines may create affordability challenges for health care systems or high out-of-pocket costs for patients in this state based on criteria adopted by the board by rule, including but not limited to:

(a) Whether the prescription drug has led to health inequities in communities of color;

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

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

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

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

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

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

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

(i) The impact on patient access to the drug considering standard prescription drug benefit designs in health insurance plans offered in this state;

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

(k) The estimated average patient copayment or other cost-sharing for the prescription drug in this state;

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

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

(2) A drug that is designated by the Secretary of the United States Food and Drug Adminis-

1 tration, under 21 U.S.C. 360bb, as a drug for a rare disease or condition is not subject to review
 2 under subsection (1) of this section.

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

6 (4)(a) If the board considers the cost-effectiveness of a prescription drug in criteria adopted by
 7 the board under subsection (1) of this section, the board may not use quality-adjusted life-years, or
 8 similar formulas that take into account a patient’s age or severity of illness or disability, to identify
 9 subpopulations for which a prescription drug would be less cost-effective. For any prescription drug
 10 that extends life, the board’s analysis of cost-effectiveness must weigh the value of the quality of life
 11 equally for all patients, regardless of the patients’ age or severity of illness or disability.

12 (b) As used in this subsection:

13 (A) “Health utility” means a measure of the degree to which having a particular form of disease
 14 or disability or having particular functional limitations negatively impacts the quality of life as
 15 compared to a state of perfect health, expressed as a number between zero and one.

16 (B) “Quality-adjusted life-year” is the product of a health utility multiplied by the extra months
 17 or years of life that a patient might gain as a result of a treatment.

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

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

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

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

24 (d) Accessing other publicly available pricing information.

25 (6) The information used to conduct an affordability review may include any document and re-
 26 search related to the introductory price or price increase of a prescription drug, including life cycle
 27 management, net average price in this state, market competition and context, projected revenue and
 28 the estimated value or cost-effectiveness of the prescription drug.

29 (7) The department and the board shall keep strictly confidential any information collected, used
 30 or relied upon for the review conducted under this section if the information is:

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

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

33 **SECTION 10. No later than January 1, 2024, the Department of Consumer and Business**
 34 **Services shall hire at least one additional full-time employee to assist in the regulation of**
 35 **pharmacy benefit managers under ORS 735.530 to 735.552.**

36 **SECTION 11. The amendments to ORS 735.534, 735.536, 735.540 and 735.542 by sections 4**
 37 **to 7 of this 2023 Act apply to contracts between pharmacies or pharmacists and pharmacy**
 38 **benefit managers that are entered into, renewed, extended or automatically renewed on or**
 39 **after January 1, 2024.**

40 **SECTION 12. (1) The amendments to ORS 646A.694, 735.530, 735.532, 735.533, 735.534,**
 41 **735.536, 735.540, 735.542 and 743A.062 by sections 1 to 9 of this 2023 Act become operative on**
 42 **January 1, 2024.**

43 **(2) The Department of Consumer and Business Services shall take all steps necessary**
 44 **before January 1, 2024, to carry out the amendments to ORS 735.532 and 735.533 by sections**
 45 **2 and 3 of this 2023 Act on and after January 1, 2024.**

1 **SECTION 13.** In addition to and not in lieu of any other appropriation, there is appro-
2 priated to the Department of Consumer and Business Services, for the biennium beginning
3 July 1, 2023, out of the General Fund, the amount of \$_____, which may be expended for
4 carrying out section 10 of this 2023 Act.

5 **SECTION 14.** Section 10 of this 2023 Act is repealed on January 2, 2025.

6 **SECTION 15.** This 2023 Act being necessary for the immediate preservation of the public
7 peace, health and safety, an emergency is declared to exist, and this 2023 Act takes effect
8 on its passage.
9
