

B-Engrossed House Bill 2123

Ordered by the House June 14
Including House Amendments dated April 3 and June 14

Introduced and printed pursuant to House Rule 12.00. Pre-session 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.

Requires [*State Board of Pharmacy to license*] pharmacy benefit managers **to register with Department of Consumer and Business Services.**

Imposes limits on audits of pharmacies by pharmacy benefit managers and other entities.

Places restrictions on use of maximum allowable cost pricing index by pharmacy benefit managers.

A BILL FOR AN ACT

1
2 Relating to prescription drugs.

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

4 **SECTION 1. Sections 2 to 11 of this 2013 Act are added to and made a part of the In-**
5 **surance Code.**

6 **SECTION 2. As used in sections 2 to 11 of this 2013 Act:**

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

10 (2) **"Insurer" has the meaning given that term in ORS 731.106.**

11 (3) **"Pharmacist" has the meaning given that term in ORS 689.005.**

12 (4) **"Pharmacy" has the meaning given that term in ORS 689.005.**

13 (5)(a) **"Pharmacy benefit manager" means a person that contracts with pharmacies on**
14 **behalf of an insurer, a third party administrator or the Oregon Prescription Drug Program**
15 **established in ORS 414.312 to:**

16 (A) **Process claims for prescription drugs or medical supplies or provide retail network**
17 **management for pharmacies or pharmacists;**

18 (B) **Pay pharmacies or pharmacists for prescription drugs or medical supplies; or**

19 (C) **Negotiate rebates with manufacturers for drugs paid for or procured as described in**
20 **this paragraph.**

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

23 (6) **"Third party administrator" means a person licensed under ORS 744.702.**

24 **SECTION 3. (1) To conduct business in this state, a pharmacy benefit manager must**
25 **register with the Department of Consumer and Business Services and annually renew the**
26 **registration.**

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.

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

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

4 (b) Pay a registration fee, not to exceed \$50, adopted by the department by rule.

5 (3) To renew a registration under this section, a pharmacy benefit manager must pay a
6 renewal fee, not to exceed \$50, adopted by the department by rule.

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

9 **SECTION 4.** As used in sections 4 to 10 of this 2013 Act:

10 (1) "Audit" means an on-site or remote review of the records of a pharmacy by or on
11 behalf of an entity.

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

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

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

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

18 (3) "Entity" includes:

19 (a) A pharmacy benefit manager;

20 (b) An insurer;

21 (c) A third party administrator;

22 (d) A state agency; or

23 (e) A person that represents or is employed by one of the entities described in this sub-
24 section.

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

29 **SECTION 5.** An entity that audits claims or an independent third party that contracts
30 with an entity to audit claims:

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

34 (2) May not conduct an audit of a claim more than 24 months after the date the claim
35 was adjudicated by the entity;

36 (3) Must give at least 15 days' advance written notice of an on-site audit to the pharmacy
37 or corporate headquarters of the pharmacy;

38 (4) May not conduct an on-site audit during the first five days of any month without the
39 pharmacy's consent;

40 (5) Must conduct the audit in consultation with a pharmacist who is licensed by this or
41 another state if the audit involves clinical or professional judgment;

42 (6) May not conduct an on-site audit of more than 250 unique prescriptions of a pharmacy
43 in any 12-month period except in cases of alleged fraud;

44 (7) May not conduct more than one on-site audit of a pharmacy in any 12-month period;

45 (8) Must audit each pharmacy under the same standards and parameters that the entity

1 uses to audit other similarly situated pharmacies;

2 (9) Must pay any outstanding claims of a pharmacy no more than 45 days after the ear-
3 lier of the date all appeals are concluded or the date a final report is issued under section 9
4 (3) of this 2013 Act;

5 (10) May not include dispensing fees or interest in the amount of any overpayment as-
6 sessed on a claim unless the overpaid claim was for a prescription that was not filled cor-
7 rectly;

8 (11) May not recoup costs associated with:

9 (a) Clerical errors; or

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

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

13 **SECTION 6.** An entity's finding that a claim was incorrectly presented or paid must be
14 based on identified transactions and not based on probability sampling, extrapolation or other
15 means that project an error using the number of patients served who have a similar diag-
16 nosis or the number of similar prescriptions or refills for similar drugs.

17 **SECTION 7.** An entity that contracts with an independent third party to conduct audits
18 may not:

19 (1) Agree to compensate the independent third party based on a percentage of the
20 amount of overpayments recovered; or

21 (2) Disclose information obtained during an audit except to the contracting entity, the
22 pharmacy subject to the audit or the holder of the policy or certificate of insurance that paid
23 the claim.

24 **SECTION 8.** For purposes of sections 4 to 10 of this 2013 Act, an entity, or an independent
25 third party that contracts with an entity to conduct audits, must allow as evidence of vali-
26 dation of a claim:

27 (1) An electronic or physical copy of a prescription that complies with ORS chapter 689
28 if the prescribed drug was, within 14 days of the dispensing date:

29 (a) Picked up by the patient or the patient's designee;

30 (b) Delivered by the pharmacy to the patient; or

31 (c) Sent by the pharmacy to the patient using the United States Postal Service or other
32 common carrier;

33 (2) Point of sale electronic register data showing purchase of the prescribed drug, med-
34 ical supply or service by the patient or the patient's designee; or

35 (3) Electronic records, including electronic beneficiary signature logs, electronically
36 scanned and stored patient records maintained at or accessible to the audited pharmacy's
37 central operations and any other reasonably clear and accurate electronic documentation
38 that corresponds to a claim.

39 **SECTION 9.** (1)(a) After conducting an audit, an entity must provide the pharmacy that
40 is the subject of the audit with a preliminary report of the audit. The preliminary report
41 must be received by the pharmacy no later than 45 days after the date on which the audit
42 was completed and must be sent:

43 (A) By mail or common carrier with a return receipt requested; or

44 (B) Electronically with electronic receipt confirmation.

45 (b) An entity shall provide a pharmacy receiving a preliminary report under this sub-

1 section no fewer than 45 days after receiving the report to contest the report or any findings
2 in the report in accordance with the appeals procedure established under section 5 (1) of this
3 2013 Act and to provide additional documentation in support of the claim. The entity shall
4 consider a reasonable request for an extension of time to submit documentation to contest
5 the report or any findings in the report.

6 (2) If an audit results in the dispute or denial of a claim, the entity conducting the audit
7 shall allow the pharmacy to resubmit the claim using any commercially reasonable method,
8 including facsimile, mail or electronic mail.

9 (3) An entity must provide a pharmacy that is the subject of an audit with a final report
10 of the audit no later than 60 days after the later of the date the preliminary report was re-
11 ceived or the date the pharmacy contested the report using the appeals procedure established
12 under section 5 (1) of this 2013 Act. The final report must include a final accounting of all
13 moneys to be recovered by the entity.

14 (4) Recoupment of disputed funds from a pharmacy by an entity or repayment of funds
15 to an entity by a pharmacy, unless otherwise agreed to by the entity and the pharmacy, shall
16 occur after the audit and the appeals procedure established under section 5 (1) of this 2013
17 Act are final. If the identified discrepancy for an individual audit exceeds \$40,000, any future
18 payments to the pharmacy may be withheld by the entity until the audit and the appeals
19 procedure established under section 5 (1) of this 2013 Act are final.

20 **SECTION 10.** Sections 4 to 10 of this 2013 Act do not:

21 (1) Preclude an entity from instituting an action for fraud against a pharmacy;

22 (2) Apply to an audit of pharmacy records when fraud or other intentional and willful
23 misrepresentation is evidenced by physical review, review of claims data or statements or
24 other investigative methods; or

25 (3) Apply to a state agency that is conducting audits or a person that has contracted with
26 a state agency to conduct audits of pharmacy records for prescription drugs paid for by the
27 state medical assistance program.

28 **SECTION 11.** (1) As used in this section:

29 (a) "List" means the list of drugs for which maximum allowable costs have been estab-
30 lished.

31 (b) "Maximum allowable cost" means the maximum amount that a pharmacy benefit
32 manager will reimburse a pharmacy for the cost of a drug.

33 (c) "Multiple source drug" means a therapeutically equivalent drug that is available from
34 at least two manufacturers.

35 (d) "Network pharmacy" means a retail drug outlet registered under ORS 689.305 that
36 contracts with a pharmacy benefit manager.

37 (e) "Therapeutically equivalent" has the meaning given that term in ORS 689.515.

38 (2) A pharmacy benefit manager:

39 (a) May not place a drug on a list unless there are at least two therapeutically equivalent,
40 multiple source drugs, or at least one generic drug available from only one manufacturer,
41 generally available for purchase by network pharmacies from national or regional whole-
42 salers.

43 (b) Shall ensure that all drugs on a list are generally available for purchase by pharma-
44 cies in this state from national or regional wholesalers.

45 (c) Shall ensure that all drugs on a list are not obsolete.

1 (d) Shall make available to each network pharmacy at the beginning of the term of a
2 contract, and upon renewal of a contract, the sources utilized to determine the maximum
3 allowable cost pricing of the pharmacy benefit manager.

4 (e) Shall make a list available to a network pharmacy upon request in a format that is
5 readily accessible to and usable by the network pharmacy.

6 (f) Shall update each list maintained by the pharmacy benefit manager every seven
7 business days and make the updated lists, including all changes in the price of drugs, avail-
8 able to network pharmacies in a readily accessible and usable format.

9 (g) Shall ensure that dispensing fees are not included in the calculation of maximum al-
10 lowable cost.

11 (3) A pharmacy benefit manager must establish a process by which a network pharmacy
12 may appeal its reimbursement for a drug subject to maximum allowable cost pricing. A net-
13 work pharmacy may appeal a maximum allowable cost if the reimbursement for the drug is
14 less than the net amount that the network pharmacy paid to the supplier of the drug. An
15 appeal requested under this section must be completed within 30 calendar days of the phar-
16 macy making the claim for which appeal has been requested.

17 (4) A pharmacy benefit manager must provide as part of the appeals process established
18 under subsection (3) of this section:

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

21 (b) A final response to an appeal of a maximum allowable cost within seven business
22 days; and

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

26 (5)(a) If an appeal is upheld under this section, the pharmacy benefit manager shall make
27 an adjustment on the date that the pharmacy benefit manager makes the determination. The
28 pharmacy benefit manager shall make the adjustment effective for all similarly situated
29 pharmacies in this state that are within the network.

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

34 (6) This section does not apply to the state medical assistance program.

35 **SECTION 12.** The amendments to section 11 of this 2013 Act by section 13 of this 2013
36 Act become operative on January 1, 2015.

37 **SECTION 13.** Section 11 of this 2013 Act is amended to read:

38 **Sec. 11.** (1) As used in this section:

39 (a) "List" means the list of drugs for which maximum allowable costs have been established.

40 (b) "Maximum allowable cost" means the maximum amount that a pharmacy benefit manager
41 will reimburse a pharmacy for the cost of a drug.

42 (c) "Multiple source drug" means a therapeutically equivalent drug that is available from at
43 least two manufacturers.

44 (d) "Network pharmacy" means a retail drug outlet registered under ORS 689.305 that contracts
45 with a pharmacy benefit manager.

1 (e) "Therapeutically equivalent" has the meaning given that term in ORS 689.515.

2 (2) A pharmacy benefit manager:

3 (a) May not place a drug on a list unless there are at least two therapeutically equivalent,
4 multiple source drugs, or at least one generic drug available from only one manufacturer, generally
5 available for purchase by network pharmacies from national or regional wholesalers.

6 (b) Shall ensure that all drugs on a list are generally available for purchase by pharmacies in
7 this state from national or regional wholesalers.

8 (c) Shall ensure that all drugs on a list are not obsolete.

9 (d) Shall make available to each network pharmacy at the beginning of the term of a contract,
10 and upon renewal of a contract, the sources utilized to determine the maximum allowable cost
11 pricing of the pharmacy benefit manager.

12 (e) Shall make a list available to a network pharmacy upon request in a format that is readily
13 accessible to and usable by the network pharmacy.

14 (f) Shall update each list maintained by the pharmacy benefit manager every seven business days
15 and make the updated lists, including all changes in the price of drugs, available to network phar-
16 macies in a readily accessible and usable format.

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

19 (3) A pharmacy benefit manager must establish a process by which a network pharmacy may
20 appeal its reimbursement for a drug subject to maximum allowable cost pricing. A network phar-
21 macy may appeal a maximum allowable cost if the reimbursement for the drug is less than the net
22 amount that the network pharmacy paid to the supplier of the drug. An appeal requested under this
23 section must be completed within 30 calendar days of the pharmacy making the claim for which
24 appeal has been requested.

25 (4) A pharmacy benefit manager must provide as part of the appeals process established under
26 subsection (3) of this section:

27 (a) A telephone number at which a network pharmacy may contact the pharmacy benefit man-
28 ager 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
32 maximum allowable cost.

33 (5)(a) If an appeal is upheld under this section, the pharmacy benefit manager shall make an
34 adjustment [*on the date that the pharmacy benefit manager makes the determination. The pharmacy*
35 *benefit manager shall make the adjustment effective for all similarly situated pharmacies in this state*
36 *that are within the network.*] **for the pharmacy that requested the appeal from the date of initial**
37 **adjudication forward.**

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

42 (6) This section does not apply to the state medical assistance program.

43 **SECTION 14. (1) Section 11 of this 2013 Act applies to contracts between pharmacies and**
44 **pharmacy benefit managers that are entered into, renewed or extended on or after the ef-**
45 **fective date of this 2013 Act.**

1 **(2) The amendments to section 11 of this 2013 Act by section 13 of this 2013 Act apply to**
2 **contracts between pharmacies and pharmacy benefit managers that are entered into, re-**
3 **newed or extended on or after the operative date specified in section 12 of this 2013 Act.**

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