

## HOUSE AMENDMENTS TO HOUSE BILL 3013

By COMMITTEE ON RULES

May 24

- 1 On page 1 of the printed bill, delete lines 5 through 25.
- 2 On page 2, delete lines 1 through 30 and insert:
- 3 **“SECTION 1.** ORS 735.530 is amended to read:
- 4 “735.530. As used in ORS 735.530 to 735.552:
- 5 “(1) ‘Claim’ means a request from a pharmacy or pharmacist to be reimbursed for the cost of
- 6 filling or refilling a prescription for a drug or for providing a medical supply or service.
- 7 “(2) ‘Enrollee’ means an individual who has enrolled for coverage in a health benefit plan for
- 8 which a pharmacy benefit manager has contracted with the insurer to reimburse claims submitted
- 9 by pharmacies or pharmacists for the costs of drugs prescribed for the individual.
- 10 “(3) ‘Health benefit plan’ has the meaning given that term in ORS 743B.005.
- 11 “(4) ‘Insurer’ has the meaning given that term in ORS 731.106.
- 12 “(5) ‘Long term care pharmacy’ means a pharmacy for which the primary business is to serve
- 13 a:
- 14 “(a) Licensed long term care facility, as defined in ORS 442.015;
- 15 “(b) Licensed residential facility, as defined in ORS 443.400; or
- 16 “(c) Licensed adult foster home, as defined in ORS 443.705.
- 17 “(6) ‘Mail order pharmacy’ means a pharmacy for which the primary business is to receive pre-
- 18 scriptions by mail, telephone or electronic transmission and dispense drugs to patients through the
- 19 use of the United States Postal Service, a package delivery service or home delivery.
- 20 “(7) ‘Network pharmacy’ means a pharmacy that contracts with a pharmacy benefit manager.
- 21 **“(8) ‘Oregon Average Actual Acquisition Cost’ means the rate established by the Oregon**
- 22 **Health Authority, in accordance with 42 C.F.R. 447.518, that represents the average invoice**
- 23 **amounts for individual drug products based on surveys conducted by or on behalf of the au-**
- 24 **thority of pharmacies that participate in the state medical assistance program.**
- 25 “[8] (9) ‘Pharmacist’ has the meaning given that term in ORS 689.005.
- 26 “[9] (10) ‘Pharmacy’ includes:
- 27 “(a) A pharmacy as defined in ORS 689.005;
- 28 “(b) A long term care pharmacy; and
- 29 “(c) An entity that provides or oversees administrative services for two or more pharmacies.
- 30 “[10] (11) ‘Pharmacy benefit’ means the payment for or reimbursement of an enrollee’s cost for
- 31 prescription drugs.
- 32 “[11](a) (12)(a) ‘Pharmacy benefit manager’ means a person that contracts with pharmacies on
- 33 behalf of *[an insurer offering a health benefit plan, a third party administrator]* **an insurer, an em-**
- 34 **ployer who is self-insured, entities that accept risk, third-party payers of claims, coordinated**
- 35 **care organizations, as defined in ORS 414.025, or the Oregon Prescription Drug Program estab-**

1 lished in ORS 414.312 to:

2 “(A) Process claims for prescription drugs or medical supplies or provide retail network man-  
3 agement for pharmacies or pharmacists;

4 “(B) Pay pharmacies or pharmacists for prescription drugs or medical supplies; [or]

5 “(C) Negotiate rebates, **discounts or other financial incentives or arrangements** with man-  
6 ufacturers for drugs paid for or procured as described in this paragraph;

7 **“(D) Receive payments for pharmacy services;**

8 **“(E) Disburse or distribute rebates;**

9 **“(F) Manage or participate in incentive programs or arrangements with manufacturers**  
10 **of drugs;**

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

12 **“(H) Develop formularies;**

13 **“(I) Design pharmacy benefit programs; or**

14 **“(J) Advertise or promote pharmacy services.**

15 “(b) ‘Pharmacy benefit manager’ does not include a health care service contractor as defined in  
16 ORS 750.005.

17 **“(13) ‘Pharmacy services’ means the provision of products, goods or services in the**  
18 **course of the practice of pharmacy.**

19 “[12] (14) ‘Specialty drug’ means a drug that:

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

21 “(b) Requires special handling, provider coordination or patient education that cannot be pro-  
22 vided by a retail pharmacy.

23 “[13] (15) ‘Specialty pharmacy’ means a pharmacy capable of meeting the requirements appli-  
24 cable to specialty drugs.

25 “[14] (16) ‘Third party administrator’ means a person licensed under ORS 744.702.

26 “[15] (17) ‘340B pharmacy’ means a pharmacy that is authorized to purchase drugs at a dis-  
27 count under 42 U.S.C. 256b.

28 **“(18) ‘Wholesale acquisition cost’ has the meaning given that term in 42 U.S.C.**  
29 **1395w-3a(c)(6)(B).”.**

30 On page 3, delete lines 36 through 45 and delete pages 4 and 5.

31 On page 6, delete lines 1 through 4 and insert:

32 **“SECTION 4.** ORS 735.534 is amended to read:

33 “735.534. (1) As used in this section:

34 **“(a) ‘Critical access pharmacy’ means a pharmacy that is farther than 10 miles from any**  
35 **other pharmacy, as defined by the Oregon Health Authority by rule for purposes related to**  
36 **the Oregon Prescription Drug Program.**

37 “[*(a)(A)*] (b)(A) ‘Generally available for purchase’ means a drug is available for purchase in this  
38 state by a pharmacy from a national or regional wholesaler at the time a claim for reimbursement  
39 is submitted by a network pharmacy.

40 “(B) A drug is not ‘generally available for purchase’ if the drug:

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

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

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

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

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

2 “[*b*] (c) ‘List’ means the list of drugs for which maximum allowable costs have been established.

3 “[*c*] (d) ‘Maximum allowable cost’ means the maximum amount that a pharmacy benefit man-  
4 ager will reimburse a pharmacy for the cost of a drug.

5 “[*d*] (e) ‘Multiple source drug’ means a therapeutically equivalent drug that is available from  
6 at least two manufacturers.

7 “[*e*] (f) ‘Therapeutically equivalent’ has the meaning given that term in ORS 689.515.

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

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

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

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

13 “(d) Shall make available to each network pharmacy at the beginning of the term of a contract,  
14 and upon renewal of a contract, the specific authoritative industry sources, other than proprietary  
15 sources, the pharmacy benefit manager uses to determine the maximum allowable cost set by the  
16 pharmacy benefit manager.

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

18 “(A) Is electronic;

19 “(B) Is computer accessible and searchable;

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

21 “(D) For each drug specifies:

22 “(i) The national drug code; and

23 “(ii) The maximum allowable cost.

24 “(f) Shall update each list maintained by the pharmacy benefit manager every seven business  
25 days and make the updated lists, including all changes in the price of drugs, available to network  
26 pharmacies in the format described in paragraph (e) of this subsection.

27 “(g) Shall ensure that dispensing fees are not included in the calculation of maximum allowable  
28 cost.

29 “(h) May not reimburse a 340B pharmacy differently than any other network pharmacy based  
30 on its status as a 340B pharmacy.

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

32 “(j) **Shall pay a solo network pharmacy or a network pharmacy chain a professional dis-**  
33 **persing fee in an amount no less than the dispensing fee established by the Oregon Health**  
34 **Authority by rule and reimburse the cost of the ingredients of the drug in an amount that**  
35 **is the lesser of the following, but in no event less than the fee-for-service rate paid by the**  
36 **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 on the Oregon Average Actual Acquisition Cost rates list, the**  
40 **National Average Drug Acquisition Cost published by the Centers for Medicare and Medicaid**  
41 **Services; or**

42 “(iii) **If the drug is not on the Oregon Average Actual Acquisition Cost rates list or the**  
43 **National Average Drug Acquisition Cost rates list, the wholesale acquisition cost.**

44 “[*i*] (k) May not retroactively deny or reduce **payment on** a claim for reimbursement of the  
45 cost of services 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;

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

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)(k)** 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  
11 appeal its reimbursement for a drug [*subject to maximum allowable cost pricing*]. A network phar-  
12 macy may appeal [*a maximum allowable cost if*] the reimbursement for the drug **if the reimburse-**  
13 **ment** is less than the [*net amount that the network pharmacy paid to the supplier of the drug*]  
14 **amount specified in subsection (2)(j) of this section.** The process must allow a network pharmacy  
15 a period of no less than 60 days after a claim is reimbursed in which to file the appeal. An appeal  
16 requested under this section must be completed within 30 calendar days of the pharmacy making the  
17 claim for which appeal has been requested.

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

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

22 “(b) Refuse to adjudicate an appeal for the reason that the appeal is submitted along with other  
23 claims that are denied; or

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

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

28 “(a) A telephone number at which a network pharmacy may contact the pharmacy benefit man-  
29 ager and speak with an individual who is responsible for processing appeals;

30 “(b) A final response to an appeal of [*a maximum allowable cost*] **the reimbursement for a drug**  
31 **within seven business days; and**

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

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

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

38 “(B) Allow the pharmacy to reverse the claim and resubmit an adjusted claim without any ad-  
39 ditional charges.

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

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

45 “(8) **A pharmacy may file a complaint with the Department of Consumer and Business**

1 **Services to contest a finding of a pharmacy benefit manager in response to an appeal under**  
2 **subsection (4) of this section or a pharmacy benefit manager’s failure to comply with the**  
3 **provisions of this section.**

4 “(9) The Department of Consumer and Business Services may adopt rules to carry out the pro-  
5 visions of this section.”.

6 On page 7, delete lines 19 through 45.

7 On page 8, delete lines 1 through 7 and insert:

8 “**SECTION 7.** ORS 735.542 is amended to read:

9 “735.542. An entity that audits claims or an independent third party that contracts with an en-  
10 tity to audit claims:

11 “(1) Must establish, in writing, a procedure for a pharmacy to appeal the entity’s findings with  
12 respect to a claim and must provide a pharmacy with a notice regarding the procedure, in writing  
13 or electronically, prior to conducting an audit of the pharmacy’s claims;

14 “(2) **Must submit requests for records from a pharmacy for the purpose of an audit by:**

15 “(a) **Electronic mail; and**

16 “(b) **Facsimile or certified mail;**

17 “[2] (3) May not conduct an audit of a claim more than [24] **12** months after the date the claim  
18 was adjudicated by the entity;

19 “[3] (4) Must give at least 15 days’ advance written notice of an [on-site] audit to the pharmacy  
20 or corporate headquarters of the pharmacy **by electronic mail;**

21 “[4] (5) May not conduct an on-site audit during the first five days of any month without the  
22 pharmacy’s consent;

23 “[5] (6) Must conduct the audit in consultation with a pharmacist who is licensed by this or  
24 another state if the audit involves clinical or professional judgment;

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

27 “(a) **250 unique prescriptions during an on-site audit; or**

28 “(b) **250 unique prescriptions through a remote audit;**

29 “[7] (8) May not conduct more than one on-site audit of a pharmacy in any 12-month period;

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

31 “[8] (10) Must audit each pharmacy under the same standards and parameters that the entity  
32 uses to audit other similarly situated pharmacies;

33 “[9] (11) Must pay any outstanding claims of a pharmacy no more than 45 days after the earlier  
34 of the date all appeals are concluded or the date a final report is issued under ORS 735.550 (3);

35 “[10] (12) May not include dispensing fees or interest in the amount of any overpayment as-  
36 sessed on a claim unless the overpaid claim was for a prescription that was not filled correctly;

37 “[11] (13) May not recoup costs associated with:

38 “(a) Clerical errors; or

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

40 “[12] (14) May not charge a pharmacy for a denied or disputed claim until the audit and the  
41 appeals procedure established under subsection (1) of this section are final.”.

42 In line 42, delete “or”.

43 Delete lines 43 through 45.

44 On page 9, delete line 1 and insert:

45 “(e) May not discriminate in the reimbursement of a prescription for 340B drugs from other

1 prescription drugs;  
2 “(f) May not assess a fee, chargeback, clawback or other adjustment for the dispensing of a 340B  
3 drug;  
4 “(g) May not exclude a pharmacy from a pharmacy network on the basis that the pharmacy  
5 dispenses a 340B drug;  
6 “(h) May not restrict the methods by which a 340B drug may be dispensed or delivered; or  
7 “(i) May not restrict the number of pharmacies within a pharmacy network that may dispense  
8 or deliver 340B drugs.”.  
9 After line 10, insert:  
10 “(7) Notwithstanding ORS 750.055 (1)(h), this section does not apply to a health maintenance  
11 organization as defined in ORS 750.005.”.  
12 In line 11, delete “(7)” and insert “(8)”.  
13 On page 10, line 37, delete “or pharmacists”.  
14 \_\_\_\_\_