HB 2387-3 (LC 1285) 4/12/17 (LHF/ps)lhf

Requested by HOUSE COMMITTEE ON HEALTH CARE

PROPOSED AMENDMENTS TO HOUSE BILL 2387

1 On page 1 of the printed corrected bill, delete lines 8 through 20.

2 On page 2, delete lines 1 through 42 and insert:

³ "SECTION 1. As used in sections 1 to 4 of this 2017 Act:

4 "(1) 'Drug' has the meaning given that term in ORS 689.005.

5 "(2) 'Enrollee' has the meaning given that term in section 5 of this
6 2017 Act.

7 "(3) 'Excess cost' means:

"(a) For a brand name prescription drug, the difference between the
wholesale acquisition cost of the prescription drug and the foreign
price cap for the prescription drug only if the drug:

"(A) Has been approved by the United States Food and Drug Ad ministration for longer than 24 months; and

13 "(B) Has a wholesale acquisition cost that is greater than:

14 "(i) The foreign price cap; and

15 **"(ii) \$12,000.**

"(b) For a generic, biosimilar or off-patent prescription drug, the
 amount of any cumulative increase in the wholesale acquisition cost
 of the drug that exceeds 3.4 percent over a 12-month period.

"(4) 'Foreign price cap' means the median of the five highest prices
 paid for a prescription drug in any country other than the United
 States that is:

"(a) A member of the Organisation for Economic Co-operation and
 Development; or

"(b) One of 35 economically developed countries specified by the
Department of Consumer and Business Services by rule, if the
Organisation for Economic Co-operation and Development ceases to
exist.

"(5) 'Health care practitioner' means an individual or entity that is
licensed, certified or registered in this state to provide health care,
including by dispensing prescription drugs.

10 **"(6)(a) 'Manufacture' means:**

"(A) The production, preparation, propagation, compounding, conversion or processing of a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; and

"(B) The packaging or repackaging of a drug or labeling or rela beling of a drug container.

"(b) 'Manufacture' does not include the preparation or compound ing of a drug by an individual for the individual's own use or the
 preparation, compounding, packaging or labeling of a drug:

"(A) By a health care practitioner incidental to administering or
 dispensing a drug in the course of professional practice;

"(B) By a health care practitioner or at the practitioner's authori zation and supervision for the purpose of or incidental to research,
 teaching or chemical analysis activities and not for sale:

"(C) By a health care service contractor, as defined in ORS 750.005,
 for dispensing to a subscriber; or

"(D) By a health care facility, as defined in ORS 442.015, for dis pensing to a patient of the health care facility.

30 "(7) 'Manufacturer' means a person that manufactures a pre-

1 scription drug that is sold in this state.

"(8) 'Off-patent' means any drug for which all exclusive marketing
rights, if any, granted under the Federal Food, Drug and Cosmetic Act
and federal patent law have expired.

5 "(9) 'Payer' has the meaning given that term in section 5 of this 6 2017 Act.

7 "(10) 'Plan' has the meaning given that term in section 5 of this 2017
8 Act.

9 "(11) 'Prescription drug' means a drug that must:

"(a) Under federal law, be labeled 'Caution: Federal law prohibits
 dispensing without prescription' prior to being dispensed or delivered;
 or

"(b) Under any applicable federal or state law or regulation, be
 dispensed only by prescription or that is restricted to use only by
 health care practitioners.

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

18 "<u>SECTION 2.</u> (1) The Oregon Premium Protection Program is cre-19 ated in the Department of Consumer and Business Services. The pur-20 pose of the program is to reduce the burden on consumers and 21 insurers in this state of the excessive costs of prescription drugs.

"(2) The department shall prescribe by rule a formula to determine 22the excess costs incurred by a payer calculated as a percentage of a 23payer's premium revenue and based on the utilization by the payer's 24enrollees of drugs that are subject to the excess costs calculation. 25Payers shall submit claims for rebates of the excess costs to the de-26partment in the form and manner prescribed by the department and 27shall provide supporting data or documentation that the department 28deems necessary to validate the accuracy of the claims. 29

30 "(3)(a) The department shall adopt by rule a method for determin-

ing the amount of rebates owed by a manufacturer based on claims for
rebates of excess costs submitted by payers under subsection (2) of this
section.

4 "(b) The department shall charge to and collect from manufacturers
5 the amount of rebates owed, as determined under this subsection.

"(4) A payer or a manufacturer may appeal a determination made
by the department under subsection (2) or (3) of this section by requesting a contested case hearing in accordance with ORS chapter 183.
"(5) The department shall take into account any rebates paid under
this section in determining whether an insurer's premium rates meet
the requirements of ORS 743.018 (4).

"(6) Subsections (3) and (4) of this section do not apply to core antiretroviral therapeutics listed by the United States Secretary of Health and Human Services in accordance with 42 U.S.C. 300ff-26(e) and prescribed for individuals participating in the Aids Drug Assistance Program authorized by 42 U.S.C. 300ff-26.

"(7) A manufacturer shall provide advance written notice to payers not less than 60 days prior to the effective date of an increase in the wholesale acquisition cost of a prescription drug that results in a cumulative increase of more than 3.4 percent in the price of the prescription drug over the 12-month period immediately preceding the effective date of the increase.

"<u>SECTION 3.</u> (1) The Department of Consumer and Business Ser vices, in carrying out the provisions of sections 1 to 4 of this 2017 Act,
 shall have the power to:

²⁶ "(a) Administer oaths and affirmations;

27 **"(b) Subpoena witnesses;**

²⁸ "(c) Compel witnesses to testify under oath; and

"(d) Subpoena the production of books, papers, correspondence,
 memoranda, agreements or other documents or records that the de-

HB 2387-3 4/12/17 Proposed Amendments to HB 2387 1 partment considers relevant or material to the inquiry.

"(2) Each witness who appears before the department under a
subpoena shall receive the fees and mileage provided for witnesses
under ORS 44.415 (2).

5 "(3) If a person fails to comply with a subpoena or a party or wit-6 ness refuses to testify on any matters, the judge of the circuit court 7 for any county, on the application of the department, shall compel 8 obedience by proceedings for contempt as in the case of disobedience 9 of the requirements of a subpoena issued from the court or a refusal 10 to testify in the court.

11 "<u>SECTION 4.</u> (1) The Oregon Premium Protection Fund is estab-12 lished in the State Treasury, separate and distinct from the General 13 Fund. The Oregon Premium Protection Fund consists of moneys paid 14 to the Department of Consumer and Business Services by manufac-15 turers under section 2 of this 2017 Act.

"(2) Moneys in the Oregon Premium Protection Fund are contin uously appropriated to the department for the purposes of:

"(a) Reimbursing payers for excess costs in accordance with section
2 of this 2017 Act; and

20 "(b) Administering the Oregon Premium Protection Program cre-21 ated in section 2 of this 2017 Act.".

On page 3, line 1, delete "2" and insert "5".

In line 22, delete "during a plan year".

In line 23, delete "\$500" and insert "\$200".

²⁵ In line 24, delete "\$250" and insert "\$100".

26 Delete lines 31 through 44 and insert:

²⁷ "<u>SECTION 6.</u> (1) As used in this section:

"(a) 'Manufacturer' has the meaning given that term in section 1 of this
2017 Act.

30 "(b) 'Patient assistance program' means a program offered to the general

HB 2387-3 4/12/17 Proposed Amendments to HB 2387

public by a manufacturer in which a patient may, using coupons, discount
cards or other means, reduce the patient's out-of-pocket costs for prescription
drugs.

4 "(c) 'Prescription drug' has the meaning given that term in section 1 of 5 this 2017 Act.

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

8 "(2) A manufacturer shall report to the Department of Consumer and 9 Business Services, in the form and manner prescribed by the department:

"(a) Not later than 30 days after the United States Food and Drug Ad ministration has approved for marketing a prescription drug with an intro ductory wholesale acquisition cost of \$12,000 or more per year:

"(A) The justification for the introductory wholesale acquisition cost, in cluding:".

15 On page 4, after line 24, insert:

"(c) At least annually, for each prescription drug described in paragraph (a) or (b) of this subsection, the 10 highest prices paid for the drug in the countries for which the foreign price cap for the drug is calculated under section 1 (4) of this 2017 Act.".

20 On page 5, line 11, delete "4" and insert "7".

21 After line 19, insert:

²² "(7) To the extent that the material described in subsection (2) of this ²³ section, or any portion of the material, would otherwise qualify as a trade ²⁴ secret under ORS 192.501, the action taken by the department or any expert ²⁵ or consultant employed by the department in reviewing the material does not ²⁶ affect the status of the material as a trade secret.

27 "(8) The department may adopt rules as necessary for carrying out the 28 provisions of this section.".

In line 20, delete "4" and insert "7" and after "fails" insert "to make a payment in accordance with sections 1 to 4 of this 2017 Act or". 1 In line 21, delete "3" and insert "6".

In line 35, delete "5" and insert "8" and delete "6" and insert "9".

3 In line 36, delete "6" and insert "9".

4 Delete lines 44 and 45 and insert "enrollee or potential enrollee, an ex-5 planation of how an enrollee can request coverage for a prescription drug 6 that is not on the insurer's drug formulary.".

7 On page 6, delete lines 1 through 11 and insert:

8 "(3) No less than 30 days prior to removing a prescription drug from a 9 drug formulary, an insurer shall post a notice of the intended removal on its 10 website.

"(4) Notwithstanding subsection (3) of this section, an insurer shall post a notice on its website informing the public about the removal of a prescription drug from the insurer's drug formulary as soon as practicable and without unreasonable delay if:

¹⁵ "(a) The drug is no longer available on the market;

16 "(b) The drug becomes available without a prescription;

"(c) The United States Food and Drug Administration issues a boxed warning concerning the drug because of serious or life-threatening risks to individuals taking the drug; or

20 "(d) A generic substitute for the drug becomes available.".

In line 15, delete "7" and insert "10".

22 On page 7, delete lines 6 through 29 and insert:

"(8) Health benefit plans offered by the board may not require eligible
employees and their family members to incur out-of-pocket costs that exceed
the prescription drug cost cap specified in section 5 of this 2017 Act.

"(9) The board or an insurer offering a health benefit plan to eligible employees shall make available online, and in writing upon request by an eligible employee, an explanation of how an eligible employee or family member can request coverage for a prescription drug that is not on the health benefit plan's drug formulary. "(10) No less than 30 days prior to removing a prescription drug from a drug formulary, the board or the insurer shall post a notice of the intended removal on its website.

"(11) Notwithstanding subsection (10) of this section, the board or an
insurer shall post a notice on its website informing the public about the removal of a prescription drug from the health benefit plan's drug formulary
as soon as practicable and without unreasonable delay if:

8 "(a) The drug is no longer available on the market;

9 "(b) The drug becomes available without a prescription;

"(c) The United States Food and Drug Administration issues a boxed
 warning concerning the drug because of serious or life-threatening risks to
 individuals taking the drug; or

13 "(d) A generic substitute for the drug becomes available.".

14 In line 33, delete "8" and insert "11".

15 On page 8, delete lines 26 through 45.

16 On page 9, delete lines 1 through 4 and insert:

"(9) Health benefit plans offered by the board may not require eligible employees and their family members to incur out-of-pocket costs that exceed the prescription drug cost cap specified in section 2 of this 2017 Act.

"(10) The board or an insurer offering a health benefit plan to eligible employees shall make available online, and in writing upon request by an eligible employee, an explanation of how an eligible employee or family member can request coverage for a prescription drug that is not on the health benefit plan's drug formulary.

"(11) No less than 30 days prior to removing a prescription drug from a
drug formulary, the board or the insurer shall post a notice of the intended
removal on its website.

"(12) Notwithstanding subsection (11) of this section, the board or an insurer shall post a notice on its website informing the public about the removal of a prescription drug from the health benefit plan's drug formulary

- 1 as soon as practicable and without unreasonable delay if:
- 2 "(a) The drug is no longer available on the market;
- 3 "(b) The drug becomes available without a prescription;
- "(c) The United States Food and Drug Administration issues a boxed
 warning concerning the drug because of serious or life-threatening risks to
 individuals taking the drug; or
- 7 "(d) A generic substitute for the drug becomes available.".
- 8 In line 8, delete "9" and insert "12".
- 9 On page 13, line 6, delete "2" and insert "5".
- 10 Delete lines 8 and 9.
- In line 13, delete "10" and insert "13".
- 12 On page 15, line 27, delete "2" and insert "5".
- 13 Delete lines 28 and 29.
- In line 33, delete "11" and insert "14".
- ¹⁵ On <u>page 17</u>, line 36, delete "2" and insert "5".
- 16 Delete lines 37 and 38.
- In line 42, delete "12" and insert "15".
- 18 On page 18, line 26, delete the second "2" and insert "5".
- 19 In line 42, delete "13" and insert "16".
- 20 On page 19, line 29, delete the second "2" and insert "5".
- In line 45, delete "14" and insert "17".
- 22 On page 20, line 32, delete "2" and insert "5".
- 23 On page 21, line 6, delete "15" and insert "18".
- In line 36, delete "2" and insert "5".
- 25 Delete page 22 and insert:
- ²⁶ "<u>SECTION 19.</u> Notwithstanding the deadline imposed under section
- 6 (2)(a) of this 2017 Act, a manufacturer shall report as required under
- section 6 (2)(a) of this 2017 Act, by a date designated by the Depart-
- 29 ment of Consumer and Business Services by rule, with respect to any
- 30 prescription drug approved by the United States Food and Drug Ad-

HB 2387-3 4/12/17 Proposed Amendments to HB 2387 ministration before the effective date of this 2017 Act that has a
wholesale acquisition cost, as defined in section 1 of this 2017 Act, of
\$12,000 or more on the effective date of this 2017 Act.

"SECTION 20. Section 5 of this 2017 Act and the amendments to
ORS 743B.013, 743B.105, 743B.125, 750.055 and 750.333 by sections 12 to
18 of this 2017 Act apply to health benefit plans for which a carrier,
on the effective date of this 2017 Act, has not filed rates with the Department of Consumer and Business Services for approval under ORS
743.018.

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"NONSEVERABILITY

"SECTION 21. It is the intent of the Legislative Assembly that 13 sections 1 to 9 of this 2017 Act and the amendments to ORS 243.135, 14 243.866, 743B.013, 743B.105, 743B.125, 750.055 and 750.333 by sections 10 15to 18 of this 2017 Act are essentially and inseparably connected with 16 and dependent upon each other. The Legislative Assembly does not 17 intend that sections 1 to 9 of this 2017 Act and the amendments to ORS 18 243.135, 243.866, 743B.013, 743B.105, 743B.125, 750.055 and 750.333 by 19 sections 10 to 18 of this 2017 Act be the law if any of those sections or 20amendments to statutes are held unconstitutional. 21

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"UNIT CAPTIONS

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²⁵ "<u>SECTION 22.</u> The unit captions used in this 2017 Act are provided ²⁶ only for the convenience of the reader and do not become part of the ²⁷ statutory law of this state or express any legislative intent in the ²⁸ enactment of this 2017 Act.".

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