HOUSE AMENDMENTS TO HOUSE BILL 2387

By COMMITTEE ON HEALTH CARE

April 27

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

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

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

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

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

"(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 Administration for longer than 24 months; and

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

"(i) The foreign price cap; and

"(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.

"(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 relabeling of a drug container.

"(b) 'Manufacture' does not include the preparation or compounding 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 authorization 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 dispensing to a patient of the health care facility.

"(7) 'Manufacturer' means a person that manufactures a prescription 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.

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

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

"(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).

"**SECTION 2.** **(1) The Oregon Premium Protection Program is created in the Department of Consumer and Business Services. The purpose of the program is to reduce the burden on consumers and insurers in this state of the excessive costs of prescription drugs.**

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

"(3)(a) The department shall adopt by rule a method for determining 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.

"(b) The department shall charge to and collect from manufacturers 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.

"**SECTION 3.** **(1) The Department of Consumer and Business Services, in carrying out the provisions of sections 1 to 4 of this 2017 Act, shall have the power to:**

"(a) Administer oaths and affirmations;

"(b) Subpoena witnesses;

"(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 department 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).

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

"**SECTION 4.** **(1) The Oregon Premium Protection Fund is established in the State Treasury, separate and distinct from the General Fund. The Oregon Premium Protection Fund consists of moneys paid to the Department of Consumer and Business Services by manufacturers under section 2 of this 2017 Act.**

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

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

"(b) Administering the Oregon Premium Protection Program created 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".

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

Delete lines 31 through 44 and insert:

"**SECTION 6.** (1) As used in this section:

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

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

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

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

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

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

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

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.".

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

After line 19, insert:

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

"(8) The department may adopt rules as necessary for carrying out the 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".

In line 21, delete "3" and insert "6".

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

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

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

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

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

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

"(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

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

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

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:

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

"(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

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

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

On page 8, delete lines 26 through 45.

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 as soon as practicable and without unreasonable delay if:

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

"(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

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

In line 8, delete "9" and insert "12".

On page 13, line 6, delete "2" and insert "5".

Delete lines 8 and 9.

In line 13, delete "10" and insert "13".

On page 15, line 27, delete "2" and insert "5".

Delete lines 28 and 29.

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

On page 17, line 36, delete "2" and insert "5".

Delete lines 37 and 38.

In line 42, delete "12" and insert "15".

On page 18, line 26, delete the second "2" and insert "5".

In line 42, delete "13" and insert "16".

On page 19, line 29, delete the second "2" and insert "5".

In line 45, delete "14" and insert "17".

On page 20, line 32, delete "2" and insert "5".

On page 21, line 6, delete "15" and insert "18".

In line 36, delete "2" and insert "5".

Delete page 22 and insert:

"**SECTION 19. 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 Department of Consumer and Business Services by rule, with respect to any prescription drug approved by the United States Food and Drug Administration 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.

"NONSEVERABILITY

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

"UNIT CAPTIONS

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