

Requested by Senator STEINER HAYWARD

**PROPOSED AMENDMENTS TO  
SENATE BILL 793**

1 On page 1 of the printed bill, delete lines 7 through 9 and insert:

2 “(A)(i) Greater than 10 percent for a prescription drug:

3 “(I) For which the active ingredient has been approved by the United  
4 States Food and Drug Administration for more than five years; and

5 “(II) That costs more than \$30 and less than \$100 for a one-month supply;

6 “(ii) Greater than five percent for a prescription drug:

7 “(I) For which the active ingredient has been approved by the United  
8 States Food and Drug Administration for more than five years; and

9 “(II) That costs \$100 or more, up to \$5,000, for a 12-month supply;

10 “(iii) Greater than 3.4 percent for a brand name drug that costs more than  
11 \$5,000 for a 12-month supply; or

12 “(iv) Greater than 15 percent for a brand name drug for which the active  
13 ingredient has been approved by the United States Food and Drug Adminis-  
14 tration for less than five years.”.

15 On page 2, delete lines 3 through 42 and insert:

16 “(g) ‘Price’ means:

17 “(A) The lowest wholesale acquisition cost for the drug since it has been  
18 on the market; or

19 “(B) For generic drugs, the average wholesale acquisition cost for the  
20 previous calendar quarter.

21 “(h) ‘Wholesale acquisition cost’ has the meaning given that term in 42

1 U.S.C. 1395w-3a(c)(6)(B).

2 “(2) The period for which a prescription drug has been approved by the  
3 United States Food and Drug Administration under subsection (1)(b)(A) of  
4 this section is the period in which the active ingredient in the drug has been  
5 delivered in the same manner, regardless of any changes to the size, shape  
6 or color of the drug.

7 “(3) The Department of Consumer and Business Services shall prescribe  
8 the form and manner for a manufacturer to submit annually to the depart-  
9 ment:

10 “(a) The prices of the prescription drugs sold in this state by the man-  
11 ufacturer;

12 “(b) Notice of any excessive price increase that will occur in the next 12  
13 months for prescription drugs sold by the manufacturer in this state;

14 “(c) The justification for any price increase described in paragraph (b) of  
15 this subsection; and

16 “(d) Any supporting documentation that is required to support the justi-  
17 fication described in paragraph (c) of this subsection.

18 “(4) A manufacturer may not increase the price of a prescription drug  
19 that is sold to residents of this state by an amount that is excessive without  
20 the department’s prior approval.

21 “(5) The department shall review a justification provided under subsection  
22 (3) of this section to determine if the price increase is excessive based upon  
23 criteria adopted by the department by rule that take into account:

24 “(a) The direct costs incurred by the manufacturer:

25 “(A) In the research and development of the prescription drug;

26 “(B) To obtain approval of the prescription drug by the United States  
27 Food and Drug Administration; and

28 “(C) In marketing the prescription drug during the 12-month period fol-  
29 lowing approval by the United States Food and Drug Administration;

30 “(b) The manufacturer’s financial position, including but not limited to

1 profitability, surplus, reserves and investments;

2 “(c) The manufacturer’s historical and projected administrative expenses;  
3 and

4 “(d) Expected sales based on market demand for the prescription drug.

5 “(6) The department may approve an excessive price increase if the de-  
6 partment finds the increase to be justified.

7 “(7) The department shall post the prices of prescription drugs reported  
8 under subsection (3)(a) of this section to a website accessible by the public.

9 “(8) To the extent that the material described in subsection (3) of this  
10 section, or any portion of the material, would otherwise qualify as a trade  
11 secret under ORS 192.501, the action taken by the department or any expert  
12 or consultant employed by the department in reviewing the material does not  
13 affect the status of the material as a trade secret.

14 “(9) Employees of the department who have responsibilities for evaluating  
15 a justification submitted by a manufacturer under subsection (3) of this sec-  
16 tion may not have a direct or indirect financial interest or involvement, or  
17 have a family member with a direct or indirect financial interest or in-  
18 volvement, in a manufacturer, other than an incidental interest.

19 “(10) If a manufacturer increases the price of a prescription drug by an  
20 amount that is excessive without the department’s prior approval, the de-  
21 partment shall order the manufacturer to refund to purchasers of the pre-  
22 scription drug the portion of the price increase that is excessive.

23 “(11) The department shall have in place a process for consumers to file  
24 a complaint, online or by telephone, about an excessive price increase.

25 “(12) The denial of an excessive price increase or an order under sub-  
26 section (10) of this section is an order in a contested case subject to appeal  
27 and judicial review in accordance with ORS chapter 183.

28 “(13) The department shall adopt by rule a fee to be imposed on man-  
29 ufacturers to cover the cost of reviewing the justification for excessive price  
30 increases and any action taken by the department in response to an excessive

1 price increase. The fee must consist of a base fee plus a percentage of the  
2 wholesale acquisition cost of the drug that is under review.

3 “(14) The department may adopt rules as necessary for carrying out the  
4 provisions of this section.”.

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