

B-Engrossed
House Bill 2658

Ordered by the Senate May 31
Including House Amendments dated April 15 and Senate Amendments
dated May 31

Sponsored by Representative SALINAS; Representatives ALONSO LEON, FAHEY, HELT, HOLVEY, KENY-GUYER, NERON, NOSSE, PRUSAK, SCHOUTEN, SMITH DB, SMITH WARNER, WALLAN, WILLIAMS, Senator WAGNER (Pre-session filed.)

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 manufacturer of prescription drugs to report to Department of Consumer and Business Services [*planned*] **specified** increase in price of certain prescription drugs at least 60 days before date of increase. Provides exceptions.

A BILL FOR AN ACT

1
2 Relating to prescription drug costs.

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

4 **SECTION 1. The legislative intent of section 2 of this 2019 Act is to improve public health**
5 **and safety by taking steps to address the spiraling health care costs for residents of this**
6 **state.**

7 **SECTION 2. (1) As used in this section:**

8 (a) **“Drug” has the meaning given that term in ORS 689.005.**

9 (b)(A) **“Manufacture” means:**

10 (i) **The production, preparation, propagation, compounding, conversion or processing of**
11 **a drug, either directly or indirectly by extraction from substances of natural origin or inde-**
12 **pendently by means of chemical synthesis, or by a combination of extraction and chemical**
13 **synthesis; and**

14 (ii) **The packaging or repackaging of a drug or labeling or relabeling of a drug container.**

15 (B) **“Manufacture” does not include the preparation or compounding of a drug by an in-**
16 **dividual for the individual’s own use or the preparation, compounding, packaging or labeling**
17 **of a drug:**

18 (i) **By a health care practitioner incidental to administering or dispensing a drug in the**
19 **course of professional practice;**

20 (ii) **By a health care practitioner or under the practitioner’s authorization and super-**
21 **vision for the purpose of or incidental to research, teaching or chemical analysis activities**
22 **and not for sale;**

23 (iii) **By a health care service contractor for dispensing to a subscriber or delivery to a**
24 **health care facility or outpatient clinic owned or operated by the health care service con-**
25 **tractor or an affiliate of the health care service contractor;**

26 (iv) **By a centralized repackaging operation for distribution to subscribers of health care**

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 service contractors or to pharmacies, health care facilities or outpatient clinics whether or
2 not operated by or affiliated with a health care service contractor; or

3 (v) By a health care facility for dispensing to a patient of the health care facility.

4 (c) "Manufacturer" means a person that manufactures a prescription drug that is sold
5 in this state.

6 (d) "Prescription drug" means a drug that must:

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

9 (B) Under any applicable federal or state law or regulation, be dispensed only by pre-
10 scription or restricted to use only by health care practitioners.

11 (e) "Price" means the wholesale acquisition cost as defined in 42 U.S.C. 1395w-3a(c)(6)(B).

12 (2) At least 60 days before a prescription drug manufacturer increases the price of a
13 prescription drug, as described in subsection (3) of this section, the prescription drug man-
14 ufacturer shall report to the Department of Consumer and Business Services, in the form
15 and manner prescribed by the department, all the following information about the pre-
16 scription drug:

17 (a) The date that the increase will become effective;

18 (b) The current price of the prescription drug;

19 (c) The dollar amount of the planned increase in the price of the prescription drug;

20 (d) A statement of whether the price increase is necessitated by a change to or im-
21 mprovement in the prescription drug and, if so, a description of the change or improvement;
22 and

23 (e) The year the drug became available for sale in the United States.

24 (3) Subsection (2) of this section applies to:

25 (a) An increase in the price of a brand-name prescription drug for which there will be,
26 on the date that the increase goes into effect, a cumulative increase of 10 percent or more
27 or an increase of \$10,000 or more in the price of the brand-name prescription drug within a
28 12-month period beginning on or after July 1, 2019.

29 (b) An increase in the price of a generic prescription drug for which there will be, on the
30 date that the increase goes into effect, a cumulative increase of 25 percent or more and an
31 increase of \$300 or more in the price of the generic prescription drug within a 12-month pe-
32 riod beginning on or after July 1, 2019.

33 (4) Subsection (2) of this section does not apply to a prescription drug that is a retail
34 drug, manufactured by four or more companies, that is:

35 (a) Marketed and distributed pursuant to an abbreviated new drug application, approved
36 under 21 U.S.C. 355(j);

37 (b) An authorized generic drug as defined by 41 C.F.R. 447.502; or

38 (c) A drug that entered the market before the year 1962 and was not originally marketed
39 under a new drug application.

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