A-Engrossed House Bill 2658

Ordered by the House April 15 Including House Amendments dated April 15

Sponsored by Representative SALINAS; Representatives ALONSO LEON, FAHEY, HOLVEY, KENY-GUYER, NERON, NOSSE, PRUSAK, SMITH WARNER, WALLAN, WILLIAMS (Presession 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 increase in price of certain prescription drugs at least 60 days before date of increase. **Provides exceptions.**

A BILL FOR AN ACT

2 Relating to prescription drug costs.

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

4 <u>SECTION 1.</u> 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 <u>SECTION 2.</u> (1) As used in this section:

8 (a) "Drug" has the meaning given that term in ORS 689.005.

9 (b)(A) "Manufacture" means:

(i) The production, preparation, propagation, compounding, conversion or processing of
 a drug, either directly or indirectly by extraction from substances of natural origin or inde 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:

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

(ii) By a health care practitioner or under the practitioner's authorization and supervision for the purpose of or incidental to research, teaching or chemical analysis activities
and not for sale;

(iii) By a health care service contractor for dispensing to a subscriber or delivery to a
health care facility or outpatient clinic owned or operated by the health care service contractor or an affiliate of the health care service contractor;

(iv) By a centralized repackaging operation for distribution to subscribers of health care
 service contractors or to pharmacies, health care facilities or outpatient clinics operated by

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or affiliated with a health care service contractor; or 1 2 (v) By a health care facility for dispensing to a patient of the health care facility. (c) "Manufacturer" means a person that manufactures a prescription drug that is sold 3 in this state. 4 $\mathbf{5}$ (d) "Prescription drug" means a drug that must: (A) Under federal law, be labeled "Caution: Federal law prohibits dispensing without 6 prescription" prior to being dispensed or delivered; or 7 (B) Under any applicable federal or state law or regulation, be dispensed only by pre-8 9 scription or restricted to use only by health care practitioners. (e) "Price" means the wholesale acquisition cost as defined in 42 U.S.C. 1395w-3a(c)(6)(B). 10 (2) At least 60 days before a planned increase in the price of a prescription drug described 11 12 in subsection (3) of this section, a prescription drug manufacturer shall report to the Department of Consumer and Business Services, in the form and manner prescribed by the 13 department, all the following information about the prescription drug: 14 15 (a) The date that the increase will become effective; (b) The current price of the prescription drug; 16

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

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

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

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

(a) A brand-name prescription drug for which there was a cumulative increase of 10
 percent or more or an increase of \$10,000 or more in the price of the brand-name pre scription drug during the previous 12-month period.

(b) A generic prescription drug for which there was a cumulative increase of 25 percent
 or more and an increase of \$300 or more in the price of the generic prescription drug during
 the previous 12-month period.

(4) Subsection (2) of this section does not apply to a prescription drug that is a retail
 drug that is marketed or distributed pursuant to:

31 (a) An abbreviated new drug application, approved under 21 U.S.C. 355(j);

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

(c) A drug that entered the market before the year 1962, was not originally marketed
 under a new drug application and is manufactured by four or more companies.

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