

House Bill 3486

Sponsored by Representatives KENY-GUYER, GREENLICK; Representative NOSSE, Senators KRUSE, MONNES ANDERSON

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 **as introduced**.

Requires manufacturer of prescription drug with annual wholesale acquisition cost of \$10,000 or more, or with wholesale acquisition cost of \$10,000 or more per course of treatment, to file annual report with Oregon Health Authority on costs associated with prescription drug for previous calendar year.

A BILL FOR AN ACT

1
2 Relating to prescription drugs.

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

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

5 (a) "Manufacturer" has the meaning given that term in ORS 689.005.

6 (b) "Prescription drug" has the meaning given that term in ORS 689.005.

7 (2) **If a prescription drug has an annual wholesale acquisition cost of \$10,000 or more, or**
8 **has a wholesale acquisition cost of \$10,000 or more per course of treatment, and the man-**
9 **ufacturer of the prescription drug distributes the prescription drug for sale in this state, the**
10 **manufacturer shall file an annual report with the Oregon Health Authority on costs associ-**
11 **ated with the prescription drug for the previous calendar year. A report filed under this**
12 **subsection must be filed on or before May 1 of each year in a form and manner prescribed**
13 **by the authority.**

14 (3) **A report filed under subsection (1) of this section must contain an itemized account**
15 **of the following:**

16 (a) **Costs paid by the manufacturer for researching and developing the prescription drug;**

17 (b) **Costs paid by any predecessor manufacturer for researching and developing the pre-**
18 **scription drug;**

19 (c) **Costs paid by the manufacturer and any predecessor manufacturer for researching**
20 **and developing the prescription drug with moneys made available to the manufacturer or**
21 **predecessor manufacturer through a federal, state or other governmental program or**
22 **through a subsidy, grant or other form of monetary support;**

23 (d) **Costs paid by the manufacturer for clinical trials for the prescription drug;**

24 (e) **Costs paid by any predecessor manufacturer for clinical trials for the prescription**
25 **drug;**

26 (f) **Costs paid by the manufacturer for manufacturing and distributing the prescription**
27 **drug;**

28 (g) **Costs paid by the manufacturer for acquiring the prescription drug, including costs**
29 **paid by the manufacturer for purchasing patents for or licensing the prescription drug or**
30 **costs paid by the manufacturer for acquiring property rights to the prescription drug;**

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 (h) Costs paid by the manufacturer for marketing and advertising the prescription drug
 2 to consumers of the prescription drug, including any costs associated with offering and re-
 3 deeming coupons; and

4 (i) Costs paid by the manufacturer for marketing and advertising the prescription drug
 5 to prescribers of the prescription drug.

6 (4) In addition to an itemized accounting of the costs described in subsection (3) of this
 7 section, a report filed under subsection (1) of this section must contain the following:

8 (a) Each increase in the average wholesale price of the prescription drug for that year,
 9 expressed as a percentage of the average wholesale price, and the date on which each in-
 10 crease occurred;

11 (b) Each increase in the wholesale acquisition cost for the prescription drug for that
 12 year, expressed as a percentage of the wholesale acquisition cost, and the date on which each
 13 increase occurred;

14 (c) The total profit derived from sales of the prescription drug, expressed in total dollars
 15 and as a percentage of the manufacturer's total profit for that year; and

16 (d) The total amount of financial assistance that the manufacturer has provided through
 17 patient prescription assistance programs for the prescription drug.

18 (5)(a) An independent third party must audit a report prepared pursuant to this section
 19 before the report is filed under subsection (1) of this section. The manufacturer of the pre-
 20 scription drug must select the third party from among a list of potential auditors made
 21 available by the authority.

22 (b) Upon completing an audit pursuant to this subsection, the third party must file a
 23 summary of the audit with the authority. A summary filed under this subsection must be
 24 filed on or before May 1 of each year in a form and manner prescribed by the authority.

25 (c) The manufacturer of the prescription drug must pay all costs associated with auditing
 26 and filing a summary under this subsection.

27 (6) The authority shall publish on a website maintained by the authority reports filed
 28 under subsection (1) of this section and any information that the authority deems necessary
 29 to assist the general public in understanding reports filed under subsection (1) of this sec-
 30 tion.

31 (7) The authority shall adopt rules necessary to implement this section.

32 **SECTION 2.** (1) The Oregon Health Authority shall adopt rules necessary to implement
 33 section 1 of this 2015 Act no later than January 1, 2017. For purposes of adopting the initial
 34 rules necessary to implement section 1 of this 2015 Act, the authority shall convene a rules
 35 advisory committee as described in ORS 183.333.

36 (2) At a minimum, the rules advisory committee convened pursuant to subsection (1) of
 37 this section must include:

38 (a) An individual who represents the pharmaceutical industry;

39 (b) An individual who represents an insurer offering an insurance policy that is not a
 40 health benefit plan as defined in ORS 743.730;

41 (c) An individual who represents an insurer offering an insurance policy that is a health
 42 benefit plan as defined in ORS 743.730;

43 (d) An individual who represents pharmacy benefit managers;

44 (e) One or more individuals who represent consumers of prescription drugs;

45 (f) One or more individuals who represent health care practitioners with prescriptive

1 **privileges;**

2 **(g) The Director of the Department of Consumer and Business Services or the director's**
3 **designee; and**

4 **(h) The Director of the Oregon Health Authority or the director's designee.**

5 **SECTION 3. A manufacturer of a prescription drug for which an annual report must be**
6 **filed under section 1 of this 2015 Act must file the initial report on or before May 1, 2017.**

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