

**PROPOSED AMENDMENTS TO
SENATE BILL 71**

1 On page 1 of the printed bill, after line 4, insert:

2
3 **“PRESCRIPTION MONITORING PROGRAM**

4
5 On page 8, after line 36, insert:

6
7 **“PRESCRIPTION DRUG MANUFACTURER REPORTING**

8
9 **“SECTION 4. (1) As used in this section:**

10 **“(a) ‘Manufacturer’ has the meaning given that term in ORS**
11 **689.005.**

12 **“(b) ‘Prescription drug’ has the meaning given that term in ORS**
13 **689.005.**

14 **“(2) If a prescription drug has an annual wholesale acquisition cost**
15 **of \$10,000 or more, or has a wholesale acquisition cost of \$10,000 or**
16 **more per course of treatment, and the manufacturer of the pre-**
17 **scription drug distributes the prescription drug for sale in this state,**
18 **the manufacturer shall file an annual report with the Oregon Health**
19 **Authority on costs associated with the prescription drug for the pre-**
20 **vious calendar year. A report filed under this subsection must be filed**
21 **on or before May 1 of each year in a form and manner prescribed by**
22 **the authority.**

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

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

5 **“(b) Costs paid by any predecessor manufacturer for researching**
6 **and developing the prescription drug;**

7 **“(c) Costs paid by the manufacturer and any predecessor manufac-**
8 **turer for researching and developing the prescription drug with mon-**
9 **eys made available to the manufacturer or predecessor manufacturer**
10 **through a federal, state or other governmental program or through a**
11 **subsidy, grant or other form of monetary support;**

12 **“(d) Costs paid by the manufacturer for clinical trials for the pre-**
13 **scription drug;**

14 **“(e) Costs paid by any predecessor manufacturer for clinical trials**
15 **for the prescription drug;**

16 **“(f) Costs paid by the manufacturer for manufacturing and distrib-**
17 **uting the prescription drug;**

18 **“(g) Costs paid by the manufacturer for acquiring the prescription**
19 **drug, including costs paid by the manufacturer for purchasing patents**
20 **for or licensing the prescription drug or costs paid by the manufac-**
21 **turer for acquiring property rights to the prescription drug;**

22 **“(h) Costs paid by the manufacturer for marketing and advertising**
23 **the prescription drug to consumers of the prescription drug, including**
24 **any costs associated with offering and redeeming coupons; and**

25 **“(i) Costs paid by the manufacturer for marketing and advertising**
26 **the prescription drug to prescribers of the prescription drug.**

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

30 **“(a) Each increase in the average wholesale price of the prescription**

1 drug for that year, expressed as a percentage of the average wholesale
2 price, and the date on which each increase occurred;

3 “(b) Each increase in the wholesale acquisition cost for the pre-
4 scription drug for that year, expressed as a percentage of the whole-
5 sale acquisition cost, and the date on which each increase occurred;

6 “(c) The total profit derived from sales of the prescription drug,
7 expressed in total dollars and as a percentage of the manufacturer’s
8 total profit for that year; and

9 “(d) The total amount of financial assistance that the manufacturer
10 has provided through patient prescription assistance programs for the
11 prescription drug.

12 “(5)(a) An independent third party must audit a report prepared
13 pursuant to this section before the report is filed under subsection (1)
14 of this section. The manufacturer of the prescription drug must select
15 the third party from among a list of potential auditors made available
16 by the authority.

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

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

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

28 “(7) The authority shall adopt rules necessary to implement this
29 section.

30 **SECTION 5.** (1) The Oregon Health Authority shall adopt rules

1 necessary to implement section 4 of this 2015 Act no later than Janu-
2 ary 1, 2017. For purposes of adopting the initial rules necessary to
3 implement section 4 of this 2015 Act, the authority shall convene a
4 rules advisory committee as described in ORS 183.333.

5 “(2) At a minimum, the rules advisory committee convened pursu-
6 ant to subsection (1) of this section must include:

7 “(a) An individual who represents the pharmaceutical industry;

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

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

12 “(d) An individual who represents pharmacy benefit managers;

13 “(e) One or more individuals who represent consumers of pre-
14 scription drugs;

15 “(f) One or more individuals who represent health care practitioners
16 with prescriptive privileges;

17 “(g) The Director of the Department of Consumer and Business
18 Services or the director’s designee; and

19 “(h) The Director of the Oregon Health Authority or the director’s
20 designee.

21 “SECTION 6. A manufacturer of a prescription drug for which an
22 annual report must be filed under section 4 of this 2015 Act must file
23 the initial report on or before May 1, 2017.

24
25 **“MISCELLANEOUS**

26
27 “SECTION 7. The unit captions used in this 2015 Act are provided
28 only for the convenience of the reader and do not become part of the
29 statutory law of this state or express any legislative intent in the
30 enactment of this 2015 Act.”.

1 In line 37, delete "4" and insert "8".

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