SB 71-3 (LC 1059) 4/3/15 (MBM/ps)

## PROPOSED AMENDMENTS TO SENATE BILL 71

- On page 1 of the printed bill, after "drugs" delete the rest of the line and delete line 3 and insert a period.
- Delete lines 5 through 31 and delete pages 2 through 8 and insert:
- 4 "SECTION 1. (1) As used in this section:

22

- 5 "(a) 'Manufacturer' has the meaning given that term in ORS 689.005.
- "(b) 'Prescription drug' has the meaning given that term in ORS 689.005.
- "(2) If a prescription drug has an annual wholesale acquisition cost 9 of \$10,000 or more, or has a wholesale acquisition cost of \$10,000 or 10 more per course of treatment, and the manufacturer of the pre-11 scription drug distributes the prescription drug for sale in this state, 12 the manufacturer shall file an annual report with the Oregon Health 13 Authority on costs associated with the prescription drug for the previous calendar year. A report filed under this subsection must be filed 15 on or before May 1 of each year in a form and manner prescribed by 16 the authority. 17
- 18 "(3) A report filed under subsection (1) of this section must contain 19 an itemized account of the following:
- 20 "(a) Costs paid by the manufacturer for researching and developing
  21 the prescription drug;
  - "(b) Costs paid by any predecessor manufacturer for researching

and developing the prescription drug;

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

29

30

- "(c) Costs paid by the manufacturer and any predecessor manufacturer for researching and developing the prescription drug with moneys made available to the manufacturer or predecessor manufacturer through a federal, state or other governmental program or through a subsidy, grant or other form of monetary support;
- "(d) Costs paid by the manufacturer for clinical trials for the presentation drug;
  - "(e) Costs paid by any predecessor manufacturer for clinical trials for the prescription drug;
  - "(f) Costs paid by the manufacturer for manufacturing and distributing the prescription drug;
  - "(g) Costs paid by the manufacturer for acquiring the prescription drug, including costs paid by the manufacturer for purchasing patents for or licensing the prescription drug or costs paid by the manufacturer for acquiring property rights to the prescription drug;
  - "(h) Costs paid by the manufacturer for marketing and advertising the prescription drug to consumers of the prescription drug, including any costs associated with offering and redeeming coupons; and
  - "(i) Costs paid by the manufacturer for marketing and advertising the prescription drug to prescribers of the prescription drug.
  - "(4) In addition to an itemized accounting of the costs described in subsection (3) of this section, a report filed under subsection (1) of this section must contain the following:
  - "(a) Each increase in the average wholesale price of the prescription drug for that year, expressed as a percentage of the average wholesale price, and the date on which each increase occurred;
  - "(b) Each increase in the wholesale acquisition cost for the prescription drug for that year, expressed as a percentage of the wholesale acquisition cost, and the date on which each increase occurred;

- "(c) The total profit derived from sales of the prescription drug, expressed in total dollars and as a percentage of the manufacturer's total profit for that year; and
- "(d) The total amount of financial assistance that the manufacturer has provided through patient prescription assistance programs for the prescription drug.
  - "(5)(a) An independent third party must audit a report prepared pursuant to this section before the report is filed under subsection (1) of this section. The manufacturer of the prescription drug must select the third party from among a list of potential auditors made available by the authority.
  - "(b) Upon completing an audit pursuant to this subsection, the third party must file a summary of the audit with the authority. A summary filed under this subsection must be filed on or before May 1 of each year in a form and manner prescribed by the authority.
  - "(c) The manufacturer of the prescription drug must pay all costs associated with auditing and filing a summary under this subsection.
  - "(6) The authority shall publish on a website maintained by the authority reports filed under subsection (1) of this section and any information that the authority deems necessary to assist the general public in understanding reports filed under subsection (1) of this section.
  - "(7) The authority shall adopt rules necessary to implement this section.
- "SECTION 2. (1) The Oregon Health Authority shall adopt rules necessary to implement section 1 of this 2015 Act no later than January 1, 2017. For purposes of adopting the initial rules necessary to implement section 1 of this 2015 Act, the authority shall convene a rules advisory committee as described in ORS 183.333.
  - "(2) At a minimum, the rules advisory committee convened pursu-

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

30

ant to subsection (1) of this section must include:

2

7

10

11

12

13

14

15

16

17

18

- "(a) An individual who represents the pharmaceutical industry;
- "(b) An individual who represents an insurer offering an insurance policy that is not a health benefit plan as defined in ORS 743.730;
- 5 "(c) An individual who represents an insurer offering an insurance 6 policy that is a health benefit plan as defined in ORS 743.730;
  - "(d) An individual who represents pharmacy benefit managers;
- 8 "(e) One or more individuals who represent consumers of pre-9 scription drugs;
  - "(f) One or more individuals who represent health care practitioners with prescriptive privileges;
  - "(g) The Director of the Department of Consumer and Business Services or the director's designee; and
  - "(h) The Director of the Oregon Health Authority or the director's designee.
  - "SECTION 3. A manufacturer of a prescription drug for which an annual report must be filed under section 1 of this 2015 Act must file the initial report on or before May 1, 2017."

\_\_\_\_\_