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State of Minnesota

HOUSE OF REPRESENTATIVES

A bill for an act

relating to health; requiring cost disclosure for qualifying prescription drugs;

EIGHTY-NINTH SESSION

H. F. No.

2525

03/08/2016 Authored by Mullery

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The bill was read for the first time and referred to the Committee on Health and Human Services Reform

| 1.3 | proposing coding for new law in Minnesota Statutes, chapter 144. | | |
|------|-------------------------------------------------------------------------------------------------|--|--|
| 1.4 | BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA: | | |
| | | | |
| 1.5 | Section 1. [144.7031] PRESCRIPTION DRUG COST TRANSPARENCY. | | |
| 1.6 | Subdivision 1. Intent and findings. It is the intent of the legislature to make | | |
| 1.7 | information available to the public about the cost of ultra-high-priced pharmaceuticals in | | |
| 1.8 | order to make pharmaceutical pricing as transparent as the pricing in other sectors of the | | |
| 1.9 | health care industry. To fulfill this goal, the legislature finds that there should be annual | | |
| 1.10 | cost reporting on the most expensive drugs that would allow policy makers, government | | |
| 1.11 | agencies, and others to understand costs for these important products. | | |
| 1.12 | Subd. 2. Definitions. (a) For purposes of this section, the following definitions apply. | | |
| 1.13 | (b) "Manufacturer" has the meaning provided in section 151.01, subdivision 14a. | | |
| 1.14 | (c) "Wholesale acquisition cost" or "WAC" means the manufacturer's list price | | |
| 1.15 | for a drug or biological to wholesalers or direct purchasers in the United States, not | | |
| 1.16 | including prompt pay or other discounts, rebates, or reductions in price, for the most | | |
| 1.17 | recent month for which information is available, as reported in wholesale price guides | | |
| 1.18 | or other publications of drug or biological pricing data. | | |
| 1.19 | Subd. 3. Cost reporting for qualifying drugs. (a) Each manufacturer of a | | |
| 1.20 | prescription drug, made available in Minnesota, that has a wholesale acquisition cost | | |
| 1.21 | of \$10,000 or more annually or per course of treatment, shall file a report with the | | |
| 1.22 | commissioner as provided in this subdivision on the costs for each qualifying drug. | | |
| 1.23 | (b) The report shall include all of the following for each qualifying drug: | | |
| | | | |

(1) the total costs for the production of the drug, including all of the following:

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| 2.1 | (i) the total research and development costs paid by the manufacturer, and separately |
|------|---------------------------------------------------------------------------------------------|
| 2.2 | the total research and development costs paid by any predecessor in the development of |
| 2.3 | the drug; |
| 2.4 | (ii) the total costs of clinical trials and other regulatory costs paid by the |
| 2.5 | manufacturer, and separately the total costs of clinical trials and other regulatory costs |
| 2.6 | paid by any predecessor in the development of the drug; |
| 2.7 | (iii) the total costs for materials, manufacturing, and administration attributable to |
| 2.8 | the drug; |
| 2.9 | (iv) the total costs paid by any entity other than the manufacturer or predecessor |
| 2.10 | for research and development, including any amount from federal, state, or other |
| 2.11 | governmental programs or any form of subsidies, grants, or other support; |
| 2.12 | (v) any other costs to acquire the drug, including all or any costs for the purchase of |
| 2.13 | patents, licensing, or acquisition of any corporate entity owning any rights to the drug |
| 2.14 | while in development; and |
| 2.15 | (vi) the total marketing and advertising costs for the promotion of the drug directly to |
| 2.16 | consumers, including but not limited to costs associated with direct-to-consumer coupons |
| 2.17 | and the amount redeemed, total marketing and advertising costs for promotion of the drug |
| 2.18 | directly or indirectly to prescribers, and any other advertising for the drug; |
| 2.19 | (2) a cumulative annual history of average wholesale price (AWP) and WAC |
| 2.20 | increases for the drug, expressed as percentages, including the month each increase in |
| 2.21 | each category, AWP and WAC, took effect; |
| 2.22 | (3) the total profit attributable to the drug as represented in total dollars and as a |
| 2.23 | percentage of the total company profits that were derived from the sale of the drug; and |
| 2.24 | (4) the total amount of financial assistance the manufacturer has provided through |
| 2.25 | patient prescription assistance programs, if available. |
| 2.26 | (c) All of the information in paragraph (b) shall be itemized and documented by the |
| 2.27 | manufacturer and audited by a fully independent third-party auditor prior to filing. |
| 2.28 | (d) No later than May 1, 2017, and each May 1 thereafter, manufacturers shall file |
| 2.29 | the information required by this subdivision annually with the commissioner on a form |
| 2.30 | prescribed by the commissioner. |
| 2.31 | Subd. 4. Report to the legislature. No later than August 1, 2017, and each August |
| 2.32 | 1 thereafter, the commissioner shall issue a report annually to the legislature summarizing |
| 2.33 | the information submitted under this section. The commissioner shall also make the report |
| 2.34 | available to the public on the agency Web site. |
| 2.35 | Subd. 5. Advisory committee. The commissioner shall convene an advisory |
| 2.36 | committee to develop the form required by this section. The committee shall include, but |

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- is not limited to, representatives of the pharmaceutical industry, health carriers, pharmacy
- benefit managers, state agencies, consumer advocates, pharmacists, and physicians.

3.3 **EFFECTIVE DATE.** This section is effective the day following final enactment.

Section 1. 3