



State of Wisconsin
2021 - 2022 LEGISLATURE

LRB-4364/1
TJD:emw

2021 ASSEMBLY BILL 512

August 31, 2021 - Introduced by Representatives CONLEY, HEBL, ANDRACA, SHELTON, POPE, CABRERA, VRUWINK, SPREITZER, VINING, CABRAL-GUEVARA, SHANKLAND, BOWEN, SINICKI, NEUBAUER and SNODGRASS, cosponsored by Senators AGARD, ERPENBACH, JOHNSON, RINGHAND, CARPENTER, LARSON, PFAFF and SMITH. Referred to Committee on Health.

1 **AN ACT to create** 146.901 of the statutes; **relating to:** prescription drug cost
2 reporting by manufacturers and providing a penalty.

Analysis by the Legislative Reference Bureau

This bill requires certain cost reporting by manufacturers of brand-name and generic drugs. The bill requires a manufacturer to notify the Department of Health Services and the Office of the Commissioner of Insurance if it is 1) increasing the wholesale acquisition cost of a brand-name drug on the market in Wisconsin by more than 25 percent over a 24-month period; 2) intending to introduce in Wisconsin a brand-name drug that has an annual wholesale acquisition cost of \$30,000 or more; 3) increasing the wholesale acquisition cost of a generic drug on the market in Wisconsin by more than 25 percent or by more than \$300 during any 12-month period; or 4) intending to introduce in Wisconsin a generic drug that has an annual wholesale acquisition cost of \$3,000 or more. The manufacturer must provide the notice at least 30 days before the planned date of the increase or introduction and must provide a justification including a description described in the bill. A manufacturer is also required to annually report to DHS and OCI the value of price concessions provided to each pharmacy benefit manager for each drug sold in Wisconsin for which a notice was required. The bill also requires each manufacturer of a brand-name or generic drug sold in Wisconsin to submit to DHS and OCI a report containing a description of each manufacturer-sponsored assistance program in effect during the previous year that includes the criteria for participation, the program terms, and the number of prescriptions and the total market value of assistance provided to residents of Wisconsin under the program. The manufacturer

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must certify the information provided in a notice or report required under the bill under penalty of perjury, and failure to provide the notice or report is subject to a forfeiture determined by DHS but not to exceed \$10,000 per day past due.

The bill requires DHS to publish the pricing justification information reported by manufacturers on its Internet site. DHS must also analyze the information and publish a report on its Internet site describing trends in drug pricing.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

1 **SECTION 1.** 146.901 of the statutes is created to read:

2 **146.901 Prescription drug cost reporting by manufacturers. (1)**

3 DEFINITIONS. In this section:

4 (a) “Brand-name drug” is a prescription drug approved under 21 USC 355 (b)
5 or 42 USC 262.

6 (b) “Generic drug” is a prescription drug approved under 21 USC 355 (j).

7 (c) “Manufacturer” has the meaning given in s. 450.01 (12). “Manufacturer”
8 does not include an entity that is engaged only in the dispensing, as defined in s.
9 450.01 (7), of a brand-name drug or a generic drug.

10 (d) “Manufacturer-sponsored assistance program” means a program offered by
11 a manufacturer or an intermediary under contract with a manufacturer through
12 which a brand-name drug or a generic drug is provided to a patient at no charge or
13 at a discount.

14 (e) “Office” means the office of the commissioner of insurance.

15 (f) “Pharmacy benefit manager” has the meaning given in s. 632.865 (1) (c).

16 (g) “Wholesale acquisition cost” means the most recently reported
17 manufacturer list or catalog price for a brand-name drug or a generic drug available
18 to wholesalers or direct purchasers in the United States, before application of
19 discounts, rebates, or reductions in price.

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1 **(2) PRICE INCREASE OR INTRODUCTION NOTICE; JUSTIFICATION REPORT.** (a) A
2 manufacturer shall notify the department and the office if it is increasing the
3 wholesale acquisition cost of a brand-name drug on the market in this state by more
4 than 25 percent over a 24-month period or if it intends to introduce to market in this
5 state a brand-name drug that has an annual wholesale acquisition cost of \$30,000
6 or more.

7 (b) A manufacturer shall notify the department and the office if it is increasing
8 the wholesale acquisition cost of a generic drug on the market in this state by more
9 than 25 percent or by more than \$300 during any 12-month period or if it intends
10 to introduce to market in this state a generic drug that has an annual wholesale
11 acquisition cost of \$3,000 or more.

12 (c) The manufacturer shall provide the notice under par. (a) or (b) in writing
13 at least 30 days before the planned effective date of the cost increase or drug
14 introduction and shall provide a justification that includes all documents and
15 research related to the manufacturer's selection of the price increase or introduction
16 price and includes a description of all of the following:

- 17 1. The estimated cost-effectiveness of the drug.
- 18 2. The price and effectiveness of similar drugs available in this state and the
19 anticipated sales performance of the drug as compared to similar drugs.
- 20 3. The impact of negotiated or mandated discounts to pharmacy benefit
21 managers, insurers, and other payers of health care costs on the pricing
22 determination for the drug.

23 (d) By March 1 annually, each manufacturer shall report to the department and
24 the office the value of price concessions, expressed as a percentage of the wholesale
25 acquisition cost, provided to each pharmacy benefit manager for each drug sold by

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1 the manufacturer in this state for which a notice is required under par. (a) or (b) in
2 the previous calendar year.

3 **(3) MANUFACTURER-SPONSORED ASSISTANCE PROGRAMS.** By March 1 annually,
4 each manufacturer of a brand-name drug or generic drug sold in this state shall
5 submit to the department and the office a report containing a description of each
6 manufacturer-sponsored assistance program in effect during the previous calendar
7 year that includes all of the following:

8 (a) The criteria for participation in the manufacturer-sponsored assistance
9 program and the manufacturer-sponsored assistance program terms.

10 (b) The number of prescriptions provided to residents of this state under the
11 manufacturer-sponsored assistance program.

12 (c) The total market value of assistance provided to residents of this state under
13 the manufacturer-sponsored assistance program.

14 **(4) PENALTY.** The manufacturer shall certify the information reported under
15 sub. (2) or (3) as accurate under penalty of perjury. A manufacturer that fails to
16 provide the notice or report under sub. (2) or (3) is subject to a forfeiture as
17 determined by the department but not to exceed \$10,000 for each day the notice or
18 report is past due.

19 **(5) POSTING OF REPORT; HEARING.** (a) The department shall publish on its
20 Internet site the justification documentation provided under sub. (2) (c).

21 (b) The department shall analyze the information submitted under subs. (2)
22 and (3) and publish a report on its Internet site describing trends in drug pricing.
23 The department shall conduct at least one public hearing annually on the findings
24 of the report.

25

(END)