

State of Misconsin 2019 - 2020 LEGISLATURE

LRB-1471/1 EKL:cdc

# 2019 ASSEMBLY BILL 62

March 7, 2019 – Introduced by Representatives Myers, Anderson, Subeck, Sinicki, VRUWINK, ZAMARRIPA, FIELDS, BROSTOFF, SPREITZER, SHANKLAND and HEBL, cosponsored by Senators L. TAYLOR and CARPENTER. Referred to Committee on Insurance.

1 AN ACT *to create* 632.863, 632.864 and 632.865 (2) (c) of the statutes; **relating** 

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to: manufacturer and insurer disclosure of prescription drug costs.

#### Analysis by the Legislative Reference Bureau

This bill imposes disclosure requirements related to prescription drug costs on drug manufacturers and health insurers.

First, the bill requires that a manufacturer of a prescription drug whose wholesale acquisition cost exceeds \$40 notify certain purchasers of the drug, including the state, health insurers, and pharmacy benefit managers doing business in Wisconsin, when the cost for a course of therapy increases by more than 16 percent. The notice must be provided at least 60 days prior to the increase to the purchasers who have registered with the Office of the Commissioner of Insurance to receive notification. In addition to notifying the purchasers, the manufacturer must provide OCI with specified information about the increase, including the financial and nonfinancial factors used to make the decision to increase the drug's cost. Under the bill, a drug manufacturer must also notify OCI if the manufacturer releases a new drug whose wholesale acquisition cost exceeds the specialty drug tier threshold under the Medicare Part D program, which is currently \$670 for a one-month supply. The bill directs OCI to publish the information it receives from manufacturers about cost increases and high-cost new drugs on its website. A manufacturer who fails to report information to OCI may be liable for a penalty of \$1,000 for each day of the failure.

Second, the bill requires that an insurer issuing health insurance coverage in this state annually file a report with OCI that identifies which of the plan's covered

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drugs have the highest prescription rates and costs and, for large group plans, provides information about the relationship between prescription drug costs and premium rates. The bill directs OCI to use this information to annually compile a report that analyzes the overall impact in this state of drug costs on health care premiums. The report must be distributed to the legislature and published on OCI's website.

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

**SECTION 1.** 632.863 of the statutes is created to read:

### 2 **632.863 Prescription drug manufacturer notifications. (1)** DEFINITIONS.

- 3 In this section:
- 4 (a) "Course of therapy" means the recommended daily dosage units of a 5 prescription drug pursuant to its prescribing label as approved by the federal food 6 and drug administration for 30 days or for a normal course of treatment that is less 7 the 20 d
- 7 than 30 days.
- 8 (b) "Manufacturer" means a manufacturer of a prescription drug that is
  9 purchased or reimbursed by any of the following:
- 1. A state or local government purchaser in Wisconsin or an entity acting on
   behalf of the state or local government.
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- 2. An insurer, as defined in s. 632.745 (15).
- 13 3. A pharmacy benefit manager, as defined in s. 632.865 (1) (c).
- 14 4. Any other purchaser identified in rules promulgated by the commissioner.

(2) NOTIFICATION TO PURCHASER. A manufacturer of a prescription drug with a wholesale acquisition cost of more than \$40 for a course of therapy shall notify each purchaser described in sub. (1) (b) 1. to 4. who registers with the commissioner to receive notification if the increase in the wholesale acquisition cost of the drug exceeds 16 percent, including the proposed increase and the cumulative increases

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1 that occurred within the previous 2 calendar years prior to the current year. The  $\mathbf{2}$ commissioner shall make available to manufacturers a list of purchasers who 3 register to receive notification under this subsection. The notice shall be provided 4 at least 60 days prior to the planned effective date of the increase and shall include 5all of the following: 6

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(a) The date of the increase.

(b) The current wholesale acquisition cost of the drug.

8 (c) The dollar amount of the future increase in the wholesale acquisition cost 9 of the drug.

10 (d) A statement of whether a change or improvement in the drug necessitates 11 the price increase and a description of any change or improvement.

- 12 (3) NOTIFICATION TO COMMISSIONER. A manufacturer required to report an 13 increase in the wholesale acquisition cost of a drug under sub. (2) shall report to the 14 commissioner, at the time and in the format prescribed by the commissioner, all of 15the following information:
- 16 (a) The amount of the increase and a description of the specific financial and 17nonfinancial factors used to make the decision to increase the cost, including an 18 explanation of how the factors justify the increase.
- 19 20

(b) A schedule of the manufacturer's wholesale acquisition cost increases for the drug during the previous 5 years.

21(c) If the drug was acquired by the manufacturer within the previous 5 years, 22the name of the company from which it was acquired, the date acquired, the purchase 23price, and the drug's wholesale acquisition cost on the date acquired, the date one 24year prior to acquisition, and the date the drug was introduced to market.

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(d) The patent expiration date of the drug if under patent.

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(e) A statement of whether the drug is a multiple source drug, an innovator
 multiple source drug, a noninnovator multiple source drug, or a single source drug,
 as each of these terms is defined in 42 USC 1396r-8 (k) (7) (A).

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(f) A description of any change or improvement in the drug that necessitates the cost increase.

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(g) The volume of sales of the drug in the United States for the previous year.

7 (4) NOTIFICATION FOR NEW DRUGS. A manufacturer that introduces a new 8 prescription drug to market at a wholesale acquisition cost that exceeds the specialty 9 tier threshold set by the federal centers for medicare and medicaid services under the 10 Medicare Part D program shall notify the commissioner no later than 3 days after 11 the release of the drug in the commercial market. A manufacturer may make this notification pending approval by the federal food and drug administration if 12commercial availability is expected within 3 days of approval. No later than 30 days 1314 after providing the notification, the manufacturer shall file with the commissioner 15a report, in a format prescribed by the commissioner, that contains all of the 16 following:

- 17 (a) A description of the marketing and pricing plans used in the launch of the18 drug in the United States and internationally.
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(b) The estimated volume of patients that may be prescribed the drug.

20 (c) A statement of whether the drug was granted breakthrough therapy
21 designation or priority review by the federal food and drug administration prior to
22 final approval.

23 (d) The date and price of acquisition if the drug was not developed by the24 manufacturer.

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1 (5) LIMITS ON DISCLOSURE. A manufacturer may limit the information reported  $\mathbf{2}$ to the commissioner under sub. (3) or (4) to information that is in the public domain 3 or publicly available.

4 (6) PUBLIC DISCLOSURE OF INFORMATION. The commissioner shall publish the  $\mathbf{5}$ information it receives under subs. (3) and (4) on its Internet site within 60 days of 6 receiving the information from a manufacturer. The information shall be published in a manner that identifies the information that is disclosed on a per-drug basis and 7 8 may not be aggregated in a manner that does not allow identification of each drug.

9 (7) PENALTY. A manufacturer that fails to provide information to the 10 commissioner under sub. (3) or (4) when due may be subject to a \$1,000 penalty for 11 each day the manufacturer fails to provide the information. The commissioner may reduce or waive a penalty under this subsection for good cause. The commissioner 12may commence civil proceedings to enforce this subsection if a manufacturer fails to 1314 provide any information required under sub. (3) or (4) when due.

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**SECTION 2.** 632.864 of the statutes is created to read:

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632.864 Reporting related to prescription drug costs. (1) In this section: (a) "Covered prescription drug" means a drug covered under a disability 1718 insurance policy or group health benefit plan that is dispensed at a plan pharmacy. 19 network pharmacy, or mail order pharmacy for outpatient use.

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(b) "Group health benefit plan" has the meaning given in s. 632.745 (9).

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(c) "Insurer" has the meaning given in s. 632.745 (15).

22(d) "Specialty drug" means a drug whose cost exceeds the specialty tier 23threshold set by the federal centers for medicare and medicaid services under the 24Medicare Part D program.

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1	(2) Annually no later than October 1, an insurer shall file a report with the
<b>2</b>	commissioner that contains all of the following information for each health benefit
3	plan covering individuals in this state or eligible employees of one or more employers
4	in this state:
5	(a) The 25 covered prescription drugs that are most frequently prescribed.
6	(b) The 25 covered prescription drugs that are the most costly as measured by
7	total annual plan spending.
8	(c) The 25 covered prescription drugs with the highest year-over-year increase
9	in total annual plan spending.
10	(3) Annually no later than October 1, an insurer issuing a group health benefit
11	plan in the large group market, as defined in s. 632.745 (17), shall file with the
12	commissioner a report, in a format prescribed by the commissioner, that contains all
13	of the following:
14	(a) For each of the following categories of covered prescription drugs, the
15	percentage of the premium that is attributable to prescription drug costs for the prior
16	year and the year-over-year increase, as a percentage, in per-member, per-month
17	total health insurer spending:
18	1. Generic drugs excluding specialty generic drugs.
19	2. Brand name drugs excluding specialty drugs.
20	3. Brand name and generic specialty drugs.
21	(b) The year-over-year increase in per-member, per-month costs for drug
22	prices compared to other components of the premium.
23	(c) The specialty tier formulary list.

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1 (d) The percentage of the premium that is attributable to prescription drugs  $\mathbf{2}$ administered in a doctor's office that are covered under the medical benefit as 3 separate from the pharmacy benefit, if available.

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(e) If the insurer uses a pharmacy benefit manager, the name of the pharmacy benefit manager and a statement identifying the components of the plan's  $\mathbf{5}$ prescription drug coverage that are managed by the pharmacy benefit manager. 6

7 (4) Annually no later than February 1, the commissioner shall compile the 8 information received in the prior year under subs. (2) and (3) into a report that 9 demonstrates the overall impact in this state of drug costs on health care premiums. 10 The data in the report shall be aggregated and may not reveal information specific to individual insurers. The report shall be submitted to the chief clerk of each house 11 12 of the legislature, for distribution to the legislature under s. 13.172 (2), and published 13 on the commissioner's Internet site.

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**SECTION 3.** 632.865 (2) (c) of the statutes is created to read:

15632.865 (2) (c) A pharmacy benefit manager who receives notice under s. 16 632.863 (2) of an increase in a wholesale acquisition cost of a prescription drug shall 17notify any contracting purchaser that provides coverage to more than 500 18 individuals of the increase in cost.

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## **SECTION 4. Nonstatutory provisions.**

20 (1) REPORT BY LEGISLATIVE AUDIT BUREAU. No later than January 1, 2023, the 21legislative audit bureau shall submit a report to the chief clerk of each house of the 22legislature, for distribution to the legislature under s. 13.172 (2), that analyzes the 23effectiveness of this act in addressing the following goals:

24(a) Promoting transparency in pharmaceutical pricing for the state and other 25payers.

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1	(b) Enhancing understanding about pharmaceutical spending trends	5.		
2	(c) Assisting the state and other payers in management of pharmaceutical drug			
3	costs.			
4	SECTION 5. Effective date.			
5	(1) This act takes effect on January 1, 2020.			
6	(END)			