



State of Wisconsin  
2017 - 2018 LEGISLATURE

LRB-5578/1  
KP:kjf

## 2017 ASSEMBLY BILL 1046

March 22, 2018 - Introduced by Representatives ANDERSON, CONSIDINE, SARGENT, SUBECK, POPE, BERCEAU, OHNSTAD and ZEPNICK, cosponsored by Senators HANSEN, RINGHAND and L. TAYLOR. Referred to Committee on Health.

\*\*\*AUTHORS SUBJECT TO CHANGE\*\*\*

- 1     **AN ACT** *to create* 134.91 and 250.04 (15) of the statutes; **relating to:** price  
2           restrictions for certain off-patent or generic drugs and providing a penalty.

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### *Analysis by the Legislative Reference Bureau*

This bill prohibits a manufacturer or wholesale distributor from selling or offering to sell an essential off-patent or generic drug at a price that results in price gouging.

Under the bill, price gouging means increasing the price of an essential off-patent or generic drug if both of these conditions apply: 1) the price increase is excessive and not justified by the cost of producing the drug or the cost of appropriately expanding access to the drug; and 2) the price increase results in a consumer who is prescribed the drug having no meaningful choice about whether to purchase the drug because the drug is important to the consumer's health or because insufficient competition exists in the market for the drug. The bill applies to off-patent or generic drugs, which are defined as prescription drugs made available for sale in this state that are manufactured by three or fewer manufacturers in the United States, and for which all exclusive marketing rights granted under federal law have expired. For purposes of the bill, an off-patent or generic drug is essential if the drug is listed on the list of essential medicines adopted by the World Health Organization or if the Department of Health Services designates the drug as essential due to its efficacy in treating a life-threatening health condition or chronic health condition.

Under the bill, the attorney general may request the manufacturer or wholesale distributor of an essential off-patent or generic drug to submit a

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statement within 45 days that does all of the following: 1) itemizes the components of the cost of producing the drug; 2) identifies the circumstances and timing of any increase in materials or manufacturing costs that cause a price increase; 3) identifies the circumstances and timing of any expenditures made to expand access to the drug; 4) explains improvements in public health associated with any expenditures made to expand access to the drug; and 5) provides any other information that the manufacturer believes is relevant to whether it violated the prohibition on price gouging. The bill also authorizes the attorney general to require a manufacturer or wholesale distributor of a prescription drug to produce records or other documents that may be relevant to investigating price gouging of an essential off-patent or generic drug.

The bill also authorizes the attorney general to petition a circuit court for various orders, including compelling a manufacturer or wholesale distributor to provide a statement or other records required under the bill, enjoining price gouging, restoring money to a consumer, requiring a manufacturer to make drugs available to state public assistance and the group health insurance programs at their previous prices, and a civil forfeiture of up to \$10,000 for each instance of price gouging. The attorney general must generally provide a manufacturer or wholesale distributor with an opportunity to meet to offer a justification for an increase in the price of an essential off-patent or generic drug before filing a petition authorized by the bill.

For further information see the *state* fiscal estimate, which will be printed as an appendix to this bill.

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

1           **SECTION 1.** 134.91 of the statutes is created to read:

2           **134.91 Price gouging of certain drugs. (1) DEFINITIONS.** In this section:

3           (a) “Essential off-patent or generic drug” means any of the following:

4           1. A prescription drug if all of the following apply:

5           a. All exclusive marketing rights for the prescription drug, if any, have expired.

6           b. The prescription drug appears on the model list of essential medicines most  
7 recently adopted by the World Health Organization or is designated by the  
8 department of health services as an essential medicine under s. 250.04 (15).

9           c. The prescription drug is actively manufactured and marketed for sale in the  
10 United States by 3 or fewer manufacturers.

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1 d. The prescription drug is made available for sale in this state.

2 2. A drug-device combination product for which all exclusive marketing rights,  
3 if any, have expired and used for the delivery of an essential off-patent or generic  
4 drug defined under subd. 1.

5 (b) "Exclusive marketing rights" means exclusive marketing rights granted  
6 under the federal act, the federal public health service act under 42 USC 262, or  
7 federal patent law.

8 (c) "Federal act" means the federal food, drug, and cosmetic act, 21 USC 301  
9 et seq.

10 (d) "Prescription drug" has the meaning given in s. 450.01 (20).

11 (e) "Price gouging" means to unconscionably increase the price of an essential  
12 off-patent or generic drug.

13 (f) "State public assistance program" means any of the following:

14 1. The medical assistance program under subch. IV of ch. 49.

15 2. A program for assisting victims of disease under ss. 49.68, 49.683, and  
16 49.685, and drug reimbursement under s. 49.686.

17 3. The program for prescription drug assistance for the elderly under s. 49.688.

18 (g) "Unconscionably increase" means to increase the price of an essential  
19 off-patent or generic drug if all of the following apply:

20 1. The increase in price is excessive and not justified by the cost of producing  
21 the drug or the cost of appropriate expansion of access to the drug to promote public  
22 health.

23 2. The increase in price results in a consumer for whom the essential off-patent  
24 or generic drug has been prescribed having no meaningful choice about whether to  
25 purchase the drug at an excessive price because any of the following applies:

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1           a. The essential off-patent or generic drug is important to the consumer's  
2 health.

3           b. Insufficient competition exists in the market for the essential off-patent or  
4 generic drug.

5           **(2) PRICE GOUGING OF CERTAIN DRUGS PROHIBITED.** (a) Except as provided in par.  
6 (b), no manufacturer or wholesale distributor may sell or offer to sell an essential  
7 off-patent or generic drug at a price that results in price gouging.

8           (b) A wholesale distributor does not violate par. (a) by increasing the price of  
9 an essential off-patent or generic drug if the price increase is directly attributable  
10 to additional costs for the drug imposed on the wholesale distributor by the  
11 manufacturer of the drug.

12           **(3) ENFORCEMENT.** (a) The attorney general may require a manufacturer or  
13 wholesale distributor of an essential off-patent or generic drug to provide the  
14 following information within 45 days:

15           1. The components of the cost of producing the drug.

16           2. The circumstances and timing of any increase in materials or manufacturing  
17 costs that caused any increase in the price of the drug within the one-year period  
18 preceding the date of the price increase.

19           3. The circumstances and timing of any expenditures made by the  
20 manufacturer to expand access to the drug.

21           4. An explanation of any improvement in public health associated with any  
22 expenditures described in subd. 3.

23           5. Any other information that the manufacturer believes to be relevant to a  
24 determination of whether a violation of sub. (2) (a) has occurred.

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1 (b) The attorney general may require a manufacturer or wholesale distributor  
2 to produce any records or other documents that may be relevant to a determination  
3 of whether a violation of sub. (2) (a) has occurred.

4 (c) On petition of the attorney general, a circuit court may issue an order doing  
5 any of the following:

6 1. Compelling a manufacturer or wholesale distributor to do all of the following:

7 a. Provide the information required under par. (a).

8 b. Produce specific records or other documents requested by the attorney  
9 general under par. (b) that may be relevant to a determination of whether a violation  
10 of sub. (2) (a) has occurred.

11 2. Restraining or enjoining a violation of sub. (2) (a).

12 3. Restoring to any consumer, including a 3rd-party payer, any money acquired  
13 as a result of a price increase that violates sub. (2) (a).

14 4. Requiring a manufacturer that has engaged in price gouging in the sale of  
15 an essential off-patent or generic drug to make the drug available to participants in  
16 any state public assistance program or state group health insurance program under  
17 s. 40.51 (6) for a period of up to one year at the price at which the drug was made  
18 available to participants in the state public assistance program or state group health  
19 insurance program under s. 40.51 (6) immediately prior to the manufacturer's  
20 violation of sub. (2) (a).

21 5. Imposing a civil forfeiture of up to \$10,000 for each violation of sub. (2) (a).

22 (d) The attorney general may not bring an action for a remedy or penalty under  
23 par. (c) 2. to 5. unless the attorney general provides the manufacturer or wholesale  
24 distributor an opportunity to meet with the attorney general to offer a justification  
25 for the increase in the price of the essential off-patent or generic drug.

