State of Wisconsin
2017 - 2018 LEGISLATURE

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SENATE AMENDMENT 1,

TO ASSEMBLY BILL 608

March 20, 2018 – Offered by Senators HANSEN, LARSON, SCHACHTNER, VINEHOUT, CARPENTER, ERPENBACH, RISSER, RINGHAND, MILLER, SHILLING, BEWLEY and L. TAYLOR.

At the locations indicated, amend the bill as follows:

1. Page 1, line 2: delete "pharmacy and" and substitute "pharmacy, price restrictions for certain off–patent or generic drugs,".

2. Page 1, line 3: delete "authority" and substitute "authority, and providing a penalty".

3. Page 1, line 4: before that line insert:

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

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

(a) "Essential off–patent or generic drug" means any of the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

b. Insufficient competition exists in the market for the essential off–patent or generic drug.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4. Requiring a manufacturer that has engaged in price gouging in the sale of an essential off–patent or generic drug to make the drug available to participants in any state public assistance program or state group health insurance program under s. 40.51 (6) for a period of up to one year at the price at which the drug was made available to participants in the state public assistance program or state group health

insurance program under s. 40.51 (6) immediately prior to the manufacturer's violation of sub. (2) (a).

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

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

(e) Any information provided by a manufacturer or a wholesale distributor to the attorney general under par. (a) or (b) is not subject to the right of public inspection and copying under s. 19.35 (1).

(f) In an action brought by the attorney general under par. (c), a person who is alleged to have violated a requirement of this section may not assert as a defense that the person did not deal directly with a consumer residing in this state.

SECTION 1m. 250.04 (15) of the statutes is created to read:

250.04 **(15)** The department may designate a prescription drug, as defined in s. 450.01 (20), as an essential medicine for purposes of s. 134.91 (1) (a) 1. b. if it is effective in treating a life–threatening health condition or a chronic health condition that substantially impairs an individual's ability to engage in activities of daily living.".

(END)