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In Senate, March 22, 2021

An Act To Prevent Excessive Prices for Prescription Drugs

Received by the Secretary of the Senate on March 18, 2021. Referred to the Committee on Health Coverage, Insurance and Financial Services pursuant to Joint Rule 308.2 and ordered printed.

A handwritten signature in black ink, appearing to read 'D M Grant'.

DAREK M. GRANT
Secretary of the Senate

Presented by President JACKSON of Aroostook.
Cosponsored by Speaker FECTION of Biddeford and
Senators: CLAXTON of Androscoggin, MAXMIN of Lincoln, RAFFERTY of York,
SANBORN of Cumberland, Representatives: DOUDERA of Camden, TEPLER of Topsham,
WHITE of Waterville.

1 **Be it enacted by the People of the State of Maine as follows:**

2 **Sec. 1. 5 MRSA c. 166** is enacted to read:

3 **CHAPTER 166**

4 **PROHIBITION ON EXCESSIVE INCREASES IN GENERIC PRESCRIPTION**
5 **DRUG PRICES**

6 **§2035. Definitions**

7 As used in this chapter, unless the context otherwise indicates, the following terms
8 have the following meanings.

9 **1. Consumer Price Index.** "Consumer Price Index" means the Consumer Price Index,
10 Annual Average, for All Urban Consumers, CPI-U: U.S. City Average, All items, reported
11 by the United States Department of Labor, Bureau of Labor Statistics, or its successor or,
12 if the index is discontinued, an equivalent index reported by a federal authority or, if no
13 such index is reported, "Consumer Price Index" means a comparable index chosen by the
14 Bureau of Labor Statistics.

15 **2. Generic or off-patent prescription drug.** "Generic or off-patent prescription
16 drug" means any prescription drug for which any exclusive marketing rights granted under
17 the Federal Food, Drug, and Cosmetic Act; the federal Public Health Service Act, Public
18 Law 78-410, Section 351; and federal patent law have expired including any drug-device
19 combination product for the delivery of a generic drug.

20 **3. Prescription drug.** "Prescription drug" has the same meaning as in Title 32, section
21 13702-A, subsection 30.

22 **4. Prescription drug manufacturer.** "Prescription drug manufacturer" means a
23 business operating in this State that manufactures prescription drugs for sale to another
24 person or business in this State.

25 **5. Wholesale acquisition cost.** "Wholesale acquisition cost" has the meaning stated
26 in 42 United States Code, Section 1395w-3a.

27 **§2036. Excessive price increases for generic or off-patent prescription drugs**
28 **prohibited**

29 **1. Excessive price increases prohibited.** A prescription drug manufacturer may not
30 impose an excessive price increase, whether directly or through a wholesale distributor,
31 pharmacy or similar intermediary or intermediaries, on the sale of any generic or off-patent
32 prescription drug sold, dispensed or delivered to any consumer in this State.

33 **2. Determination of excessive price increases.** A price increase of a generic or off-
34 patent prescription drug is excessive for purposes of this section when:

35 A. The price increase, adjusted for inflation using the Consumer Price Index, exceeds:

36 (1) Fifteen percent of the wholesale acquisition cost of the immediately preceding
37 calendar year; or

1 (2) Forty percent of the wholesale acquisition cost of 3 years prior to the current
2 year; and

3 B. The price increase, adjusted for inflation using the Consumer Price Index, exceeds
4 \$30 for a 30-day supply of the generic or off-patent prescription drug or for a course
5 of treatment of the generic or off-patent prescription drug that lasts less than 30 days.

6 **3. Exception.** It is not a violation of this section for a wholesale distributor or
7 pharmacy to increase the price of a generic or off-patent prescription drug if the price
8 increase is directly attributable to additional costs for the generic or off-patent prescription
9 drug imposed on the wholesale distributor or pharmacy by the prescription drug
10 manufacturer of the generic or off-patent prescription drug.

11 **4. Registered agent.** Any entity that sells, distributes, delivers or offers for sale any
12 generic or off-patent prescription drug in this State is required to maintain a registered agent
13 within the State.

14 **5. Enforcement.** The following provisions govern the enforcement of this section.

15 A. The administrator of benefits for state employees, or any entity of State Government
16 that provides or purchases a prescription drug benefit, any entity under contract with
17 State Government to provide prescription drug benefits or any other state agency shall
18 notify a prescription drug manufacturer and the Attorney General of any price increase
19 for a generic or off-patent prescription drug that is an excessive price increase in
20 violation of this section.

21 B. Within 45 days of receipt of notice under paragraph A, the prescription drug
22 manufacturer of the generic or off-patent prescription drug shall submit a statement to
23 the Attorney General:

24 (1) Itemizing the components of the cost of producing the drug;

25 (2) Identifying the circumstances and timing of any increase in materials or
26 manufacturing costs that caused any increase during the preceding year in the price
27 of the drug; and

28 (3) Providing any other information that the prescription drug manufacturer
29 believes to be pertinent to a determination of whether a violation of this chapter
30 has occurred.

31 C. The Attorney General may require a prescription drug manufacturer and wholesale
32 distributor to produce any records or documents that may be relevant to a determination
33 of whether a violation of this section has occurred.

34 D. On petition of the Attorney General, a court may issue an order to:

35 (1) Compel the prescription drug manufacturer of the generic or off-patent
36 prescription drug to:

37 (a) Provide a statement required under paragraph B; or

38 (b) Produce records or documents requested by the Attorney General under
39 paragraph C that may be relevant to a determination of whether a violation of
40 this section has occurred;

41 (2) Restrain or enjoin a violation of this section, including an order requiring that
42 prices be restored to levels that comply with this section;

1 (3) Require the prescription drug manufacturer to provide an accounting to the
2 Attorney General of all revenues generated in violation of this section;

3 (4) Restore to any consumer, including any 3rd-party payor, any money acquired
4 as a result of an excessive price increase in violation of this section. With respect
5 to this subparagraph, every individual transaction in violation of this section is
6 determined to be a separate violation;

7 (5) Require that all revenues generated in violation of this section be remitted to
8 the State to be used for efforts designed to reduce the cost to consumers of
9 acquiring prescription drugs, if a prescription drug manufacturer is unable to
10 determine the individual transactions necessary to provide the restitution described
11 in subparagraph (4);

12 (6) Impose a civil penalty of up to \$10,000 per day for each violation of this
13 section; and

14 (7) Provide for any other appropriate relief, including attorney's fees and costs
15 reasonably incurred by the Attorney General in bringing an action against a
16 prescription drug manufacturer found in violation of this section.

17 **§2037. Prohibition on withdrawal of generic or off-patent prescription drugs for sale**

18 **1. Withdrawal from sale prohibited.** It is a violation of this chapter for any
19 prescription drug manufacturer of a generic or off-patent prescription drug to withdraw that
20 prescription drug from sale or distribution within this State, whether directly or through a
21 wholesale distributor, for the purpose of avoiding the prohibition on excessive price
22 increases set forth in section 2036.

23 **2. Notice required.** Any prescription drug manufacturer that intends to withdraw a
24 generic or off-patent prescription drug from sale or distribution within the State must
25 provide 180 days' prior notice to the Attorney General of the withdrawal in order to avoid
26 the prohibition on excessive price increases set forth in section 2036, subsection 1.

27 **3. Penalty.** The Attorney General shall assess a penalty of \$500,000 on any
28 prescription drug manufacturer of a generic or off-patent prescription drug that the
29 Attorney General determines has withdrawn that generic or off-patent prescription drug
30 from sale or distribution in this State, whether directly or through a wholesale distributor,
31 in violation of this section.

32 **Sec. 2. Legislative findings; impact of price increases for prescription**
33 **drugs.** In order to protect the safety, health and economic well-being of the residents of
34 this State by guarding them from the negative and harmful impact of excessive and
35 unconscionable prices for prescription drugs, the enactment of this Act is necessary and the
36 Legislature finds that:

37 1. Access to prescription drugs is necessary for consumers in this State to maintain or
38 acquire good health;

39 2. Excessive and unconscionable prices negatively impact the ability of consumers in
40 this State to obtain prescription drugs and excessive and unconscionable price increases
41 thereby endanger the health and safety of consumers in this State to maintain or acquire
42 good health;

