

MAINE STATE LEGISLATURE

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128th MAINE LEGISLATURE

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Legislative Document

No. 1605

S.P. 563

In Senate, May 16, 2017

An Act To Increase Consumer Prescription Drug Protections

Submitted by the Department of the Attorney General pursuant to Joint Rule 204.
Reference to the Committee on Health and Human Services suggested and ordered printed.

A handwritten signature in cursive script, reading "Heather J.R. Priest".

HEATHER J.R. PRIEST
Secretary of the Senate

Presented by Senator VITELLI of Sagadahoc.
Cosponsored by Representatives: GATTINE of Westbrook, HERBIG of Belfast.

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

2 **Sec. 1. 5 MRSA §200-K** is enacted to read:

3 **§200-K. Consumer protections; prescription drugs**

4 **1. Definitions.** As used in this section, unless the context otherwise indicates, the
5 following terms have the following meanings.

6 A. "Brand-name drug" means a prescription drug approved under 21 United States
7 Code, Section 355(b), 42 United States Code, Section 262(a) or 42 United States
8 Code, Section 262(k).

9 B. "Essential off-patent or generic drug" means a prescription drug or drug-device
10 combination product used for the delivery of a drug:

11 (1) For which all exclusive marketing rights, if any, granted under the Federal
12 Food, Drug, and Cosmetic Act, Section 351 of the federal Public Health Service
13 Act and federal patent law have expired;

14 (2) That appears on the model list of essential medicines most recently adopted
15 by the World Health Organization or that is otherwise an essential medicine due
16 to its efficacy in treating a life-threatening health condition or a chronic health
17 condition that substantially impairs an individual's ability to engage in activities
18 of daily living; and

19 (3) That is made available for sale in the State.

20 C. "Generic drug" means a prescription drug approved under 21 United States Code,
21 Section 355(j).

22 D. "Manufacturer" means an entity that is engaged in producing, preparing,
23 propagating, compounding, processing, packaging, repackaging or labeling a
24 brand-name drug or a generic drug but does not include an entity that is engaged in
25 the preparation and dispensing of a brand-name or generic drug pursuant to a
26 prescription.

27 E. "Manufacturer-sponsored assistance program" means a program offered by a
28 manufacturer or a manufacturer-supported intermediary through which a brand-name
29 drug or a generic drug is offered to a patient at no charge or at a discounted cost.

30 F. "Net price" means the price after all discounts and rebates have been applied.

31 G. "Pharmacy benefits manager" means an entity that directly or indirectly manages
32 prescription drug coverage provided by a 3rd-party payor, including, but not limited
33 to, processing and payment of claims for prescription drugs, performance of drug
34 utilization reviews, processing of prior authorization requests for prescription drugs,
35 adjudication of appeals or grievances related to prescription drug coverage,
36 contracting with network pharmacies and controlling the cost of covered prescription
37 drugs.

38 H. "Price gouging" means an increase in the price of a prescription drug that:

1 (1) Is excessive and not justified by the cost of producing the drug or the cost of
2 appropriate expansion of access to the drug to promote public health; and

3 (2) Results in consumers for whom the drug has been prescribed having no
4 meaningful choice about whether to purchase the drug at an excessive price
5 because of:

6 (a) The importance of the drug to their health; and

7 (b) Insufficient competition in the market for the drug.

8 I. "Wholesale acquisition cost" means the manufacturer's list price for a brand-name
9 drug or a generic drug per person per year or course of treatment to wholesalers or
10 direct purchasers in the United States, not including discounts or rebates, for the most
11 recent month for which information is available.

12 J. "Wholesale distributor" means a person engaged in the distribution of an essential
13 off-patent or generic drug to persons other than consumers or patients.

14 **2. Price gouging in essential off-patent or generic drugs; prohibition.** A
15 manufacturer or wholesale distributor may not engage in price gouging in the sale of an
16 essential off-patent or generic drug.

17 A. The Attorney General may obtain data from the Maine Health Data Organization
18 as established in Title 22, section 8703 concerning any increase in the price of an
19 essential off-patent or generic drug when:

20 (1) Three or fewer manufacturers are actively manufacturing and marketing the
21 drug for sale in the United States;

22 (2) The price increase, by itself or in combination with other price increases:

23 (a) Would result in an increase of 50% or more in the wholesale acquisition
24 cost of the drug within the preceding 3-year period; or

25 (b) Would result in an increase of 50% or more in the price paid for the drug
26 within the preceding 3-year period; and

27 (3) One of the following applies:

28 (a) A 30-day supply of the maximum recommended dosage of the drug for
29 any indication, according to the label for the drug approved under the Federal
30 Food, Drug, and Cosmetic Act, would cost more than \$80 at the drug's
31 wholesale acquisition cost;

32 (b) A full course of treatment with the drug, according to the label for the
33 drug approved under the Federal Food, Drug, and Cosmetic Act, would cost
34 more than \$80 at the drug's wholesale acquisition cost; or

35 (c) If the drug is made available to consumers only in quantities that do not
36 correspond to a 30-day supply or a full course of treatment or in a single
37 dose, it would cost more than \$80 at the drug's wholesale acquisition cost to
38 obtain a 30-day supply or a full course of treatment.

1 B. On request of the Attorney General, the manufacturer of an essential off-patent or
2 generic drug identified under paragraph A shall submit a statement to the Attorney
3 General within 20 days after the request:

4 (1) Itemizing the components of the cost of producing the drug and identifying
5 the circumstances and timing of any increase in materials or manufacturing costs
6 that caused the increase in the price of the drug within the 3-year period
7 preceding the date of the price increase;

8 (2) Identifying the circumstances and timing of any expenditures made by the
9 manufacturer to expand access to the drug and explaining any improvement in
10 public health associated with those expenditures; and

11 (3) Providing any other information that the manufacturer believes to be relevant
12 to a determination of whether a violation of this section has occurred.

13 C. The Attorney General may require a manufacturer or a wholesale distributor to
14 produce any records or other documents that may be relevant to a determination of
15 whether a violation of this section has occurred.

16 **3. Pharmaceutical cost transparency.** Upon the request of the Attorney General,
17 the Maine Health Data Organization as established in Title 22, section 8703 shall identify
18 annually up to 15 prescription drugs on which the State spends significant amounts of
19 money and for which the wholesale acquisition cost has increased by 50% or more over
20 the past 5 years or by 15% or more over the past 12 months.

21 A. The Maine Health Data Organization shall provide to the Attorney General a list
22 of prescription drugs identified pursuant to this subsection and the percentage of the
23 wholesale acquisition cost increase for each drug.

24 B. For each prescription drug identified on the list provided to the Attorney General
25 pursuant to paragraph A, the Attorney General shall require the drug's manufacturer
26 to provide a justification for the increase in the wholesale acquisition cost of the drug
27 in a format that the Attorney General determines to be understandable and
28 appropriate. The manufacturer shall submit to the Attorney General all relevant
29 information and supporting documentation necessary to justify the manufacturer's
30 wholesale acquisition cost increase, which may include:

31 (1) All factors that have contributed to the wholesale acquisition cost increase;

32 (2) The percentage of the total wholesale acquisition cost increase attributable to
33 each factor; and

34 (3) An explanation of the role of each factor in contributing to the wholesale
35 acquisition cost increase.

36 C. Nothing in this section may be construed to restrict the legal ability of a
37 prescription drug manufacturer to change prices to the extent permitted under federal
38 law.

39 D. The Attorney General shall provide a report to the joint standing committee of the
40 Legislature having jurisdiction over health and human services matters on or before
41 December 1st of each year based on the information received from manufacturers

