

2018 Regular Session

HOUSE BILL NO. 243

BY REPRESENTATIVE TALBOT

DRUGS/PRESCRIPTION: Prohibits a manufacturer or wholesale distributor from engaging in price gouging in the sale of an essential off-patent or generic drug

1 AN ACT

2 To amend and reenact R.S. 44:4.1(B)(26) and to enact Part IX of Chapter 12 of Title 40 of
3 the Louisiana Revised Statutes of 1950, to be comprised of R.S. 40:2255.21 through
4 2255.23, relative to prescription drug prices; to provide for definitions; to prohibit
5 price gouging in the sale of certain drugs; to provide for an exception; to provide for
6 the powers and duties of the attorney general; to provide for remedies for violations;
7 to authorize a suit for injunction; to establish civil penalties; to provide for
8 confidentiality of certain information; to provide for a public records exception; to
9 provide for an effective date; and to provide for related matters.

10 Be it enacted by the Legislature of Louisiana:

11 Section 1. Part IX of Chapter 12 of Title 40 of the Louisiana Revised Statutes of
12 1950, comprised of R.S. 40:2255.21 through 2255.23, is hereby enacted to read as follows:

13 PART IX. PROHIBITION AGAINST PRICE GOUGING FOR ESSENTIAL
14 OFF-PATENT OR GENERIC DRUGS

15 §2255.21. Definitions

16 As used in this Part, the following words have the following meanings unless
17 the context indicates otherwise:

18 (1)(a) "Essential off-patent or generic drug" means any prescription drug that
19 meets all of the following criteria:

1 (i) All exclusive marketing rights for the drug, if any, granted pursuant to the
2 federal Food, Drug, and Cosmetic Act, Section 351 of the federal Public Health
3 Service Act, or federal patent law have expired.

4 (ii) The drug appears on the model list of essential medicines most recently
5 adopted by the World Health Organization or has been designated by the secretary
6 as an essential medicine due to its efficacy in treating a life-threatening health
7 condition or a chronic health condition that substantially impairs an individual's
8 ability to engage in activities of daily living.

9 (iii) The drug is actively manufactured and marketed for sale in the United
10 States by three or fewer manufacturers.

11 (iv) The drug is made available for sale in Louisiana.

12 (b) "Essential off-patent or generic drug" includes any drug-device
13 combination product used for the delivery of a drug for which all exclusive
14 marketing rights, if any, granted under the federal Food, Drug, and Cosmetic Act,
15 Section 351 of the federal Public Health Service Act, or federal patent law have
16 expired.

17 (2) "Medical assistance program" means the medical assistance program
18 provided for in Title XIX of the Social Security Act as administered by the Louisiana
19 Department of Health.

20 (3) "Price gouging" means an unconscionable increase in the price of a
21 prescription drug.

22 (4) "Secretary" means the secretary of the Louisiana Department of Health.

23 (5) "Unconscionable increase" means an increase in the price of a
24 prescription drug that is excessive and not justified by the cost of producing the drug
25 or the cost of appropriate expansion of access to the drug to promote public health
26 and results in consumers for whom the drug has been prescribed having no
27 meaningful choice about whether to purchase the drug at an excessive price because
28 of the importance of the drug to their health and insufficient competition in the
29 market for the drug.

1 (6) "Wholesale acquisition cost" has the meaning stated in 42 U.S.C. 1395w-

2 3a.

3 §2255.22. Off-patent or generic drug; price gouging prohibited; exception

4 A. A manufacturer or wholesale distributor of an essential off-patent or
5 generic drug is prohibited from engaging in price gouging in the sale of the drug.

6 B. It is not a violation of Subsection A of this Section for a wholesale
7 distributor to increase the price of an essential off-patent or generic drug if the price
8 increase is directly attributable to additional costs for the drug imposed on the
9 wholesale distributor by the manufacturer of the drug.

10 §2255.23. Attorney general; notice of price increase; powers and duties; remedies
11 for violations; confidential information

12 A. The secretary may notify the attorney general of any increase in the price
13 of an essential off-patent or generic drug if the price increase, by itself or in
14 combination with other price increases, would result in an increase of fifty percent
15 or more in the wholesale acquisition cost of the drug within the preceding one-year
16 period or would result in an increase of fifty percent or more in the price paid by the
17 medical assistance program for the drug within the preceding one-year period and
18 at least one of the following criteria is met:

19 (1) A thirty-day supply of the maximum recommended dosage of the drug
20 for any indication, according to the label for the drug approved under the federal
21 Food, Drug, and Cosmetic Act, would cost more than eighty dollars at the drug's
22 wholesale acquisition cost.

23 (2) A full course of treatment with the drug, according to the label for the
24 drug approved under the federal Food, Drug, and Cosmetic Act, would cost more
25 than eighty dollars at the drug's wholesale acquisition cost.

26 (3) If the drug is made available to consumers only in quantities that do not
27 correspond to a thirty-day supply, a full course of treatment, or a single dose, it
28 would cost more than eighty dollars at the drug's wholesale acquisition cost to obtain
29 a thirty-day supply or a full course of treatment.

1 B. On request of the attorney general, the manufacturer of an essential off-
2 patent or generic drug identified in a notice pursuant to Subsection A of this Section,
3 no later than forty-five days after the request, shall submit a statement to the attorney
4 general containing all of the following:

5 (1)(a) An itemization of the components of the cost of producing the drug.

6 (b) An identification of the circumstances and timing of any increase in
7 materials or manufacturing costs that caused any increase in the price of the essential
8 generic drug within the one-year period preceding the date of the price increase.

9 (2)(a) An identification of the circumstances and timing of any expenditures
10 made by the manufacturer to expand access to the drug.

11 (b) An explanation of any improvement in public health associated with
12 those expenditures.

13 (3) Any other information that the manufacturer believes to be relevant to
14 a determination of whether a violation of this Part has occurred.

15 C. The attorney general may require a manufacturer or a wholesale
16 distributor to produce any records or other documents that may be relevant to a
17 determination of whether a violation of this Part has occurred.

18 D. On petition of the attorney general and subject to Subsection E of this
19 Section, a court may issue an order to do any combination of the following:

20 (1) Compel a manufacturer or a wholesale distributor to do any of the
21 following:

22 (a) Provide the statement required pursuant to Subsection B of this Section.

23 (b) Produce specific records or other documents requested by the attorney
24 general pursuant to Subsection C of this Section that may be relevant to a
25 determination of whether a violation of this Part has occurred.

26 (2) Restrain or enjoin a violation of this Part.

27 (3) Restore to any consumer, including a third party payor, any money
28 acquired as a result of a price increase that violates this Part.

- (2) An identification of the circumstances and timing of any increase in materials or manufacturing costs that caused any increase in the price of the essential generic drug within the one-year period preceding the date of the price increase.
- (3) An identification of 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 those expenditures.
- (5) Any other information that the manufacturer believes to be relevant to a determination of whether a violation has occurred.

Proposed law authorizes the attorney general to require a manufacturer or a wholesale distributor to produce any records or other documents that may be relevant to a determination of whether a violation of proposed law has occurred.

Proposed law authorizes a court to issue an order to do any combination of the following:

- (1) Compel a manufacturer or a wholesale distributor to provide the statement required by the attorney general or produce specific records or other documents requested by the attorney general that may be relevant to a determination of whether a violation has occurred.
- (2) Restrain or enjoin a violation of proposed law.
- (3) Restore to any consumer, including a third party payor, any money acquired as a result of a price increase that violates proposed law.
- (4) Require 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 residents of La. for a period of up to one year at the price at which the drug was made available prior to the manufacturer's violation.
- (5) Impose a civil penalty of up to \$10,000 for each violation.

Proposed law prohibits the attorney general from bringing an action for a remedy unless the attorney general has provided the manufacturer or wholesale distributor an opportunity to offer a justification for the increase in the price of the essential off-patent or generic drug.

Proposed law provides that any information provided by a manufacturer or a wholesale distributor to the attorney general shall be considered confidential commercial information not subject to public disclosure pursuant to the Public Records Act unless the confidentiality of the information is waived by the manufacturer or wholesale distributor.

Effective upon signature of the governor or lapse of time for gubernatorial action.

(Amends R.S. 44:4.1(B)(26); Adds R.S. 40:2255.21-2255.23)