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

AN ACT

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

Be it enacted by the Legislature of Louisiana:

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

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

§2255.21. Definitions

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

(1)(a) "Essential off-patent or generic drug", "drug", and "prescription drug" mean any prescription drug that meets all of the following criteria:

(i) The drug is marketed under section 505 of the federal Food, Drug and Cosmetic Act and all exclusive marketing rights for the drug pursuant to that law, if any, have expired and exclusivity under federal patent law has expired.

(ii) The drug appears on the model list of essential medicines most recently adopted by the World Health Organization or has been designated by the secretary as an essential medicine due to its efficacy 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.

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

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

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

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

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

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

(5) "Unconscionable increase" means an increase in the price of a prescription drug that 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 and results in consumers for whom the drug has been prescribed having no meaningful choice about whether to purchase the drug at an excessive price because of the importance of the drug to their health and insufficient competition in the market for the drug.

(6) "Wholesale acquisition cost" has the meaning stated in 42 U.S.C. 1395w-3a.

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

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

B. It is not a violation of Subsection A of this Section for a wholesale distributor to increase 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.

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

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

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

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

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

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

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

(b) 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.

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

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

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

C. The attorney general may 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 this Part has occurred.

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

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

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

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

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

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

(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 Louisiana for a period of up to one year at the price at which the drug was made available to residents of Louisiana immediately prior to the manufacturer's violation of this Part.

(5) Impose a civil penalty of up to ten thousand dollars for each violation of this Part.

E. The attorney general shall not bring an action for a remedy pursuant to Paragraphs (D)(2) through (5) of this Section unless the attorney general has provided 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.

F. Any information provided by a manufacturer or a wholesale distributor to the attorney general pursuant to Subsections B and C of this Section shall be considered confidential commercial information not subject to public disclosure pursuant to the Public Records Law, R.S. 44:1 et seq., unless the confidentiality of the information is waived by the manufacturer or wholesale distributor.

G. In any action brought by the attorney general pursuant to Subsection D of this Section, a person who is alleged to have violated a provision of this Part shall not assert as a defense that the person did not deal directly with a consumer residing in Louisiana.

Section 2. R.S. 44:4.1(B)(26) is hereby amended and reenacted to read as follows:

§4.1. Exceptions

* * *

B. The legislature further recognizes that there exist exceptions, exemptions, and limitations to the laws pertaining to public records throughout the revised statutes and codes of this state. Therefore, the following exceptions, exemptions, and

limitations are hereby continued in effect by incorporation into this Chapter by citation:

* * *

(26) R.S. 40:3.1, 31.14, 31.27, 39.1, 41, 73, 95, 96, 526, 528, 1007, 1061.21, 1079.18, 1081.10, 1105.6, 1105.8, 1133.8, 1171.4, 1203.4, 1231.4, 1379.1.1(D), 1379.3, 2009.8, 2009.14, 2010.5, 2017.9, 2018, 2019, 2020, 2106, 2138, 2255.23, 2532, 2845.1

* * *

Section 3. This Act shall become effective upon signature by the governor or, if not signed by the governor, upon expiration of the time for bills to become law without signature by the governor, as provided by Article III, Section 18 of the Constitution of Louisiana. If vetoed by the governor and subsequently approved by the legislature, this Act shall become effective on the day following such approval.

DIGEST

The digest printed below was prepared by House Legislative Services. It constitutes no part of the legislative instrument. The keyword, one-liner, abstract, and digest do not constitute part of the law or proof or indicia of legislative intent. [R.S. 1:13(B) and 24:177(E)]

HB 243 Engrossed 2018 Regular Session Talbot

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

Proposed law defines "essential off-patent or generic drug", "price gouging", "unconscionable increase", and "wholesale acquisition cost" for purposes of proposed law.

Proposed law prohibits a manufacturer or wholesale distributor of an essential off-patent or generic drug from engaging in price gouging in the sale of the drug.

Proposed law authorizes the secretary of the La. Dept. of Health to notify the attorney general of any increase in the price of an essential off-patent or generic drug if the price increase, by itself or in combination with other price increases, would result in an increase of 50% or more in the wholesale acquisition cost of the drug or the price paid by the state Medicaid program for the drug within the preceding one-year period and a 30-day supply of the maximum recommended dosage of the drug for any indication or a full course of treatment with the drug, according to the label for the drug approved under the federal Food, Drug, and Cosmetic Act, would cost more than $100 at the drug's wholesale acquisition cost.

Proposed law requires that upon request of the attorney general, the manufacturer of an essential off-patent or generic drug, no later than 90 days after the request, shall submit a statement to the attorney general containing all of the following:

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

(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 governor or lapse of time for gubernatorial action.

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

Summary of Amendments Adopted by House

The Committee Amendments Proposed by House Committee on Health and Welfare to the original bill:

1. Revise the definition of "essential off-patent or generic drug" in proposed law to provide that such drug, in part, is one that is marketed under section 505 of the federal Food, Drug and Cosmetic Act and all exclusive marketing rights for it

pursuant to that law, if any, have expired and exclusivity under federal patent law has expired.

2. Increase the price threshold for a 30-day supply of, or full course of treatment with, a drug that triggers a violation of <u>proposed law</u> <u>from</u> $80 <u>to</u> $100.

3. Extend the time period within which a manufacturer of an essential off-patent or generic drug must respond to certain requests from the attorney general relative to drug costs and pricing <u>from</u> 45 days <u>to</u> 90 days.

4. Make technical changes.