DIGEST

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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 proposed law from $80 to $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 from 45 days to 90 days.

4. Make technical changes.