H-3556.1

HOUSE BILL 2556

State of Washington 65th Legislature 2018 Regular Session

By Representatives Jinkins, Appleton, Stonier, Robinson, Gregerson, Reeves, Fey, Wylie, Sawyer, Valdez, Tharinger, and Macri

Read first time 01/10/18. Referred to Committee on Health Care & Wellness.

AN ACT Relating to protecting consumers and purchasers from excessive increases in generic prescription drug prices; and adding a new chapter to Title 69 RCW.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

NEW SECTION. **Sec. 1.** The legislature finds that excessive price increases to prescription drugs that lack justification based on market forces create a public health risk to consumers who rely on prescription drugs. In order to prevent a manufacturer from taking unfair advantage of consumers who rely upon and may lose access to the prescription drugs if the medication has a sudden and excessive price increase, the legislature declares that unjustified and excessive price increases of generic drugs are considered violations of the consumer protection act.

NEW SECTION. **Sec. 2.** The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Drug manufacturer" means a facility licensed by the pharmacy quality assurance commission under chapter 18.64 RCW that engages in the manufacture of generic drugs.

(2) "Excessive" means an increase to the wholesale acquisition cost of a generic drug by a percent equal to or greater than one hundred percent at any one time or in the aggregate in any twelve-month period that the prescription drug program determines is not justified based on their review under section 6 of this act.

(3) "Price increase notification form" or "form" means the price increase notification form produced and distributed by the prescription drug program under section 4 of this act.

(4) "Wholesale acquisition cost" means the price for each dosage, size, or concentration of the generic drug offered or sold by the manufacturer.

NEW SECTION. **Sec. 3.** (1) If a drug manufacturer increases the wholesale acquisition cost of a generic drug by a percent equal to or greater than one hundred percent at any one time or in the aggregate in any twelve-month period, the drug manufacturer must use the price increase notification form established under section 4 of this act to notify the office of the insurance commissioner and the prescription drug program of the increase. This notice must be provided to the insurance commissioner and the prescription drug program at least thirty days before the increase takes effect.

(2) Failure to provide the notice required under this section may result in the attorney general taking action under section 6 of this act.

NEW SECTION. **Sec. 4.** The prescription drug program must produce and make available to drug manufacturers a price increase notification form. The form must require drug manufacturers to disclose:

(1) The most recent wholesale acquisition cost of the generic drug before an increase equal to or greater than one hundred percent at any one time or in the aggregate in any twelve-month period in either pricing measure;

(2) The wholesale acquisition cost of the generic drug when exceeding the one hundred percent threshold;

(3) Any material change in ingredient, production, or manufacturing costs resulting in the price increase;

(4) Whether the drug is a sole source drug;

(5) Changes to the drug manufacturer's corporate structure within the last two years including, but not limited to, whether the drug

manufacturer has been or is in the process of merging with or acquiring another company; and

(6) Any other information the drug manufacturer deems relevant to the prescription drug program's review.

NEW SECTION. **Sec. 5.** Upon receipt of a price increase notification form, the insurance commissioner must direct all insurance plans to require prior authorization for the drug listed on the form. This prior authorization requirement goes into effect as of the date of the price increase and will continue until the prescription drug program makes the determination required under section 6 of this act.

NEW SECTION. **Sec. 6.** (1) Upon receipt of a price notification form, the prescription drug program must review the price increase and make a determination as to whether the price increase is excessive. In making a determination, the board must consider:

(a) The wholesale acquisition cost of the drug in comparison to any generic equivalent or therapeutically equivalent drug;

(b) The United States food and drug administration's approved or compendium supported use of the drug and critical need to the patient;

(c) Any known market factors justifying the price increase including, but not limited to:

(i) Whether the drug has been absent from the market for any period of time; and

(ii) Changes in manufacturing or regulatory requirements or costs;

(d) Any material change in the prevalence or severity of the disease or medical condition or conditions that the drug is approved to treat;

(e) Any changes to the corporate structure of the drug manufacturer in the last two years including, but not limited to, whether the drug manufacturer has been or is in the process of merging with or acquiring another company; and

(f) Whether the drug is a sole source drug.

(2) If the prescription drug program finds that the price increase instituted by the drug manufacturer is not excessive, the prior authorization requirement under section 5 of this act must cease.

(3) If the prescription drug program finds that the price increase instituted by the drug manufacturer is excessive:

(a) The prior authorization requirement under section 5 of this act must continue until the prescription drug program determines otherwise or the drug manufacturer successfully appeals the decision. The drug manufacturer may appeal the decision by filing with the office of administrative hearings a notice of appeal within thirty days of receiving the program's decision. Appeals must be conducted in accordance with chapter 34.05 RCW; and

(b) If the drug manufacturer does not file an appeal or does not prevail upon appeal, the prescription drug program must refer the matter to the attorney general to take action under chapter 19.86 RCW. The legislature finds that the practices covered by this chapter are unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce and vitally affect the public interest for the purpose of the attorney general's application of the consumer protection act, chapter 19.86 RCW. A price increase instituted by a drug manufacturer that is determined to be excessive is not reasonable in relation to the development and preservation of business and is injurious to the public interest for the purpose of the attorney general's application of the consumer protection act, chapter 19.86 RCW.

NEW SECTION. **Sec. 7.** Sections 1 through 6 of this act constitute a new chapter in Title 69 RCW.

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