S-0588.1

SENATE BILL 5371

State of Washington 66th Legislature 2019 Regular Session

By Senators Keiser, Kuderer, Bailey, Cleveland, Rivers, Rolfes, Saldaña, Darneille, Van De Wege, and Frockt

AN ACT Relating to protecting consumers and purchasers from excessive increases in insulin 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.** (1) The legislature finds that excessive price increases not justified by market forces for insulin products used to manage diabetes create a public health risk to Washington consumers who rely on those drugs.

(2) In order to prevent a manufacturer from taking unfair advantage of Washington consumers who rely upon and may lose access to these drugs if the medication has a sudden and excessive price increase, the legislature finds that a price increase instituted by a drug manufacturer that is determined to be excessive under this act is an unfair method of competition and an unfair or deceptive act or practice in the conduct of any trade or commerce, and vitally affects the public interest for the purpose of the attorney general's application of the consumer protection act, chapter 19.86 RCW.

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 insulin drugs for sale in Washington state.

(2) "Excessive" means an increase to the wholesale acquisition cost of an insulin drug by a percent equal to or greater than ten 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 5 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 insulin drug offered or sold by the manufacturer.

NEW SECTION. **Sec. 3.** (1) If a drug manufacturer increases the wholesale acquisition cost of an insulin drug by ten 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 health care authority 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 5 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 drug before an increase equal to or greater than ten 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 drug when exceeding the ten percent threshold;

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

(4) 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

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

NEW SECTION. **Sec. 5.** (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 other insulin drug currently on the market;

(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; and

(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.

(2) If the prescription drug program finds that the price increase instituted by the drug manufacturer is not excessive, the inquiry ends.

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

(4) 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.

NEW SECTION. **Sec. 6.** Sections 1 through 5 of this act constitute a new chapter in Title 69 RCW.

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