H.713

Introduced by Representative Lippert of Hinesburg

Referred to Committee on

Date:

Subject: Health; prescription drugs; essential off-patent or generic drugs; price gouging; Attorney General

Statement of purpose of bill as introduced: This bill proposes to prohibit prescription drug manufacturers and wholesale distributors from engaging in price gouging in the sale of essential off-patent or generic drugs.

An act relating to prohibiting price gouging for essential off-patent or generic drugs

It is hereby enacted by the General Assembly of the State of Vermont:

Sec. 1. 18 V.S.A. chapter 91, subchapter 5 is added to read:

Subchapter 5. Prohibition Against Price Gouging for Essential Off-Patent or Generic Drugs

§ 4651. DEFINITIONS

As used in this subchapter:

(1)(A) "Essential off-patent or generic drug" means any prescription drug:

(i) for which all exclusive marketing rights, if any, granted under the Federal Food, Drug, and Cosmetic Act; Section 351 of the federal Public Health Service Act, 42 U.S.C. § 351; and federal patent law, have expired;

(ii) that either:

(I) appears on the Model List of Essential Medicines most recently adopted by the World Health Organization; or

(II) has been designated by the Secretary of Human Services 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) that is actively manufactured and marketed for sale in the United States by three or fewer manufacturers; and

(iv) that is made available for sale in this State.

(B) The term "essential off-patent or generic drug" includes a 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; Section 351 of the federal Public Health Service Act, 42 U.S.C. § 351; and federal patent law, have expired.

(2) "Health insurance plan" means any health insurance policy or health benefit plan offered by a health insurer, as well as Medicaid and any other

public health care assistance program offered or administered by the State or by any subdivision or instrumentality of the State.

(3) "Health insurer" shall have the same meaning as in section 9402 of this title.

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

(5) "Unconscionable increase" means an increase in the price of a prescription drug that:

(A) 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

(B) 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:

(i) the importance of the drug to their health; and

(ii) insufficient competition in the market for the drug.

(6) "Wholesale acquisition cost" shall have the same meaning as in 42 U.S.C. § 1395w-3a.

§ 4652. PROHIBITION ON PRICE GOUGING

(a) A manufacturer or wholesale distributor shall not engage in price gouging in the sale of an essential off-patent or generic drug.

(b) It shall not be considered 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.

§ 4653. NOTIFICATION OF POSSIBLE PRICE GOUGING

(a) The Department of Vermont Health Access may notify the Attorney General of any increase in the price of an essential off-patent or generic drug when:

(1) the price increase, by itself or in combination with other price increases, would either:

(A) result in an increase of 50 percent or more in the wholesale acquisition cost of the drug within the preceding one-year period; or

(B) result in an increase of 50 percent or more in the price paid for the drug by the Department of Vermont Health Access on behalf of Medicaid beneficiaries within the preceding one-year period; and

(2) one or more of the following circumstances apply:

(A) a 30-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 $80.00 at the drug's wholesale acquisition cost;

(B) 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 $80.00 at the drug's wholesale acquisition cost; or

(C) if the drug is made available to consumers only in quantities that do not correspond to a 30-day supply, a full course of treatment, or a single dose, it would cost more than $80.00 at the drug's wholesale acquisition cost to obtain a 30-day supply or a full course of treatment.

(b) Upon 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, within 45 days following the request, shall submit a statement to the Attorney General:

(1)(A) itemizing the components of the cost of producing the drug; and

(B) identifying the circumstances and timing of any increase in materials or manufacturing costs that caused any increase in the price of the drug within the one-year period preceding the date of the price increase;

(2)(A) identifying the circumstances and timing of any expenditures made by the manufacturer to expand access to the drug; and

(B) explaining any improvement in public health associated with those expenditures; and

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

(c) The Attorney General may require a manufacturer or wholesale distributor to produce any records or other documents that may be relevant to a determination of whether a violation of this subchapter has occurred.

(d) On petition of the Attorney General to the Civil Division of the Superior Court, Washington County and subject to subsection (e) of this section, the court may issue an order:

(1) compelling a manufacturer or a wholesale distributor to do either or both of the following:

(A) provide the statement required under subsection (b) of this section; and

(B) produce specific records or other documents required by the Attorney General pursuant to subsection (c) of this section that may be relevant to a determination of whether a violation of this subchapter has occurred;

(2) restraining or enjoining a violation of this subchapter;

(3) restoring to any consumer, including a health insurer or the Department of Vermont Health Access, any money acquired as a result of a price increase that violates this subchapter;

(4) requiring 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 participants in any health insurance plan in this State for a period of up to one year at the price at which the drug was made available to participants in the plan immediately prior to the manufacturer's violation of this subchapter; and

(5) imposing a civil penalty of up to $10,000.00 for each violation of this subchapter.

(e) The Attorney General shall not bring an action for a remedy under subdivisions (d)(2)–(5) of this section unless the Attorney General has provided the manufacturer or wholesale distributor an opportunity to meet with the Attorney General or his or her representative to offer a justification for the increase in the price of the essential off-patent or generic drug.

(f) Information provided to the Attorney General pursuant to subsections (b) and (c) of this section is exempt from public inspection and copying under the Public Records Act and shall not be released unless the confidentiality of the information is waived by the manufacturer or wholesale distributor.

(g) In any action brought by the Attorney General under subsection (d) of this section, a person who is alleged to have violated a requirement of this subchapter shall not assert as a defense that the person did not deal directly with a consumer residing in this State.

Sec. 2. EFFECTIVE DATE

This act shall take effect on October 1, 2018.