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SENATE BILL NO. 223

Offered January 10, 2018

Prefiled January 3, 2018

A BILL to amend the Code of Virginia by adding a section numbered 32.1-330.5 and by adding in Title 32.1 a chapter numbered 20, consisting of sections numbered 32.1-373 through 32.1-376, relating to prescription drug price gouging; prohibited.

Patron—Edwards

Referred to Committee on Education and Health

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding a section numbered 32.1-330.5 and by adding in Title 32.1 a chapter numbered 20, consisting of sections numbered 32.1-373 through 32.1-376, as follows:

§ 32.1-330.5. Prescription drug price gouging; notification to Attorney General.

A. As used in this section, "wholesale acquisition cost" has the same meaning as in 42 U.S.C. § 1395w-3a.

B. The Director shall notify the Attorney General of an increase in the price of an essential off-patent or generic drug, as defined in § 32.1-373, if (i) the increased price, alone or in combination with other price increases, would result in a price increase of 50 percent or more in the wholesale acquisition cost of the drug as compared to the wholesale acquisition price for the same drug prior to the increase or the price paid by the Department for the drug prior to the price increase, (ii) the cost of a 30-day supply of the maximum recommended dosage of the drug for any indication approved by the U.S. Food and Drug Administration would cost more than $80 at the wholesale acquisition cost, or (iii) in cases in which the drug is made available to consumers only in quantities that do not correspond to a 30-day supply, a full course of treatment of the drug would exceed $80.

CHAPTER 20.

PRESCRIPTION DRUG PRICING.

§ 32.1-373. Definitions.

As used in this chapter,

"Essential off-patent or generic drug" means any prescription drug (i) for which all exclusive marketing rights granted under the federal Food, Drug, and Cosmetic Act, § 351 of the federal Public Health Service Act, and federal patent law have expired; (ii) that appears on the Model List of Essential Medicines most recently adopted by the World Health Organization or that 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 or 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 the Commonwealth. "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 granted under the federal Food, Drug, and Cosmetic Act, § 351 of the federal Public Health Act, and federal patent law have expired.

"Manufacturer" has the same meaning as set forth in § 54.1-3401.

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

"Unconscionable increase" means an increase in the price of a prescription drug that (i)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 (ii) 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.

"Wholesale distributor" has the same meaning as set forth in § 54.1-3401.

§ 32.1-374. Price gouging prohibited.

A. No manufacturer or wholesale distributor shall engage in price gouging in the sale of an essential off-patent or generic drug.

B. An increase in the price of an essential off-patent or generic drug charged by a wholesale distributor shall not constitute price gouging if the increase is directly attributable to additional costs for the drug imposed on the wholesale distributor by the manufacturer.

§ 32.1-375. Designation of essential drugs.

The Secretary may designate a drug as an essential drug for the purposes of this chapter. Such designation shall be based on a finding of the drug's unique efficacy in treating a life-threatening health

condition or a chronic health condition that substantially impairs an individual's ability to engage in activities or daily living. A list of all drugs identified as essential drugs for the purposes of this chapter shall be posted on a website maintained by the Department.

§ 32.1-376. Enforcement.

Upon receipt of notification of suspected price gouging pursuant to § 32.1-330.5 or in any other case in which the Attorney General has reasonable cause to believe that any person has engaged in, is engaging in, or is about to engage in, any violation of this chapter, the Attorney General is empowered to issue a civil investigative demand. The provisions of § 59.1-9.10 shall apply mutatis mutandis to civil investigative demands issued pursuant to this section.