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HOUSE BILL NO. 1559

Offered January 13, 2020

A BILL to amend the Code of Virginia by adding in Title 38.2 a chapter numbered 65, consisting of sections numbered 38.2-6500 through 38.2-6506, relating to prescription drug price transparency; penalties.

Patrons—Hurst, Helmer, Campbell, J.L., Hope, Jenkins, Plum and Simonds

Referred to Committee on Labor and Commerce

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Title 38.2 a chapter numbered 65, consisting of sections numbered 38.2-6500 through 38.2-6506, as follows:

CHAPTER 65.

PRESCRIPTION DRUG PRICE TRANSPARENCY.

§ 38.2-6500. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Animal health product" means a medical product approved and licensed for use in animal or veterinary medicine, including a pharmaceutical, a biologic, an insecticide, and a parasiticide.

"Costly prescription drug" means a prescription drug with a wholesale acquisition cost of at least $50 for a 30-day supply before the effective date of a major price increase.

"Covered person" means a policyholder, subscriber, enrollee, or other individual participating in a health benefit plan.

"Health benefit plan" means a policy, contract, certificate, or agreement offered by a health carrier to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services.

"Health carrier" means an entity subject to the insurance laws and regulations of the Commonwealth and subject to the jurisdiction of the Commission that contracts or offers to contract to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services, including an insurer licensed to sell accident and sickness insurance, a health maintenance organization, a health services plan, or any other entity providing a plan of health insurance, health benefits, or health care services, pursuant to the terms of a health benefit plan.

"Major price increase" means an increase of 25 percent or more over the preceding three calendar years or 10 percent or more over the preceding calendar year in the wholesale acquisition cost of a prescription drug.

"Pharmaceutical drug manufacturer" means a person engaged in the business of producing, preparing, propagating, compounding, converting, processing, packaging, labeling, or distributing a drug. "Pharmaceutical drug manufacturer" does not include a wholesale distributor or retailer of prescription drugs or a licensed pharmacist.

"Pharmacy benefits management service" means any service provided in connection with the administration or management of prescription drug benefits provided by a health carrier under a health benefit plan and includes the purchase, resale, and distribution of any prescription drug.

"Pharmacy benefits manager" means a person that provides a pharmacy benefits management service. "Pharmacy benefits manager" includes (i) a person acting for a pharmacy benefits manager in a contractual or employment relationship in the performance of a pharmacy benefits management service and (ii) any health carrier that provides pharmacy benefits management services internally or affiliate or subsidiary of a health carrier that provides pharmacy benefits management services for such health carrier.

"Prescription drug" means any drug required by federal law or regulation to be dispensed only pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 353(b). "Prescription drug" does not include a device or an animal health product.

"Rebate" means a discount or concession that affects the price of a prescription drug to a pharmacy benefits manager or health carrier for a prescription drug manufactured by the pharmaceutical drug manufacturer.

"Specialty drug" means a prescription drug covered under Medicare Part D that exceeds the specialty tier cost threshold established by the Centers for Medicare and Medicaid Services.

"Utilization management" means a set of formal techniques designed to monitor the use of, or evaluate the medical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings.

"Wholesale acquisition cost" means, with respect to a drug, the pharmaceutical drug manufacturer's list price for the drug charged to wholesalers or direct purchasers in the United States, as reported in wholesale price guides or other publications of drug pricing data. "Wholesale acquisition cost" does not include any rebates, prompt pay or other discounts, or other reductions in price.

§ 38.2-6501. Pharmaceutical drug manufacturer information.

A. By January 15 of each year, each pharmaceutical drug manufacturer shall submit to the Commissioner a report stating the current wholesale acquisition cost information for the U.S. Food and Drug Administration-approved drugs sold in or into the Commonwealth by that pharmaceutical drug manufacturer.

B. The Commissioner shall develop a website to provide to the general public the wholesale acquisition cost information submitted under subsection A. The Commissioner shall make such information available on the website in a consumer-friendly, searchable format The website shall be made available through the Commission's website via a dedicated link that is prominently displayed on the home page or by a separate easily identifiable Internet address.

C. Within 30 days after the effective date of a major price increase of a costly prescription drug, the pharmaceutical drug manufacturer of the costly prescription drug shall submit a report to the Commissioner that includes:

1. The name of the costly prescription drug;

2. Whether the costly prescription drug is a brand name or generic;

3. The effective date of the change in the costly prescription drug's wholesale acquisition cost;

4. Aggregate, company-level research and development costs for the most recent year for which final audit data is available;

5. The name of each of the pharmaceutical drug manufacturer's prescription drugs approved by the U.S. Food and Drug Administration in the previous three calendar years;

6 The name of each of the pharmaceutical drug manufacturer's prescription drugs that lost patent exclusivity in the United States in the previous three calendar years; and

7. A statement regarding the factor or factors that caused the increase in the costly prescription drug's wholesale acquisition cost and an explanation of how each factor affected the cost.

D. The quality and types of information and data that a pharmaceutical drug manufacturer submits to the Commissioner under subsection C shall be consistent with the quality and types of information and data that the pharmaceutical drug manufacturer includes in the pharmaceutical drug manufacturer's annual consolidated report on U.S. Securities and Exchange Commission Form 10-K or any other public disclosure.

E. Not later than the sixtieth day after receipt of the report submitted under subsection C, the Commissioner shall publish the report on the website described in subsection B.

§ 38.2-6502. Pharmacy benefits manager information.

A. By February 1, 2021, each pharmacy benefits manager shall file with the Commissioner a report that discloses for the preceding calendar year and the immediately preceding three calendar years, and by February 1 of each year thereafter, each pharmacy benefits manager shall file with the Commissioner a report that discloses for the immediately preceding calendar year:

1 The aggregated rebates, fees, price protection payments, and any other payments collected from pharmaceutical drug manufacturers; and

2. The aggregated dollar amount of rebates, fees, price protection payments, and any other payments collected from pharmaceutical drug manufacturers that were:

a. Passed to health carriers or covered persons at the point of sale of a prescription drug; or

b. Retained as revenue by the pharmacy benefits manager.

B. A report submitted by a pharmacy benefits manager pursuant to subsection A shall not disclose the identity of a specific health benefit plan or covered person, the price charged for a specific prescription drug or class of prescription drugs, or the amount of any rebate or fee provided for a specific prescription drug or class of prescription drugs.

C. Not later than May 1 of each year, the Commissioner shall publish the aggregated data from all reports for that year required by this section in an appropriate location on the Commission's website described in subsection B of § 65.2-6501. The combined aggregated data from the reports shall be published in a manner that does not disclose or tend to disclose proprietary or confidential information of any pharmacy benefits manager.

§ 38.2-6503. Health carrier information.

A. Not later than February 1 of each year, each health carrier shall submit to the Commissioner a report that states for the immediately preceding calendar year:

1. The names of the 25 most frequently prescribed prescription drugs across all health benefit plans;

2. The percent increase in annual net spending for prescription drugs across all health benefit plans;

3. The percent increase in premiums that were attributable to prescription drugs across all health benefit plans;

4. The percentage of specialty drugs with utilization management requirements across all health benefit plans; and

5. The premium reductions that were attributable to specialty drug utilization management.

B. A report submitted by a health carrier shall not disclose the identity of a specific health benefit plan or the price charged for a specific prescription drug or class of prescription drugs.

C. By May 1 of each year, the Commissioner shall publish the aggregated data from all reports for that year required by this section in an appropriate location on the Commission's website described in subsection B of § 65.2-6501. The combined aggregated data from the reports shall be published in a manner that does not disclose or tend to disclose proprietary or confidential information of any health carrier.

§ 38.2-6504. Regulations.

The Commission shall adopt any regulations necessary to implement the provisions of this chapter.

§ 38.2-6505. Hearings; audits; corrective action plan.

A. The Commission may call one or more public hearings and may subpoena any prescription drug manufacturer, pharmacy benefits manager, or health carrier to explain its reporting pursuant to § 38.2-6501, 38.2-6502, or 38.2-6503.

B. The Commission may audit any data submitted to it by a prescription drug manufacturer, pharmacy benefits manager, or health carrier pursuant to § 38.2-6501, 38.2-6502, or 38.2-6503. The prescription drug manufacturer, pharmacy benefits manager, or health carrier shall pay all costs associated with the audit.

C. The Commission may require a prescription drug manufacturer, pharmacy benefits manager, or health carrier to submit a corrective action plan, in a form and manner specified by the Commission, to correct deficiencies in reporting pursuant to § 38.2-6501, 38.2-6502, or 38.2-6503.

§ 38.2-6506. Failure to report; penalties.

The Commission shall notify, in writing, a prescription drug manufacturer, pharmacy benefits manager, or health carrier of a failure to meet a reporting deadline under this chapter. If the Commission determines that a prescription drug manufacturer, pharmacy benefits manager, or health carrier has failed to make a good faith effort to submit a required report within two weeks following receipt of the written notice, the prescription drug manufacturer, pharmacy benefits manager, or health carrier shall be deemed to have committed a knowing and willful violation of this section and shall be punished by the Commission as set forth in subsection A of § 38.2-218, except that the penalty for each day following receipt of the written notice that the required report is not submitted shall not exceed $30,000.