## 2021 SESSION

INTRODUCED

	20104406D
1	HOUSE BILL NO. 1559
2 3	Offered January 13, 2020
4 5	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.
6	Patrons—Hurst, Helmer, Campbell, J.L., Hope, Jenkins, Plum and Simonds
7 8	Referred to Committee on Labor and Commerce
9	Be it exected by the Conceal Accomply of Vincinia.
10 11 12	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 a setting work and 28.2 (500 threads 28.2 (500 cm follows))
12 13	of sections numbered 38.2-6500 through 38.2-6506, as follows: CHAPTER 65.
13 14	PRESCRIPTION DRUG PRICE TRANSPARENCY.
15	§ 38.2-6500. Definitions.
16	As used in this chapter, unless the context requires a different meaning:
17	"Animal health product" means a medical product approved and licensed for use in animal or
18	veterinary medicine, including a pharmaceutical, a biologic, an insecticide, and a parasiticide.
19	"Costly prescription drug" means a prescription drug with a wholesale acquisition cost of at least
20	\$50 for a 30-day supply before the effective date of a major price increase.
21 22	"Covered person" means a policyholder, subscriber, enrollee, or other individual participating in a health benefit plan.
$\frac{12}{23}$	"Health benefit plan" means a policy, contract, certificate, or agreement offered by a health carrier
24	to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services.
25	"Health carrier" means an entity subject to the insurance laws and regulations of the Commonwealth
26	and subject to the jurisdiction of the Commission that contracts or offers to contract to provide, deliver,
27 28	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
20 29	any other entity providing a plan of health insurance, health benefits, or health care services, pursuant
<b>3</b> 0	to the terms of a health benefit plan.
31	"Major price increase" means an increase of 25 percent or more over the preceding three calendar
32	years or 10 percent or more over the preceding calendar year in the wholesale acquisition cost of a
33 34	prescription drug.
34 35	"Pharmaceutical drug manufacturer" means a person engaged in the business of producing, preparing, propagating, compounding, converting, processing, packaging, labeling, or distributing a
36 37	drug. "Pharmaceutical drug manufacturer" does not include a wholesale distributor or retailer of
37 38	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
40	benefit plan and includes the purchase, resale, and distribution of any prescription drug.
41	"Pharmacy benefits manager" means a person that provides a pharmacy benefits management
42 43	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
43 44	service and (ii) any health carrier that provides pharmacy benefits management services internally or
45	affiliate or subsidiary of a health carrier that provides pharmacy benefits management services for such
46	health carrier.
47	"Prescription drug" means any drug required by federal law or regulation to be dispensed only
48	pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503(b) of
49 50	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.
51	"Rebate" means a discount or concession that affects the price of a prescription drug to a pharmacy
52	benefits manager or health carrier for a prescription drug manufactured by the pharmaceutical drug
53	manufacturer.
54	"Specialty drug" means a prescription drug covered under Medicare Part D that exceeds the
55 56	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
50 57	evaluate the medical necessity, appropriateness, efficacy, or efficiency of, health care services,
58	procedures, or settings.

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59 "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 60 61 62 include any rebates, prompt pay or other discounts, or other reductions in price.

63 § 38.2-6501. Pharmaceutical drug manufacturer information.

64 A. By January 15 of each year, each pharmaceutical drug manufacturer shall submit to the 65 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 66 67 manufacturer.

B. The Commissioner shall develop a website to provide to the general public the wholesale 68 acquisition cost information submitted under subsection A. The Commissioner shall make such 69 70 information available on the website in a consumer-friendly, searchable format The website shall be 71 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. 72

73 C. Within 30 days after the effective date of a major price increase of a costly prescription drug, the 74 pharmaceutical drug manufacturer of the costly prescription drug shall submit a report to the 75 Commissioner that includes: 76

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;

79 4. Aggregate, company-level research and development costs for the most recent year for which final 80 audit data is available;

81 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; 82

6 The name of each of the pharmaceutical drug manufacturer's prescription drugs that lost patent 83 84 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 85 86 drug's wholesale acquisition cost and an explanation of how each factor affected the cost.

87 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 88 89 and data that the pharmaceutical drug manufacturer includes in the pharmaceutical drug manufacturer's 90 annual consolidated report on U.S. Securities and Exchange Commission Form 10-K or any other public 91 disclosure.

92 E. Not later than the sixtieth day after receipt of the report submitted under subsection C, the 93 Commissioner shall publish the report on the website described in subsection B. 94

§ 38.2-6502. Pharmacy benefits manager information.

A. By February 1, 2021, each pharmacy benefits manager shall file with the Commissioner a report 95 that discloses for the preceding calendar year and the immediately preceding three calendar years, and 96 by February 1 of each year thereafter, each pharmacy benefits manager shall file with the 97 98 Commissioner a report that discloses for the immediately preceding calendar year:

99 1 The aggregated rebates, fees, price protection payments, and any other payments collected from pharmaceutical drug manufacturers; and 100

101 2. The aggregated dollar amount of rebates, fees, price protection payments, and any other payments 102 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 103 104

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 105 106 prescription drug or class of prescription drugs, or the amount of any rebate or fee provided for a 107 108 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 109 reports for that year required by this section in an appropriate location on the Commission's website 110 described in subsection B of § 65.2-6501. The combined aggregated data from the reports shall be 111 published in a manner that does not disclose or tend to disclose proprietary or confidential information 112 113 of any pharmacy benefits manager. 114

## § 38.2-6503. Health carrier information.

115 A. Not later than February 1 of each year, each health carrier shall submit to the Commissioner a 116 report that states for the immediately preceding calendar year:

117 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; 118 119 3. The percent increase in premiums that were attributable to prescription drugs across all health

120 benefit plans; 121 4. The percentage of specialty drugs with utilization management requirements across all health122 benefit plans; and

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

124 B. A report submitted by a health carrier shall not disclose the identity of a specific health benefit 125 plan or the price charged for a specific prescription drug or class of prescription drugs.

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

## 131 § 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 subpoend 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.

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

## 144 § 38.2-6506. Failure to report; penalties.

145 The Commission shall notify, in writing, a prescription drug manufacturer, pharmacy benefits 146 manager, or health carrier of a failure to meet a reporting deadline under this chapter. If the 147 Commission determines that a prescription drug manufacturer, pharmacy benefits manager, or health 148 carrier has failed to make a good faith effort to submit a required report within two weeks following 149 receipt of the written notice, the prescription drug manufacturer, pharmacy benefits manager, or health 150 carrier shall be deemed to have committed a knowing and willful violation of this section and shall be 151 punished by the Commission as set forth in subsection A of § 38.2-218, except that the penalty for each 152 day following receipt of the written notice that the required report is not submitted shall not exceed 153 \$30,000.

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