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HOUSE BILL NO. 2007

Offered January 13, 2021

Prefiled January 11, 2021

A BILL to amend the Code of Virginia by adding in Article 3 of Chapter 1 of Title 32.1 a section numbered 32.1-23.3, by adding a section numbered 38.2-3407.15:6, by adding in Article 1 of Chapter 34 of Title 38.2 a section numbered 38.2-3407.22, by adding in Article 3 of Chapter 34 of Title 54.1 a section numbered 54.1-3436.1, and by adding in Article 4 of Chapter 34 of Title 54.1 a section numbered 54.1-3442.02, relating to prescription drug price transparency.

Patrons—Sickles, Guzman, Subramanyam, Ayala, Fowler, Gooditis, Keam, Levine, Murphy, Price, Tran and Willett; Senator: Surovell

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Article 3 of Chapter 1 of Title 32.1 a section numbered 32.1-23.3, by adding a section numbered 38.2-3407.15:6, by adding in Article 1 of Chapter 34 of Title 38.2 a section numbered 38.2-3407.22, by adding in Article 3 of Chapter 34 of Title 54.1 a section numbered 54.1-3436.1, and by adding in Article 4 of Chapter 34 of Title 54.1 a section numbered 54.1-3442.02 as follows:

§ 32.1-23.3. Prescription drug price transparency; civil penalty.

A. The Department shall annually collect, compile, and make available on its website publicly available information about prescription drug prices submitted by health carriers and pharmacy benefits managers pursuant to § 38.2-3407.15:6, wholesale distributors pursuant to § 54.1-3436.1, and manufacturers pursuant to § 54.1-3442.02. Such data and information shall be made available in aggregate in a form and manner that does not disclose or tend to disclose proprietary or confidential information of any health carrier, pharmacy benefits manager, wholesale distributor, or manufacturer.

B. A health carrier, pharmacy benefits manager, wholesale distributor, or manufacturer that fails to report information required to be reported pursuant to this section or § 38.2-3407.15:6, 54.1-3436.1, or 54.1-3442.02, respectively, shall be subject to a civil penalty not to exceed $1,000 per day from the date on which such reporting is required, to be collected by the Commissioner and deposited into the Literary Fund. However, the Commissioner may reduce or waive a civil penalty imposed pursuant to this section if he determines that the violation was reasonable or resulting from good cause.

C. The Department shall adopt regulations to implement the provisions of this section, which shall include (i) provisions related to the specification of prescription drugs for the purpose of data collection and procedures for auditing information provided by health carriers, pharmacy benefits managers, wholesale distributors, and manufacturers, and (ii) a schedule of civil penalties for failure to report information required pursuant to this section or § 38.2-3407.15:6, 54.1-3436.1, or 54.1-3442.02, which shall be based on the level of severity of the violation.

§ 38.2-3407.15:6. Prescription drug price transparency.

A. As used in this section:

"Carrier" has the same meaning as set forth in § 38.2-3407.10.

"Health benefit plan" has the same meaning as set forth in § 38.2-3438.

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

"Pharmacy benefits management" has the same meaning as set forth in § 38.2-3407.15:4.

"Pharmacy benefits manager" has the same meaning as set forth in § 38.2-3407.15:4.

B. Every carrier offering a health benefit plan shall report annually by April 1 to the Department of Health information on spending on prescription drugs before enrollee cost sharing in total and for each of the 25 most frequently prescribed prescription drugs across all health benefit plans offered by the carrier, including:

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

2. The percent increase in annual net spending for prescription drugs after accounting for aggregated rebates, discounts, or other reductions in price across all health benefit plans;

3. The percent increase in premiums that were attributable to each health care service, including 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.

C. A report submitted by a carrier pursuant to this section 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.

D. Every carrier offering a health benefit plan shall require each pharmacy benefits manager with which it enters into a contract for pharmacy benefits management to report annually by April 1 to the Department of Health the following information for each drug specified by the Department of Health:

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 (i) passed to carriers or to covered persons at the point of sale of a prescription drug or (ii) retained as revenue by the pharmacy benefits manager.

E. A report submitted by a pharmacy benefits manager pursuant to subsection D 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.

§ 38.2-3407.22. Calculation of enrollee's contribution to out-of-pocket maximum or cost-sharing requirement.

A. As used in this section:

"Carrier" has the same meaning as set forth in § 38.2-3407.10; however, "carrier" also includes any person required to be licensed pursuant to this title that offers or operates a managed care health insurance plan subject to the requirements of Chapter 58 (§ 38.2-5800 et seq.) or that provides or arranges for the provision of health care services, health plans, networks, or provider panels that are subject to regulation as the business of insurance. "Carrier" also includes any health insurance issuer that offers health insurance coverage, as defined in 42 U.S.C. §300gg-91.

"Defined cost sharing" means a deductible payment or coinsurance amount imposed on an enrollee for a covered prescription drug under the enrollee's health plan.

"Enrollee" means any person entitled to health care services from a carrier.

"Health care services" means items or services furnished to any individual for the purpose of preventing, alleviating, curing, or healing human illness, injury, or physical disability.

"Health plan" means any individual or group health care plan, subscription contract, evidence of coverage, certificate, health services plan, medical or hospital services plan, accident or sickness insurance policy or certificate, managed care health insurance plan, or other similar certificate, policy, contract, or arrangement, and any endorsement or rider thereto, to cover all or a portion of the cost of persons receiving covered health care services, that is subject to state regulation and that is required to be offered, arranged, or issued in the Commonwealth by a carrier licensed under this title. "Health plan" includes a state or local government employer plan. "Health plan" does not mean (i) coverages issued pursuant to Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. (Medicare), Title XIX of the Social Security Act, 42 U.S.C. § 1396 et seq. (Medicaid), Title XXI of the Social Security Act, 42 U.S.C. § 1397aa et seq. (CHIP), 5 U.S.C. § 8901 et seq. (federal employees), or 10 U.S.C. § 1071 et seq. (TRICARE); or (ii) accident only, credit or disability insurance ,long-term care insurance, TRICARE supplement, Medicare Supplement, or workers' compensation coverages.

"Pharmacy benefits manager" has the same meaning as set forth in § 38.2-3407.15:4.

"Price protection rebate" means a negotiated price concession that accrues directly or indirectly to the carrier, health plan, or pharmacy benefits manager in the event of an increase in the wholesale acquisition cost of a drug above a specified threshold.

"Rebate" means (i) negotiated price concessions, including base price concessions and reasonable estimates of any price protection rebates and performance-based price concessions, that may accrue directly or indirectly to a carrier, health plan, or pharmacy benefits manager during the coverage year from a manufacturer, dispensing pharmacy, or other party in connection with the dispensing or administration of a prescription drug and (ii) reasonable estimates of any negotiated price concessions, fees, or other administrative costs that are passed through or are reasonably anticipated to be passed through, to the carrier, health plan, or pharmacy benefits manager, and serve to reduce the liability of a carrier, health plan, or pharmacy benefits manager for a prescription drug.

B. An enrollee's defined cost sharing for each prescription drug shall be calculated at the point of sale based on a price that is reduced by an amount equal to at least 80 percent of all rebates received, or to be received, in connection with the dispensing or administration of the prescription drug.

C. Nothing in this section shall preclude a carrier, health plan, or pharmacy benefits manager from decreasing an enrollee's defined cost sharing by an amount greater than the amount by which such cost sharing is required to be reduced pursuant to subsection B.

D. The provisions of this section shall only apply to a carrier, health plan, or pharmacy benefits manager to the extent permissible under applicable law.

E. In complying with the provisions of this section, a carrier, health plan, pharmacy benefits manager, or its respective agents shall not publish or otherwise reveal information regarding the actual amount of rebates a carrier, health plan, or pharmacy benefits manager receives on a product-specific,

manufacturer-specific, or pharmacy-specific basis. Such information shall be protected as a trade secret and shall not be public record or disclosed, directly or indirectly. A carrier, health plan, or pharmacy benefits manager shall require any vendor or third party with which the carrier, health plan, or pharmacy benefits manager contracts for health care or administrative services on behalf of the carrier, health plan, or pharmacy benefits manager that may receive or have access to rebate information to comply with the provisions of this subsection related to protection of information regarding the amount of rebates a carrier, health plan, or pharmacy benefits manager receives on a product-specific, manufacturer-specific, or pharmacy-specific basis.

F. The Commission may, pursuant to the provisions of § 38.2-223, adopt such rules and regulations as may be necessary to implement and enforce the provisions of this section.

§ 54.1-3436.1. Prescription drug price transparency.

A. As used in this section:

"Brand-name drug" means a prescription drug approved under 21 U.S.C. § 355(b) or 42 U.S.C. § 262.

"Generic drug" means a prescription drug approved under 21 U.S.C. § 355(j).

"Pharmacy benefits manager" has the same meaning as set forth in § 38.2-3407.15:4.

"Wholesale acquisition cost" has the same meaning as set forth in 42 U.S.C. § 1395w-3a(c)(6)(B).

B. Every whole sale distributor shall report annually by April 1 to the Department of Health for each drug specified by the Department of Health the following information:

1. The maximum and minimum wholesale acquisition cost that the wholesale distributor has negotiated directly with the manufacturer in the last calendar year, related to prescriptions issued in the Commonwealth;

2. The maximum and minimum wholesale acquisition cost that the wholesale distributor has negotiated directly with the manufacturer in the current calendar year, related to prescriptions issued in the Commonwealth;

3. Aggregate total rebates, discounts, and price concessions negotiated directly with the manufacturer in the last calendar year, for business in the Commonwealth, in total and for each payer type specified by the Department of Health;

4. Aggregate total discounts, dispensing fees, and other fees negotiated in the last calendar year with pharmacies, prescription drug networks, or pharmacy services administrative organizations, for business in the Commonwealth, in total and for each payer type specified by the Department of Health; and

5. The total net income received in the last calendar year, for business in the Commonwealth, in total and for each payer type specified by the Department of Health.

C. A report submitted by a wholesale distributor pursuant to subsection B shall not disclose the identity of a specific wholesale distributor, the price charged for a specific prescription drug or class of prescription drugs, or the amount of any price concession, rebate, or fee provided for a specific prescription drug or class of prescription drugs.

§ 54.1-3442.02. Prescription drug price transparency.

A. As used in this section:

"Brand-name drug" means a prescription drug approved under 21 U.S.C. § 355(b) or 42 U.S.C. § 262.

"Generic drug" means a prescription drug approved under 21 U.S.C. § 355(j) or 42 U.S.C. 262(k).

"New prescription drug" means a drug or biological product receiving initial approval under an original new drug application pursuant to 21 U.S.C. § 355(b), under an abbreviated new drug application under 21 U.S.C. § 355(j), or under a biologics license application under 42 U.S.C. § 262

"Pharmacy benefits manager" has the same meaning as set forth in § 38.2-3407.15:4.

"Wholesale acquisition cost" has the same meaning as set forth in 42 U.S.C. § 1395w-3a(c)(6)(B).

B. Every manufacturer shall report annually by April 1 to the Department of Health, for each prescription drug with a wholesale acquisition cost of at least $100 for a 30-day supply, any increase of 50 percent or more over the preceding three calendar years or 20 percent more over the preceding calendar year in the wholesale acquisition cost of such drug, with such increase calculated by comparing the lowest wholesale acquisition cost for such drug within the preceding three calendar years or preceding one calendar year, as may be appropriate, with the wholesale acquisition cost for such drug after the increase. Such report shall include:

1. The name of the prescription drug;

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

3. The effective date of the change in 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 manufacturer's new prescription drugs approved by the U.S. Food and Drug Administration within the previous three calendar years;

6. The name of each of the manufacturer's prescription drugs that, within the previous three calendar years, became subject to generic competition and for which there is a therapeutically equivalent generic version; and

7. A concise statement regarding the factor or factors that caused the increase in wholesale acquisition cost.

C. The quality and types of information and data reported to the Department of Health pursuant to this section shall be consistent with the quality and types of information and data that the manufacturer includes in the manufacturer's annual consolidated report on U.S. Securities and Exchange Commission Form 10-K or any other public disclosure, and the requirements of this section shall be satisfied by submission by a manufacturer to the Department of Health of information and data that the manufacturer includes in its annual consolidated report on U.S. Securities and Exchange Commission Form 10-K or any other public disclosure.

2. That the provisions of § 38.2-3407.22 of the Code of Virginia, as created by this act, shall become effective on January 1, 2022.

3. That the Bureau of Insurance of the State Corporation Commission (the Bureau) shall (i) identify all statutory and regulatory provisions from which health plans subject to the Employee Retirement Income Security Act of 1974 (ERISA) are exempted and (ii) determine the financial impact, if any, of application of such statutory and regulatory provisions such health plans. The Bureau shall report its finding to the Chairman of the House Committees on Health, Welfare and Institutions and Labor and Commerce and the Chairmen of the Senate Committees on Commerce and Labor and Education and Health by October 1, 2021.