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HOUSE BILL NO. 876

Offered January 8, 2020
Prefiled January 7, 2020

A BILL to amend the Code of Virginia by adding in Article 3 of Chapter 1 of Title 32.1 a section numbered 32.1-23.2, by adding a section numbered 38.2-3407.15:5, 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—Subramanyam, Hurst and Simonds

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 32.1-23.2, by adding a section numbered 38.2-3407.15:5, 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:

§ 32.1-23.2. Prescription drug price transparency; civil penalty.

A. The Department shall annually collect, compile, and make available on its website information about prescription drug prices submitted by health carriers and pharmacy benefits managers pursuant to § 38.2-3407.15:5, wholesale distributers pursuant to § 54.1-3436.1, and manufacturers pursuant to § 54.1-3442.02.

B. The Department shall adopt regulations to implement the provisions of this section, which shall include provisions related to specification of drugs and drug groups for the purpose of data collection and procedures for auditing information provided by wholesale distributers, manufacturers, health carriers, and pharmacy benefits managers.

C. A health carrier, pharmacy benefits manager, wholesale distributor, or manufacturer that fails to report information required to be reported pursuant to this section or § 38.2-3407.15:5, 54.1-3436.1 or 54.1-3442.02, respectively, shall be subject to a civil penalty not to exceed $30,000 per day from the date on which such reporting is required, to be collected by the Commissioner and deposited into the Literary Fund.

§ 38.2-3407.15:5. Prescription drug price transparency.

A. As used in this section:

"Drug group" means a group of similar drugs specified by the Department of Health for the purpose of facilitating revenue and cost reporting by manufacturers.

"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.

"Wholesale acquisition cost" means, with respect to a prescription drug, the manufacturer's list price for such drug charged to wholesalers or direct purchasers in the United States, as reported in the manufacturer's wholesale price guide or other publication of drug pricing data. "Wholesale acquisition cost" does not include any rebate, prompt payment or other discount, or other reduction in price provided to a wholesaler or direct purchaser for such prescription drug.

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

1. The greatest total spending before enrollee cost sharing in the previous calendar year;

2. The greatest total spending per user of any drug in the drug group before enrollee cost sharing in the previous calendar year;

3. The highest year-over-year increase in total spending before enrollee cost sharing; and

4. The highest year-over-year increase in total spending per user of any drug in the drug group before enrollee cost sharing.

C. Every health carrier offering a health benefit plan shall report annually, by February 1, to the Department of Health, for each drug and drug group specified by the Department of Health:

2. Projected total spending before enrollee cost sharing for the current calendar year;

3. Price concession sand fees paid to pharmacy benefits managers, including margins and fees paid directly to pharmacy benefits managers or pharmacy services administrative organizations in the

previous calendar year; and

4. Other retail price concessions and fees, including other retail discounts, price concessions, and fees paid in the previous calendar year.

D. Every health 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 February 1, to the Department of Health, the following information, by drug or drug group for each drug or drug group specified by the Department of Health:

1. The wholesale acquisition cost, including the minimum and maximum wholesale acquisition cost, for each drug and drug group for which the pharmacy benefits manager has negotiated directly with the manufacturer, for prescriptions issued in the Commonwealth, for the previous calendar year and the current calendar year;

2. The volume in wholesale acquisition cost units that the pharmacy benefits manager negotiated directly with the manufacturer in the previous calendar year, for business in the Commonwealth, in total and for each payer type as relevant, including the total volume and the total volume for each of the following: commercial insurance payers, Medicaid, Medicare, and other payers;

3. The projected volume in wholesale acquisition cost units that the pharmacy benefits manager negotiated directly with the manufacturer in the current calendar year, for business in the Commonwealth, in total and for each payer type as relevant, including the total volume and the total volume for each payer type specified by the Department of Health;

4. Total rebates, discounts, and price concessions received or negotiated directly with the manufacturer in the previous calendar year, for business in the Commonwealth, in total and for each payer type specified by the Department of Health;

5. Projected total rebates, discounts, or price concessions that the pharmacy benefits manager expects to receive or to negotiate directly with the manufacturer in the current calendar year, for business in the Commonwealth, in total and for each payer type specified by the Department of Health;

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

7. Projected total discounts, dispensing fees, or other fees that the pharmacy benefits manager expects to negotiate in the current calendar year with pharmacies, prescription drug networks, or pharmacy services administrative organizations in the current calendar year, for business in the Commonwealth, in total and for each payer type specified by the Department of Health;

8. 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; and

9. Projected net income that the pharmacy benefits manager expects to receive in the current calendar year, for business in the Commonwealth, in total and for each payer type specified by the Department of Health.

§ 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.

"Drug group" means a group of similar drugs specified by the Department of Health for the purpose of facilitating revenue and cost reporting by manufacturers.

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

"Manufacturer-sponsored assistance program" means a program offered by a manufacturer, or a manufacturer-contracted intermediary, through which brand-name or generic drugs are provided to patients at a discount or no charge.

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

"Wholesale acquisition cost" means, with respect to a prescription drug, the manufacturer's list price for such drug charged to wholesalers or direct purchasers in the United States, as reported in the manufacturer's wholesale price guide or other publication of drug pricing data. "Wholesale acquisition cost" does not include any rebate, prompt payment or other discount, or other reduction in price provided to a wholesaler or direct purchaser for such prescription drug.

B. Every wholesale distributor shall report annually to the Department of Health, by February 1, the following information for each drug and drug group specified by the Department of Health:

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

3. Volume in wholesale acquisition cost units that the wholesale distributor negotiated directly with

the manufacturer in the last calendar year, for business in the state, in total and for each payer type specified by the Department;

4. Projected volume in wholesale acquisition cost units that the wholesale distributor expects to negotiate directly with the manufacturer for the current calendar year, for business in the Commonwealth, in total and for each payer type specified by the Department of Health;

5. 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;

6. Projected total rebates, discounts, or price concessions that the wholesale distributor expects to negotiate directly with the manufacturer in the current calendar year, for business in the Commonwealth, in total and for each payer type as specified by the Department of Health;

7. Total discounts, dispensing fees, and other fees negotiated in the previous 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;

8. Projected total discounts, dispensing fees, or other fees that the wholesale drug distributor expects to negotiate in the current 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;

9. 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; and

10. Projected total margin that the wholesale distributor expects to receive in the current calendar year, for business in the Commonwealth, in total and for each payer type specified by the Department of Health.

§ 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.

"Drug group" means a group of similar drugs specified by the Department of Health for the purpose of facilitating revenue and cost reporting by manufacturers.

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

"Manufacturer-sponsored assistance program" means a program offered by a manufacturer, or a manufacturer-contracted intermediary, through which brand-name or generic drugs are provided to patients at a discount or no charge.

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

"Wholesale acquisition cost" means, with respect to a prescription drug, the manufacturer's list price for such drug charged to wholesalers or direct purchasers in the United States, as reported in the manufacturer's wholesale price guide or other publication of drug pricing data. "Wholesale acquisition cost" does not include any rebate, prompt payment or other discount, or other reduction in price provided to a wholesaler or direct purchaser for such prescription drug.

B. Every manufacturer shall provide notice to the Department of Health of any introduction to the market of any new name-brand or generic drug, at least 60 days prior to such introduction, if the wholesale acquisition cost of the new drug will be $670 or more per year. Such notice shall include:

1. Identifying information for the drug and the manufacturer, including national drug code, proprietary drug name, non-proprietary drug name, whether the drug is brand-named or generic, manufacturer tax identification number, manufacturer name, drug grouper, and drug group code or name;

2. The proposed date of market introduction;

3. The wholesale acquisition cost unit for the drug;

4. Current calendar year projects for patient volume for the drug and drug group in the United States;

5. Current calendar year projects for patient volume in the drug and drug group in the Commonwealth;

6. Projected revenue for the drug and drug group in the current year in the United States; and

7. The wholesale acquisition cost of the drug at the time of market introduction.

C. Every manufacturer shall provide notice to the Department of Health of any increase in the price of a drug manufactured by the manufacturer and sold in the Commonwealth within 60 days of the proposed increase in price, if such increase will result in (i) a 20 percent increase in the wholesale acquisition cost of a brand-name drug as compared with the average wholesale acquisition cost of the brand-name drug the during the previous year or (ii) a 200 percent increase in the wholesale acquisition cost of a generic drug priced at $100 or more per wholesale acquisition cost unit as compared with the average wholesale acquisition cost of the generic drug the during the previous year.

Such notice shall include:

1. Identifying information for the drug and the manufacturer, including the national drug code, proprietary drug name, non-proprietary drug name, manufacturer tax identification number, manufacturer name, drug grouper, and drug group code or name;

2. Drug acquisition information for the drug, if applicable, including the acquisition date, the company from which the drug was acquired, and the wholesale acquisition cost in dollars at the time the drug was acquired;

3. The wholesale acquisition cost unit for the drug;

4. Wholesale price information, including the year of market introduction, the wholesale acquisition cost at introduction, the current wholesale acquisition cost, and the average wholesale acquisition cost in each of the previous four calendar years, the wholesale acquisition cost after the proposed increase, and the justification for such increase in the wholesale acquisition cost;

5. Sales volume in the United States by drug and drug group, as specified by the Department of Health, by wholesale acquisition cost units, including projected sales volume in the current calendar year and sales volume in each of the previous four previous calendar years;

6. Sales volume in the Commonwealth by drug and drug group, as specified by the Department of Health, by wholesale acquisition cost units, including projected sales volume in the current calendar year and sales volume in each of the previous four previous calendar years;

7. Information about revenue from the sale of the drug or drug group in the United States, by drug and drug group as specified by the Department of Health, in dollars, including the projected revenue in the current calendar year and revenue in each of the four previous calendar years;

8. Information about revenue from the sale of the drug or drug group in the Commonwealth, by drug and drug group as specified by the Department of Health, in dollars, including the projected revenue in the current calendar year and revenue in each of the four previous calendar years;

9. The manufacturer's cost associated with sales of the drug in the United States, by drug or drug group, as specified by the Department of Health, including projected costs in the current calendar year and in each of the four previous calendar years; and

10. Current calendar year projects or year-to-date incurred costs, as specified by the Department, related directly or allocated specifically to sales of the drug and drug group in the United States, including the number of wholesale acquisition units produced; cost of production; research and development costs; a description of such research and development costs; other company-level capital expenditures allocated to the drug and drug group; a description of such company-level expenditures allocated to the drug and drug group; financial assistance provided to patients in the United States through patient prescription assistance programs or coupons provided to customers; rebates provided to pharmacy benefits managers; other rebates, discounts, and price concessions; marketing and advertising expenses; other administrative expenses allocated to the drug or drug group; and a description of other administrative expenditures and the rationale for each such expenditure.