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HOUSE BILL NO. 1405

Offered January 8, 2020

Prefiled January 8, 2020

A BILL to amend and reenact § 32.1-276.4 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 32.1-276.7:2, by adding in Chapter 34 of Title 38.2 an article numbered 9, consisting of sections numbered 38.2-3465, 38.2-3466, and 38.2-3467, 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; prescription drugs for the treatment of diabetes; reports by drug manufacturers and pharmacy benefits managers; registration of pharmacy benefits managers; civil penalty.

Patron—Leftwich

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That § 32.1-276.4 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding a section numbered 32.1-276.7:2, by adding in Chapter 34 of Title 38.2 an article numbered 9, consisting of sections numbered 38.2-3465, 38.2-3466, and 38.2-3467, and by adding in Article 4 of Chapter 34 of Title 54.1 a section numbered 54.1-3442.02 as follows:

§ 32.1-276.4. Agreements for certain data services.

A. The Commissioner shall negotiate and enter into contracts or agreements with a nonprofit organization for the compilation, storage, analysis, and evaluation of data submitted by health care providers pursuant to this chapter; for the operation of the *Virginia* All-Payer Claims Database pursuant to § *§§* 32.1-276.7:1 *and 32.1-276.7:2*; and for the development and administration of a methodology for the measurement and review of the efficiency and productivity of health care providers. Such nonprofit organization shall be governed by a board of directors composed of representatives of state government, including the Commissioner, representatives of the Department of Medical Assistance Services and the Bureau of Insurance, health plans and health insurance issuers, and the consumer, health care provider, and business communities. Of the health care provider representatives, there shall be an equal number of hospital, nursing home, physician, and health plan representatives. The articles of incorporation of such nonprofit organization shall require the nomination of such board members by organizations and associations representing those categories of persons specified for representation on the board of directors.

B. In addition to providing for the compilation, storage, analysis, and evaluation services described in subsection A, any contract or agreement with a nonprofit, tax-exempt health data organization made pursuant to this section shall require the board of directors of such organization to:

1. Develop and disseminate other health care quality and efficiency information designed to assist businesses and consumers in purchasing health care and long-term care services;

2. Prepare and make public summaries, compilations, or other supplementary reports based on the data provided pursuant to this chapter;

3. Collect, compile, and publish Health Employer Data and Information Set (HEDIS) information or reports or other quality of care or performance information sets approved by the Board, pursuant to § 32.1-276.5, and submitted by health maintenance organizations or other health care plans;

4. Jointly determine with the Board of Medicine any data concerning safety services and quality health care services rendered by physicians to Medicaid recipients that should be identified, collected, and disseminated. The board of directors shall further determine jointly with the Board of Medicine the costs of requiring physicians to identify, submit, or collect such information and identify sufficient funding sources to appropriate to physicians for the collection of the same. No physician shall be required to collect or submit safety and quality of health care services information that is already identified, collected, or submitted under this chapter; or for which funds for collection are not appropriated;

5. Maintain the confidentiality and security of data as set forth in §§ 32.1-276.7:1 and 32.1-276.9;

6. Submit a report to the Board, the Governor, and the General Assembly no later than October 1 of each year for the preceding fiscal year. Such report shall include a certified audit, including an analysis of the efficacy and value of the *Virginia* All-Payer Claims Database, and provide information on the accomplishments, priorities, and current and planned activities of the nonprofit organization;

7. Submit, as appropriate, strategic plans to the Board, the Governor, and the General Assembly recommending specific data projects to be undertaken and specifying data elements for collection under this chapter. In developing strategic plans, the nonprofit organization shall incorporate similar activities

of other public and private entities to maximize the quality of data projects and to minimize the cost and duplication of data projects. In its strategic plans, the nonprofit organization shall also evaluate the continued need for and efficacy of current data initiatives, including the use of patient level data for public health purposes. The approval of the General Assembly shall be required prior to the implementation of any recommendations set forth in a strategic plan submitted pursuant to this section;

8. Competitively bid or competitively negotiate all aspects of all data projects, if feasible; and

9. Fulfill all funded requirements set forth for the nonprofit organization in this chapter.

C. The Department shall take steps to increase public awareness of the data and information available through the nonprofit organization's website and how consumers can use the data and information when making decisions about health care providers and services.

D. Except as provided in subdivision A 2 of § 2.2-4345, the provisions of the Virginia Public Procurement Act (§ 2.2-4300 et seq.) shall not apply to the activities of the Commissioner authorized by this section. Funding for services provided pursuant to any such contract or agreement shall come from general appropriations and from fees determined pursuant to § 32.1-276.8 and from such fees and other public and private funding sources as may be authorized by this chapter.

§ 32.1-276.7:2. Prescription drug price transparency; civil penalty.

A. As used in this section, unless the context requires a different meaning:

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

"Pharmacy benefits manager" has the same meaning as provided in § 38.2-3465.

"Wholesale acquisition cost" means the list price of a prescription drug established by the manufacturer of such drug before any rebates, discounts, allowances, or other price concessions.

B. Every manufacturer permitted or registered with the Board of Pharmacy pursuant to Article 3 (§ 54.1-3435 et seq.) of Chapter 34 of Title 54.1 shall report the following information to the Commissioner for any prescription drug made available in the Commonwealth that is indicated for use in the treatment of diabetes:

1. The amount paid for research and development of the prescription drug, including the actual cost of clinical trials for the prescription drug, together with the amount of any subsidies, grants, or other forms of support provided by any federal, state, or other governmental program;

2. The actual cost of manufacturing and distributing the prescription drug;

3. The actual cost of acquiring the prescription drug, including the cost of any patents for, licenses of, or property rights to the prescription drug;

4. The actual cost of marketing and advertising the prescription drug, including costs related to offering and redeeming any coupons for the prescription drug;

5. The wholesale acquisition cost of the drug;

6. The amount of each increase in the average wholesale acquisition cost of the prescription drug during the previous five years, both in actual dollars and as a percentage of the average wholesale acquisition cost at the time of the increase, and the date on which each increase occurred;

7. The total profit derived from sales of the prescription drug in total dollars and as a percentage of the manufacturer's total annual profit;

8. The total amount of financial assistance the manufacturer provided to recipients of the prescription drug through patient prescription assistance programs; and

9. Any other information related to prescription drug price transparency as determined by the Commissioner.

C. Additionally, each such manufacturer shall report the following information to the Commissioner if the drug is subject to an increase in the wholesale acquisition cost by a percentage greater than the percentage increase in the medical care component of the Consumer Price Index for the preceding calendar year:

1. A list of each factor that has contributed to the increase;

2. The percentage of the total increase that is attributable to each factor;

3. An explanation of the role of each factor in the increase; and

4. Any other information related to such increase as determined by the Commissioner.

D. A manufacturer shall submit the information required by subsection B by July 1 of each year and shall submit the information required by subsection C at least 30 days prior to the effective date of the wholesale acquisition cost increase.

E. Each pharmacy benefits manager shall report the following to the Commissioner for any prescription drug made available in the Commonwealth that is indicated for use in the treatment of diabetes:

1. The total amount of all rebates by drug the pharmacy benefits manager negotiated with manufacturers during the immediately preceding calendar year for such prescription drugs;

2. The total amount of all such rebates by drug retained by the pharmacy benefits manager;

3. The total amount of all such rebates that were negotiated for purchases of such drugs for use by covered lives of each category listed in subsection C of § 32.1-276.7:1; and

4. Any other information related to prescription drug price transparency as determined by the Commissioner.

F. A pharmacy benefits manager shall submit the information required by subsection E by July 1 of each year.

G. The Commissioner, in coordination with the Bureau of Insurance and the Department of Medical Assistance Services, shall conduct an analysis of the information submitted to the Commissioner pursuant to this section on the price of such prescription drugs, the reasons for any increases in those prices, and the effect of those prices on overall spending on prescription drugs in the Commonwealth, including a statement of the total cost to the Commonwealth for the year for such prescription drugs paid for through the state employee health plan and any other program for the purchase of prescription drugs administered by the Commonwealth. The Commissioner shall publish on the Department's website and report to the Chairmen of the House Committee on Appropriations, House Committee on Health, Welfare and Institutions, Senate Committee on Education and Health, and Senate Committee on Finance the data and any findings and recommendations no later than December 1 of each year.

H. Any information provided to the Commissioner pursuant to this section shall be maintained by the nonprofit organization as part of the Virginia All-Payer Claims Database. To the extent they are consistent with this section, the provisions of § 32.1-276.7:1 governing submission agreements, the reporting and release of data including compliance with state and federal privacy laws, and the confidentiality of data shall apply to data collected under this section. Additionally, any such information provided other than that required to be reported pursuant to subsection G shall be exempt from disclosure under the Virginia Freedom of Information Act (§ 2.2-3700 et seq.).

I. The nonprofit organization shall ensure the timely reporting of information by manufacturers and pharmacy benefits managers to meet the requirements of this section. The nonprofit organization shall notify manufacturers and pharmacy benefits managers of any applicable reporting deadlines. The nonprofit shall notify, in writing, a manufacturer or pharmacy benefits manager of a failure to meet a reporting deadline and that failure to respond within two weeks following receipt of the written notice may result in a penalty. The Board may assess a civil penalty of up to $1,000 per week per violation, not to exceed a total of $50,000 per violation, against a manufacturer or pharmacy benefits manager that fails, within the Board's determination, to make a good faith effort to provide the requested information within two weeks following receipt of the written notice required by this subsection. Civil penalties assessed under this subsection shall be maintained by the Department and used for the ongoing improvement of the Virginia All-Payer Claims Database.

Article 9.

Pharmacy Benefits Managers.

§ 38.2-3465. Definitions.

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

"Carrier" means:

1. Any insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis;

2. Any corporation providing individual or group accident and sickness subscription contracts;

3. Any health maintenance organization providing health care plans for health care services;

4. Any organization providing managed care medical assistance services under the Department of Medical Assistance Services managed care program; or

5. Any other person or organization that provides health benefit plans subject to state regulation, and includes an entity that arranges a provider panel for compensation.

"Health benefit plan" means a policy, contract, certificate, or agreement offered by a carrier to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services. "Health benefit plan" includes short-term and catastrophic health insurance policies and plans offered to recipients of medical assistance services through the Department of Medical Assistance Services managed care program.

"Pharmacy benefits management service" means any service provided in connection with the administration or management of prescription drug benefits provided by a 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 carrier that provides pharmacy benefits management internally or the affiliate or subsidiary of a carrier that provides pharmacy benefits management services for such carrier.

§ 38.2-3466. Pharmacy benefits managers; registration.

A. Beginning September 1, 2020, no person shall provide pharmacy benefits management services in the Commonwealth unless such person has registered as a pharmacy benefits manager with the

Commission.

B. An application for registration under this article shall be in the form and containing the information the Commission prescribes. Each applicant shall, at the time of applying for registration, pay a nonrefundable application processing fee in an amount and in a manner prescribed by the Commission.

§ 38.2-3467. Reporting requirements; revocation.

Every registered pharmacy benefits manager shall comply with the provisions of § 32.1-276.7:2. The Commission may revoke the registration of any pharmacy benefits manager that fails to comply with such provisions.

§ 54.1-3442.02. Reporting requirements; revocation.

Every permitted or registered manufacturer shall comply with the provisions of § 32.1-276.7:2. The Board may revoke the permit or registration of any manufacturer that fails to comply with such provisions.