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SENATE BILL NO. 487

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the Senate Committee on Education and Health on February 4, 2016)

(Patron Prior to Substitute—Senator Hanger)

A BILL to amend and reenact §§ 2.2-3705.5 and 32.1-276.4 of the Code of Virginia and to amend the Code of Virginia by adding in Title 32.1 a chapter numbered 7.3, consisting of sections numbered 32.1-276.12 and 32.1-276.13, relating to prescription drug price transparency.

Be it enacted by the General Assembly of Virginia:

1. That §§ 2.2-3705.5 and 32.1-276.4 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding in Title 32.1 a chapter numbered 7.3, consisting of sections numbered 32.1-276.12 and 32.1-276.13, as follows:

§ 2.2-3705.5. Exclusions to application of chapter; health and social services records.

The following records are excluded from the provisions of this chapter but may be disclosed by the custodian in his discretion, except where such disclosure is prohibited by law:

1. Health records, except that such records may be personally reviewed by the individual who is the subject of such records, as provided in subsection F of § 32.1-127.1:03.

Where the person who is the subject of health records is confined in a state or local correctional facility, the administrator or chief medical officer of such facility may assert such confined person's right of access to the health records if the administrator or chief medical officer has reasonable cause to believe that such confined person has an infectious disease or other medical condition from which other persons so confined need to be protected. Health records shall only be reviewed and shall not be copied by such administrator or chief medical officer. The information in the health records of a person so confined shall continue to be confidential and shall not be disclosed by the administrator or chief medical officer of the facility to any person except the subject or except as provided by law.

Where the person who is the subject of health records is under the age of 18, his right of access may be asserted only by his guardian or his parent, including a noncustodial parent, unless such parent's parental rights have been terminated, a court of competent jurisdiction has restricted or denied such access, or a parent has been denied access to the health record in accordance with § 20-124.6. In instances where the person who is the subject thereof is an emancipated minor, a student in a public institution of higher education, or is a minor who has consented to his own treatment as authorized by § 16.1-338 or 54.1-2969, the right of access may be asserted by the subject person.

For the purposes of this chapter, statistical summaries of incidents and statistical data concerning abuse of individuals receiving services compiled by the Commissioner of Behavioral Health and Developmental Services shall be open to inspection and copying as provided in § 2.2-3704. No such summaries or data shall include any information that identifies specific individuals receiving services.

2. Applications for admission to examinations or for licensure and scoring records maintained by the Department of Health Professions or any board in that department on individual licensees or applicants. However, such material may be made available during normal working hours for copying, at the requester's expense, by the individual who is the subject thereof, in the offices of the Department of Health Professions or in the offices of any health regulatory board, whichever may possess the material.

3. Reports, documentary evidence and other information as specified in §§ 51.5-122, 51.5-141, and 63.2-104.

4. Investigative notes; proprietary information not published, copyrighted or patented; information obtained from employee personnel records; personally identifiable information regarding residents, clients or other recipients of services; other correspondence and information furnished in confidence to the Department of Social Services in connection with an active investigation of an applicant or licensee pursuant to Chapters 17 (§ 63.2-1700 et seq.) and 18 (§ 63.2-1800 et seq.) of Title 63.2; and records and information furnished to the Office of the Attorney General in connection with an investigation or litigation pursuant to Article 19.1 (§ 8.01-216.1 et seq.) of Chapter 3 of Title 8.01 and Chapter 9 (§ 32.1-310 et seq.) of Title 32.1. However, nothing in this section shall prohibit disclosure of information from the records of completed investigations in a form that does not reveal the identity of complainants, persons supplying information, or other individuals involved in the investigation.

5. Information and records collected for the designation and verification of trauma centers and other specialty care centers within the Statewide Emergency Medical Services System and Services pursuant to Article 2.1 (§ 32.1-111.1 et seq.) of Chapter 4 of Title 32.1.

6. Reports and court documents relating to involuntary admission required to be kept confidential pursuant to § 37.2-818.

7. Data formerly required to be submitted to the Commissioner of Health relating to the

establishment of new or the expansion of existing clinical health services, acquisition of major medical equipment, or certain projects requiring capital expenditures pursuant to former § 32.1-102.3:4.

8. Information required to be provided to the Department of Health Professions by certain licensees pursuant to § 54.1-2506.1.

9. Information and records acquired (i) during a review of any child death conducted by the State Child Fatality Review team established pursuant to § 32.1-283.1 or by a local or regional child fatality review team to the extent made confidential by § 32.1-283.2; (ii) during a review of any death conducted by a family violence fatality review team to the extent made confidential by § 32.1-283.3; or (iii) during a review of any adult death conducted by the Adult Fatality Review Team to the extent made confidential by § 32.1-283.5 or by a local or regional adult fatality review team to the extent made confidential by § 32.1-283.6.

10. Patient level data collected by the Board of Health and not yet processed, verified, and released, pursuant to § 32.1-276.9, to the Board by the nonprofit organization with which the Commissioner of Health has contracted pursuant to § 32.1-276.4.

11. Records of the Health Practitioners' Monitoring Program Committee within the Department of Health Professions, to the extent such records may identify any practitioner who may be, or who is actually, impaired to the extent disclosure is prohibited by § 54.1-2517.

12. Records submitted as a grant application, or accompanying a grant application, to the Commonwealth Neurotrauma Initiative Advisory Board pursuant to Article 12 (§ 51.5-178 et seq.) of Chapter 14 of Title 51.5, to the extent such records contain (i) medical or mental health records, or other data identifying individual patients or (ii) proprietary business or research-related information produced or collected by the applicant in the conduct of or as a result of study or research on medical, rehabilitative, scientific, technical or scholarly issues, when such information has not been publicly released, published, copyrighted or patented, if the disclosure of such information would be harmful to the competitive position of the applicant.

13. Any record copied, recorded or received by the Commissioner of Health in the course of an examination, investigation or review of a managed care health insurance plan licensee pursuant to §§ 32.1-137.4 and 32.1-137.5, including books, records, files, accounts, papers, documents, and any or all computer or other recordings.

14. Records, information and statistical registries required to be kept confidential pursuant to §§ 63.2-102 and 63.2-104.

15. All data, records, and reports relating to the prescribing and dispensing of covered substances to recipients and any abstracts from such data, records, and reports that are in the possession of the Prescription Monitoring Program pursuant to Chapter 25.2 (§ 54.1-2519 et seq.) of Title 54.1 and any material relating to the operation or security of the Program.

16. Records of the Virginia Birth-Related Neurological Injury Compensation Program required to be kept confidential pursuant to § 38.2-5002.2.

17. Records of the State Health Commissioner relating to the health of any person or persons subject to an order of quarantine or an order of isolation pursuant to Article 3.02 (§ 32.1-48.05 et seq.) of Chapter 2 of Title 32.1; this provision shall not, however, be construed to prohibit the disclosure of statistical summaries, abstracts or other information in aggregate form.

18. Records containing the names and addresses or other contact information of persons receiving transportation services from a state or local public body or its designee under Title II of the Americans with Disabilities Act, (42 U.S.C. § 12131 et seq.) or funded by Temporary Assistance for Needy Families (TANF) created under § 63.2-600.

19. Records of certain health care committees and entities, to the extent that they reveal information that may be withheld from discovery as privileged communications pursuant to § 8.01-581.17.

20. Information provided to the State Health Commissioner pursuant to Chapter 7.3 (§ 32.1-276.12 et seq.) of Title 32.1.

§ 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 *and Chapter 7.3 (§ 32.1-276.12 et seq.)*; for the operation of the All-Payer Claims Database pursuant to § 32.1-276.7:1; 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 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.

CHAPTER 7.3.

PRESCRIPTION DRUG PRICE TRANSPARENCY.

§ 32.1-276.12. Definitions.

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

"Nonprofit organization" means the nonprofit organization with which the Commissioner has entered into a contract or agreement pursuant to § 32.1-276.4.

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

§ 32.1-276.13. Report required; Commissioner's report.

A. Every manufacturer of a prescription drug that is made available in the Commonwealth and has a wholesale acquisition price of $10,000 or more for a single course of treatment shall report to the Commissioner no later than July 1 of each year:

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 cost related to

offering and redeeming any coupons for the prescription drug;

5. The amount of each increase in the average wholesale price of the prescription drug during the year, both in actual dollars and as a percentage of the average wholesale price at the time of the increase, and the date on which each increase occurred;

6. The amount of each increase in the wholesale acquisition cost of the prescription drug during the year, both in actual dollars and as a percentage of the 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; and

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

B. The report made pursuant to subsection A shall be audited by an independent third party selected by the manufacturer attesting to the accuracy of the information contained therein prior to submission.

C. The Commissioner shall forward all reports received pursuant to subsection A, except information contained in the reports deemed proprietary in accordance with subsection E, to the nonprofit organization, and the nonprofit organization shall make information contained in the reports available to the public through a website operated by the nonprofit organization.

D. The Commissioner or the nonprofit organization shall review and aggregate all data received pursuant to subsection A, and the Commissioner shall report such data to the Chairmen of the House Committees on Appropriations and on Health, Welfare and Institutions and the Senate Committees on Finance and on Education and Health no later than December 1 each year. Such report shall include a statement of the total cost to the Commonwealth for the year of any prescription drugs identified in subsection A paid for through the state employee health plan and any other program for the purchase of prescription drugs administered by the Commonwealth.

E. The Commissioner shall maintain the confidentiality of any information submitted pursuant to subsection A that the Commissioner deems to be confidential, proprietary information of the prescription drug manufacturer the disclosure of which would cause the manufacturer competitive harm. Such information shall not be disclosed to the public and shall be exempt from disclosure under the Virginia Freedom of Information Act pursuant to § 2.2-3705.5. This subsection shall not limit the disclosure of information that is not attributed to a specific manufacturer or that is released in aggregate.