HOUSE BILL NO. 483
AMENDMENT IN THE NATURE OF A SUBSTITUTE
(Proposed by the Senate Committee on Commerce and Labor
on _____)
(Patron Prior to Substitute—Delegate Delaney)

A BILL to amend and reenact § 32.1-276.7:1 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 through 32.1-276.15, and by adding in Article 1 of Chapter 34 of Title 54.1 a section numbered 54.1-3431.1, relating to prescription drug affordability advisory panel established; maximum fair price; annual reports; civil penalties.

Be it enacted by the General Assembly of Virginia:

1. That § 32.1-276.7:1 of the Code of Virginia is 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 through 32.1-276.15, and by adding in Article 1 of Chapter 34 of Title 54.1 a section numbered 54.1-3431.1 as follows:

§ 32.1-276.7:1. All-Payer Claims Database created; purpose; reporting requirements.

A. The Virginia All-Payer Claims Database is hereby created to facilitate data-driven, evidence-based improvements in access, quality, and cost of health care and to promote and improve the public health through the understanding of health care expenditure patterns and operation and performance of the health care system.

B. The Commissioner shall ensure that the Department meets the requirements to be a health oversight agency as defined in 45 C.F.R. § 164.501.

C. The Commissioner, in cooperation with the Bureau of Insurance, shall collect paid claims *and non-claims payments* data for covered benefits from data suppliers, which shall include:

1. Issuers of individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; corporations providing individual or group accident and sickness subscription contracts; and health maintenance organizations providing a health care plan for health care services, for at least 1,000 covered lives in the most recent calendar year;

2. Third-party administrators and any other entities that receive or collect charges, contributions, or premiums for, or adjust or settle health care claims for, at least 1,000 Virginia covered lives on behalf of

group health plans other than ERISA plans;

3. Third-party administrators, and any other entities, that receive or collect charges, contributions, or premiums for, or adjust or settle health care claims for, an employer that maintains an ERISA plan that has opted-in to data submission to the All-Payer Claims Database pursuant to subsection P;

4. The Department of Medical Assistance Services with respect to services provided under programs administered pursuant to Titles XIX and XXI of the Social Security Act;

5. State government health insurance plans;

6. Local government health insurance plans, subject to their ability to provide such data and to the extent permitted by state and federal law; and

7. Federal health insurance plans, to the extent permitted by federal law, including Medicare, TRICARE, and the Federal Employees Health Benefits Plan.

Such collection of paid claims *and non-claims payments* data for covered benefits shall not include data related to Medigap, disability income, workers' compensation claims, standard benefits provided by long-term care insurance, disease specific health insurance, dental or vision claims, or other supplemental health insurance products;

D. The Commissioner shall ensure that the nonprofit organization executes a standard data submission and use agreement with each entity listed in subsection B that submits paid claims *and non-claims payments* data to the All-Payer Claims Database and each entity that subscribes to data products and reports. Such agreements shall include procedures for submission, collection, aggregation, and distribution of specified data. Additionally, the Commissioner shall ensure that the nonprofit organization:

1. Protects patient privacy and data security pursuant to provisions of this chapter and state and federal privacy laws, including the federal Health Insurance Portability and Accountability Act (42 U.S.C. § 1320d et seq., as amended); Titles XIX and XXI of the Social Security Act; § 32.1-127.1:03; Chapter 6 (§ 38.2-600 et seq.) of Title 38.2; and the Health Information Technology for Economic and Clinical Health (HITECH) Act, as included in the American Recovery and Reinvestment Act (P.L. 111-5, 123 Stat. 115) as if the nonprofit organization were covered by such laws;

2. Identifies the type of paid claims *and non-claims payments* to be collected by the All-Payer Claims Database and the entities that are subject to the submission of such claims as well as identification of specific data elements from existing claims systems to be submitted and collected, including but not limited to patient demographics, diagnosis and procedure codes, provider information, plan payments, member payment

responsibility, and service dates;

3. Administers the All-Payer Claims Database in a manner to allow for geographic, demographic, economic, and peer group comparisons;

4. Develops public analyses identifying and comparing health plans by public and private health care purchasers, providers, employers, consumers, health plans, health insurers, and data analysts, health insurers, and providers with regard to their provision of safe, cost-effective, and high-quality health care services;

5. Uses common data layout or other national data collection standards and methods that utilize a standard set of core data elements for data submissions, as adopted or endorsed by the APCD Council, to establish and maintain the database in a cost-effective manner and to facilitate uniformity among various all-payer claims databases of other states and specification of data fields to be included in the submitted claims, consistent with such national standards, allowing for exemptions when submitting entities do not collect the specified data or pay on a per-claim basis, such exemption process to be managed by the advisory committee created pursuant to subsection E;

6. Does not disclose or report provider-specific, facility-specific, or carrier-specific reimbursement information, or information capable of being reverse-engineered, combined, or otherwise used to calculate or derive such reimbursement information, from the All-Payer Claims Database;

7. Promotes the responsible use of claims data to improve health care value and preserve the integrity and utility of the All-Payer Claims Database; ~~and~~

8. Requires that all public reports and analyses comparing providers or health plans using data from the All-Payer Claims Database use national standards or, when such national standards are unavailable, provide full transparency to providers or health plans of the alternative methodology used*; and*

9. Provides an annual report to the Prescription Drug Affordability Advisory Panel established pursuant to § 32.1-276.12 on each prescription drug for which, during the preceding calendar year, (i) the price increased by 10 percent or more or (ii) rebate amounts decreased by 10 percent or more.

E. The Commissioner shall establish an advisory committee to assist in the formation and operation of the All-Payer Claims Database. Such committee shall consist of (i) a representative from each of the following: a statewide hospital association, a statewide association of health plans, a professional organization representing physicians, a professional organization representing pharmacists, an organization that processes insurance claims or certain aspects of employee benefits plans for a separate entity, a community mental

health center who has experience in behavioral health data collection, a nursing home health care provider who has experience with medical claims data, a nonprofit health insurer, and a for-profit health insurer; (ii) up to two representatives with a demonstrated record of advocating health care issues on behalf of consumers; (iii) two representatives of hospitals or health systems; (iv) an individual with academic experience in health care data and cost-efficiency research; (v) a representative who is not a supplier or broker of health insurance from small employers that purchase group health insurance for employees; (vi) a representative who is not a supplier or broker of health insurance from large employers that purchase health insurance for employees, and (vii) a representative who is not a supplier or broker of health insurance from self-insured employers, all of whom shall be appointed by the Commissioner. The Commissioner, the chairman of the board of directors of the nonprofit organization, the Commissioner of Insurance, the Director of the Department of Medical Assistance Services, the Director of the Department of Human Resource Management, or their designees, shall serve ex officio.

In appointing members to the advisory committee, the Commissioner shall adopt reasonable measures to select representatives in a manner that provides balanced representation within and among the appointments and that any representative appointed is without any actual or apparent conflict of interest, including conflicts of interest created by virtue of the individual's employer's corporate affiliations or ownership interests.

The nonprofit organization shall provide the advisory committee with details at least annually on the use and disclosure of All-Payer Claims Database data, including reports developed by the nonprofit organization; details on methods used to extract, transform, and load data; and efforts to protect patient privacy and data security.

The meetings of the advisory committee shall be open to the public.

F. The Commissioner shall establish a data release committee to review and approve requests for access to data. The data release committee shall consist of the Commissioner or his designee, and upon recommendation of the advisory committee, the Commissioner shall appoint an individual with academic experience in health care data and cost-efficiency research; a representative of a health insurer; a health care practitioner; a representative from a hospital with a background in administration, analytics, or research; and a representative with a demonstrated record of advocating health care issues on behalf of consumers. In making its recommendations, the advisory committee shall adopt reasonable measures to select representatives in a manner that provides balanced representation within and among the appointments and

that any representative appointed is without any actual or apparent conflict of interest, including conflicts of interest created by virtue of the individual's employer's corporate affiliations or ownership interests. The data release committee shall ensure that (i) all data approvals are consistent with the purposes of the All-Payer Claims Database as provided in subsection A; (ii) all data approvals comply with applicable state and federal privacy laws and state and federal laws regarding the exchange of price and cost information to protect the confidentiality of the data and encourage a competitive marketplace for health care services; and (iii) the level of detail, as provided in subsection H, is appropriate for each request and is accompanied by a standardized data use agreement.

G. The nonprofit organization shall implement the All-Payer Claims Database, consistent with the provisions of this chapter, to include:

1. The reporting of data that can be used to improve public health surveillance and population health, including reports on (i) injuries; (ii) chronic diseases, including but not limited to asthma, diabetes, cardiovascular disease, hypertension, arthritis, and cancer; (iii) health conditions of pregnant women, infants, and children; and (iv) geographic and demographic information for use in community health assessment, prevention education, and public health improvement. This data shall be developed in a format that allows comparison of information in the All-Payer Claims Database with other nationwide data programs and that allows employers to compare their employee health plans statewide and between and among regions of the Commonwealth and nationally.

2. The reporting of data that payers, providers, and health care purchasers, including employers and consumers, may use to compare quality and efficiency of health care, including development of information on utilization patterns and information that permits comparison of health plans and providers statewide between and among regions of the Commonwealth. The advisory committee created pursuant to subsection E shall make recommendations to the nonprofit organization on the appropriate level of specificity of reported data in order to protect patient privacy and to accurately attribute services and resource utilization rates to providers.

3. The reporting of data that permits design and evaluation of alternative delivery and payment models.

4. The reporting and release of data consistent with the purposes of the All-Payer Claims Database as set forth in subsection A as determined to be appropriate by the data release committee created pursuant to subsection F.

H. Except as provided in subsection O, the nonprofit organization shall not provide data or access to data without the approval of the data release committee. Upon approval, the nonprofit organization may provide data or access to data at levels of detail that may include (i) aggregate reports, which are defined as data releases with all observation counts greater than 10; (ii) de-identified data sets that meet the standard set forth in 45 C.F.R. § 164.514(a); and (iii) limited data sets that comply with the National Institutes of Health guidelines for release of personal health information.

I. Reporting of data shall not commence until such data has been processed and verified at levels of accuracy consistent with existing nonprofit organization data standards. Prior to public release of any report specifically naming any provider or payer, or public reports in which an individual provider or payers represents 60 percent or more of the data, the nonprofit organization shall provide affected entities with notice of the pending report and allow for a 30-day period of review to ensure accuracy. During this period, affected entities may seek explanations of results and correction of data that they prove to be inaccurate. The nonprofit organization shall make these corrections prior to any public release of the report. At the end of the review period, upon completion of all necessary corrections, the report may be released. For the purposes of this subsection, "public release" means the release of any report to the general public and does not include the preparation of reports for, or use of the All-Payer Claims Database by, organizations that have been approved for access by the data release committee and have entered into written agreements with the nonprofit organization.

J. The Commissioner and the nonprofit organization shall consider and recommend, as appropriate, integration of new data sources into the All-Payer Claims Database, based on the findings and recommendations of the advisory committee.

K. Information acquired pursuant to this section shall be confidential and shall be exempt from disclosure by the Virginia Freedom of Information Act (§ 2.2-3700 et seq.). The reporting and release of data pursuant to this section shall comply with all state and federal privacy laws and state and federal laws regarding the exchange of price and cost information to protect the confidentiality of the data and encourage a competitive marketplace for health care services.

L. No person shall assess costs or charge a fee to any health care practitioner related to formation or operation of the All-Payer Claims Database. However, a reasonable fee may be charged to health care practitioners who voluntarily access the All-Payer Claims Database for purposes other than data verification.

M. As used in this section, "provider" means a hospital or physician as defined in this chapter or any other health care practitioner licensed, certified, or authorized under state law to provide covered services represented in claims reported pursuant to this section.

N. The Commissioner, in consultation with the board of directors of the nonprofit organization, shall develop short-term and long-term funding strategies for the operation of the All-Payer Claims Database to provide necessary funding in excess of any budget appropriation by the Commonwealth.

O. The nonprofit organization, the Department of Health, the Department of Medical Assistance Services, ~~and~~ the Bureau of Insurance, *and the Prescription Drug Affordability Advisory Panel* shall have access to data reported by the All-Payer Claims Database pursuant to this section at no cost for the purposes of public health improvement research and activities.

P. Each employer that maintains an ERISA plan may opt-in to allow a third-party ~~administer~~ *administrator* or other entity to submit data to the All-Payer Claims Database. For any such employer that opts-in, the third-party administrator or other entity shall (i) submit data for the next reporting period after the opt-in and all future reporting periods until the employer opts-out and (ii) include data from any such employer as part of its data submission, if any, otherwise required by this section. Such an employer may opt-out at any time but shall provide written notice to the third-party administrator or other entity of its decision at least 30 days prior to the start of the next reporting period. No employer that maintains an ERISA plan shall be required to opt-in to data submission to the All-Payer Claims Database, and no third-party administrator or other entity shall be required to submit claims processed before it was contracted to provide services. Each third-party administrator or other entity providing claim administration services for an employer shall submit annually to the nonprofit organization by January 31 of each year a list of the ERISA plans whose employer has opted-in to data submission to the All-Payer Claims Database and a list identifying all employers that maintain an ERISA plan with Virginia employees for which it provides claim administration services. Such information submitted shall be considered proprietary and shall be exempt from disclosure by the Virginia Freedom of Information Act (§ 2.2-3700 et seq.).

Q. Any data release shall make use of a masked proxy reimbursement amount, for which the methodology is publicly available and approved by the data release committee except that the Department may request that the nonprofit organization generate the following reports based on actual reimbursement amounts: (i) the total cost burden of a disease, chronic disease, injury, or health condition across the state, health planning region, health planning district, county, or city, provided that the total cost shall be an aggregate amount

encompassing costs attributable to all data suppliers and not identifying or attributable to any individual provider, and (ii) any analyses to determine the average reimbursement that is paid for health care services that may include inpatient and outpatient diagnostic services, surgical services or the treatment of certain conditions or diseases. Any additional report of analysis based on actual reimbursement amounts shall require the approval of the data release committee.

R. The nonprofit organization shall ensure the timely reporting of information by private data suppliers to meet the requirements of this section. The nonprofit organization shall notify private data suppliers of any applicable reporting deadlines. The nonprofit shall notify, in writing, a private data supplier 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 private data supplier that fails, within its 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 All-Payer Claims Database.

CHAPTER 7.3.

AFFORDABLE MEDICINE ACT.

§ 32.1-276.12. Prescription Drug Affordability Advisory Panel established; purpose; annual report.

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

"Panel" means the Prescription Drug Affordability Advisory Panel.

"Secretary" means the Secretary of Health and Human Resources.

B. The Secretary shall establish the Prescription Drug Affordability Advisory Panel to conduct data analyses, develop policy recommendations, and identify implementation barriers related to strategies to improve prescription drug affordability, enhance price transparency, and strengthen data collection practices for prescription drugs across public and private payers.

C. By December 31, 2026, and annually thereafter, the Panel shall submit to the Governor, the State Corporation Commission, the Chairs of the Senate Committees on Commerce and Labor and Education and Health, and the Chairs of the House Committees on Labor and Commerce and Health and Human Services a report that includes (i) prescription drug pricing trends in the Commonwealth and nationally and (ii) any policy recommendations on legislation to improve prescription drug affordability in the Commonwealth. The Panel shall also provide quarterly updates to such recipients on prescription drug pricing trends in the

Commonwealth.

§ 32.1-276.13. Membership; chair and vice-chair; quorum; meetings.

A. The Panel shall have a total membership of six members that shall consist of five nonlegislative citizen members and one ex officio member. Nonlegislative citizen members shall be appointed by the Governor, subject to confirmation by the General Assembly. One nonlegislative citizen member of the Panel shall be a representative of a local government. The Panel may employ staff or contract with experts in the field of prescription drug policy, affordability policy, or health data analytics, subject to available funding. The Secretary or his designee shall serve ex officio with nonvoting privileges. Nonlegislative citizen members of the Panel shall be citizens of the Commonwealth.

The ex officio member of the Panel shall serve a term coincident with his term of office. Appointments to fill vacancies, other than by expiration of a term, shall be for the unexpired terms. Vacancies shall be filled in the same manner as the original appointments. All members may be reappointed.

B. Nonlegislative citizen members of the Panel shall have expertise in the drug discount program established pursuant to § 340B of the federal Public Health Service Act, 42 U.S.C. § 256B, and its impacts on federally qualified health centers and prescription drug policy in the Commonwealth, health economics, public health data systems, prescription drug markets, health insurance markets, or related fields. No nonlegislative citizen member of the Panel shall be an employee or board member of or consultant to a manufacturer, health plan, hospital, pharmacy benefits manager, or trade association for manufacturers, health plans, hospitals, or pharmacy benefits managers.

C. The Panel shall elect a chair and vice-chair from among its membership. A majority of the members shall constitute a quorum. The meetings of the Panel shall be held at the call of the chair or whenever the majority of the members so request.

§ 32.1-276.14. Powers and duties of the Panel.

A. The Panel shall (i) meet quarterly to review prescription drug pricing, cost and utilization trends, and trends in out-of-pocket payments; (ii) analyze drug transparency data; and (iii) report annually pursuant to subsection C of § 32.1-276.12 on topics and information, including:

1. Public and private sector drug price trends;

2. Out-of-pocket costs for patients in the Commonwealth related to prescription drug expenses;

3. Opportunities to enhance transparency in reporting prescription drug prices and any rebates, discounts, or price concessions;

4. Methods for the Department of Medical Assistance Services to best utilize the best price provisions of

the Medicaid drug rebate program under 42 C.F.R. § 447.509 to increase savings to the Commonwealth;

5. Strategies for local governments to reduce spending on prescription drugs;

6. Opportunities to improve the Commonwealth's data collection and reporting systems, including standardized electronic reporting formats; and

7. Suggested statutory or regulatory changes to improve affordability and transparency.

B. All recommendations issued by the Panel shall be provided in the report required pursuant to subsection C of § 32.1-276.12.

§ 54.1-3431.1. Maximum fair prices for certain prescription drugs; civil penalties.

A. As used in this section:

"Commissioner" means the State Health Commissioner.

"Department" means the Department of Health.

"ERISA plan" means an employee welfare benefit plan as defined in § 3(1) of the federal Employee Retirement Income Security Act of 1974.

"Generic drug" means (i) a retail drug that is marketed or distributed in accordance with an abbreviated new drug application approved under 21 U.S.C. § 355(j), (ii) an authorized generic drug as defined by 42 C.F.R. § 447.502, or (iii) a drug that entered the market before 1962 that was not originally marketed under a new drug application.

"Health plan" means an individual or group plan that provides, or pays the cost of, medical care. "Health plan" includes any entity included in such definition as set out in 45 C.F.R. § 160.103.

"Maximum fair price" means the maximum fair price established for a prescription drug by the U.S. Secretary of Health and Human Services pursuant to 42 U.S.C. § 1320f-3.

"Panel" means the Prescription Drug Affordability Advisory Panel established pursuant to § 32.1-276.12.

"Participating ERISA plan" means an ERISA plan that elects to be subject to maximum fair prices pursuant to this section.

"Pharmacy benefits manager" means the same as that term is defined in § 38.2-3465.

"Price applicability period" means the same as that term is defined in 42 U.S.C. § 1320f(b)(2).

"Rare disease or condition" means the same as that term is defined in 21 U.S.C. § 360bb.

"Referenced drug" means a prescription drug subject to a maximum fair price. "Referenced drug" does not include (i) any brand-name prescription drug or biologic that is designated for a rare disease or condition under 21 U.S.C. § 360bb and for which the only approved indication is for one or more rare diseases or conditions or (ii) any biological product that is derived from human blood or plasma.

"State entity" means any agency of state government that purchases or reimburses payers for prescription drugs on behalf of the Commonwealth for any person whose health care is paid for by the Commonwealth, including any agent, vendor, contractor, or other party acting on behalf of the Commonwealth. "State entity" does not include the medical assistance program established pursuant to 42 U.S.C. § 1396 et seq.

B. Each pharmacy benefits manager shall provide to the Panel, upon request, financial information, including administrative fees, formulary management fees, rebate retention, network access fees, shared savings programs, and the total and final payment details, including the ingredient cost and any dispensing fee, paid or payable by the pharmacy benefits manager to a pharmacy for dispensing a referenced drug. Such information shall include all associated fees, adjustments, and reconciliations. No information disclosed by a pharmacy benefit manager, an affiliate of a pharmacy benefit manager, a plan, or a pharmacy under this subsection that is not otherwise publicly available or available for purchase shall be disclosed by the Panel, except that the Panel may disclose such information as the Panel determines necessary to carry out its purposes and to the Department for purposes of oversight and enforcement of this section. However, neither the Panel nor the Department shall report on or disclose such information to the public in a manner that would identify (i) a specific pharmacy benefits manager, affiliate, pharmacy, manufacturer, wholesale distributor, or health plan or (ii) contract prices, rebates, discounts, or other remuneration for specific referenced drugs in a manner that would allow the identification of specific contracting parties or referenced drugs.

C. No manufacturer permitted pursuant to this chapter shall accept payment at an amount higher than the maximum fair price for the sale of a referenced drug intended for use by individuals in the Commonwealth in person, by mail, or by any other means, plus any applicable pharmacy dispensing fees and provider administration fees. No pharmacy licensed in the Commonwealth shall be reimbursed for a referenced drug at an amount less than the maximum fair price or the national acquisition cost, whichever is greater, plus the required dispensing fee for such referenced drug as established by the cost dispensing survey required by 12VAC30-80-40. No provision of this section shall be construed to prevent a pharmacy from receiving a dispensing fee above the maximum fair price for a referenced drug.

D. An ERISA plan may elect to be subject to the provisions of this section by notifying the Board in writing by January 1 of each calendar year.

E. Each health plan regulated under the laws of the Commonwealth shall inform the Board of how the cost savings related to the maximum fair price pursuant to this section are directed to the benefit of enrollees with a priority on enrollee cost-sharing. Any savings generated by a health plan, state entity, or participating

ERISA plan that are attributable to the implementation of the maximum fair price pursuant to this section shall be used to reduce costs to consumers, prioritizing the reduction of out-of-pocket costs for prescription drugs. On or before April 1 of each calendar year, each health plan, state entity, and participating ERISA plan shall submit to the Board a report describing the savings achieved as a result of implementing upper payment limits and how those savings were used to reduce costs to consumers.

F. No manufacturer subject to the provisions of this section shall remove a withdrawn drug from sale or distribution within the Commonwealth for the purpose of avoiding the impact of the rate limitations set forth in this section unless such manufacturer provides a written notice of withdrawal to the Board and the Department within 180 days prior to such withdrawal.

G. The Commissioner shall assess a penalty on any manufacturer that he determines has withdrawn a referenced drug from sale or distribution in the Commonwealth in violation of subsection F. With respect to each referenced drug withdrawn by such manufacturer, such civil penalty shall be equal to the greater of (i) $100,000 or (ii) the total amount of annual savings for the referenced drug, as determined by the Board pursuant to subsection E.

H. Except as provided in subsections F and G, an entity that violates any provision of this section shall be subject to a civil penalty of $10,000 per violation. Each transaction in violation of any provision of this section shall constitute a separate violation for purposes of this subsection. The Commissioner is authorized to enforce the provisions of this section, and any penalty assessed pursuant to this section shall be deposited into the Literary Fund. Any person aggrieved by a penalty assessed pursuant to this section shall be entitled to judicial review thereof in accordance with the Administrative Process Act (§ 2.2-4000 et seq.).

I. The Commissioner and the Board may adopt any regulations necessary to implement the requirements of this section.

2. That the provisions of subsections C through H of § 54.1-3431.1 of the Code of Virginia, as created by the first enactment of this act, shall become effective on January 1, 2027.