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HOUSE BILL NO. 1596

Offered January 11, 2023

Prefiled January 6, 2023

A BILL to amend and reenact § 54.1-3442.02 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 32.1-276.21, relating to Prescription Drug Affordability Board and Fund established; drug cost affordability review.

Patrons—Delaney, Clark, Willett, Adams, D.M., Bennett-Parker, Convirs-Fowler, Glass, Gooditis, Guzman, Helmer, Jenkins, Maldonado, Mullin, Mundon King, Murphy, Price, Rasoul, Roem, Scott, D.L., Sewell, Shin, Simon, Simonds, Subramanyam, VanValkenburg and Williams Graves

Referred to Committee on Commerce and Energy

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3442.02 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 32.1-276.21, as follows:

CHAPTER 7.3.

PRESCRIPTION DRUG AFFORDABILITY BOARD AND FUND.

§ 32.1-276.12. Definitions.

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

"Biologic" means a drug that is produced or distributed in accordance with a biologics license application approved under 42 U.S.C. § 262.

"Biosimilar" means a drug that is produced or distributed in accordance with a biologics license application approved under 42 U.S.C. § 262(k)(3).

"Board" means the Prescription Drug Affordability Board.

"Brand-name drug" means a drug that is produced or distributed in accordance with an original new drug application approved under 21 U.S.C. § 355(c). "Brand-name drug" does not include an authorized generic drug as defined by 42 C.F.R. § 447.502.

"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.

"Manufacturer" means an entity that (i) engages in the manufacture of a prescription drug product or (ii) enters into a lease with another manufacturer to market and distribute a prescription drug product under the entity's own name and (iii) sets or changes the wholesale acquisition cost of the prescription drug product it manufactures or markets.

"Nonprofit data services organization" has the same meaning as set forth in §32.1-23.4.

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

"Prescription drug product" means a drug or biological product receiving approval under a drug application pursuant to 21 U.S.C. § 355(b) or under a biologics license application approved under 42 U.S.C. § 262.

"Stakeholder council" means the Prescription Drug Affordability Board stakeholder council.

§ 32.1-276.13. Prescription Drug Affordability Board established.

A. There is hereby established in the Department of Health the Prescription Drug Affordability Board for the purpose of protecting citizens of the Commonwealth and other stakeholders within the health care system from the high costs of prescription drug products.

B. The Board shall be composed of five members to be appointed by the Governor and confirmed by the Senate and House of Delegates. The Governor shall appoint three alternate members of the Board who shall likewise be confirmed by the Senate and House of Delegates prior to assuming a position on the Board. Members of the Board shall have expertise in health care, health care economics, or clinical medicine. One member of the Board shall be a representative of a local government in the Commonwealth, and one member of the Board shall be a representative of a federally qualified health center. A member or alternate member of the Board may not be an employee of, a board member of, or a consultant to a manufacturer or trade association for manufacturers. Any conflict of interest, including whether an individual has an association, including a financial or personal association, that has the potential to bias or has the appearance of biasing the individual's decisions in matters related to the Board or the conduct of the Board's activities shall be disclosed and considered when appointing

members and alternate members to the Board.

C. The term of a member or alternate member of the Board shall be five years. The expiration of the terms of the members and alternate members shall be staggered as required by the provisions for members in § 32.1-276.20.

D. The chair of the Board shall hire an executive director, general counsel, and staff to support the Board's activities. Staff of the Board shall receive a salary as provided in the budget of the Board. A member of the Board may receive compensation as a member of the Board in accordance with the state budget of the Commonwealth and is entitled to reimbursement for expenses authorized by travel regulations promulgated pursuant to § 2.2-2823.

E. A majority of the members of the Board shall constitute a quorum for the purposes of conducting the business of the Board.

F. Subject to subdivision 2, the Board shall meet in open session at least four times annually to review prescription drug product information. The following provisions shall also apply to meetings of the Board:

1. The chair may cancel or postpone a meeting if there is no business to transact.

2. The following actions by the Board shall be made in open session: (i) any deliberations on whether to subject a prescription drug product to an affordability review under § 32.1-276.16; (ii) any vote on whether to impose an upper payment limit amount on purchases, payments, and payer reimbursements of prescription drug products in the Commonwealth; and (iii) any significant decision by the Board.

3. The Board may meet in closed session to discuss proprietary data and information.

4. The Board shall provide public notice of each Board meeting at least three weeks in advance of the meeting.

5. Materials for each Board meeting shall be made available to the public at least two weeks in advance of the meeting.

6. The Board shall provide an opportunity for public comment at each open meeting of the Board.

7. The Board shall provide the public with the opportunity to provide written comments on pending decisions of the Board.

8. The Board may allow expert testimony at its meetings, including when the Board meets in closed session.

G. Members of the Board shall recuse themselves from decisions related to prescription drug products if the member, or an immediate family member of the member, has received or could receive either of the following:

1. A direct financial benefit of any amount deriving from the result or finding of a study or determination by or for the Board; or

2. A financial benefit from any person that owns, manufactures, or provides prescription drug products, services, or items to be studied by the Board that in the aggregate exceeds $5,000 per year.

For the purposes of subdivision 1, a financial benefit includes honoraria, fees, stock, the value of the member's or immediate family member's stock holdings, and any direct financial benefit deriving from the finding of a review conducted pursuant to this chapter.

A conflict of interest shall be disclosed (i) by the Board when hiring Board staff, (ii) by the appointing authority when appointing members and alternate members to the Board and members to the stakeholder council, and (iii) by the Board when a member of the Board is recused in any final decision resulting from a review of a prescription drug product. A conflict of interest shall be disclosed in advance of the first open meeting after the conflict is identified or within five days after the conflict is identified, whichever is sooner.

A conflict of interest disclosed pursuant to this subsection shall be posted on the website of the Board unless the chair of the Board recuses the member from any final decision resulting from a review of a prescription drug product. Such posting shall include the type, nature, and magnitude of the interests of the member involved.

H. Members and alternate members of the Board, Board staff, and third-party contractors may not accept any gift or donation of services or property that indicates a potential conflict of interest or has the appearance of biasing the work of the Board.

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

A. The Board shall assess pricing information for prescription drug products by accessing available pricing information based on state reporting and transparency requirements, including prescription drug product price transparency information collected and compiled by a nonprofit data services organization and the Department of Health pursuant to § 32.1-23.4, and assessing spending for prescription drug products in the Commonwealth.

B. The Board may enter into a contract with a qualified, independent third party for any service necessary to carry out the powers and duties of the Board. Unless permission is granted by the Board, a third party hired by the Board shall not release, publish, or otherwise use any information to which

the third party has access under its contract with the Board.

C. In addition to the powers set forth in this chapter, the Board may promulgate regulations for the implementation of this chapter.

§ 32.1-276.15. Stakeholder council.

A. The Board shall create a stakeholder council for the purpose of providing stakeholder input to assist the Board in making decisions as required under this chapter. The stakeholder council shall consist of 11 members appointed in accordance with this section. Members shall include manufacturers of brand-name drugs and generic drugs, providers that dispense or administer prescription drug products, suppliers of prescription drug products, and consumers of prescription drug products. More than one stakeholder council member shall not be appointed to represent any single organization or entity.

B. The President pro tempore of the Senate shall appoint three members, the Speaker of the House of Delegates shall appoint five members, and the Governor shall appoint three members to the stakeholder council.

C. The members of the stakeholder council shall have knowledge in one or more of the following subjects: (i) the pharmaceutical business model, (ii) supply chain business models, (iii) the practice of medicine or clinical training, (iv) consumer or patient perspectives, (v) health care costs trends and drivers, (vi) clinical and health services research, or (vii) the health care marketplace in the Commonwealth.

D. The Board chairman shall appoint one member of the stakeholder council to serve as chair of the stakeholder council.

E. The initial term for members of the stakeholder council shall be three years, and the members shall serve staggered terms as required by the provisions for members in § 32.1-276.20.

F. A member of the stakeholder council may not receive compensation as a member of the stakeholder council but is entitled to reimbursement for expenses under standard state travel regulations promulgated pursuant to § 2.2-2823.

§ 32.1-276.16. Drug cost affordability review.

A. Nothing in this section shall be construed to prevent a manufacturer from marketing a prescription drug product approved by the U.S. Food and Drug Administration (FDA) while the product is under review by the Board.

B. The Board shall identify the following prescription drug products offered for sale in the Commonwealth:

1. Brand-name drugs or biologics that, as adjusted annually for inflation in accordance with the Consumer Price Index, have (i) a launch wholesale acquisition cost of $60,000 or more per year or course of treatment or (ii) a wholesale acquisition cost increase of $3,000 or more in any 12-month period;

2. Biosimilars that have a launch wholesale acquisition cost that is not at least 20 percent lower than the referenced brand biologic at the time the biosimilars are launched and that have been suggested for review by members of the public, medical professionals, or other stakeholders;

3. a. Generic drugs that, as adjusted for inflation in accordance with the Consumer Price Index, have a wholesale acquisition cost of $100 or more for (i) a 30-day supply lasting a patient for a period of 30 consecutive days based on the recommended dosage approved for labeling by the FDA, (ii) a supply lasting a patient fewer than 30 days based on the recommended dosage approved for labeling by the FDA, or (iii) one unit of the drug if the labeling approved by the FDA does not recommend any finite dosage;

b. Generic drugs that, as adjusted for inflation in accordance with the Consumer Price Index, have a wholesale acquisition cost of at least $100 for a 30-day supply or a course of treatment less than 30 days and that increased by 200 percent or more during the immediately preceding 12-month period, as determined by the difference between the resulting wholesale acquisition cost and the average of the wholesale acquisition cost reported over the immediately preceding 12 months; and

4. Other prescription drug products that may create affordability challenges for the health care system in the Commonwealth and high out-of-pocket costs for patients, including drugs used to address public health emergencies.

C. After identifying prescription drug products as required by subsection B and compiling preliminary information about the cost of the product, patient cost-sharing for the product, health plan spending on the product, stakeholder input, and other information as determined by the Board, the Board shall determine whether to conduct an affordability review for each identified prescription drug product. Relevant information for conducting an affordability review may include any document or research related to the manufacturer's selection of the introductory price or price increase of the prescription drug product, including lifecycle management, net average prices in the Commonwealth, market competition and context, projected revenue, and the estimated value or cost effectiveness of the

prescription drug product. Failure of a manufacturer to provide the Board with relevant information for an affordability review shall not affect the Board's authority to conduct such a review.

D. An affordability review conducted by the Board pursuant to subsection C shall determine whether the prescription drug product that is fully consistent with the labeling approved by the FDA or standard medical practice has led or will lead to affordability challenges for the health care system in the Commonwealth or high out-of-pocket costs for patients. To the extent practicable, in determining whether a prescription drug product has led or will lead to an affordability challenge, the Board shall consider the following factors:

1. The wholesale acquisition cost for the prescription drug product sold in the Commonwealth;

2. The average monetary price concession, discount, or rebate the manufacturer provides or is expected to provide to health plans in the Commonwealth as reported by manufacturers and health plans, expressed as a percentage of the wholesale acquisition cost for the prescription drug product under review;

3. The total amount of the price concession, discount, or rebate the manufacturer provides to each pharmacy benefits manager operating in the Commonwealth for the prescription drug product under review, as reported by manufacturers and pharmacy benefits managers, expressed as a percentage of wholesale acquisition cost;

4. The price at which therapeutic alternatives have been sold in the Commonwealth;

5. The average monetary concession, discount, or rebate the manufacturer provides or is expected to provide to health plan payers and pharmacy benefits managers in the Commonwealth for therapeutic alternatives;

6. The cost to health plans based on patient access consistent with FDA-labeled indications and recognized standard medical practice;

7. The impact on patient access resulting from the cost of the prescription drug product relative to insurance benefit design;

8. The current or expected dollar value of drug-specific patient access programs that are supported by the manufacturer;

9. The relative financial impacts to health, medical, or social services costs as can be quantified and compared to baseline effects of existing therapeutic alternatives;

10. The average patient copay or other cost-sharing for the prescription drug product in the Commonwealth;

11. Any information a manufacturer chooses to provide; and

12. Any other factors as determined by the Board through regulations adopted by the Board.

E. If the Board finds that the spending on a prescription drug product reviewed under this section has led or will lead to an affordability challenge for the health care system in the Commonwealth or high out-of-pocket costs for citizens of the Commonwealth, particularly patients experiencing physical and mental illnesses, communities affected by the opioid crisis, state and local governments, commercial health plans, health care providers, pharmacies licensed in the Commonwealth, and other stakeholders within the health care system, the Board shall establish an upper payment limit amount after considering the cost of administering the prescription drug product, the cost of delivering the prescription drug product to customers, and other relevant administrative costs related to the prescription drug product. In determining whether a prescription drug product creates an affordability challenge or in determining an upper payment limit amount, the Board shall not utilize a cost-effectiveness analysis that includes the cost-ber-quality adjusted life year or similar measure to identify subpopulations for which a treatment would be less cost-effective due to severity of illness, age, or preexisting disability. For any treatment that extends life, if the Board uses a cost-effective analysis, such analysis shall weigh the value of all additional lifetime gained equally for all patients regardless of severity of illness, age, or preexisting disability. If the Board establishes an upper payment limit amount pursuant to this subsection, the Board shall examine how the upper payment limit amount will affect entities operating pursuant to § 340B of the federal Public Health Service Act, 42 U.S.C. § 256b.

F. An upper payment limit amount established by the Board pursuant to subsection E shall apply to all purchases and payer reimbursements of the prescription drug product dispensed or administered to individuals in the Commonwealth in person, by mail, or by any other means. Such upper payment limit amount shall become effective no sooner than six months after it is announced by the Board. Such upper payment limit amount shall be exclusive of applicable pharmacy dispensing fees and provider administration fees. State-licensed independent pharmacies shall not be reimbursed less than an upper payment limit amount.

G. The Board may adopt the Medicare maximum fair price in § 1191(c) of Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq., for a prescription drug product as the upper payment limit amount established pursuant to subsection E. The Board shall not establish an upper payment limit amount greater than the Medicare maximum fair price for any prescription drug product included in § 1191(c) of Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq.

H. State regulated health plans shall inform the Board of how the cost savings related to an upper payment limit amount are directed to the benefit of enrollees with a priority on enrollee cost-sharing.

I. Any information submitted to the Board in accordance with this section shall be subject to public inspection only to the extent required under the Virginia Freedom of Information Act (§ 2.2-3700 et seq.).

§ 32.1-276.17. Remedies; appeals.

A. The Office of the Attorney General may pursue any appropriate available remedy under state law in enforcing the provisions of this chapter.

B. Any person aggrieved by a decision of the Board may request an appeal of the decision within 30 days after the decision of the Board is made. The Board shall hear the appeal and make a final decision within 60 days after the appeal is requested.

C. Any person aggrieved by a final decision of the Board may petition for judicial review as provided by the Administrative Process Act (§ 2.2-4000 et seq.).

§ 32.1-276.18. Prescription Drug Affordability Fund.

There is hereby created in the state treasury a special nonreverting fund to be known as the Prescription Drug Affordability Fund, referred to in this section as "the Fund," which shall be established on the books of the Comptroller. All funds appropriated for such purpose and any gifts, donations, grants, bequests, and other funds received on its behalf shall be paid into the state treasury and credited to the Fund. Interest earned on moneys in the Fund shall remain in the Fund and be credited to it. Any moneys remaining in the Fund, including interest thereon, at the end of each fiscal year shall not revert to the general fund but shall remain in the Fund. Moneys in the Fund shall be used solely for the purposes of providing funding for the Board and implementing the purposes of the Board established under this chapter, including reimbursing any costs expended by any state agency in implementing the provisions of this chapter. Expenditures and disbursements from the Fund shall be made by the State Treasurer on warrants issued by the Comptroller upon written request signed by the chair of the Board.

§ 32.1-276.19. Reporting requirements.

A. On or before December 31, 2024, and annually each year thereafter, the Board shall submit to the Chair of the Senate Committee on Education and Health, the Chair of the Senate Committee on Commerce and Labor, the Chair of the House Committee on Health, Welfare and Institutions, and the Chair of the House Committee on Commerce and Energy a report that includes the following:

1. Price trends for prescription drug products in the Commonwealth and nationwide;

2. Prescription drug products that were subject to Board review during the previous 12-month period, including the number of prescription drug projects subject to review, the results of the reviews, and the number and disposition of appeals and judicial reviews of Board decisions; and

3. Any recommendations the Board may have regarding further legislation needed to improve prescription drug affordability in the Commonwealth.

B. On or before July 1, 2024, and annually thereafter, the Board shall study the operations of the generic drug market in the United States, including a review of physician-administered drugs. The study shall consider (i) the prices of generic drugs on a year-over-year basis, (ii) the degree to which generic drug prices affect yearly insurance premium changes, (iii) annual changes in insurance cost-sharing for generic drugs, (iv) the potential for and history of generic drug shortages, (v) the degree to which generic drug prices affect yearly Medicaid spending in the Commonwealth, and (vi) any other relevant study questions. The Board shall report this study to the chair of the Senate and House committees listed in subsection A.

§ 32.1-276.20. Terms of office; initial Board and stakeholder council members.

A. The terms of the initial members and alternate members of the Board shall expire as follows:

1. One member and one alternate member in 2027;

2. Two members and one alternate member in 2028; and

3. Two members, including the chair of the Board, and one alternate member in 2029.

B. The terms of the initial members of the stakeholder council shall expire as follows:

1. Three members in 2027;

2. Four members in 2028; and

3. Four members in 2029.

§ 32.1-276.21. Relation to other health benefit plans.

The provisions of this chapter obligate state-sponsored and state-regulated health plans and health programs to limit drug reimbursements and drug payment amounts to no more than the Board-established upper payment limit amount. Plans providing health care benefits pursuant to Part D of Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq., known as Medicare Part D, shall not be bound by decisions of the Board, and any such plans may choose to reimburse more than the Board-established upper payment limit amount. Providers who dispense and administer prescription

drug products to citizens of the Commonwealth shall be bound to bill all health plan payers no more than the Board-established upper payment limit amount without regard to whether or not a Medicare Part D plan chooses to reimburse the provider above the upper payment limit amount.

§ 54.1-3442.02. Prescription drug price transparency.

A. As used in this section:

~~"Biosimilar" means a drug that is produced or distributed pursuant to a biologics license application approved under 42 U.S.C. § 262(k)(3).~~

~~"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).~~ *"Biosimilar," "brand-name drug," and "generic drug" have the same meanings as provided in § 32.1-276.12.*

"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) or under a biologics license application under 42 U.S.C. § 262.

"Nonprofit data services organization" has the same meaning as set forth in § 32.1-23.4.

"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 nonprofit organization with which the Department of Health has entered into a contract or agreement pursuant to § 32.1-23.4, for each (i) brand-name drug and biologic other than a biosimilar with a wholesale acquisition cost of $100 or more for a 30-day supply or a single course of treatment and any increase of 15 percent or more in the wholesale acquisition cost of such brand-name drug or biologic over the preceding calendar year; (ii) biosimilar with an initial wholesale acquisition cost that is not at least 15 percent less than the wholesale acquisition cost of the referenced brand biologic at the time the biosimilar is launched; and (iii) generic drug with a price increase that results in an increase in the wholesale acquisition cost of such generic drug that is equal to 200 percent or more during the preceding 12-month period, when the wholesale acquisition cost of such generic drug is equal to or greater than $100, annually adjusted by the Consumer Price Index for All Urban Consumers, for a 30-day supply, with such increase defined as the difference between the wholesale acquisition cost of the generic drug after such increase and the average wholesale acquisition cost of such generic drug during the previous 12 months, the following information:

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. A manufacturer's obligations pursuant to this section shall be fully satisfied by the submission to the nonprofit data services organization with which the Department of Health has entered into a contract pursuant to § 32.1-23.4 of information and data that a manufacturer includes in the manufacturer's annual consolidation report on Securities and Exchange Commission Form 10-K or any other public disclosure.

2. That the members of the Prescription Drug Affordability Board, as established by § 32.1-276.13 of the Code of Virginia, as created by this act, shall be appointed by January 1, 2024, and that the Prescription Drug Affordability Board may begin its work regardless of any delay in appointing members to the stakeholder council established by § 32.1-276.15 of the Code of Virginia, as created by this act.

3. That the Prescription Drug Affordability Board, established by § 32.1-276.13 of the Code of Virginia, as created by this act, shall establish pursuant to subsection E of § 32.1-267.16 of the Code of Virginia, as created by this act, no more than 12 upper payment limit amounts annually between January 1, 2024 and January 1, 2027.

4. That if any provision of this act or the application thereof to any person or circumstance is held invalid for any reason in a court of competent jurisdiction, the invalidity shall not affect other provisions or any other applications of this act that shall continue to be given effect without the invalid provision or application.

5. That the provisions of the first enactment of this act shall become effective on January 1, 2024.