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HOUSE BILL NO. 570

AMENDMENT IN THE NATURE OF A SUBSTITUTE
(Proposed by the House Committee on Labor and Commerce
on February 1, 2024)

(Patron Prior to Substitute—Delegate Delaney)

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 32.1-276.19, relating to Prescription Drug Affordability Board established; drug cost affordability review.*

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 32.1-276.19, as follows:

CHAPTER 7.3.**PRESCRIPTION DRUG AFFORDABILITY BOARD.****§ 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 nonlegislative citizen members that shall be appointed as follows: two members by the Speaker of the House of Delegates, two members by the Senate Committee on Rules, and one member by the Governor who shall be a representative of a local government in the Commonwealth. The Governor shall appoint three alternate nonlegislative citizen members of the Board. Members of the Board shall have expertise in health care, health care economics, the federal 340B Drug Pricing Program and its impacts on Virginia's federally qualified health centers, or clinical medicine. A member or alternate member of the Board shall 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. After the initial staggering of terms, members and alternate members shall be appointed for a term of five years. Vacancies occurring other than by expiration of term shall be filled for the unexpired term. Vacancies shall be filled in the same manner as the original appointments.

D. The Board shall elect a chairman and vice-chairman from among its membership. A majority of

60 the members shall constitute a quorum. The meetings of the Board shall be held at the call of the
61 chairman or whenever the majority of the members so request.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

109 **§ 32.1-276.14. Powers and duties of the Board.**

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

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

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

121 **§ 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 nonlegislative citizen 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. No more than one stakeholder council member shall be appointed to represent any single organization or entity.

B. The members of the stakeholder council shall be appointed as follows: five members by the Speaker of the House of Delegates, one of whom shall be a representative of a rare disease and patient advocacy organization, three members by the Senate Committee on Rules, and three members by the Governor.

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. After the initial staggering of terms, members shall be appointed for a term of three years. Vacancies occurring other than by expiration of term shall be filled for the unexpired term. Vacancies shall be filled in the same manner as the original appointments.

E. The Chair of the Board shall select one member of the stakeholder council to serve as chair of the stakeholder council.

F. No member of the stakeholder council shall receive compensation as a member of the stakeholder council, but members shall be 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;

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; and

5. The Board shall not be required to identify every prescription drug product that meets the criteria of this subsection.

C. After identifying prescription drug products as required by subsection B, soliciting public input on prescription drug products thought to be creating affordability challenges, 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 life-cycle management, net average prices in the Commonwealth, market

183 competition and context, projected revenue, patient assistance programs specific to a prescription drug
184 product, estimated or actual manufacturer price concessions in the market, the estimated value or cost
185 effectiveness of the prescription drug product, and other information as determined by the Board.
186 Failure of a manufacturer to provide the Board with relevant information for an affordability review
187 shall not affect the Board's authority to conduct such a review.

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

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

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

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

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

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

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

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

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

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

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

217 11. Any information a manufacturer chooses to provide; and

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

219 E. If the Board finds that the spending on a prescription drug product reviewed under this section
220 has led or will lead to an affordability challenge for the health care system in the Commonwealth or
221 high out-of-pocket costs for citizens of the Commonwealth, particularly patients experiencing physical
222 and mental illnesses, communities affected by the opioid crisis, state and local governments, commercial
223 health plans, health care providers, pharmacies licensed in the Commonwealth, and other stakeholders
224 within the health care system, the Board shall establish an upper payment limit amount after
225 considering exceptional costs of administering the prescription drug product, the cost of delivering the
226 prescription drug product to customers, and other relevant administrative costs related to the
227 prescription drug product. In determining whether a prescription drug product creates an affordability
228 challenge or in determining an upper payment limit amount, the Board shall not utilize a
229 cost-effectiveness analysis that includes the cost-per-quality adjusted life year or similar measure to
230 identify subpopulations for which a treatment would be less cost-effective due to severity of illness, age,
231 or preexisting disability. For any treatment that extends life, if the Board uses a cost-effectiveness
232 analysis, such analysis shall weigh the value of all additional lifetime gained equally for all patients
233 regardless of severity of illness, age, or preexisting disability. If the Board establishes an upper payment
234 limit amount pursuant to this subsection, the Board shall examine how the upper payment limit amount
235 will affect entities operating pursuant to § 340B of the federal Public Health Service Act, 42 U.S.C.
236 § 256b.

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

244 G. The Board may adopt the Medicare maximum fair price in § 1191(c) of Title XVII 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 different than the Medicare maximum fair price for any prescription drug product included in § 1191(c) of Title XVII 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 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. Reporting requirements.

A. On or before December 31, 2025, and annually 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 and Human Services, and the Chair of the House Committee on Labor and Commerce 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 products 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, 2025, 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 Chairs of the Senate and House committees listed in subsection A.

§ 32.1-276.19. 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).

306 B. Every manufacturer shall report annually by April 1 to the nonprofit organization with which the
307 Department of Health has entered into a contract or agreement pursuant to § 32.1-23.4, for each (i)
308 brand-name drug and biologic other than a biosimilar with a wholesale acquisition cost of \$100 or more
309 for a 30-day supply or a single course of treatment and any increase of 15 percent or more in the
310 wholesale acquisition cost of such brand-name drug or biologic over the preceding calendar year; (ii)
311 biosimilar with an initial wholesale acquisition cost that is not at least 15 percent less than the wholesale
312 acquisition cost of the referenced brand biologic at the time the biosimilar is launched; and (iii) generic
313 drug with a price increase that results in an increase in the wholesale acquisition cost of such generic
314 drug that is equal to 200 percent or more during the preceding 12-month period, when the wholesale
315 acquisition cost of such generic drug is equal to or greater than \$100, annually adjusted by the
316 Consumer Price Index for All Urban Consumers, for a 30-day supply, with such increase defined as the
317 difference between the wholesale acquisition cost of the generic drug after such increase and the average
318 wholesale acquisition cost of such generic drug during the previous 12 months, the following
319 information:

- 320 1. The name of the prescription drug;
- 321 2. Whether the drug is a brand name or generic;
- 322 3. The effective date of the change in wholesale acquisition cost;
- 323 4. Aggregate, company-level research and development costs for the most recent year for which final
324 audit data is available;
- 325 5. The name of each of the manufacturer's new prescription drugs approved by the U.S. Food and
326 Drug Administration within the previous three calendar years;
- 327 6. The name of each of the manufacturer's prescription drugs that, within the previous three calendar
328 years, became subject to generic competition and for which there is a therapeutically equivalent generic
329 version; and
- 330 7. A concise statement regarding the factor or factors that caused the increase in wholesale
331 acquisition cost.

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

337 D. *The nonprofit organization with which the Department of Health has entered into a contract or*
338 *agreement pursuant to § 32.1-23.4 shall provide the Prescription Drug Affordability Board established*
339 *pursuant to § 32.1-276.13 access to the data collected pursuant to subsection B.*

340 2. That the members of the Prescription Drug Affordability Board established by § 32.1-276.13 of
341 the Code of Virginia, as created by this act, shall be appointed by January 1, 2025, and that the
342 Prescription Drug Affordability Board may begin its work regardless of any delay in appointing
343 members to the stakeholder council established by § 32.1-276.15 of the Code of Virginia, as created
344 by this act.

345 3. That the Prescription Drug Affordability Board established by § 32.1-276.13 of the Code of
346 Virginia, as created by this act, shall establish pursuant to subsection E of § 32.1-276.16 of the
347 Code of Virginia, as created by this act, no more than 12 upper payment limit amounts annually
348 between January 1, 2025, and January 1, 2028.

349 4. That the initial appointments of nonlegislative citizen members and alternative members of the
350 Prescription Drug Affordability Board (the Board) established by § 32.1-276.13 of the Code of
351 Virginia, as created by this act, shall be staggered as follows: one member for a term of three
352 years and one member for a term of five years, appointed by the Speaker of the House of
353 Delegates; one member for a term of two years and one member for a term of four years,
354 appointed by the Senate Committee on Rules; and one member for a term of one year, one
355 alternative member for a term of three years, one alternative member for a term of four years,
356 and one alternative member for a term of five years, appointed by the Governor.

357 5. That the initial appointments of nonlegislative citizen members to the stakeholder council
358 established by § 32.1-276.15 of the Code of Virginia, as created by this act, shall be staggered as
359 follows: one member for a term of one year, two members for a term of two years, and two
360 members for a term of three years, appointed by the Speaker of the House of Delegates; one
361 member for a term of one year, one member for a term of two years, and one member for a term
362 of three years, appointed by the Senate Committee on Rules; and one member for a term of one
363 year, one member for a term of two years, and one member for a term of three years, appointed
364 by the Governor.

365 6. That the provisions of the first enactment of this act shall become effective on January 1, 2025.