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HOUSE BILL NO. 483

House Amendments in [] - February 12, 2026

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.*

Patron Prior to Engrossment—Delegate Delaney

Referred to Committee on Labor and Commerce

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.**AFFORDABLE MEDICINE ACT.***§ 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.

"ERISA plan" means an employee welfare benefit plan as defined in § 3(1) of the 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.

"Manufacturer" means an entity that (i) (a) owns the patent to a prescription drug product, (b) engages in the manufacture of a prescription drug product, (c) enters into a lease with another manufacturer to market and distribute a prescription drug product under the entity's own name, or (d) is the labeled entity of the generic product at the point of manufacture and (ii) sets or changes the wholesale acquisition cost of the prescription drug product it manufactures or markets.

"Medicare Part D plan" has the same meaning as provided in 42 C.F.R. § 423.4.

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

"Participating ERISA plan" means an ERISA plan that elects to be subject to upper payment limits pursuant to § 32.1-276.19.

"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.

"Rare disease or condition" means any disease or condition that affects fewer than 200,000 persons in the United States.

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

"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.

§ 32.1-276.13. Prescription Drug Affordability Board established.

A. There is hereby established within the Department 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 to be appointed by the Speaker of the House of Delegates, two members to be appointed by the Senate Committee on Rules, and one member to be appointed by the Governor who shall be a representative

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59 of a local government in the Commonwealth. The Secretary of Health and Human Resources or his designee
60 shall serve as an ex officio, nonvoting member of the Board. The Governor shall appoint three alternate
61 nonlegislative citizen members of the Board. Members of the Board shall have expertise in health care,
62 health care economics, the federal 340B Drug Pricing Program and its impacts on Virginia's federally
63 qualified health centers, [~~or~~ and] clinical medicine. No member or alternate member of the Board shall be
64 an employee of, a board member of, or a consultant to a manufacturer, health plan, hospital, pharmacy
65 benefits manager, or trade association for manufacturers, health plans, hospitals, or pharmacy benefits
66 managers. Any conflict of interest, including whether an individual has an association, including a financial
67 or personal association, that has the potential to bias, or has the appearance of biasing, the individual's
68 decisions in matters related to the Board or the conduct of the Board's activities shall be disclosed and
69 considered when appointing members and alternate members to the Board.

70 C. After the initial staggering of terms, members and alternate members shall be appointed for a term of
71 five years. Vacancies occurring other than by expiration of a term shall be filled for the unexpired term.
72 Vacancies shall be filled in the same manner as the original appointments.

73 D. The Board shall elect a chairman and vice-chairman from among its membership for a term of three
74 years. A majority of the members shall constitute a quorum. The meetings of the Board shall be held at the
75 call of the chairman or whenever the majority of the members so request.

76 E. The Board shall hire an executive director and any other staff as needed to support the Board's
77 activities. Staff of the Board shall receive a salary as provided in the budget of the Board and in accordance
78 with the general appropriation act. A member of the Board may receive compensation as a member of the
79 Board in accordance with the general appropriation act and is entitled to reimbursement for expenses
80 authorized by travel regulations promulgated pursuant to § 2.2-2823.

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

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

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

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

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

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

93 6. The Board shall provide an opportunity for public comment at each open meeting of the Board and
94 shall provide meaningful opportunities for stakeholder engagement throughout the affordability review
95 process, including public hearings, written comment periods, and targeted outreach to patient groups,
96 providers, payers, manufacturers, and other members of the drug supply chain.

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

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

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

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

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

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

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

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

120 H. Members and alternate members of the Board, Board staff, and third-party contractors shall not

121 *accept any gift or donation of services or property that indicates a potential conflict of interest or has the*
 122 *appearance of biasing the work of the Board.*

123 **§ 32.1-276.14. Powers and duties of the Board.**

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

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

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

135 **§ 32.1-276.15. Stakeholder council.**

136 *A. The Board shall create a stakeholder council for the purpose of providing stakeholder input to assist*
 137 *the Board in making decisions as required under this chapter. The stakeholder council shall consist of 11*
 138 *nonlegislative citizen members appointed in accordance with this section. Members shall include*
 139 *manufacturers of brand-name drugs and generic drugs, providers that dispense or administer prescription*
 140 *drug products, suppliers of prescription drug products, and consumers of prescription drug products. No*
 141 *more than one stakeholder council member shall be appointed to represent any single organization or entity.*

142 *B. The members of the stakeholder council shall be appointed as follows: five members to be appointed by*
 143 *the Speaker of the House of Delegates, three of whom shall be representatives of rare disease and patient*
 144 *advocacy organizations; three members to be appointed by the Senate Committee on Rules; and three*
 145 *members to be appointed by the Governor.*

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

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

153 *E. The chair of the Board shall select one member of the stakeholder council to serve as chair of the*
 154 *stakeholder council for a term of three years.*

155 *F. No member of the stakeholder council shall receive compensation as a member of the stakeholder*
 156 *council, but members shall be entitled to reimbursement for expenses under standard state travel regulations*
 157 *promulgated pursuant to § 2.2-2823.*

158 **§ 32.1-276.16. Drug cost affordability review.**

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

162 *B. The Board shall conduct affordability reviews of the prescription drugs identified by the federal*
 163 *Secretary of Health and Human Services pursuant to 42 U.S.C. § 1320f-1(a)(1) and set upper payment limits*
 164 *matching the maximum fair price for such prescription drugs established pursuant to 42 U.S.C. § 1320f-3 by*
 165 *March 1, 2027. The Board shall conduct affordability reviews of the prescription drugs identified by the*
 166 *federal Secretary of Health and Human Services pursuant to 42 U.S.C. § 1320f-1(a)(2) and set upper*
 167 *payment limits matching the maximum fair price for such prescription drugs established pursuant to 42*
 168 *U.S.C. § 1320f-3 by March 1, 2028. Each affordability review shall comply with the requirements of this*
 169 *section.*

170 *C. In conducting any affordability review, the Board shall seek input and data from stakeholders,*
 171 *including manufacturers, payers, providers, and patient groups. Relevant information for conducting an*
 172 *affordability review may include any document or research related to the manufacturer's selection of the*
 173 *introductory price or price increase of the prescription drug product, including life-cycle management, net*
 174 *average prices in the Commonwealth, market competition and context, projected revenue, patient assistance*
 175 *programs specific to a prescription drug product, estimated or actual manufacturer price concessions in the*
 176 *market, the estimated value or cost effectiveness of the prescription drug product, and other information as*
 177 *determined by the Board. Failure of a manufacturer to provide the Board with relevant information for an*
 178 *affordability review shall not affect the Board's authority to conduct such a review. The Board shall publicly*
 179 *disclose the full methodology used for affordability reviews, including all criteria, data sources, and*
 180 *analytical models.*

181 *D. An affordability review conducted by the Board shall determine whether the prescription drug product*
 182 *that is fully consistent with the labeling approved by the FDA or standard medical practice has led or will*

183 *lead to affordability challenges for the health care system in the Commonwealth or high out-of-pocket costs*
184 *for patients. To the extent practicable, in determining whether a prescription drug product has led or will*
185 *lead to an affordability challenge, the Board shall consider the following factors:*

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

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

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

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

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

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

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

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

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

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

208 *11. Any information a manufacturer chooses to provide; and*

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

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

230 *F. An upper payment limit amount established by the Board pursuant to subsection E shall apply to all*
231 *purchases and payer reimbursements of the prescription drug product intended for use by individuals in the*
232 *Commonwealth in person, by mail, or by any other means. Such upper payment limit amount shall become*
233 *effective between six and nine months after it is announced by the Board. Such upper payment limit amount*
234 *shall be exclusive of applicable pharmacy dispensing fees and provider administration fees. State-licensed [*
235 *~~independent~~] pharmacies shall not be reimbursed less than an upper payment limit amount plus the national*
236 *acquisition cost and dispensing fee as established by the cost dispensing survey required by 12VAC30-80-40.*

237 *G. The Board may adopt the maximum fair price established pursuant to § 1191 of Title XI of the Social*
238 *Security Act, 42 U.S.C. § 1320(f) et seq., for a prescription drug product as the upper payment limit amount*
239 *established pursuant to subsection E. The Board shall not establish an upper payment limit amount different*
240 *from the maximum fair price for any prescription drug product included in § 1191 of Title XI of the Social*
241 *Security Act, 42 U.S.C. § 1320(f) et seq.*

242 *H. State-regulated health plans shall inform the Board of how the cost savings related to an upper*
243 *payment limit amount are directed to the benefit of enrollees with a priority on enrollee cost sharing. Any*
244 *savings generated by a health benefit plan, state entity, or participating ERISA plan that are attributable to*

245 the implementation of an upper payment limit established by the Board shall be used to reduce cost to
 246 consumers, prioritizing the reduction of out-of-pocket costs for prescription drugs. On or before April 1 of
 247 each calendar year, each health benefit plan, state entity, and participating ERISA plan shall submit to the
 248 Board a report describing the savings achieved as a result of implementing upper payment limits and how
 249 those savings were used to reduce costs to consumers.

250 I. Any information submitted to the Board in accordance with this section shall be subject to public
 251 inspection only to the extent required under the Virginia Freedom of Information Act (§ 2.2-3700 et seq.),
 252 provided that any confidential, trade secret, or proprietary information submitted to the Board in accordance
 253 with this section shall be protected from public disclosure. The Board shall establish clear procedures for the
 254 handling, storage, and redaction of any confidential, trade secret, or proprietary information submitted to the
 255 Board in accordance with this section consistent with state and federal law. Only authorized Board members
 256 and staff may access such information, and all disclosures shall be logged and auditable.

257 J. Beginning July 1, 2028, the Board shall identify the following prescription drug products offered for
 258 sale in the Commonwealth:

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

262 2. Biosimilars that have [~~a wholesale acquisition cost that is not at least 20 percent lower than the~~
 263 ~~referenced brand biologic at the time the biosimilars are launched and that~~ have (i) been on the market for at
 264 least three years; (ii) a wholesale acquisition cost that is not 20 percent or more lower than the referenced
 265 brand biologic wholesale acquisition cost at the time of the biosimilar launch; and (iii)] been suggested for
 266 review by members of the public, medical professionals, or other stakeholders;

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

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

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

280 The Board shall not be required to identify every prescription drug product that meets the criteria of this
 281 subsection. The Board shall not include in such list of identified prescription drug products (i) any brand-
 282 name prescription drug or biologic that is designated for a rare disease or condition under 21 U.S.C. §
 283 360bb and for which the only approved indication is for one or more rare diseases or conditions or (ii) any
 284 biological product that is derived from human blood or plasma. The Board shall determine whether to
 285 conduct an affordability review for each identified prescription drug product pursuant to the provisions of
 286 subsections C, D, and E.

287 **§ 32.1-276.17. Remedies; appeals.**

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

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

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

295 **§ 32.1-276.18. Reporting requirements.**

296 A. On or before December 31, 2026, and annually thereafter, the Board shall submit to the Governor, the
 297 Chair of the Senate Committee on Education and Health, the Chair of the Senate Committee on Commerce
 298 and Labor, the Chair of the House Committee on Health and Human Services, and the Chair of the House
 299 Committee on Labor and Commerce a report that includes the following:

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

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

304 3. Any recommendations the Board may have regarding further legislation needed to improve
 305 prescription drug affordability in the Commonwealth. Such recommendations may include measures for
 306 stricter enforcement of drug price transparency laws or for reducing the Commonwealth's prescription drug

307 *spending through policies including bulk purchasing across state agencies and through multi-state*
 308 *consortiums or subscription-based payments. In examining how to reduce prescription drug costs and*
 309 *improve overall health care affordability in the Commonwealth, the Board shall consider strategies for using*
 310 *savings from Medicaid's best price requirement and savings attributable to the Department of Medical*
 311 *Assistance Services' contract with a state pharmacy benefits manager, as described in § 32.1-325.5.*

312 *B. On or before December 31, 2027, the Board shall study the operations of the generic drug market in*
 313 *the United States, including a review of physician-administered drugs. The study shall consider (i) the prices*
 314 *of generic drugs on a year-over-year basis, (ii) the degree to which generic drug prices affect yearly*
 315 *insurance premium changes, (iii) annual changes in insurance cost sharing for generic drugs, (iv) the*
 316 *potential for and history of generic drug shortages, (v) the degree to which generic drug prices affect yearly*
 317 *Medicaid spending in the Commonwealth, and (vi) any other relevant study questions. The Board shall report*
 318 *this study to the Governor and the Chairs of the Senate and House committees listed in subsection A.*

319 **§ 32.1-276.19. Relation to other health benefit plans.**

320 *The provisions of this chapter obligate state-sponsored and state-regulated health plans and health*
 321 *programs to limit drug reimbursements and drug payment amounts to no more than the Board-established*
 322 *upper payment limit amount. No Medicare Part D plan shall be bound by decisions of the Board, and any*
 323 *such plan may choose to reimburse more than the Board-established upper payment limit amount. [*
 324 *Providers who dispense and administer prescription drug products to citizens of the Commonwealth shall be*
 325 *bound to bill all health plan payers no more than the Board-established upper payment limit amount without*
 326 *regard to whether or not a Medicare Part D plan chooses to reimburse the provider above the upper payment*
 327 *limit amount.] An ERISA plan may elect to be subject to the upper payment limits established by the Board*
 328 *pursuant to subsection E of § 32.1-276.16.*

329 **§ 54.1-3442.02. Prescription drug price transparency.**

330 A. As used in this section:

331 "Biosimilar" means a drug that is produced or distributed pursuant to a biologics license application
 332 approved under 42 U.S.C. § 262(k)(3) has the same meaning as provided in § 32.1-276.12.

333 "Brand-name drug" means a prescription drug approved under 21 U.S.C. § 355(b) or 42 U.S.C. § 262 has
 334 the same meaning as provided in § 32.1-276.12.

335 "Generic drug" means a prescription drug approved under 21 U.S.C. § 355(j) or 42 U.S.C. 262(k) has the
 336 same meaning as provided in § 32.1-276.12.

337 "New prescription drug" means a drug or biological product receiving initial approval under an original
 338 new drug application pursuant to 21 U.S.C. § 355(b) or under a biologics license application under 42 U.S.C.
 339 § 262.

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

341 "Pharmacy benefits manager" has the same meaning as set forth in § 38.2-3407.15:4.

342 "Wholesale acquisition cost" has the same meaning as set forth in 42 U.S.C. § 1395w-3a(c)(6)(B).

343 B. Every manufacturer shall report annually by April 1 to the nonprofit organization with which the
 344 Department of Health has entered into a contract or agreement pursuant to § 32.1-23.4, for each (i)
 345 brand-name drug and biologic other than a biosimilar with a wholesale acquisition cost of \$100 or more for a
 346 30-day supply or a single course of treatment and any increase of 15 percent or more in the wholesale
 347 acquisition cost of such brand-name drug or biologic over the preceding calendar year; (ii) biosimilar with an
 348 initial wholesale acquisition cost that is not at least 15 percent less than the wholesale acquisition cost of the
 349 referenced brand biologic at the time the biosimilar is launched; and (iii) generic drug with a price increase
 350 that results in an increase in the wholesale acquisition cost of such generic drug that is equal to 200 percent or
 351 more during the preceding 12-month period, when the wholesale acquisition cost of such generic drug is
 352 equal to or greater than \$100, annually adjusted by the Consumer Price Index for All Urban Consumers, for a
 353 30-day supply, with such increase defined as the difference between the wholesale acquisition cost of the
 354 generic drug after such increase and the average wholesale acquisition cost of such generic drug during the
 355 previous 12 months, the following information:

356 1. The name of the prescription drug;

357 2. Whether the drug is a brand name or generic;

358 3. The effective date of the change in wholesale acquisition cost;

359 4. Aggregate, company-level research and development costs for the most recent year for which final
 360 audit data is available;

361 5. The name of each of the manufacturer's new prescription drugs approved by the U.S. Food and Drug
 362 Administration within the previous three calendar years;

363 6. The name of each of the manufacturer's prescription drugs that, within the previous three calendar
 364 years, became subject to generic competition and for which there is a therapeutically equivalent generic
 365 version; and

366 7. A concise statement regarding the factor or factors that caused the increase in wholesale acquisition
 367 cost.

368 C. A manufacturer's obligations pursuant to this section shall be fully satisfied by the submission to the

369 nonprofit data services organization with which the Department of Health has entered into a contract pursuant
370 to § 32.1-23.4 of information and data that a manufacturer includes in the manufacturer's annual
371 consolidation report on Securities and Exchange Commission Form 10-K or any other public disclosure.

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

375 **2. That the members of the Prescription Drug Affordability Board (the Board) established by**
376 **§ 32.1-276.13 of the Code of Virginia, as created by this act, shall be appointed by October 1, 2026, and**
377 **that the Board may begin its work regardless of any delay in appointing members to the stakeholder**
378 **council established by § 32.1-276.15 of the Code of Virginia, as created by this act.**

379 **3. That the initial appointments of nonlegislative citizen members and alternate members of the**
380 **Prescription Drug Affordability Board (the Board) established by § 32.1-276.13 of the Code of**
381 **Virginia, as created by this act, shall be staggered as follows: one member for a term of three years and**
382 **one member for a term of five years, appointed by the Speaker of the House of Delegates; one member**
383 **for a term of two years and one member for a term of four years, appointed by the Senate Committee**
384 **on Rules; and one member for a term of one year, one alternate member for a term of three years, one**
385 **alternate member for a term of four years, and one alternate member for a term of five years,**
386 **appointed by the Governor.**

387 **4. That the initial appointments of nonlegislative citizen members to the stakeholder council**
388 **established by § 32.1-276.15 of the Code of Virginia, as created by this act, shall be staggered as**
389 **follows: one member for a term of one year, two members for a term of two years, and two members**
390 **for a term of three years, appointed by the Speaker of the House of Delegates; one member for a term**
391 **of one year, one member for a term of two years, and one member for a term of three years, appointed**
392 **by the Senate Committee on Rules; and one member for a term of one year, one member for a term of**
393 **two years, and one member for a term of three years, appointed by the Governor.**

394 **5. That the provisions of subsection J of § 32.1-276.16 of the Code of Virginia, as created by this act,**
395 **shall expire unless reenacted by the 2028 Session of the General Assembly.**

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