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HOUSE BILL NO. 1041

Offered January 10, 2024

Prefiled January 10, 2024

A BILL to amend and reenact §§ 38.2-3407.22, 38.2-3465, 38.2-3466, and 38.2-3467 of the Code of Virginia and to amend the Code of Virginia by adding sections numbered 38.2-3467.1 and 38.2-3467.2, relating to health insurance; ensuring fairness in cost-sharing; pharmacy benefits managers; compensation and duties; civil penalty.

Patrons—O'Quinn and Runion

Referred to Committee on Labor and Commerce

Be it enacted by the General Assembly of Virginia:

1. That §§ 38.2-3407.22, 38.2-3465, 38.2-3466, and 38.2-3467 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding sections numbered 38.2-3467.1 and 38.2-3467.2 as follows:

§ 38.2-3407.22. Ensuring fairness in cost-sharing.

A. As used in this section:

"Carrier" has the same meaning as set forth in § 38.2-3407.10; however, "carrier" also includes any person required to be licensed pursuant to this title that offers or operates a managed care health insurance plan subject to the requirements of Chapter 58 (§ 38.2-5800 et seq.) or that provides or arranges for the provision of health care services, health plans, networks, or provider panels that are subject to regulation as the business of insurance. "Carrier" also includes any health insurance issuer that offers health insurance coverage, as defined in § 38.2-3431.

"Enrollee" means any person entitled to health care services from a carrier.

"Health care services" means items or services furnished to any individual for the purpose of preventing, alleviating, curing, or healing human illness, injury, or physical disability.

"Defined cost-sharing" means a deductible payment or coinsurance amount imposed on an enrollee for a covered prescription drug under the enrollee's health plan.

"Health plan" means any individual or group health care plan, subscription contract, evidence of coverage, certificate, health services plan, medical or hospital services plan, accident or sickness insurance policy or certificate, managed care health insurance plan, or other similar certificate, policy, contract, or arrangement, and any endorsement or rider thereto, to cover all or a portion of the cost of persons receiving covered health care services, that is subject to state regulation and that is required to be offered, arranged, or issued in the Commonwealth by a carrier licensed under this title. "Health plan" includes a state or local government employer plan. "Health plan" does not mean (i) a state or local government employer plan, including the state employee health plan under § 2.2-2818.2; (ii) coverages issued pursuant to Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. (Medicare), Title XIX of the Social Security Act, 42 U.S.C. § 1396 et seq. (Medicaid), Title XXI of the Social Security Act, 42 U.S.C. § 1397aa et seq. (CHIP), 5 U.S.C. § 8901 et seq. (federal employees), or 10 U.S.C. § 1071 et seq. (TRICARE) or (ii); (iii) accident only, credit or disability insurance, long-term care insurance, TRICARE supplement, Medicare Supplement, or workers' compensation coverages; or (iv) an employee welfare benefit plan, as defined in section 3 (1) of the Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1002 (1), that is self-insured or self-funded.

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

"Price protection rebate" means a negotiated price concession that accrues directly or indirectly to the carrier, or other party on behalf of the carrier, in the event of an increase in the wholesale acquisition cost of a drug above a specified threshold.

"Rebate" means (i) negotiated price concessions, including base price concessions and reasonable estimates of any price protection rebates and performance-based price concessions, whether described as a rebate or otherwise, that may accrue directly or indirectly to a carrier, health plan, or pharmacy benefits manager during the coverage year from a manufacturer, dispensing pharmacy, or other party in connection with the dispensing or administration of a prescription drug and (ii) reasonable estimates of any negotiated price concessions, fees, or other administrative costs that are passed through, or are reasonably anticipated to be passed through, to the carrier, health plan, or pharmacy benefits manager and serve to reduce the liability of a the carrier, health plan, or pharmacy benefits manager for a prescription drug.

B. When contracting with a carrier or health plan to administer pharmacy benefits, a pharmacy benefits manager shall offer the carrier or health plan the option of extending point-of-sale rebates to enrollees of the plan. An enrollee's defined cost-sharing for each prescription drug shall be calculated at the point of sale based on a price that is reduced by an amount equal to at least 80 percent of all rebates received or expected

59 *to be received based on information known to the carrier at the time of the transaction in connection with the*
 60 *dispensing or administration of the prescription drug.*

61 C. ~~The provisions of this section shall only apply to a carrier, health plan, or pharmacy benefits manager~~
 62 *Nothing in this section shall preclude a carrier from decreasing an enrollee's defined cost-sharing for each*
 63 *prescription drug by an amount greater than that required under subsection B.*

64 D. *In implementing the requirements of this section, the Commission shall only regulate a carrier to the*
 65 *extent permissible under applicable law.*

66 ~~D. E. In complying with the provisions of this section, a carrier, health plan, pharmacy benefits manager,~~
 67 ~~or its respective agents shall not publish or otherwise reveal information regarding the actual amount of~~
 68 ~~rebates a carrier, health plan, or pharmacy benefits manager receives on a product or therapeutic class of~~
 69 ~~products on a product-specific, manufacturer-specific, or pharmacy-specific basis. Such information shall be~~
 70 ~~protected as a trade secret and, shall not be public record as defined by the Virginia Public Records Act (§~~
 71 ~~42.1-76 et seq.), or disclosed, directly or indirectly, in a manner that would allow for the identification of an~~
 72 ~~individual product, therapeutic class of products, or manufacturer, or in a manner that has the potential to~~
 73 ~~compromise the financial, competitive, or proprietary nature of the information. A carrier, health plan, or~~
 74 ~~pharmacy benefits manager shall require any vendor or third party with which the carrier, health plan, or~~
 75 ~~pharmacy benefits manager contracts for that performs health care or administrative services on behalf of the~~
 76 ~~carrier, health plan, or pharmacy benefits manager that and may receive or have access to rebate information~~
 77 ~~to comply with the confidentiality provisions of this subsection related to protection of information regarding~~
 78 ~~the amount of rebates a carrier, health plan, or pharmacy benefits manager receives on a product-specific,~~
 79 ~~manufacturer-specific, or pharmacy-specific basis.~~

80 E. ~~The Commission may, pursuant to the provisions of § 38.2-223, adopt such rules and regulations as~~
 81 ~~may be necessary to implement and enforce the provisions of this section.~~

82 **§ 38.2-3465. Definitions.**

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

84 "Carrier" has the same meaning ascribed thereto in subsection A of § 38.2-3407.15. However, "carrier"
 85 does not include a nonprofit health maintenance organization that operates as a group model whose internal
 86 pharmacy operation exclusively serves the members or patients of the nonprofit health maintenance
 87 organization.

88 "Claim" means a request from a pharmacy or pharmacist to be reimbursed for the cost of administering,
 89 filling, or refilling a prescription for a drug or for providing a medical supply or device.

90 "Claims processing services" means the administrative services performed in connection with the
 91 processing and adjudicating of claims relating to pharmacist services that include (i) receiving payments for
 92 pharmacist services, (ii) making payments to pharmacists or pharmacies for pharmacist services, or (iii) both
 93 receiving and making payments.

94 "Contract pharmacy" means a pharmacy operating under contract with a 340B-covered entity to provide
 95 dispensing services to the 340B-covered entity, as described in 75 Fed. Reg. 10272 (March 5, 2010) or any
 96 superseding guidance published thereafter.

97 "Covered entity" means an entity described in § 340B(a)(4) of the federal Public Health Service Act, 42
 98 U.S.C. § 256B(a)(4). "Covered entity" does not include a hospital as defined in § 32.1-123 or 37.2-100.

99 "Covered individual" means an individual receiving prescription medication coverage or reimbursement
 100 provided by a pharmacy benefits manager or a carrier under a health benefit plan.

101 "Defined cost-sharing" means a deductible payment or coinsurance amount imposed on an enrollee for a
 102 covered prescription drug under the enrollee's health benefit plan.

103 "Enrollee" means any person entitled to health care services from a carrier.

104 "Health benefit plan" has the same meaning ascribed thereto in § 38.2-3438. "Health benefit plan" does
 105 not include a state or local government employer plan, including the state employee health insurance plan
 106 under § 2.2-2818.2.

107 "Health care services" means items or services furnished to any individual for the purpose of preventing,
 108 diagnosing, alleviating, curing, or healing human illness, injury, or physical disability.

109 "Mail order pharmacy" means a pharmacy whose primary business is to receive prescriptions by mail or
 110 through electronic submissions and to dispense medication to covered individuals through the use of the
 111 United States mail or other common or contract carrier services and that provides any consultation with
 112 covered individuals electronically rather than face-to-face.

113 "Pharmacy benefits management fee" means a fee that covers the cost of providing one or more pharmacy
 114 benefits management services and that does not exceed the value of the service actually performed by the
 115 pharmacy benefits manager.

116 "Pharmacy benefits management services" means the administration or management of prescription drug
 117 benefits provided by a carrier for the benefit of covered individuals (i) negotiating the price of prescription
 118 drugs, including negotiating and contracting for direct or indirect rebates, discounts, or other price
 119 concessions; (ii) managing any aspect of a prescription drug benefit, including the processing and payment

120 of claims for prescription drugs, the performance of drug utilization reviews, the processing of drug prior
 121 authorization requests for prescription drugs, the adjudication of appeals or grievances related to the
 122 prescription drug benefit, contracting with network pharmacies, controlling the cost of covered prescription
 123 drugs, or the provision of services related thereto; (iii) performing any administrative, managerial, clinical,
 124 pricing, financial, reimbursement, or billing service; and (iv) providing such other services as the
 125 Commissioner may define by regulation. "Pharmacy benefits management services" does not include any
 126 service provided by a nonprofit health maintenance organization that operates as a group model, provided
 127 that the service is furnished through the internal pharmacy operation exclusively serves the members or
 128 patients of the nonprofit health maintenance organization.

129 "Pharmacy benefits manager" or "PBM" means an entity that performs, pursuant to a written agreement
 130 with a carrier or health benefit plan, either directly or indirectly provides one or more pharmacy benefits
 131 management services on behalf of the carrier or health benefit plan and any agent, contractor, intermediary,
 132 affiliate, subsidiary, or related entity that facilitates, provides, directs, or oversees the provision of pharmacy
 133 benefits management services. "Pharmacy benefits manager" includes an entity acting for a PBM in a
 134 contractual relationship in the performance of pharmacy benefits management services for a carrier, nonprofit
 135 hospital, or third-party payor under a health program administered by the Commonwealth.

136 "Pharmacy benefits manager affiliate" means a business, pharmacy, or pharmacist that directly or
 137 indirectly, through one or more intermediaries, owns or controls, is owned or controlled by, or is under
 138 common ownership interest or control with a pharmacy benefits manager.

139 "Pharmacy benefits manager duty" means the duty of a pharmacy benefits manager to perform pharmacy
 140 benefits management services with care, skill, prudence, diligence, fairness, transparency, and
 141 professionalism, and for the best interests of the enrollee, the health benefit plan, and the provider, in
 142 accordance with § 38.2-3467.2 and any Commission regulations. "Pharmacy benefits manager duty"
 143 includes duties of care and good faith and fair dealing.

144 "Price protection rebate" means a negotiated price concession that accrues directly or indirectly to the
 145 carrier, or other party on behalf of the carrier, in the event of an increase in the wholesale acquisition cost of
 146 a drug above a specified threshold.

147 "Rebate" means a discount or other price concession, including without limitation incentives,
 148 disbursements, and reasonable estimates of a volume-based discount, or a payment that is (i) based on
 149 utilization of a prescription drug and (ii) paid by a manufacturer or third party, directly or indirectly, to a
 150 pharmacy benefits manager, pharmacy services administrative organization, or pharmacy after a claim has
 151 been processed and paid at a pharmacy (i) negotiated price concessions, including base price concessions,
 152 whether described as a rebate or otherwise, and reasonable estimates of any price protection rebates and
 153 performance-based price concessions, that may accrue directly or indirectly to a carrier or health benefit
 154 plan during the coverage year from a manufacturer, dispensing pharmacy, or other party in connection with
 155 the dispensing or administration of a prescription drug and (ii) reasonable estimates of any negotiated price
 156 concessions, fees, or other administrative costs that are passed through, or are reasonably anticipated to be
 157 passed through, to the carrier or health benefit plan and serve to reduce the liability of the carrier or health
 158 benefit plan for a prescription drug.

159 "Retail community pharmacy" means a pharmacy that is open to the public, serves walk-in customers, and
 160 makes available face-to-face consultations between licensed pharmacists and persons to whom medications
 161 are dispensed.

162 "Spread pricing" means the model of prescription drug pricing in which the pharmacy benefits manager
 163 charges a health benefit plan a contracted price for prescription drugs, and the contracted price for the
 164 prescription drugs differs from the amount the pharmacy benefits manager directly or indirectly pays the
 165 pharmacist or pharmacy for pharmacist services.

166 **§ 38.2-3466. License required to provide pharmacy benefits management services; requirements for**
 167 **a license, renewal, and revocation or suspension.**

168 A. Unless otherwise covered by a license as a carrier, no person shall provide pharmacy benefits
 169 management services or otherwise act as a pharmacy benefits manager in the Commonwealth without first
 170 obtaining a license in a manner and in a form prescribed by the Commission.

171 B. Each applicant for a license as a pharmacy benefits manager shall make application to the Commission,
 172 in the form and containing the information listed in subsection C and any other information the Commission
 173 prescribes. The Commission may require any documents reasonably necessary to verify the information
 174 contained in an application. Each applicant shall, at the time of applying for a license, pay a nonrefundable
 175 application processing fee in an amount and in a manner prescribed by the Commission. The fee shall be
 176 collected by the Commission and paid directly into the state treasury and credited to the "Bureau of Insurance
 177 Special Fund — State Corporation Commission" for the maintenance of the Bureau of Insurance as provided
 178 in subsection B of § 38.2-400.

179 C. An applicant for a license as a pharmacy benefits manager shall provide the Commission the following
 180 information:

181 1. The name, address, and telephone contact number of the pharmacy benefits manager;

182 2. The name and address of each person with management or control over the pharmacy benefits manager;
183 3. The name and address of each person with a beneficial ownership interest in the pharmacy benefits
184 manager; and

185 4. If the pharmacy benefits manager registrant (i) is a partnership or other unincorporated association, a
186 limited liability company, or a corporation and (ii) has five or more partners, members, or stockholders, the
187 registrant shall specify its legal structure and the total number of its partners, members, or stockholders who,
188 directly or indirectly, own, control, hold with the power to vote, or hold proxies representing 10 percent or
189 more of the voting securities of any other person.

190 D. An applicant shall provide the Commissioner with a signed statement indicating that, to the best of its
191 knowledge, no officer with management or control of the pharmacy benefits manager has been convicted of a
192 felony or has violated any of the requirements of state law applicable to pharmacy benefits managers, or, if
193 the applicant cannot provide such a statement, a signed statement describing the relevant conviction or
194 violation.

195 E. Except where prohibited by state or federal law, by submitting an application for a license, the
196 applicant shall be deemed to have appointed the clerk of the Commission as the agent for service of process
197 on the applicant in any action or proceeding arising in the Commonwealth out of or in connection with the
198 exercise of the license. Such appointment of the clerk of the Commission as agent for service of process shall
199 be irrevocable during the period within which a cause of action against the applicant may arise out of
200 transactions with respect to subjects of pharmacy benefits management *services* in the Commonwealth.
201 Service of process on the clerk of the Commission shall conform to the provisions of Chapter 8 (§ 38.2-800 et
202 seq.).

203 F. Each applicant that has complied with the provisions of this article and Commission regulations is
204 entitled to and shall receive a license in the form the Commission prescribes.

205 G. Each pharmacy benefits manager shall renew its license annually and shall, at the time of renewal, pay
206 a renewal fee in an amount and in a manner prescribed by the Commission. The fee shall be collected by the
207 Commission and paid directly into the state treasury and credited to the "Bureau of Insurance Special Fund —
208 State Corporation Commission" for the maintenance of the Bureau of Insurance as provided in subsection B
209 of § 38.2-400.

210 H. The Commission may refuse to issue or renew a license or may revoke or suspend a license if it finds
211 that the applicant or license holder has not complied with the provisions of this article or Commission
212 regulations.

213 **§ 38.2-3467. Prohibited conduct by carriers and pharmacy benefits managers; civil penalty.**

214 A. No carrier on its own or through its contracted pharmacy benefits manager or representative of a
215 pharmacy benefits manager shall:

216 1. Cause or knowingly permit the use of any advertisement, promotion, solicitation, representation,
217 proposal, or offer that is untrue;

218 2. Charge a pharmacist or pharmacy a fee related to the adjudication of a claim other than a reasonable fee
219 for an initial claim submission;

220 3. Reimburse a pharmacy or pharmacist an amount less than the amount that the pharmacy benefits
221 manager reimburses a pharmacy benefits manager affiliate for providing the same pharmacist services,
222 calculated on a per-unit basis using the same generic product identifier or generic code number and reflecting
223 all drug manufacturer's rebates, direct and indirect administrative fees, and costs and any remuneration;

224 4. Penalize or retaliate against a pharmacist or pharmacy for exercising rights provided pursuant to the
225 provisions of this article;

226 5. Impose requirements, exclusions, reimbursement terms, or other conditions on a covered entity or
227 contract pharmacy that differ from those applied to entities or pharmacies that are not covered entities or
228 contract pharmacies on the basis that the entity or pharmacy is a covered entity or contract pharmacy or that
229 the entity or pharmacy dispenses 340B-covered drugs. Nothing in this subdivision shall (i) apply to drugs
230 with an annual estimated per-patient cost exceeding \$250,000 or (ii) prohibit the identification of a 340B
231 reimbursement request; or

232 6. Interfere with a covered individual's right to choose a pharmacy or provider, based on the pharmacy or
233 provider's status as a covered entity or contract pharmacy.

234 B. No carrier, on its own or through its contracted pharmacy benefits manager or representative of a
235 pharmacy benefits manager, shall restrict participation of a pharmacy in a pharmacy network for provider
236 accreditation standards or certification requirements if a pharmacist meets such accreditation standards or
237 certification standards.

238 C. No carrier, on its own or through its contracted pharmacy benefits manager or representative of a
239 pharmacy benefits manager, shall include any mail order pharmacy or pharmacy benefits manager affiliate in
240 calculating or determining network adequacy under any law or contract in the Commonwealth.

241 D. No carrier, on its own or through its contracted pharmacy benefits manager or representative of a
242 pharmacy benefits manager, shall conduct spread pricing in the Commonwealth.

243 E. Each carrier on its own or through its contracted pharmacy benefits manager or representative of a

244 pharmacy benefits manager shall comply with the provisions of this section in addition to complying with the
 245 provisions of § 38.2-3407.15:1.

246 *F. No pharmacy benefits manager shall derive income from pharmacy benefits management services
 247 provided to a carrier or health benefit plan in the Commonwealth except for income derived from a
 248 pharmacy benefits management fee. The amount of any pharmacy benefits management fees shall be set forth
 249 in the agreement between the pharmacy benefits manager and the carrier or health benefit plan. The
 250 pharmacy benefits management fee charged by or paid to a pharmacy benefits manager from a carrier or
 251 health benefit plan shall not be directly or indirectly based or contingent upon (i) the acquisition cost or any
 252 other price metric of a drug; (ii) the amount of savings, rebates, or other fees charged, realized, or collected
 253 by or generated based on the activity of the pharmacy benefits manager; or (iii) the amount of premiums,
 254 deductibles, or other cost-sharing or fees charged, realized, or collected by the pharmacy benefits manager
 255 from enrollees or other persons on behalf of an enrollee. Annually by December 31, each pharmacy benefits
 256 manager operating in the Commonwealth shall certify to the Commission that it has fully and completely
 257 complied with the requirements of this section. Such certification shall be signed by the chief executive officer
 258 or chief financial officer of the pharmacy benefits manager. The Commission shall impose a civil penalty not
 259 to exceed \$1,000 per claim for a violation of this section.*

260 **§ 38.2-3467.1. Ensuring fairness in cost-sharing.**

261 *A. An enrollee's defined cost-sharing for each prescription drug shall be calculated at the point of sale
 262 based on a price that is reduced by an amount equal to at least 80 percent of all rebates received or expected
 263 to be received based on information known to the pharmacy benefits manager at the time of the transaction in
 264 connection with the dispensing or administration of the prescription drug.*

265 *B. Nothing in this section shall preclude a pharmacy benefits manager from decreasing an enrollee's
 266 defined cost-sharing for each prescription drug by an amount greater than that required under subsection A.*

267 *C. In complying with the provisions of this section, a pharmacy benefits manager or its agents shall not
 268 publish or otherwise reveal information regarding the actual amount of rebates a pharmacy benefits
 269 manager receives on a product or therapeutic class of products on a product-specific, manufacturer-specific,
 270 or pharmacy-specific basis. Such information shall be protected as a trade secret, shall not be public record
 271 as defined by the Virginia Public Records Act (§ 42.1-76 et seq.), or disclosed, directly or indirectly, in a
 272 manner that would allow for the identification of an individual product, therapeutic class of products, or
 273 manufacturer, or in a manner that has the potential to compromise the financial, competitive, or proprietary
 274 nature of the information. A pharmacy benefits manager shall require any vendor or third party that
 275 performs health care or administrative services on behalf of the pharmacy benefits manager or contracts for
 276 health care or administrative services on behalf of the pharmacy benefits manager that may receive or have
 277 access to rebate information to comply with the confidentiality provisions of this subsection.*

278 **§ 38.2-3467.2. Pharmacy benefit manager duty.**

279 *A. A pharmacy benefits manager shall owe the pharmacy benefits manager duty to any enrollee, health
 280 benefit plan, or provider that receives pharmacy benefits management services from the pharmacy benefits
 281 manager or that furnishes, covers, receives, or is administered a unit of a prescription drug for which the
 282 pharmacy benefits manager has provided pharmacy benefits management services. The Commission shall
 283 adopt regulations defining the scope of the duties, which shall include the obligation of a pharmacy benefits
 284 manager to:*

285 *1. Provide all pharmacy benefits management services to enrollees related to formulary design, utilization
 286 management, and grievances and appeals in a transparent manner that is consistent with the best interest of
 287 the enrollees;*

288 *2. Provide transparency to providers and health benefit plans regarding the amounts charged or claimed
 289 by the pharmacy benefits manager including identifying all instances of spread pricing; and*

290 *3. Disclose all conflicts of interest to enrollees, health benefit plans, and providers.*

291 *B. If any conflict of interest exists between the pharmacy benefits manager duties owed to enrollees,
 292 providers, and health plans, the duty to an enrollee shall be primary over the duty owed to any other party
 293 and the duty owed to a provider shall be primary over the duty owed to a health benefit plan.*

294 *C. Any person who is aggrieved by the breach of the pharmacy benefits manager duty by a pharmacy
 295 benefits manager may bring an action in a court of competent jurisdiction.*

296 *D. For the purposes of this section, "provider" means any person that furnishes, provides, dispenses, or
 297 administers one or more units of a prescription drug.*