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HOUSE BILL NO. 1459

Offered January 8, 2020

Prefiled January 8, 2020

A *BILL* to amend the Code of Virginia by adding in Chapter 34 of Title 38.2 an article numbered 9, consisting of sections numbered 38.2-3465 through 38.2-3471, relating to regulation of pharmacy benefits managers.

Patrons—O'Quinn and Edmunds

Referred to Committee on Labor and Commerce

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Chapter 34 of Title 38.2 an article numbered 9, consisting of sections numbered 38.2-3465 through 38.2-3471, as follows:

Article 9.**Pharmacy Benefits Managers.****§ 38.2-3465. Definitions.**

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

"Carrier" has the same meaning ascribed thereto in subsection A of § 38.2-3407.15.

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

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

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

"Health benefit plan" has the same meaning ascribed thereto in § 38.2-3438.

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

"Maximum Allowable Cost List" means a listing of drugs or other methodology used by a pharmacy benefits manager, directly or indirectly, setting the maximum allowable payment to a pharmacy or pharmacist for a generic drug, brand-name drug, biologic product, or other prescription drug. Maximum Allowable Cost List includes (i) average acquisition cost, including national average drug acquisition cost; (ii) average manufacturer price; (iii) average wholesale price; (iv) brand effective rate or generic effective rate; (v) discount indexing; (vi) federal upper limits; (vii) wholesale acquisition cost; and (viii) any other term that a pharmacy benefits manager or a carrier may use to establish reimbursement rates to a pharmacist or pharmacy for pharmacist services.

"Pharmacy benefits management" means the administration or management of prescription drug benefits provided by a carrier for the benefit of covered individuals.

"Pharmacy benefits manager" or "PBM" means a person that performs pharmacy benefits management. "Pharmacy benefits manager" includes a person acting for a PBM in a contractual or employment relationship in the performance of pharmacy benefits management for a carrier, nonprofit hospital, or third-party payor under a health program administered by the Commonwealth.

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

"Rebate" means a discount or other price concession, including without limitation incentives, disbursements, and reasonable estimates of a volume-based discount, or a payment that is (i) based on utilization of a prescription drug and (ii) paid by a manufacturer or third party, directly or indirectly, to a pharmacy benefits manager, pharmacy services administrative organization, or pharmacy after a claim has been processed and paid at a pharmacy.

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

"Spread pricing" means the model of prescription drug pricing in which the pharmacy benefits manager charges a health benefit plan a contracted price for prescription drugs, and the contracted

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59 price for the prescription drugs differs from the amount the pharmacy benefits manager directly or
60 indirectly pays the pharmacist or pharmacy for pharmacist services.

61 **§ 38.2-3466. Registration.**

62 A. A person may not establish or operate as a pharmacy benefits manager in the Commonwealth for
63 health benefit plans without registering with the Commissioner.

64 B. The Commissioner shall prescribe the registration process to operate in the Commonwealth as a
65 pharmacy benefits manager and may charge an initial application fee of \$1,000 and an annual renewal
66 fee of \$500.

67 C. The form for registration of a pharmacy benefits manager shall collect the following information:

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

69 2. The name and address of the pharmacy benefits manager's agent for service of process in the
70 Commonwealth;

71 3. The name and address of each person with management or control over the pharmacy benefits
72 manager;

73 4. The name and address of each person with a beneficial ownership interest in the pharmacy
74 benefits manager; and

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

80 D. A pharmacy benefits manager applicant shall provide the Commissioner with a signed statement
81 indicating that, to the best of its knowledge, no officer with management or control of the pharmacy
82 benefits manager has been convicted of a felony or has violated any of the requirements of state law
83 applicable to pharmacy benefits managers, or, if the applicant cannot provide such a statement, a
84 signed statement describing the relevant conviction or violation.

85 **§ 38.2-3467. Prohibited conduct by carriers.**

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

88 1. Cause or knowingly permit the use of any advertisement, promotion, solicitation, representation,
89 proposal, or offer that is untrue, deceptive, or misleading;

90 2. Charge a pharmacist or pharmacy a fee related to the adjudication of a claim;

91 3. Engage, with the express intent or purpose of driving out competition or financially injuring
92 competitors, in a pattern or practice of reimbursing retail community pharmacies or pharmacists in the
93 Commonwealth consistently less than the amount that the pharmacy benefits manager reimburses a
94 pharmacy benefits manager affiliate for providing the same pharmacist services;

95 4. Collect or require a pharmacy or pharmacist to collect from an insured a copayment for a
96 prescription drug at the point of sale in an amount that exceeds the lesser of:

97 a. The contracted copayment amount;

98 b. The amount an individual would pay for a prescription drug if that individual was paying cash; or

99 c. The contracted amount for the drug;

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

105 6. Penalize or provide an inducement to a covered individual for the purpose of having the covered
106 individual use a specific retail community pharmacy, mail order pharmacy, or another network
107 pharmacy provider that is a pharmacy benefits manager affiliate;

108 7. Prohibit a pharmacist or pharmacy from offering and providing direct and limited delivery
109 services, including incidental mailing services, to an insured as an ancillary service of the pharmacy;

110 8. Charge a fee related to the adjudication of a claim without providing the cause for each
111 adjustment or fee; or

112 9. Directly or indirectly engage in steering a covered individual to a pharmacy in which the
113 pharmacy benefits manager maintains an ownership interest or control without making a written
114 disclosure to and receiving acknowledgment from the covered individual. The disclosure shall provide
115 notice that (i) the pharmacy benefits manager has an ownership interest in or control of the pharmacy
116 and (ii) the covered individual has the right to use any alternative pharmacy that the covered individual
117 chooses. No pharmacy benefits manager shall retaliate or further attempt to influence the covered
118 individual or treat the covered individual or the covered individual's claim any differently if the covered
119 individual chooses to use the alternative pharmacy; or

120 10. Penalize or retaliate against a pharmacist or pharmacy for exercising rights provided pursuant

to the provisions of this article.

B. No carrier, on its own or through its contracted pharmacy benefits manager or representative of a pharmacy benefits manager, shall impose pharmacy or other provider accreditation standards or certification requirements that are inconsistent with, more stringent than, or in addition to requirements of the Virginia Board of Pharmacy or other state or federal entity.

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

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

§ 38.2-3468. Required carrier business practices.

A. Each carrier, on its own or through its contracted pharmacy benefits manager or representative of a pharmacy benefits manager, shall:

1. Ensure that, before a particular drug is placed or continues to be placed on a Maximum Allowable Cost List, the drug shall:

a. Be listed as "A" or "B" rated in the most recent version of the federal Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book, or has an "NR" or "NA" rating, or a similar rating, by a nationally recognized reference;

b. Be available for purchase in the Commonwealth from national or regional wholesalers operating in the Commonwealth; and

c. Not be obsolete;

2. Provide a process for network pharmacy providers to readily access the maximum allowable cost specific to that provider;

3. Update its Maximum Allowable Cost List at least once every seven calendar days;

4. Provide a process for each pharmacy subject to the Maximum Allowable Cost List to access any updates to the Maximum Allowable Cost List;

5. Ensure that dispensing fees are not included in the calculation of maximum allowable cost; and

6. Establish a reasonable administrative appeal procedure by which a contracted pharmacy can appeal the provider's reimbursement for a drug subject to maximum allowable cost pricing if the reimbursement for the drug is less than the net amount that the network provider paid to the suppliers of the drug. The reasonable administrative appeal procedure shall include:

a. A dedicated telephone number and email address or website for the purpose of submitting administrative appeals; and

b. The ability to submit an administrative appeal directly to the pharmacy benefits manager regarding the pharmacy benefits plan or program or through a pharmacy service administrative organization if the pharmacy service administrative organization has a contract with the pharmacy benefits manager that allows for the submission of such appeals.

B. A pharmacy shall be allowed no less than 10 calendar days after the applicable fill date to file an administrative appeal.

C. If an appeal is initiated, the carrier either directly or through its pharmacy benefits manager shall within 10 calendar days after receipt of notice of the appeal either:

1. If the appeal is upheld:

a. Notify the pharmacy or pharmacist or his designee of the decision;

b. Make the change in the Maximum Allowable Cost effective as of the date the appeal is resolved;

c. Permit the appealing pharmacy or pharmacist to reverse and rebill the claim in question; and

d. Make the change effective for each similarly situated pharmacy as defined by the payor subject to the Maximum Allowable Cost List effective as of the date the appeal is resolved; or

2. If the appeal is denied, provide the appealing pharmacy or pharmacist the reason for the denial, the National Drug Code number, and the names of the national or regional pharmaceutical wholesalers operating in the Commonwealth.

§ 38.2-3469. Examination of books and records; reports; access to records.

A. Each carrier, on its own or through its contract for pharmacy benefits, shall ensure that the Commissioner may examine or audit the books and records of a pharmacy benefits manager providing claims processing services or other prescription drug or device services for a carrier that are relevant to determining if the pharmacy benefits manager is in compliance with this article. The carrier shall be responsible for the charges incurred in the examination, including the expenses of the Commissioner or his designee and the expenses and compensation of his examiners and assistants. The Commissioner or his designee promptly shall institute a civil action to recover the expenses of examination in any case where there is a refusal or failure to pay such expenses and compensation.

B. Any carrier, on its own or through its contract for pharmacy benefits, shall report to the

182 Commissioner on a quarterly basis for each health benefit plan the following information:

183 1. The aggregate amount of rebates received by the pharmacy benefits manager;

184 2. The aggregate amount of rebates distributed to the appropriate health benefit plan;

185 3. The aggregate amount of rebates passed on to the enrollees of each health benefit plan at the
186 point of sale that reduced the enrollees' applicable deductible, copayment, coinsurance, or other
187 cost-sharing amount;

188 4. The individual and aggregate amount paid by the health benefit plan to the pharmacy benefits
189 manager for services itemized by pharmacy, by product, and by goods and services; and

190 5. The individual and aggregate amount a pharmacy benefits manager paid for services itemized by
191 pharmacy, by product, and by goods and services.

192 C. The information or data acquired from reports or an examination pursuant to this section is
193 considered proprietary and confidential and is not subject to the Virginia Freedom of Information Act
194 (§ 2.2- 3700 et seq.).

195 **§ 38.2-3470. Enforcement; regulations.**

196 A. The Commission shall enforce this article. However, the Commission shall have no jurisdiction to
197 adjudicate individual controversies arising out of this article.

198 B. Pursuant to the authority granted by § 38.2-223, the Commission may promulgate such rules and
199 regulations as it may deem necessary to implement this article.

200 **§ 38.2-3471. Scope of article.**

201 This article shall not apply with respect to claims under (i) an employee welfare benefit plan as
202 defined in section 3 (1) of the Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1002(1),
203 that is self-insured or self-funded; (ii) coverages issued pursuant to Title XIX of the Social Security Act,
204 42 U.S.C. § 1396 et seq. (Medicaid); or (iii) prescription drug coverages issued pursuant to Part D of
205 Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. (Medicare Part D).

206 2. That provisions of the first enactment of this act shall become effective on October 1, 2020,
207 except that the provisions of the first enactment that apply to contracts between a carrier and a
208 pharmacy benefits manager shall apply to all such contracts delivered, renewed, reissued, or
209 extended on or after October 1, 2020, and to all such contracts to which a term is changed on or
210 after such date.

211 3. That the State Corporation Commission shall establish a procedure, to be in effect by August 1,
212 2020, for any pharmacy benefits manager to apply for registration, prior to October 1, 2020, for a
213 registration to be issued on or after October 1, 2020, pursuant to § 38.2-3466 of the Code of
214 Virginia, as created by the first enactment of this act.