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& Sen. Sokola
Reps. Baumbach, Briggs King, Osienski, K. Williams,
Bush; Sens. Gay, Hansen, Hocker, Lawson, Lopez,
Pettyjohn, Poore, Walsh, Wilson

HOUSE OF REPRESENTATIVES
151st GENERAL ASSEMBLY

HOUSE BILL NO. 219

AN ACT TO AMEND TITLE 18 OF THE DELAWARE CODE RELATING TO PHARMACY BENEFITS MANAGERS.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE (Three-fifths of all members elected to each house thereof concurring therein):

Section 1. Amend § 3302A, Title 18 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 3302A. Definitions.

For purposes of this subchapter:

(1) "Entity" means a pharmacy benefits manager or any person or organization that represents these companies, groups, or organizations.

(2) "Pharmacy benefits manager" or "PBM" means an entity that contracts with pharmacists or pharmacies on behalf of ~~an insurer or third-party administrator to:~~ a person to do any of the following:

a. Process claims for prescription drugs or medical supplies or provide retail network management for pharmacies or ~~pharmacists;~~ pharmacists.

b. Pay pharmacies or pharmacists for prescription drugs or medical ~~supplies;~~ or supplies.

c. Negotiate rebates with manufacturers for drugs paid for or procured as described in this chapter.

(3) "Plan sponsor" ~~has the meaning given in~~ means as defined under § 4405 of this title.

Section 2. Amend Chapter 33A, Title 18 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

Subchapter II. Maximum Allowable Cost Pricing for Prescription Drugs and Reimbursement for and Provision of Pharmacy Goods or Services.

Section 3. Amend § 3323A, Title 18 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 3323A. Requirements for maximum allowable cost pricing.

(a) To place a drug on a maximum allowable cost list, a pharmacy benefits manager must ensure that the drug meets all of the following requirements:

(1) It is listed as "A" or "B" rated in the most recent version of the ~~FDA's~~ United States 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.

(2) It is generally available for purchase by pharmacies in this State from national or regional wholesalers.

(3) It is not obsolete, temporarily unavailable, or listed on a drug shortage list as in shortage.

(4) If it is manufactured by more than 1 manufacturer, the drug is available for purchase by a contracted pharmacy, including a contracted retail pharmacy, in this State from a wholesale distributor with a permit in this ~~State~~ State, with whom the pharmacy has an existing relationship.

(5) If it is manufactured by only 1 manufacturer, the drug is generally available for purchase by a contracted pharmacy, including a contracted retail pharmacy, in this State from at least 2 wholesale distributors with a permit in this State.

Section 4. Amend § 3324A, Title 18 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 3324A. Appeals.

(a) A pharmacy benefits manager must establish a process by which a contracted pharmacy can appeal the provider's reimbursement for a drug subject to maximum allowable cost pricing. A contracted pharmacy has 10 calendar days after the applicable fill date to appeal a maximum allowable cost if the reimbursement for the drug is less than the net amount that the network provider paid to the supplier of the drug. A pharmacy benefits manager must respond with notice that the ~~challenge~~ appeal has been denied or ~~sustained~~ granted within 10 calendar days of the contracted pharmacy making the claim for which an appeal has been submitted.

(b) At the beginning of the term of a network provider's contract, and upon renewal, a pharmacy benefits manager must provide to network providers a telephone number ~~or~~ and e-mail address at which a network provider can contact the pharmacy benefits manager to process an appeal under this section.

(c) If an appeal is denied, the pharmacy benefits manager must provide the reason for the denial and the name and ~~the national drug code number from of the~~ national or regional wholesalers operating in Delaware this State that have the drug in stock at a price below the maximum allowable cost.

(d) If the appeal is ~~sustained~~, granted the pharmacy benefits manger shall do the following:

(1) For an appealing pharmacy, do all of the following:

- 51 a. Adjust the maximum allowable cost for the drug as of the date of the original claim for payment.
- 52 b. Without requiring the appealing pharmacy to reverse and rebill the claims, provide reimbursement for
- 53 the claim and any subsequent and similar claims under similarly applicable contracts with the pharmacy benefits
- 54 manager as follows:

55 1. For the original claim, in the first remittance to the pharmacy after the date the appeal was

56 ~~determined, granted.~~

57 2. For subsequent and similar claims under similarly applicable contracts, in the second remittance to

58 the pharmacy after the date the appeal was ~~determined granted.~~

59 (2) For a similarly situated contracted pharmacy in this State, do all of the following:

60 a. Adjust the maximum allowable cost for the drug as of the date the appeal was ~~determined granted.~~

61 b. Provide notice to the pharmacy or the pharmacy's contracted agent of all of the following:

62 1. That an appeal was ~~upheld granted.~~

63 2. That without filing a separate appeal, the pharmacy or the pharmacy's contracted agent may

64 reverse and rebill a similar claim.

65 (e) A pharmacy benefits manager shall make available on its website information about the appeal process,

66 including all of the following:

67 (1) A telephone number at which the contracted pharmacy may contact the department or office responsible

68 for processing appeals for the pharmacy benefits manager to speak to an individual specifically or leave a message for

69 an individual or office who is responsible for processing appeals.

70 (2) An email address of the department or office responsible for processing appeals to which an individual

71 who is responsible for processing appeals has access.

72 (f) A pharmacy benefits manager may not charge a contracted pharmacy a fee related to the re-adjudication of a

73 claim resulting from a ~~sustained granted~~ appeal under subsection (d) of this section or the ~~upholding~~ granting of an appeal

74 under subsection (h) of this section.

75 (g) A pharmacy benefits manager may not retaliate against a contracted pharmacy for exercising its right to appeal

76 ~~or filing a complaint with the Commissioner, as permitted under this section to the pharmacy benefits manager under~~

77 subsection (a) of this section or to the Commissioner under subsection (h) of this section.

78 (h)(1) If a pharmacy benefits manager denies an appeal and a ~~contract~~ contracted pharmacy files ~~a complaint an~~

79 appeal with the Commissioner, the Commissioner shall do all of the following:

a. Review the pharmacy benefits manager's compensation program to ensure that the reimbursement for pharmacy benefits management services paid to the pharmacist or a pharmacy complies with this subchapter and the terms of the contract.

b. Based on a determination made by the Commissioner under paragraph (h)(1)a. of this section, do 1 of the following.

1. ~~Dismiss-Deny~~ the appeal.

2. ~~Uphold-Grant~~ the appeal and order the pharmacy benefits manager to pay the claim in accordance with the Commissioner's findings.

(2) All pricing information and data collected by the Commissioner during a review required by paragraph (h)(1) of this section is confidential and not subject to subpoena or the Freedom of Information Act, Chapter 100 of Title 29.

Section 5. Amend Subchapter II, Chapter 33A, Title 18 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 3325A. Reimbursement for and Provision of Pharmacy Goods or Services.

(a) For purposes of this section:

(1) "Affiliate" means a pharmacy or pharmacist that directly or indirectly, through 1 or more intermediaries, owns or controls, is owned or controlled by, or is under common ownership or control with, a pharmacy benefits manager.

(2) "Pharmaceutical wholesaler" means a person that sells and distributes a pharmaceutical product and offers regular and private delivery to a pharmacy.

(3) "Pharmacy acquisition cost" means the amount that a pharmaceutical wholesaler charges for a pharmaceutical product as listed on the pharmacy's billing invoice.

(4) "Pharmacy goods or services" means 1 or more of the following provided by a pharmacist or pharmacy:

a. A single-sourced drug, multi-sourced drug, or compounded drug.

b. A medical product.

c. A medical device.

d. A service.

(b) A pharmacy benefits manager may not reimburse a pharmacist or pharmacy for pharmacy goods or services in an amount less than the amount the pharmacy benefits manager reimburses itself or an affiliate for the same pharmacy goods or services.

(c) If the amount reimbursed by a pharmacy benefits manager for pharmacy goods or services is less than the pharmacy acquisition cost for the same pharmacy goods or services, a pharmacist or pharmacy may decline to provide the pharmacy goods or services to a patient.

(d) A pharmacist or pharmacy acting under subsection (c) of this section shall do all of the following:

(1) Inform the patient that the pharmacist or pharmacy has made the decision not to provide pharmacy goods or services to the patient under subsection (c) of this section because of the costs associated with providing the pharmacy goods or services.

(2) Provide the patient with a list of pharmacies in the area that may provide the pharmacy goods or services.

Section 6. Amend § 3331A, Title 18 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows and by redesignating accordingly:

§ 3331A. Definitions.

~~As used in~~ For purposes of this subchapter:

(1) ~~“Health insurance” means as defined in § 903 of this title.~~

(2) ~~“Insured” means an individual covered by health insurance offered by an insurer.~~

(3) ~~“Insurer” means any entity that provides health insurance in this State.~~

(4) “Pharmacist” means as defined in § 2502 of Title 24.

(5) “Pharmacy” means as defined in § 2502 of Title 24.

(6) “Pharmacy benefit manager” means as defined under § 3302A of this title.

(7) “Substitute” means as defined in § 2502 of Title 24.

Section 7. Amend § 3332A, Title 18 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 3332A. Permitted disclosures related to prescription drugs.

A contract between a pharmacy benefits manager and a pharmacy may not prohibit a pharmacy or pharmacist from doing any of the following:

(1) Providing ~~an insured~~ a patient with information regarding the retail price of a prescription drug or the amount of the cost share for which the ~~insured~~ patient is responsible for a prescription drug.

(2) Discussing with ~~an insured~~ a patient information regarding the retail price of a prescription drug or the amount of the cost share for which the ~~insured~~ patient is responsible for a prescription drug.

(3) If a more affordable substitute is available, selling the more affordable substitute to the ~~insured~~ patient.

Section 8. Amend § 3351A, Title 18 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 3351A. Definitions.

For purposes of this subchapter:

(1) “Pharmacy benefits management services” means all of the following:

a. The procurement of prescription drugs at a negotiated rate for dispensation within this State to beneficiaries.

b. The administration or management of prescription drug coverage provided by a purchaser for beneficiaries.

c. Any of the following services provided with regard to the administration of prescription drug coverage:

1. Mail service pharmacy.

2. Claims processing, retail network management, and payment of claims to pharmacies for prescription drugs dispensed to beneficiaries.

3. Clinical formulary development and management services.

4. Rebate contracting and administration. For purposes of this paragraph (1)c.4., “rebate” means as defined in § 3361A of this title.

5. Patient compliance, therapeutic intervention, and generic substitution programs.

6. Disease management programs.

(2) “Pharmacy benefits manager” means as defined under § 3302A of this title.

(3) “Purchaser” means ~~an insurance company, health service corporation, health maintenance organization, managed care organization, and any other entity~~ a person that does all of the following:

a. Provides prescription drug coverage or benefits in this State.

b. Enters into agreement with a pharmacy benefits manager for the provision of pharmacy benefits management services.

Section 9. Amend § 3353A, Title 18 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 3353A. Registration required.

(c) A pharmacy benefits manager applying for registration shall do all of the following:

(1) File with the Commissioner an application on the form that the Commissioner provides.

(2) Pay to the Commissioner a \$150 \$1,000 nonrefundable registration fee.

(f) Except where prohibited by state or federal law, a pharmacy benefits manager applying for registration is deemed to have appointed the Commissioner as agent for service of process in an action or proceeding arising in this State out of or in connection with the exercise of the registration. The appointment of the Commissioner as agent for service of process is irrevocable during the period within which a cause of action against the pharmacy benefits manager may arise out of transactions with respect to pharmacy benefits management services provided in this State. The process must be served on the Commissioner or a Deputy Insurance Commissioner or another person designated by the Commissioner by rule or regulation.

Section 10. Amend § 3354A, Title 18 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 3354A. Expiration and renewal of registration.

(b) A pharmacy benefits manager may renew its registration for an additional 1-year term if the pharmacy benefits manager otherwise is entitled to be registered and does all of the following:

(1) Files with the Commissioner a registration renewal application on the form that the Commissioner requires.

(2) Pays to the Commissioner a ~~\$150~~ \$1,000 nonrefundable renewal fee.

Section 11. Amend § 3355A, Title 18 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 3355A. Denial, suspension, or revocation of registration.

(a) The Commissioner may ~~issue a cease and desist order to~~ deny a registration to a pharmacy benefits manager applicant or refuse to renew, suspend, or revoke the registration of, or issue a cease and desist order to, a pharmacy benefits manager ~~that is registered or seeking renewal of a registration~~ if the pharmacy benefits manager, or an officer, director, or employee of the pharmacy benefits ~~manager~~ manager, does any of the following:

(1) Makes a material misstatement, misrepresentation, or omission in a registration or registration renewal application.

(2) Fraudulently or deceptively obtains or attempts to obtain a registration or renewal of a registration.

(3) In connection with the administration of pharmacy benefits management services, commits fraud or engages in illegal or dishonest activities.

(4) Violates any provision of this chapter or a regulation adopted under this chapter.

(b) ~~If a pharmacy benefits manager that is registered or seeking renewal of a registration does not comply with a cease and desist order issued by the Commissioner under subsection (a) of this section, the Commissioner may deny, refuse to renew, suspend, or revoke its registration. [Repealed.]~~

Section 12. Amend Chapter 33A, Title 18 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

Subchapter VI. Pharmacy Benefits Manager Network Requirements.

§ 3361A. Definitions.

For purposes of this subchapter:

(1) “Claim” means as defined under § 3321A of this title.

(2) “Insured” means an individual covered by health insurance offered by an insurer.

(3) “Insurer” means as defined under § 3321A of this title.

(4) “Pharmacist” means as defined under § 2502 of Title 24.

(5) “Pharmacy” means as defined under § 2502 of Title 24.

(6) “Pharmacy benefits manager” means as defined under § 3302A of this title.

(7) “Pharmacy benefits manager network” means a network of pharmacists or pharmacies that are offered by an agreement or contract to provide pharmacy goods or services.

(8) “Pharmacy goods or services” means as defined under § 3325A of this title.

(9)a. “Rebate” means a discount or other price concession, or a payment that is both of the following:

1. Based on utilization of a prescription drug.

2. Paid by a manufacturer or third party, directly or indirectly, to the pharmacy benefits manager, pharmacy services administrative organization, or pharmacy after a claim has been processed and paid at a pharmacy.

b. “Rebate” includes incentives, disbursements, and reasonable estimates of a volume-based or category-based discount.

§ 3362A. Pharmacy benefits manager network.

(a) A pharmacy benefits manager shall provide a reasonably adequate and accessible pharmacy benefits manager network for the provision of prescription drugs, which provides for convenient patient access to pharmacies within a reasonable distance from a patient’s residence.

(b) A pharmacy benefits manager may not deny a pharmacy the opportunity to participate in a pharmacy benefits manager network at preferred participation status if the pharmacy is willing to accept the terms and conditions that the pharmacy benefits manager has established for other pharmacies as a condition of preferred network participation status.

(c) A mail-order pharmacy may not be included in the calculations for determining pharmacy benefits manager network adequacy under this section.

§ 3363A. Reports.

(a) A pharmacy benefits manager shall provide a pharmacy benefits manager network adequacy report describing the pharmacy benefits manager network and the pharmacy benefits manager network's accessibility in this State. The Commissioner shall adopt regulations setting the time and manner for providing the report.

(b) A pharmacy benefits manager shall report to the Commissioner on a quarterly basis all of the following information for each insurer:

(1) The itemized amount of pharmacy benefits manager revenue sources, including professional fees, administrative fees, processing fees, audits, direct and indirect remuneration fees, or any other fees.

(2) The aggregate amount of rebates distributed to the appropriate insurer.

(3) The aggregate amount of rebates passed on to insureds of each insurer at the point of sale that reduced the insureds' applicable deductible, copayment, coinsurance, or other cost-sharing amount.

(4) The individual and aggregate amount the insurer paid to the pharmacy benefits manager for pharmacy goods or services itemized by all of the following:

a. Pharmacy.

b. Product.

c. Goods and services.

(5) The individual and aggregate amount a pharmacy benefits manager paid for pharmacy goods or services itemized by all of the following:

a. Pharmacy.

b. Product.

c. Goods and services.

(c) The information provided under subsection (b) of this section is confidential and not subject to subpoena or the Freedom of Information Act, Chapter 100 of Title 29.

Section 13. Amend Chapter 33A, Title 18 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

Subchapter VII. Prohibited Practices; Penalties; Enforcement.

§ 3371A. Definitions.

For purposes of this subchapter:

(1) “Board of Pharmacy” means the Delaware State Board of Pharmacy.

(2) “Claim” means as defined under § 3321A of this title.

(3) “Insurer” means as defined under § 3321A of this title.

(4) “Pharmacist” means as defined under § 2502 of Title 24.

(5) “Pharmacy” means as defined under § 2502 of Title 24.

(6) “Pharmacy benefits manager” means as defined under § 3302A of this title.

(7) “Pharmacy benefits manager network” means a network of pharmacists or pharmacies that are offered by an agreement or contract to provide pharmacy goods or services.

(8) “Pharmacy goods or services” means as defined under § 3325A of this title.

(9) “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 price for the prescription drugs differs from the amount the pharmacy benefits manager directly or indirectly pays the pharmacist or pharmacy for pharmacy goods or services.

§ 3372A. Prohibited practices.

A pharmacy benefits manager or representative of a pharmacy benefits manager may not do any of the following:

(1) Engage in spread pricing.

(2) Cause or knowingly permit the use of any advertisement, promotion, solicitation, representation, proposal, or offer that is untrue, deceptive, or misleading.

(3) Unless reviewed and approved by the Commissioner, charge a pharmacist or pharmacy a fee related to the adjudication of a claim, including a fee for any of the following:

a. The receipt and processing of a pharmacy claim.

b. The development or management of claims processing services in a pharmacy benefits manager network.

c. Participation in a pharmacy benefits manager network.

(4) Unless reviewed and approved by the Commissioner in coordination with the Board of Pharmacy, require pharmacy accreditation standards or certification requirements inconsistent with, more stringent than, or in addition to requirements of the Board of Pharmacy.

(5) Violate § 3325A(b) of this title.

(6) Violate § 3362A of this title.

(7) Pay or reimburse a pharmacy or pharmacist for the ingredient drug product component of pharmacist services less than the national average drug acquisition cost, or if the national average drug acquisition cost is unavailable, the wholesale acquisition cost.

(8) Make or permit any reduction of payment for pharmacy goods or services by a pharmacy benefits manager or an insurer directly or indirectly to a pharmacy under a reconciliation process to an effective rate of reimbursement, including generic effective rates, brand effective rates, direct and indirect remuneration fees, or any other reduction or aggregate reduction of payment.

(9) After adjudication of a claim for pharmacy goods or services, directly or indirectly retroactively deny or reduce the claim unless 1 or more of the following applies:

a. The original claim was intentionally submitted fraudulently.

b. The original claim payment was incorrect because the pharmacy or pharmacist had already been paid for the pharmacy goods or services.

c. The pharmacy goods or services were not properly rendered by the pharmacy or pharmacist.

Section 14. Amend Subchapter V, Chapter 33A, Title 18 and Subchapter VII, Chapter 33A, Title 18 of the Delaware Code by transferring § 3359A of Title 18 to Subchapter VII, Chapter 33A, Title 18, redesignating § 3359A as § 3373A, and then by making deletions as shown by strike through and insertions as shown by underline as follows:

~~§ 3359A.~~ 3373A. Penalties and enforcement.

(a) If the Commissioner determines that a pharmacy benefits manager has violated any provision of this chapter or any regulation adopted under this chapter, the Commissioner may, after notice and a hearing, issue an order that requires the pharmacy benefits manager to do 1 or more of the following:

(1) Cease and desist from the identified violation and further similar violations.

(2) Take specific affirmative action to correct the violation.

(3) Make restitution of money, property, or other assets to a person that has suffered financial injury because of the violation.

(4) Pay a fine in an amount determined by the Commissioner, not to exceed \$10,000, for each violation of this chapter.

(5) Pay the costs, including applicable attorneys' fees, incurred by the Commissioner in bringing the action.

314 (b) A hearing under this section must be held under §§ 323 through 328 of this title and any regulations adopted by
315 the Commissioner.

316 (c) The Commissioner may adopt regulations to enforce this chapter and to establish a complaint process and set
317 associated fees to address grievances and appeals brought under this chapter.

318 Section 15. This Act applies to contracts between pharmacy benefit managers and pharmacies or pharmacists that
319 are entered into, renewed, or extended on or after the effective date of this Act.

SYNOPSIS

Over 80% of pharmaceuticals in the United States are purchased through pharmacy benefits manager ("PBM") networks. PBMs serve as intermediaries between health plans, pharmaceutical manufacturers, and pharmacies or pharmacists, and PBMs establish networks for patients to receive reimbursement for drugs. Given the scope of PBMs in the healthcare delivery system, this Act is designed to provide enhanced oversight and transparency as it relates to PBMs.

Specifically, this Act does the following:

(1) If a PBM denies an appeal for reimbursement subject to maximum allowable cost pricing, requires the PBM to provide the national drug code number of wholesalers in Delaware that have the drug in stock below maximum allowable cost.

(2) Authorizes a pharmacy or pharmacist to decline to dispense a prescription drug or provide a pharmacy service to a patient if the amount reimbursed by a PBM is less than the pharmacy acquisition cost. If a pharmacy or pharmacist declines to provide a drug or service, the pharmacy or pharmacist must inform the patient that the pharmacy or pharmacist did this because of the costs of providing the drug or service and provide the patient with a list of pharmacies in the area that may provide the drug or service.

(3) Requires PBMs to provide a reasonably adequate and accessible pharmacy benefits manager network.

(4) Increases transparency by requiring PBMs to provide reports to the Insurance Commissioner on network adequacy and the amount of rebates received by PBMs to provide reports to the Insurance Commissioner on network adequacy and the amount of rebates received by PBMs and distributed to insurers or patients.

(5) Prohibits PBMs from engaging in certain conduct, such as spread pricing, false advertising, and reimbursing a pharmacist or pharmacy in an amount less than the PBM reimburses itself or an affiliate for the same drug or service. If a PBM engages in prohibited conduct, the Insurance Commissioner is authorized to deny, suspend, or revoke the PBM's registration under § 3355A of Title 18 or impose penalties or take other enforcement action under § 3359A of Title 18.

(6) Clarifies that the Insurance Commissioner is authorized to deny an application for registration filed by a PBM.

(7) Increases the registration and renewal fee to be paid by a PBM to better reflect the cost of the registration and renewal process and better align with the fee assessed by other states that require PBMs to register.

(8) Transfers § 3359A of Title 18 (regarding penalties and enforcement) to a separate subchapter focused on prohibited practices, penalties, and enforcement.

In addition, this Act makes technical corrections to conform existing law to the standards of the Delaware Legislative Drafting Manual.

Finally, this Act requires a greater than majority vote for passage because § 10 of Article VIII of the Delaware Constitution requires the affirmative vote of three-fifths of the members elected to each house of the General Assembly to increase the effective rate of any tax levied or license fee imposed.