SPONSOR: Rep. Bennett & Sen. Paradee
Reps. Baumbach, Bush, Dorsey Walker, Griffith, Q. Johnson, Matthews, Seigfried, D. Short, Spiegelman, Viola, K. Williams; Sens. Delcollo, Hansen, Sokola, Townsend

HOUSE OF REPRESENTATIVES
150th GENERAL ASSEMBLY

HOUSE BILL NO. 194

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 § 3321A, Title 18 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 3321A. Definitions. [For application of this section, see 80 Del. Laws, c. 245, § 2]

As used in this subchapter:

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

(2) “Contracted pharmacy” means a pharmacy that participates in the network of a pharmacy benefits manager through a contract with a pharmacy benefits manager, a pharmacy services administration organization, or a group purchasing organization.

(3) “Drug shortage list” means a list of drug products listed on the federal Food and Drug Administration’s Drug Shortages website.

~~(2)~~ (4) "Insurer" means any entity that provides health insurance coverage in this State as defined in § 903 of this title.

~~(3) "List" means the list of drugs for which a pharmacy benefit manager has established a maximum allowable cost.~~

~~(4)~~ (5) "Maximum allowable cost" means the maximum amount that a pharmacy ~~benefit~~ benefits manager will reimburse a pharmacist or pharmacy for the cost of a multi-sourced ~~drug.~~ drug, medical product, or device.

(6) “Maximum allowable cost list” means the multi-source generic drugs, medical products, and devices for which a maximum allowable cost has been established by a pharmacy benefits manager or a purchaser.

~~(5)~~ (7) "Network providers" means those pharmacists and pharmacies who provide covered health-care services or supplies to an insured or a member pursuant to a contract with an insurer or pharmacy benefits manager.

~~(6)~~ (8) "Pharmacist" ~~has the meaning given that term in~~ means as defined under § 2502 of Title 24.

~~(7)~~ (9) "Pharmacy" ~~has the meaning given that term in~~ means as defined under § 2502 of Title 24.

(10) "Pharmacy benefits management services" means as defined under § 3341A of this title.

~~(8)~~ (11) "Pharmacy ~~benefit~~ benefits manager" ~~has the meaning given in~~ means as defined under § 3302A of this title.

(12) "Purchaser" means as defined under § 3341A of this title.

Section 2. 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. [For application of this section, see 80 Del. Laws, c. 245, § 2]

(a) To place a drug on a maximum allowable cost list, a pharmacy ~~benefit~~ 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 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 ~~the state~~ this State from national or regional wholesalers.

(3) It is not ~~obsolete.~~ 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.

(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.

(b) A pharmacy ~~benefit~~ benefits manager engaging in maximum allowable cost pricing ~~must:~~ must do all of the following:

(1) Make available to each network provider at the beginning of the term of the network provider's contract, and upon renewal of the contract, the sources utilized to determine the maximum allowable cost ~~pricing;~~ pricing.

(2) Provide a process for a network pharmacy ~~providers~~ provider to readily access the most recent maximum allowable cost specific to that ~~provider;~~ provider in an electronic format as updated in accordance with the requirements of this section.

(3) Review and update maximum allowable cost price information at least once every 7 business days and update the information when there is a modification of maximum allowable cost ~~pricing; and~~ pricing.

(4) Ensure that dispensing fees are not included in the calculation of maximum allowable cost.

(5) On the next day after a pricing information update under paragraph (b)(3) of this section, use the updated pricing information in calculating the payments made to all contracted pharmacies.

(6) Maintain a procedure to eliminate products from the maximum allowable cost list as necessary to do all of the following:

a. Remain consistent with price changes.

b. Remove from the maximum allowable cost list a drug that no longer meets the requirements of subsection (a) of this section.

c. Reflect the most recent availability of drugs in the marketplace.

Section 3. 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. [For application of this section, see 80 Del. Laws, c. 245, § 2]

(a) A pharmacy ~~benefit~~ 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 ~~ten~~ 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 ~~benefit~~ benefits manager must respond with notice that the challenge has been denied or sustained 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 ~~benefit~~ benefits manager must provide to network providers a telephone number or e-mail address at which a network provider can contact the pharmacy ~~benefit~~ benefits manager to process an appeal under this section.

(c) If an appeal is denied, the pharmacy ~~benefit~~ benefits manager must provide the reason for the denial and the name and the national drug code number from national or regional wholesalers operating in Delaware.

(d) If the appeal is sustained, the pharmacy benefits manager shall do the following: ~~make the price correction, permit the reporting pharmacy to reverse and rebill the appealed claim, and make the price correction effective for all similarly situated pharmacies from the date of the approved appeal.~~

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

a. Adjust the maximum allowable cost for the drug as of the date of the original claim for payment.

b. Without requiring the appealing pharmacy to reverse and rebill the claims, provide reimbursement for the claim and any subsequent and similar claims under similarly applicable contracts with the pharmacy benefits manager as follows:

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

2. For subsequent and similar claims under similarly applicable contracts, in the second remittance to the pharmacy after the date the appeal was determined.

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

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

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

1. That an appeal was upheld.

2. That without filing a separate appeal, the pharmacy or the pharmacy's contracted agent may reverse and rebill a similar claim.

(e) A pharmacy benefits manager shall make available on its website information about the appeal process, including all of the following:

(1) A telephone number at which the contracted pharmacy may contact the department or office responsible for processing appeals for the pharmacy benefits manager to speak to an individual specifically or leave a message for an individual or office who is responsible for processing appeals.

(2) An email address of the department or office responsible for processing appeals to which an individual who responsible for processing appeals has access.

(f) A pharmacy benefits manager may not charge a contracted pharmacy a fee related to the re-adjudication of a claim resulting from a sustained appeal under subsection (d) of this section or the upholding of an appeal under subsection (h) of this section.

(g) A pharmacy benefits manager may not retaliate against a contracted pharmacy for exercising its right to appeal or filing a complaint with the Commissioner, as permitted under this section.

(h)(1) If a pharmacy benefits manager denies an appeal and a contract pharmacy files a complaint 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 the appeal.

2. Uphold 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 4. 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 V. Registration of Pharmacy Benefits Managers.

§ 3341A. 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.

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 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.

§ 3342A. Registration required.

(a) A pharmacy benefits manager shall register with the Commissioner as a pharmacy benefits manager before providing pharmacy benefits management services in this State to a purchaser.

(b) A purchaser may not enter into an agreement or contract with a pharmacy benefits manager that has not registered with the Commissioner.

(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 non-refundable registration fee.

(d) The Commissioner may require any additional information or submissions from a pharmacy benefits manager that may be reasonably necessary to verify the information contained in the application.

(e) Subject to § 3344A of this title, the Commissioner shall register each pharmacy benefits manager that meets the requirements of this section.

§ 3343A. Expiration and renewal of registration.

(a) A pharmacy benefits manager registration expires on May 1 after its effective date unless it is renewed as provided under this section.

(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 non-refundable renewal fee.

(c) An application for renewal of a pharmacy benefits manager registration is to be considered made in a timely manner if it is postmarked on or before the date the pharmacy benefits manager's registration expires.

(d) The Commissioner may require additional information or submissions from a pharmacy benefits manager that may be reasonably necessary to verify the information contained in the registration renewal application.

(e) Subject to § 3344A of this title, the Commissioner shall renew the registration of each pharmacy benefits manager that meets the requirements of this section.

§ 3344A. Denial, suspension, or revocation of registration.

(a) The Commissioner may 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 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.

(c) If the action by the Commissioner is to deny or not renew a registration, the Commissioner shall notify the pharmacy benefits manager of the decision, in writing, including the reason for the denial or nonrenewal of the registration. The pharmacy benefits manager may, within 10 days after the Commissioner provides notice under this subsection, make written demand on the Commissioner for a hearing before the Commissioner to determine the reasonableness of the Commissioner's action. A hearing under this subsection must be held under §§ 323 through 328 of this title.

(d) This section does not limit any other regulatory authority of the Commissioner under this title.

§ 3345A. Recordkeeping requirements.

A pharmacy benefits manager shall maintain adequate books and records about each purchaser for which the pharmacy benefits manager provides pharmacy benefits management services as follows:

(1) In accordance with prudent standards of record keeping.

(2) For the duration of the agreement between the pharmacy benefits manager and the purchaser.

(3) For 3 years after the pharmacy benefits manager ceases to provide pharmacy benefits management services for the purchaser.

§ 3346A. Examination of affairs, transactions, accounts, and records.

(a) Whenever the Commissioner considers it advisable, the Commissioner may examine the affairs, transactions, accounts, and records of a registered pharmacy benefits manager.

(b) The examination must be conducted under § 320 of this title.

(c) The expense of an examination is to be borne by the pharmacy benefits manager being examined. The expense includes the reasonable and proper expenses of the Commissioner, and the Commissioner's examiners and assistants, including expert assistance, and a reasonable per diem as to the examiners and assistants as necessarily incurred in the examination. The pharmacy benefits manager examined shall promptly pay the examination expense on presentation by the Commissioner or the Commissioner's examiner of a reasonably detailed written account of the examination expense.

(d) The Commissioner shall issue reports of the examination and investigation under § 321 of this title.

§ 3347A. Permit required for nonresident pharmacy to deliver prescription drugs or devices.

A pharmacy benefits manager may not ship, mail, or deliver prescription drugs or devices to a person in this State through a nonresident pharmacy unless the nonresident pharmacy holds a permit issued under § 2535 of Title 24.

§ 3348A. 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.

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

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

Section 5. This Act takes effect on June 1, 2020.

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, and PBMs establish networks for consumers 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 PBMs. Specifically, this Act does the following:

(1) Requires PBMs to register with the Insurance Commissioner.

(2) Permits the Insurance Commissioner to issue cease and desist orders based on fraudulent acts or violations of Chapter 33A of Title 18 committed by PBMs.

(3) Requires PBMs to maintain certain records.

(4) Permits the Insurance Commissioner to examine the affairs of PBMs.

(5) Grants the Insurance Commissioner the authority to enforce Chapter 33A of Title 18 by imposing fines, requiring PBMs to take affirmative actions, and suspending, denying, or revoking a PBM's registration.

In addition, this Act updates existing law regarding maximum allowable cost lists and establishes a more transparent appeals process for a pharmacy to rely on if a PBM does not reimburse the pharmacy the amount owed under their contract or the maximum allowable cost list.

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