SPONSOR: Rep. B. Short & Sen. Henry
Reps. Gray, Baumbach, Kowalko, Potter; Sen. Cloutier

HOUSE OF REPRESENTATIVES
148th GENERAL ASSEMBLY

HOUSE BILL NO. 284

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

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. 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:

CHAPTER 33A. PHARMACY ~~AUDIT INTEGRITY PROGRAM~~ BENEFITS MANAGERS

Subchapter I. Pharmacy Audit Integrity Program

§ 3301A. Pharmacy Audit Integrity Program.

The Pharmacy Audit Integrity Program is established to provide standards for an audit of pharmacy records carried out by a pharmacy benefits manager or any entity that represents pharmacy benefits managers.

§ 3302A. Definitions.

For purposes of this ~~chapter~~ 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 ~~a person, business, or other entity that performs pharmacy benefits management. The term includes a person or entity acting for a PBM in a contractual or employment relationship in the performance of pharmacy benefits management.~~ an entity that contracts with pharmacists or pharmacies on behalf of an insurer or third party administrator to:

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

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

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

(3) "Plan sponsor" has the meaning given in § 4405 of this title.

§ 3306A. Documentation.

(b) Any legal prescription that meets the requirements in this ~~chapter~~ subchapter may be used to validate claims in connection with prescriptions, refills, or changes in prescriptions, including medication administration records, faxes, e-prescriptions, or documented telephone calls from the prescriber or the prescriber's agents.

§ 3310A. Applicability of other laws and regulations.

This ~~chapter~~ subchapter does not apply to any investigative audit that involves suspected fraud, willful misrepresentation, abuse, or any audit completed by the State.

Subchapter II. Maximum Allowable Cost Pricing for Prescription Drugs.

§ 3321A. Definitions.

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) "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) "Maximum allowable cost" means the maximum amount that a pharmacy benefit manager will reimburse a pharmacist or pharmacy for the cost of a multi-sourced drug.

(5) "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) "Pharmacist" has the meaning given that term in § 2502 of Title 24.

(7) "Pharmacy" has the meaning given that term in § 2502 of Title 24.

(8) "Pharmacy benefit manager" has the meaning given in § 3302A of this chapter.

§ 3322B. Exclusions.

This subchapter does not apply to the Department of Health and Human Services in the performance of its duties in administering fee-for-service Medicaid under Titles XIX and XXI of the Social Security Act.

§ 3323B. Requirements for maximum allowable cost pricing.

(a) To place a drug on a maximum allowable cost list, a pharmacy benefit manager must ensure that the drug meets 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 from national or regional wholesalers.

(3) It is not obsolete.

(b) A pharmacy benefit manager engaging in maximum allowable cost pricing must:

(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;

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

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

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

§ 3324B. Appeals.

(a) A pharmacy benefit 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 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 manager must respond with notice that the challenge has been denied or sustained within ten 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 manager must provide to network providers a telephone number or e-mail address at which a network provider can contact the pharmacy benefit manager to process an appeal under this section and receive a response regarding the appeal status within 2 business days.

(c) If an appeal is denied, the pharmacy benefit 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 an appeal is sustained, the pharmacy benefit manager must make an adjustment in the drug price effective the date of service for the first claim appealed and make the adjustment applicable to all similarly situated network pharmacy providers as of the time the claim was appealed, as determined by the managed care organization or pharmacy benefit manager, as appropriate.

Section 2. This Act is applicable to contracts between pharmacies and pharmacy benefit managers that are entered into, renewed, or extended on or after the effective date of this Act.

Section 3. This Act is effective on January 1, 2017.

SYNOPSIS

This bill requires pharmacy benefit managers who employ "maximum allowable cost," or "MAC" pricing for multi-sourced drugs to follow set standards in composing and updating the list, to provide information on MAC and how it is determined to pharmacies in their networks, and to create an appeal process for a participating pharmacy who believes the MAC has been set in error. This bill will encourage more efficient operation of the prescription drug market by setting ground rules and encouraging transparency, resulting in savings to consumers and protecting pharmacies who are small businesses. Similar laws have been passed in at least 11 states.

These new rules surrounding MAC pricing will be subchapter II of Chapter 33A, which was added to the code last year to address pharmacy audits conducted by pharmacy benefit managers. A conforming change is made so that the definition of pharmacy benefit manager is consistent across both subchapters.