

SPONSOR: Sen. Sokola & Rep. Burns
Sens. Sturgeon, Hoffner, Walsh, Hocker, Seigfried; Reps. Morrison, Romer, Snyder-Hall, Wilson-Anton, Lambert, Griffith

DELAWARE STATE SENATE
153rd GENERAL ASSEMBLY

SENATE BILL NO. 271
AS AMENDED BY
SENATE AMENDMENT NO. 1

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:

Section 1. Amend Subchapter I, Chapter 33A, 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:

§ 3302A. Definitions.

For purposes of this subchapter:

(4) "Recoupment" means a reduction, offset, adjustment, or other act that lowers or lessens the payment of a claim or any other amount owed to a pharmacy or pharmacist for any reason unrelated to that claim or other amount owed to that pharmacy or pharmacist.

(5) "Similarly situated contracted pharmacy" includes any contracted pharmacy that has the capability of complying with standard terms and conditions for a pharmacy type, even if the pharmacy does not operate exclusively as that type of pharmacy.

(6) "Wholesale invoice audit" means review of supplier invoices to verify accuracy, compliance with contracted rates, and receipt of goods.

§ 3304A. Procedure and process for conducting and reporting an audit.

(a) Audit procedures. — Unless otherwise prohibited by federal requirements or regulations, any entity conducting a pharmacy audit must adhere to the following procedures:

(1) A pharmacy must be given notice 14 days before an ~~initial on-site~~ audit is conducted.

(2) An audit that involves clinical or professional judgment must be conducted by or in consultation with a licensed pharmacist.

(3) Each pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies.

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(4) A pharmacy must be given a range of prescription numbers ~~in advance of~~ no less than 5 business days before the audit.

(5) A pharmacy benefits manager shall provide a pharmacy or pharmacist being audited with a phone number, secured facsimile number, or, if available, access to a secure portal that the pharmacy or pharmacist may use to ask questions regarding the audit.

(6) An entity may not initiate an audit of a pharmacy more often than once every 12 months.

(b) Audit process. — Unless otherwise prohibited by federal requirements or regulations, for any entity conducting a pharmacy audit all of the following audit items apply:

(2) If an entity uses random sampling as a method for selecting a set of claims for examination, the sample size must be appropriate for a statistically reliable sample. The auditing entity shall provide the pharmacy a masked list that provides a prescription number or date range that the auditing entity is seeking to ~~audit.~~ audit no less than 5 business days before an audit.

(3) An ~~on-site~~ audit may not take place during the first 5 business days of the month or on a federal holiday unless consented to by the pharmacy.

(8) If an entity conducts a wholesale invoice audit, the audit must be limited to verification of purchased inventory specific to the pharmacy claims paid by the plan sponsor or pharmacy benefits manager conducting the audit. Redacted copies of supplier invoices in the pharmacy's or pharmacist's possession are acceptable to support the validity of a pharmacy claim.

(9) The cost of any audit subject to this subchapter shall be borne by the pharmacy benefits manager conducting the audit. The pharmacy benefits manager may not impose a fee or charge, other than a recoupment or chargeback, or pass costs along related to an audit to the audited pharmacy or pharmacist.

§ 3309A. Disclosures to plan sponsor.

Where contractually required, an auditing entity must provide a copy to the plan sponsor of ~~its~~ all claims that were included in the audit, and any recouped money shall be returned to the plan sponsor.

§ 3310A. Applicability of other laws and regulations.

The provisions of this subchapter do not apply to an investigative audit of pharmacy records when any of the following apply:

(1) Fraud, waste, abuse, or ~~other~~ intentional misconduct is indicated by physical review or review of claims data or statements.

Section 2. 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 and by redesignating accordingly:

§ 3321A. Definitions.

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

(7) "Net amount" means the dollar amount that is the result of the invoice price that the pharmacy paid to the supplier for the prescription drug modified as follows, as are attributable to the drug:

a. Increased by the dollar amount of all taxes, fees, and other costs.

b. Decreased by the dollar amount of all discounts and other cost reductions.

(14) "Similarly situated contracted pharmacy" means as defined in § 3302A of this title.

§ 3324A. Appeals.

(a) (1)a. A pharmacy benefits manager must establish a process by which a contracted pharmacy can appeal the amount of the provider's reimbursement for a drug ~~subject to maximum allowable cost pricing.~~ that was reimbursed by the pharmacy benefits manager.

b. A contracted pharmacy's representative may take actions and receive notices under this section on behalf of the contracted pharmacy.

(2) A contracted pharmacy has ~~10~~ 40 calendar days after the applicable fill date to appeal a ~~maximum allowable cost~~ reimbursement if the reimbursement for the drug is less than ~~the~~ any of the following:

a. The net amount that the network provider paid to the supplier of the drug.

b. The reimbursement amount required under § 3372A(7) of this title.

(3) A pharmacy benefits manager must respond with notice that the appeal has been denied or granted within 10 calendar days of the contracted pharmacy making the claim for which an appeal has been submitted.

(c) (1) If an appeal is denied, the pharmacy benefits manager must provide ~~the~~ a detailed reason for the ~~denial and~~ denial. If the appeal is related to a maximum allowable cost reimbursement, the pharmacy benefits manager must also provide the name and national drug code number of the national or regional wholesalers operating in this State that have the drug in stock at a price below the maximum allowable ~~cost.~~ cost at the time the pharmacy or pharmacist purchased the drug.

(2) At the time the pharmacy benefits manager provides the written notice of a final appeal determination under paragraph (c)(1) of this section, the pharmacy benefits manager shall provide notice to the pharmacy of the right to appeal an adverse determination to the Department.

(3) The notice under paragraph (c)(2) of this section may be separate from or a part of the written notice of the final determination under paragraph (c)(1) of this section and must, at a minimum, contain all of the following:

a. A statement that says "You have the right to appeal the final appeal determination through the Delaware Department of Insurance. All appeals must be filed with the Department within 10 calendar days from the date you receive the pharmacy benefits manager's final determination."

b. The Department website the pharmacy can use to file an appeal.

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

(1) a. Adjust the ~~maximum allowable cost~~ reimbursement 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 granted.

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

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

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

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

1. That an appeal was granted.

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~~ provide information 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 is responsible for processing appeals has access.

(3) The information required under paragraph (c)(3) of this section.

(h) (1) If a pharmacy benefits manager denies an appeal and a contracted pharmacy files an 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.~~ the reimbursement requirements under § 3372A(7) of this title.

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

1. Deny the appeal.

2. 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.

(3) The non-prevailing party shall pay the costs incurred by the Department in processing an appeal under this subsection.

(4) On request, parties shall provide the Commissioner all mathematical calculations, accounts, records, documents, files, logs, correspondence, or other information necessary to complete the Commissioner's review of an appeal under this subsection.

Section 3. Amend Subchapter III, Chapter 33A, Title 18 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 3331A. Definitions.

For purposes of this subchapter:

(3) "Pharmacy ~~benefit~~ benefits manager" means as defined ~~under~~ in § 3302A of this title.

§ 3333A. Prohibited retaliation due to permitted disclosures.

(a) A pharmacy benefits manager may not retaliate against a pharmacist or pharmacy for disclosing information in any proceeding if the pharmacist or pharmacy has reasonable cause to believe that the disclosed information is evidence of

a violation of a state or federal law, rule, or regulation. Proceedings under this subsection include information disclosed as follows:

(1) To a court.

(2) During an administrative investigation or hearing.

(3) To a legislative commission or committee.

(b) A pharmacy benefits manager may not retaliate against a pharmacist or pharmacy for disclosing information to a government, regulatory, or law enforcement agency, if the pharmacist or pharmacy has reasonable cause to believe that the disclosed information is evidence of a violation of a state or federal law, rule, or regulation.

(c) A pharmacist or pharmacy shall, to the extent possible, limit the disclosure of confidential and proprietary information when making a disclosure under subsection (a) or (b) of this section.

(d) Retaliatory actions against a pharmacist or pharmacy include the cancellation or restriction of, the refusal to renew, or the refusal to offer a contract solely because the pharmacy or pharmacist has done 1 or more of the following:

(1) Disclosed information under subsection (a) or (b) of this section.

(2) Filed complaints with a pharmacy benefits manager.

(3) Filed complaints against an insurer or pharmacy benefits manager with the Department.

(4) Filed an appeal with the Commissioner under § 3324A(h) of this title.

(e) If a contract entered into, amended, extended, or renewed after December 31, 2026, includes a provision that prohibits a disclosure permitted under this section, that provision is against public policy and is void and unenforceable.

Section 4. Amend Subchapter IV, Chapter 33A, 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:

§ 3335A. Definitions.

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

(1) "Chronic or long-term condition" means any of the following:

a. A "complex or chronic medical condition" as defined in § 3364(a) of this title.

b. A "rare medical condition" as defined in § 3364(a) of this title.

~~(1) "Emergency"~~ (2) "Emergency medical condition" means ~~a situation that will result in loss of life, limb or organ function.~~ as defined in § 3349(e) of this title.

~~(2)~~ (3) "Pharmacy ~~benefit~~ benefits manager" ~~has the meaning given~~ means as defined in § 3302A of this title.

§ 3336A. Prior authorization of emergency prescriptions.

A pharmacy ~~benefit~~ benefits manager may not require prior authorization for coverage of a 72-hour supply of medication that is for a noncontrolled substance ~~in~~ prescribed for an emergency ~~situation.~~ medical condition.

§ 3337A. Prior authorization of prescriptions for chronic or long-term conditions.

(a) A prior authorization form for a prescription medication ~~shall~~ must include a question regarding whether the prescription medication is for a chronic or long-term condition for which the prescription medication may be necessary for the life of the patient.

(b) If a prescriber indicates on a prior authorization form that the prescription medication is for a chronic or long-term condition for which the prescription medication may be necessary for the life of the patient, the pharmacy ~~benefit~~ benefits manager may not request a reauthorization for the same prescription medication more frequently than every 12 months.

(c) In the same communication in which a pharmacy ~~benefit~~ benefits manager or the pharmacy ~~benefit~~ benefits manager's agent requests a prior authorization for a prescription medication that has therapeutically equivalent medications that do not require a prior authorization from a prescriber, the pharmacy ~~benefit~~ benefits manager or the pharmacy ~~benefit~~ benefits manager's agent shall provide the prescriber with a list of alternative prescription medications of the same class and family as the requested medication.

(d) Prescribers that utilize e-prescribing shall receive alternate medications from the pharmacy ~~benefit~~ benefits manager for prescription medications that do not require a prior authorization before the completion of the e-prescribing transaction.

(e) A pharmacy ~~benefit~~ benefits manager or the pharmacy benefit manager's agent shall provide alternative medications for therapeutically equivalent medications to the pharmacy that require prior authorization on the National Council for Prescription Drug Programs response transaction to a denied claim for prior authorization.

Section 5. Amend Subchapter VI, Chapter 33A, 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:

§ 3363A. Reports.

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

(1) ~~The~~ On an annual basis, no later than March 31, all of the following:

a. The itemized amount of pharmacy benefits manager revenue sources, including professional fees, administrative fees, processing fees, audits, direct and indirect renumeration fees, or any other fees.

~~(2) The aggregate amount of rebates distributed to the appropriate insurer.~~ [Transferred.]

~~(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.~~ [Transferred.]

~~(4)~~ b.The individual and aggregate amount the insurer paid to the pharmacy benefits manager for pharmacy goods or services provided in this State, itemized by all of the following:

~~a.~~ 1. Pharmacy.

~~b.~~ 2. Product.

~~c.~~ 3, Goods and services.

~~(5)~~ c. The individual and aggregate amount a pharmacy benefits manager paid for pharmacy goods or services provided in this State, itemized by all of the following:

~~a.~~ 1. Pharmacy.

~~b.~~ 2. Product.

~~c.~~ 3. Goods and services.

(2) On an annual basis, all of the following:

a. The aggregate amount of the rebates distributed to the appropriate insurer.

b. The aggregate amount of the 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.

(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 6. Amend Subchapter VII, Chapter 33A, 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:

§ 3372A. Prohibited practices.

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

(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 that was in effect on the date of service. ~~or if~~ If the national average drug acquisition cost is unavailable, the wholesale acquisition ~~cost.~~ cost should be applied. The wholesale acquisition cost price must be the price published in effect on the date of service for the drug claim.

(10) Amend a contract between a pharmacy benefits manager and a pharmacy or pharmacist without providing at least 60 days' notice to the affected pharmacy or pharmacist.

(11) Require pharmacists to break open unit-of-use items beyond manufacturer recommendations if the only commercially available package size exceeds the minimum days' supply. Packaging labeled "for single-patient-use only" shall be deemed to be the smallest package size available.

(12) Require a pharmacy to dispense a therapeutically equivalent or therapeutically alternative drug that costs the enrollee more out-of-pocket than the prescribed drug, unless the substitution is made for medical reasons that benefit the enrollee.

(13) Transfer or share prescription information containing enrollee-identifiable or prescriber-identifiable data to an affiliated pharmacy for any commercial purpose other than the purposes of facilitating pharmacy reimbursement, formulary compliance, or utilization review.

Section 7. This Act becomes effective upon enactment and applies to contracts between pharmacy benefits managers and pharmacies or pharmacists that are entered into, renewed, amended, or extended 6 months after enactment.