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THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 668 Session of 2015

INTRODUCED BY ALLOWAY, YUDICHAK, YAW, WHITE, BLAKE, TOMLINSON, MENSCH, VULAKOVICH, STEFANO, AUMENT, McGARRIGLE, McILHINNEY, SCARNATI, HUGHES AND ARGALL, APRIL 28, 2016

REFERRED TO BANKING AND INSURANCE, APRIL 28, 2016

AN ACT

Providing for pharmacy audit procedures.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Short title.

This act shall be known and may be cited as the Pharmacy Audit Integrity Act.

Section 2. Scope of act.

This act covers any audit of the records of a pharmacy conducted by a managed care company, third-party payer, pharmacy benefits manager, a health program administered by a department of the Commonwealth or any entity that represents a company, group or department.

Section 3. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Audit." A review of one or more pharmacy records conducted

by an auditing entity for payment for the provision of prescription or nonproprietary drugs or pharmacy services.

"Auditing entity." A person, company or government entity that performs a pharmacy audit, including a plan sponsor, pharmacy benefit manager, managed care organization or third-party administrator.

"Business day." Any day of the week excluding Saturday, Sunday and any legal holiday.

"Department." The Department of Health of the Commonwealth.

"Health care practitioner." As defined in section 102 of the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act.

"Nonproprietary drug." As defined in section 2(7.1) of the act of September 27, 1961 (P.L.1700, No.699), known as the Pharmacy Act.

"Pharmacy." As defined in section 2(12) of the Pharmacy Act.

"Pharmacy benefits management." Any entity that performs any of the following:

(1) The procurement of prescription drugs at a negotiated contracted rate for dispensation within this Commonwealth to covered individuals.

(2) The administration or management of prescription drug benefits provided by a covered entity for the benefit of covered individuals.

(3) The provision of any of the following in conjunction with the administration of pharmacy benefits:

(i) Mail service pharmacy.

(ii) Claims processing.

(iii) Retail network management.

(iv) Payment of claims to pharmacies for

prescription drugs dispensed to covered individuals via retail or mail order pharmacy.

(v) Clinical formulary development and management services, including, but not limited to, utilization management and quality assurance programs.

(vi) Rebate contracting and administration.

(vii) Certain patient compliance, therapeutic intervention and generic substitution programs.

(viii) Disease management programs.

(ix) Setting pharmacy reimbursement pricing and methodologies, including maximum allowable cost, and determining single or multiple source drugs.

"Pharmacy benefits manager" or "PBM." A person, business or other entity that performs pharmacy benefits management.

"Pharmacy record." Any record stored electronically or as a hard copy by a pharmacy that relates to the provision of prescription or nonproprietary drugs or pharmacy services or any other component of pharmacist care that is included in the practice of pharmacy.

"Pharmacy Services Administration Organization" or "PSAO." Any entity that contracts with pharmacies to assist with third-party payer interactions and can provide a variety of other administrative services. Administrative services may include, but are not limited to, contracting with PBMs on behalf of pharmacies and managing pharmacies' claims payments from third-party payers.

"Plan sponsor." Any of the following that pays for or processes a claim for payment for prescription drugs or pharmacy services:

(1) A health insuring corporation.

(2) A person authorized to engage in the business of sickness and accident.

(3) A person or government entity providing coverage of prescription or nonproprietary drugs or pharmacy services to individuals on a self-insurance basis.

(4) A group health plan, as defined in 29 U.S.C. § 1167 (relating to definitions and special rules).

(5) A service benefit plan, as referenced in 42 U.S.C. § 1396a(a)(25) (relating to state plans for medical assistance).

(6) A Medicaid managed care organization that has entered into a contract with the Commonwealth.

(7) Any other person or government entity that is, by law, contract or agreement, responsible for paying or processing a claim for payment for the provision of prescription or nonproprietary drugs or pharmacy services.

Section 4. Procedures for conducting audits.

(a) Procedure.--An entity conducting an audit under this act shall conform to the following rules:

(1) The pharmacy contract between a PBM and a pharmacy, or alternatively, a PBM and a pharmacy's contracting representative or agent shall identify and describe in detail the audit procedures.

(2) The entity conducting an audit shall give the pharmacy written notice at least 30 days prior to conducting an onsite audit or requesting records for any audit conducted offsite. The audit may be delayed 30 days at the request of the pharmacy, one time per year, and shall only be granted if there is good cause, including, but not limited to, a planned medical procedure or planned absence from work of a necessary

pharmacist. If a delay is requested by the pharmacy, the pharmacy shall provide notice to the PBM 10 business days prior to the day the audit is to commence.

(3) The entity conducting the audit shall audit no more than 100 prescription records per onsite audit.

(4) A pharmacy may do any of the following when an audit is performed:

(i) Validate a pharmacy record by using an original or photocopied record of a hospital or health care practitioner for drugs or medicinal supplies written or transmitted electronically for purposes of validating the pharmacy record with respect to orders of prescription drugs.

(ii) Validate one or more claims for payment for the provision of prescription or nonproprietary drugs or pharmacy services by using either of the following:

(A) an original pharmacy record or photocopy of the record; or

(B) any legal prescription complying with the Board of Pharmacy requirements may be used to validate claims in connection with prescriptions, refills or changes in prescriptions. This shall include prescription records in an electronic form or otherwise contained digital media.

(iii) Resubmit a disputed or denied claim for payment using any commercially reasonable method of resubmission, including resubmission by facsimile, mail or electronic means, provided that the period of time when a claim may be resubmitted has not expired as mutually agreed upon by the contracting parties.

(5) An audit must be conducted applying only the applicable Federal or Pennsylvania laws and regulations.

(6) A clerical or recordkeeping error, such as a typographical error, scrivener's error or computer error regarding a required document or record does not constitute fraud, and claims relating thereto shall be subject to neither recoupment nor criminal penalties without proof of intent to commit fraud or absent an indication there was an error in dispensing the prescribed drug.

(7) The finding of an overpayment shall not include the dispensing fee amount. This provision specifically does not include the payment of multiple dispensing fees for the same prescription, exclusive of refills.

(8) The period of time covered by an audit may not be more than 12 months from the scheduled date of the audit.

(9) An onsite audit may not be initiated or scheduled during the first three business days of any month unless consented to by the pharmacy.

(10) The auditing entity may not receive payment, by contract, based on a percentage of the amount recovered.

(11) An entity conducting an audit under this act shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits. An extrapolation audit means an audit of a sample of prescription drug benefit claims submitted by a pharmacy to the entity conducting the audit that is then used to estimate audit results for a larger group of claims not reviewed by the auditor.

(12) When calculating for days' supply for topical and ophthalmic products, the pharmacist's reasonable,

professional judgment based on communication with the patient or prescriber shall take precedence.

(13) The auditing entity shall not recoup payment for a prescription which has been used by the patient in accordance with the prescriber's instructions even if the prescriber's instructions are different than the manufacturer's suggested use.

(14) When directions for use include variable dosing instructions, the highest prescribed dose must be used to calculate day's supply, copay and allowable refill date and quantity.

(15) The pharmacy's usual and customary price for compounded medications shall be considered the reimbursable cost unless the pricing methodology is published in the provider contract and mutually agreed upon by the contracting parties.

(16) A pharmacy shall be permitted to utilize information regarding the availability of third-party resources provided by a PBM and shall not be liable to repay any amount for which a third party is liable only if a pharmacy has actual knowledge regarding the availability of third-party resources available to a claimant for pharmacy benefits. PBMs and prescription drug plans may pursue claims for such third-party resources.

(17) With the exception of overpayments, if a PBM approves a claim through adjudication, the auditor may not retroactively deny or modify the claim based upon retroactively obtained ineligibility information, unless the claim was fraudulent.

(18) An auditor may not deny or reject any claim

retroactively through audits in the event that the PBM or auditor has subsequently become aware of another payer responsible for payment of the claim following adjudication or payment of the claim.

(b) Written report.--An auditing entity shall provide the pharmacy with a written report of the audit and comply with the following requirements:

(1) The preliminary audit report must be delivered to the pharmacy or its corporate parent within 60 days after the completion of the audit. The preliminary report shall include contact information for the individual who conducted the audit, including telephone number, facsimile number, e-mail and auditing firm, so that audit results, discrepancies and procedures can be reviewed. The preliminary audit report shall include, but is not limited to, claim level information for any discrepancy found and total dollar amount of claims subject to recovery.

(2) A pharmacy shall be allowed at least 60 days following receipt of the preliminary audit report to produce documentation to address any discrepancy found during the audit. This shall include prescriptions not initially provided in the audit.

(3) A final audit report shall be delivered to the pharmacy or its corporate parent within 120 days after receipt of the preliminary audit report or final appeal.

(4) The audit report must be signed and include the signature of any pharmacist participating in the audit.

(5) Any recoupments of disputed funds shall only occur after final internal disposition of the audit. Any recoupment shall be provided in writing to the pharmacy for payment.

(6) Interest shall not accrue during the audit period.

(7) Each entity conducting an audit shall provide a copy of the final audit report, after completion of any review process, to the plan sponsor. The final audit report may be delivered electronically.

Section 5. Appeals process.

(a) General rule.--An auditing entity shall establish a written appeals process under which a pharmacy may appeal an unfavorable final audit report to the entity.

(b) Adjudication.--The adjudication of a claim cannot be appealed through the audit process.

Section 6. Limitations.

(a) Exceptions.--Any rights derived from this act shall not apply to:

(1) Audits which are the result of a complaint to the PBM or Board of Pharmacy in which suspected fraudulent activity or other intentional and willful misrepresentation is evidenced by a physical review, review of claims data or statements or other investigative methods.

(2) Concurrent reviews or desk audits that occur within three business days of transmission of a claim where no chargeback or recoupment is demanded.

(b) Federal law.--This act does not supersede any audit requirements established by Federal law, including extrapolation audits when required.

Section 7. Enforcement.

The department shall have enforcement authority and shall take action or impose penalties to bring noncomplying entities into full compliance with this act, including the promulgation of any regulations necessary to carry out this act.

Section 8. Effective date.

This act shall take effect in 90 days.