[40 Pa. Stat. and Pa. Cons. Stat. §§ 4501 through 4503, 4531 through 4535, 4551 through 4562.]

§§ 4501 through 4503, 4531 through 4535, 4551 through 4562: Pharmacy Audit Integrity and Transparency Act

§ 4501. Short title.

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

§ 4502. 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, or an entity that represents a covered entity.

§ 4503. 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:

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

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

"Covered entity." A contract holder or policy holder providing pharmacy benefits to a covered individual under a health insurance policy pursuant to a contract administered by a pharmacy benefit manager.

"Covered individual." A member, participant, enrollee, or beneficiary of a covered entity who is provided health coverage by the covered entity. The term includes a dependent or other person provided health coverage through the policy or contract of a covered individual.

"Department." The Insurance Department of the Commonwealth.

"Extrapolation." The practice of inferring a frequency of dollar amount of overpayments, underpayments, nonvalid claims or other errors on any portion of claims submitted, based on the frequency of dollar amount of overpayments, underpayments, nonvalid claims or other errors actually measured in a sample of claims.

"Health care practitioner." As defined in section 103 of the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act.

"Health insurance policy." A policy, subscriber contract, certificate or plan that provides prescription drug coverage. The term includes both comprehensive and limited benefit health policies.

"Health insurer." An entity licensed by the department with authority to issue a policy, subscriber contract, certificate or plan that provides prescription drug coverage that is offered or governed under any of the following:

(1) The act of May 17, 1921 (P.L.682, No.284), known as The Insurance Company Law of 1921, including section 630 and Article XXIV thereof.

(2) The act of December 29, 1972 (P.L.1701, No.364), known as the Health Maintenance Organization Act.

(3) 40 Pa.C.S. Ch. 61 (relating to hospital plan corporations) or 63 (relating to professional health services plan corporations).

"Maximum allowable cost." The maximum amount that a pharmacy benefits manager will reimburse a pharmacy for the cost of a drug or a medical product or device.

"Multiple source drug." A covered outpatient drug for which there is at least one other drug product that is rated as therapeutically equivalent under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations."

"Multiple source generic list." A list of drugs, medical products or devices, or both, for which a maximum allowable cost has been established by a pharmacy benefits manager.

"Network." A pharmacy or group of pharmacies that agree to provide prescription services to covered individuals on behalf of a covered entity or group of covered entities in exchange for payment for its services by a pharmacy benefits manager or pharmacy services administration organization. The term includes a pharmacy that generally dispenses outpatient prescriptions to covered individuals or dispenses particular types of prescriptions, provides pharmacy services to particular types of covered individuals or dispenses prescriptions in particular health care settings, including networks of specialty, institutional or long-term care facilities.

"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.

"Pharmacist." As defined in section 2(10) of the Pharmacy Act.

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

"Pharmacy audit." An audit, conducted on-site by or on behalf of an auditing entity of any records of a pharmacy for prescription or nonproprietary drugs dispensed by a pharmacy to a covered individual.

"Pharmacy benefits management." The performance of 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 administration of pharmacy benefits , including:

(i) Operating a mail-service pharmacy.

(ii) Claims processing.

(iii) Managing a retail pharmacy network .

(iv) Paying claims to a pharmacy for prescription drugs dispensed to covered individuals via retail or mail-order pharmacy.

(v) Developing and managing a clinical formulary , including utilization management and quality assurance programs. (vi) Rebate contracting and administration.

(vii) Managing a patient compliance, therapeutic intervention and generic substitution program.

(viii) Operating a disease management program.

(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 for covered entities.

“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 other component of pharmacist care that is included in the practice of pharmacy.

“Pharmacy Services Administration Organization” or “PSAO.” Any entity that contracts with a pharmacy to assist with third-party payer interactions and that may provide a variety of other administrative services , including contracting with PBMs on behalf of pharmacies and managing pharmacies” claims payments from third-party payers.

§ 4531. Multiple source generic list and reimbursement.

(a) General rule.— In order to place a particular drug on a multiple source generic list, a PBM shall, at a minimum, ensure that:

(1) the drug is listed as “A” or “B” rated in the most recent version of the Food and Drug Administration’s “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly known as the orange book , or “NR” or “NA” rated, or similar rating, by a nationally recognized reference;

(2) There are at least two therapeutically equivalent multiple source drugs or at least one generic drug available from only one manufacturer; and

(3) the drug is available for purchase by all pharmacies in this Commonwealth from national or regional wholesalers and is not obsolete or temporarily unavailable.

(b) Removal from listing.— A PBM must maintain a procedure to eliminate drugs from the list of drugs subject to multiple source drug pricing or modify the maximum allowable cost in a timely fashion.

(c) Substitutions.— A PBM may not penalize a pharmacist or pharmacy on audit if the pharmacist or pharmacy performs a generic substitution pursuant to the act of November 24, 1976 (P.L.1163, No.259), referred to as the Generic Equivalent Drug Law.

§ 4532. Availability of multiple source generic list.

(a) General rule.— Upon each contract execution or renewal, a PBM shall, with respect to contracts between a PBM and a pharmacy, or its representative, including a PSAO:

(1) Include in the contract the sources utilized to determine multiple source drug pricing, including, if applicable, the maximum allowable cost or any successive pricing formula of the PBM.

(2) Update the pricing information every seven calendar days.

(3) Establish a reasonable process by which pharmacies have a method to access relevant or current maximum allowable cost pricing lists in effect and any successive pricing formulas in a timely fashion.

(b) Confidentiality provision.— Nothing in this section may prohibit a PBM from establishing a reasonable confidentiality provision with a pharmacy or its representative , including a PSAO.

§ 4533. Multiple source drug pricing appeals process.

(a) Process to be established.— All contracts between a PBM or a pharmacy, or alternatively, a pharmacy's contracting agent, such a PSAO, shall include a process to appeal, investigate and resolve disputes regarding multiple source drug pricing. The contract provision establishing the process shall include the following:

(1) The right to appeal shall be limited to 14 calendar days following the initial claim.

(2) The appeal shall be investigated and resolved by the PBM through an internal process within 14 calendar days of receipt of the appeal by the PBM.

(3) A telephone number at which a pharmacy may contact the PBM and speak with an individual who is involved in the appeals process.

(b) Denial.— If a PBM denies an appeal, the PBM shall provide the reason for the denial and identify the national drug code of an equivalent drug that is available for purchase by network retail pharmacies in this Commonwealth from wholesalers at a price that is equal to or less than the maximum allowable cost for the appealed drug as determined by the PBM.

(c) Approval.— If a PBM grants an appeal, the PBM shall 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.

§ 4534. Regulations.

The department may promulgate regulations as necessary and appropriate to implement the provisions of this chapter.

§ 4535. Applicability.

This chapter shall apply to all contracts and agreements for pharmacy benefits management services executed or renewed on or after the effective date of this section.

§ 4551. Scope of enforcement authority.

(a) Scope.— The department may investigate and enforce the provisions of this act only insofar as the actions or inactions being investigated relate to prescription drug coverage under a health insurance policy.

(b) Remedy.— Actions or inactions within the scope of the department's investigative and enforcement authority under subsection (a) found to violate this act constitute "unfair methods of competition" and "unfair or deceptive acts or practices" within the meaning of section 5 of the act of July 22, 1974 (P.L.589, No.205), known as the Unfair Insurance Practices Act. A proceeding under this section shall be conducted in accordance with 2 Pa.C.S. Ch. 5 Subch. A (relating to practice and procedure of Commonwealth agencies).

§ 4561. Repeals.

Repeals are as follows:

(1) The General Assembly declares that the repeals under paragraph (2) are necessary to effectuate Chapter 8.

(2) Sections 509(6) and 510(a) and (b) of the act of August 26, 1971 (P.L.351, No.91), known as the State Lottery Law, are repealed.

§ 4562. Effective date.

This act shall take effect as follows:

(1) The following provisions shall take effect immediately:

(i) This chapter.

(ii) Chapter 8.

(2) Chapters 5 and 9 shall take effect in 90 days.

(3) The remainder of this act shall take effect in 180 days.