PHARMACY AUDIT INTEGRITY AND TRANSPARENCY ACT - ENACTMENT

Act of Nov. 21, 2016, P.L. 1318, No. 169 Cl. 35

AN ACT

Providing for pharmacy audit procedures, for registration of pharmacy benefits managers and auditing entities, for maximum allowable cost transparency and for prescription drugs reimbursed under the PACE and PACENET program; and making related repeals.

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

CHAPTER 1
PRELIMINARY PROVISIONS

Section 101. Short title.

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

Section 102. 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.

Section 103. 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 agrees 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 act of September 27, 1961 (P.L.1700, No.699), known as the Pharmacy Act.

"Pharmacy." As defined in section 2(12) of the act of September 27, 1961 (P.L.1700, No.699), known as 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.

CHAPTER 3
PHARMACY AUDITS

Section 301. Procedures for conducting pharmacy audits.

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

(1) Except as otherwise provided by Federal or State law, an auditing entity conducting a pharmacy audit may have access to a pharmacy's previous audit report only if the report was prepared by that auditing entity.

(2) Information collected during a pharmacy audit shall be confidential by law, except that the auditing entity conducting the pharmacy audit may share the information with the pharmacy benefits manager and the covered entity for which a pharmacy audit is being conducted.

(3) The auditing entity conducting a pharmacy audit may not solely compensate an employee or contractor with which an auditing entity contracts to conduct a pharmacy audit, solely based on the amount claimed or the actual amount recouped by the pharmacy being audited.

(4) The auditing entity shall provide the pharmacy being audited with at least 14 calendar days' prior written notice before conducting a pharmacy audit, unless both parties agree otherwise. If a delay is requested by the pharmacy, the pharmacy shall provide notice to the PBM within 72 hours of receiving notice of the audit.

(5) The auditing entity may not initiate or schedule a pharmacy audit during the first five business days of any month for a pharmacy that averages in excess of 600 prescriptions filled per week, without the express consent of the pharmacy.

(6) The auditing entity shall accept paper or electronic signature logs that document the delivery of prescription or nonproprietary drugs and pharmacist services to a health plan beneficiary or the beneficiary's caregiver or guardian.

(7) The auditing entity shall provide to the representative of the pharmacy, prior to leaving the pharmacy at the conclusion of the on-site portion of the pharmacy audit, a complete list of pharmacy records reviewed.

(8) A pharmacy audit that involves clinical judgment shall be conducted by or in consultation with a pharmacist.

(9) A pharmacy audit may not cover:

(i) a period of more than 24 months after the date a claim was submitted by the pharmacy to the pharmacy benefits manager or covered entity unless a longer period is required by law; or

(ii) more than 250 prescriptions, provided that a refill does not constitute a separate prescription for the purposes of this subparagraph.

(10) The auditing entity may not use extrapolation to calculate penalties or amounts to be charged back or recouped unless otherwise required by Federal requirements or Federal plans.

(11) The auditing entity may not include dispensing fees in the calculation of overpayments unless a prescription is considered a misfill. As used in this paragraph, "misfill" means a prescription that was not dispensed, a prescription error, a prescription where the prescriber denied the

authorization request or a prescription where an extra dispensing fee was charged.

(12) A pharmacy may do any of the following when a pharmacy audit is performed:

(i) To validate the pharmacy record and delivery, a pharmacy may use authentic and verifiable statements or records, including, but not limited to, medication administration records of a nursing home, assisted living facility, hospital or health care practitioner with prescriptive authority.

(ii) To validate claims in connection with prescriptions or changes in prescriptions, or refills of prescription or nonproprietary drugs, a pharmacy may use any valid prescription, including, but not limited to, medication administration records, facsimiles, electronic prescriptions, electronically stored images of prescriptions, electronically created annotations or documented telephone calls from the prescribing health care practitioner or practitioner's agent. Documentation of an oral prescription order that has been verified by the prescribing health care practitioner shall meet the provisions of this subparagraph for the initial audit review.

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

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

(2) A pharmacy shall be allowed 30 calendar days following receipt of the preliminary audit report to respond to the findings of the preliminary report.

(3) A final audit report shall be delivered to the pharmacy or its corporate parent not later than 60 calendar days after any responses from the pharmacy or corporate parent are received by the auditing entity. The auditing entity shall issue a final pharmacy audit report that takes into consideration any responses provided to the auditing entity by the pharmacy or corporate parent.

(4) The final audit report may be delivered electronically.

(5) A pharmacy may not be subject to a charge-back or recoupment for a clerical or recordkeeping error in a required document or record, including a typographical error, scrivener's error or computer error, unless the error resulted in overpayment to the pharmacy.

(6) An auditing entity conducting a pharmacy audit or person acting on behalf of the entity may not charge back or recoup or collect penalties from a pharmacy until the time period to file an appeal of a final pharmacy audit report has passed or the appeals process has been exhausted, whichever is later.

(7) If an identified discrepancy in a pharmacy audit exceeds $25,000, future payments to the pharmacy in excess of that amount may be withheld pending adjudication of an appeal.

(8) No interest shall accrue for any party during the audit period, beginning with the notice of the pharmacy audit and ending with the conclusion of the appeals process.

Section 302. Appeals process.

A pharmacy may appeal a final audit report in accordance with the procedures established by the entity conducting the pharmacy audit.

Section 303. Limitations.

(a) General rule.--The provisions of this chapter do not apply to an investigative audit of pharmacy records when:

(1) fraud, waste, abuse or other intentional misconduct is indicated by physical review or review of claims data or statements; or

(2) other investigative methods indicate a pharmacy is or has been engaged in criminal wrongdoing, fraud or other intentional or willful misrepresentation.

(b) Federal law.--This chapter does not supersede any audit requirements established by Federal law.

Section 304. Regulations.

The department may promulgate regulations as necessary and appropriate to carry out this chapter.

CHAPTER 5
REGISTRATION

Section 501. PBM and auditing entity registration.

(a) General rule.--To conduct business in this Commonwealth, a PBM or auditing entity must register with the department. The department shall make an application form available on its publicly accessible Internet website that shall require:

(1) The identity, address and telephone number of the applicant.

(2) The name, business address and telephone number of the contact person for the applicant.

(3) When applicable, the Federal employer identification number for the applicant.

(b) Term and fee.--

(1) The term of registration shall be two years from the date of issuance.

(2) The department shall set an initial application fee and a renewal application fee, which shall be submitted with an application for registration. An initial application fee shall be nonrefundable. A renewal application fee shall be returned if the renewal of the registration is not granted.

(3) The amount of the initial application fee and renewal application fee shall be sufficient to fund the department's duties in relation to its responsibilities under this chapter but may not exceed $1,000.

(c) Registration.--

(1) The department shall issue a registration, as appropriate, to an applicant when the department determines that the applicant has submitted a completed application and paid the required registration fee.

(2) The registration may be in paper or electronic form, shall be nontransferable and shall prominently list the expiration date of the registration.

(d) Duplicate registration.--

(1) A licensed insurer or a managed care plan with a certificate of authority shall comply with the standards and procedures of this act but shall not be required to separately register as either a PBM or auditing entity.

(2) A PBM that is registered under this chapter shall comply with the standards and procedures of this act but shall not be required to register separately as an auditing entity.

CHAPTER 7
PBM COST TRANSPARENCY REQUIREMENTS

Section 701. 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.

Section 702. 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.

Section 703. 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.

Section 704. Regulations.

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

Section 705. 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.

CHAPTER 8
PACE AND PACENET PROGRAM PAYMENTS

Section 801. Definitions.

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

"A-rated generic therapeutically equivalent drug." A drug product that the Commissioner of Food and Drugs of the United States Food and Drug Administration has approved as safe and effective and has determined to be therapeutically equivalent, as listed in "The Approved Drug Products with Therapeutic Equivalence Evaluations" (Food and Drug Administration "Orange Book"), with a specific "A" code designation only.

"Claimant." An eligible person who is enrolled in the program.

"Department." The Department of Aging of the Commonwealth.

"Less expensive." The lowest net cost to the program. The net cost shall include the amount paid by the Commonwealth to a pharmacy for a drug under a current retail pharmacy reimbursement formula less any discount or rebates, including those paid during the previous calendar quarter and inclusive of all dispensing fees.

"NADAC per unit." The current National Average Drug Acquisition Cost per unit.

"Prescription drug." All drugs requiring a prescription in this Commonwealth, insulin, insulin syringes and insulin needles. Experimental drugs or drugs prescribed for wrinkle removal or hair growth are prohibited.

"Program." The Pharmaceutical Assistance Contract for the Elderly (PACE) and the Pharmaceutical Assistance Contract for the Elderly Needs Enhancement Tier (PACENET) as established by

the act of August 26, 1971 (P.L.351, No.91), known as the State Lottery Law.

"Provider." A pharmacy, dispensing physician or certified registered nurse practitioner enrolled as a provider in the program.

"Wholesale acquisition cost." The cost of a dispensed drug based upon the price published in a national drug pricing system in current use by the Department of Aging as the wholesale acquisition cost of a prescription drug in the most common package size.

Section 802. Program payment.

In addition to the requirements under section 509 of the act of August 26, 1971 (P.L.351, No.91), known as the State Lottery Law, the department shall administer the program in accordance with the following:

(1) If the NADAC per unit is available, the program payment shall be the lower of the following amounts:

(i) the NADAC per unit:

(A) with the addition of a professional dispensing fee of $13 per prescription; and

(B) the subtraction of the copayment; or

(ii) the pharmacy's usual and customary charge for the drug dispensed with the subtraction of the copayment.

(2) If the NADAC per unit is unavailable, the program payment shall be the lower of the following amounts:

(i) the wholesale acquisition cost plus 3.2%:

(A) with the addition of a professional dispensing fee of $13 per prescription; and

(B) the subtraction of the copayment; or

(ii) the pharmacy's usual and customary charge for the drug dispensed with the subtraction of the copayment.

Section 803. Generic drugs.

(a) General rule.--Notwithstanding any other statute or regulation, a brand name product shall be dispensed and not substituted with an A-rated generic therapeutically equivalent drug if it is less expensive to the program. If a less expensive A-rated generic therapeutically equivalent drug is available for dispensing to a claimant, the provider shall dispense the A-rated generic therapeutically equivalent drug to the claimant. The department shall reimburse providers based upon the most current listing of the NADAC per unit plus a professional dispensing fee of $13 per prescription. The department shall not reimburse providers for brand name products except in the following circumstances:

(1) There is no A-rated generic therapeutically equivalent drug available on the market. This paragraph does not apply to the lack of availability of an A-rated generic therapeutically equivalent drug in the providing pharmacy unless it can be shown to the department that the provider made reasonable attempts to obtain the A-rated generic therapeutically equivalent drug or that there was an unforeseeable demand and depletion of the supply of the A-rated generic therapeutically equivalent drug. In either case, the department shall reimburse the provider for the NADAC per unit plus a professional dispensing fee of $13 per prescription.

(2) An A-rated generic therapeutically equivalent drug is deemed by the department, in consultation with a utilization review committee, to have too narrow a therapeutic index for safe and effective dispensing in the community setting. The department shall notify providing pharmacies of A-rated generic therapeutically equivalent

drugs that are identified pursuant to this paragraph on a regular basis.

(3) The Department of Health has determined that a drug shall not be recognized as an A-rated generic therapeutically equivalent drug for purpose of substitution under section 5(b) of the act of November 24, 1976 (P.L.1163, No.259), referred to as the Generic Equivalent Drug Law.

(4) At the time of dispensing, the provider has a prescription on which the brand name drug dispensed is billed to the program by the provider at a usual and customary charge which is equal to or less than the least expensive usual and customary charge of any A-rated generic therapeutically equivalent drug reasonably available on the market to the provider.

(5) The brand name drug is less expensive to the program.

(b) Generic not accepted.--If a claimant chooses not to accept the A-rated generic therapeutically equivalent drug required by subsection (a), the claimant shall be liable for the copayment and the NADAC per unit.

CHAPTER 9
ENFORCEMENTS

Section 901. 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).

CHAPTER 11
MISCELLANEOUS PROVISIONS

Section 1101. 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.

Section 1102. 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.