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THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 461 Session of 2013

INTRODUCED BY STACK, EICHELBERGER, FERLO, BREWSTER, SOLOBAY, RAFFERTY, FARNESE, ALLOWAY, KITCHEN, ERICKSON, COSTA AND BOSCOLA, FEBRUARY 11, 2013

REFERRED TO BANKING AND INSURANCE, FEBRUARY 11, 2013

AN ACT

Providing for pharmacy audit procedures; and establishing the Pharmacy Error Reduction Committee and providing for its powers and duties.

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. Purpose and intent.

The purpose of this act is to establish minimum and uniform standards and criteria for the audit of pharmacy records.

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:

"Pharmacy benefits manager" or "PBM." 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 for a managed care company, nonprofit hospital or medical service organization, insurance company, third-party payor or health program administered by a department of the Commonwealth.

Section 4. Scope of act.

This act covers an audit of the records of a pharmacy conducted by a managed care company, nonprofit hospital or medical service organization, insurance company, third-party payor, pharmacy benefits manager, a health program administered by a department of the Commonwealth or any entity that represents a company, group or department.

Section 5. Procedures for conducting and reporting an audit.

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

(1) The pharmacy contract shall identify and describe in detail the audit procedures.

(2) The entity conducting an audit shall give the pharmacy written notice at least two weeks prior to conducting an initial onsite audit for each audit cycle or requesting records for an audit conducted offsite.

(3) The entity conducting the onsite audit shall not interfere with the delivery of pharmacist services to a patient and shall utilize every effort to minimize inconvenience and disruption to pharmacy operations during the audit process.

(4) An audit that involves clinical or professional judgment must be conducted by or in consultation with a licensed pharmacist applying all applicable Pennsylvania law and regulations.

(5) 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 to the error shall be subject to neither recoupment nor criminal penalties without proof of intent to commit fraud. However, recoupment of any payment or overpayment made due to error, strictly limited to the amount of the payment or overpayment plus interest, is permissible in situations in which the pharmacy knew that services were not covered or were provided to an ineligible recipient and in which restitution of the amounts paid constitutes a proper remedy pursuant to 13 Pa.C.S. Div. 2 (relating to sales).

(6) A pharmacy may use the records of a hospital, physician or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders of refills of a legend or narcotic drug.

(7) A finding of an overpayment or underpayment must be based on the actual overpayment or underpayment and may not be a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs. This paragraph or any other section of this act does not prevent any entity from using its collected data to target audit resources or to detect fraud.

(8) A finding of an overpayment shall not include the dispensing fee amount. However, the dispensing fee does not have to be paid in the event that a filled prescription was not finally dispensed to or picked up for the intended

patient.

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

(10) The period of time covered by an audit may not go back in time more than 18 months from the scheduled date of the audit.

(11) An onsite audit may not be initiated or scheduled during the first seven calendar days of any month due to the high volume of prescriptions filled in the pharmacy during that time unless otherwise consented to by the pharmacy.

(12) The auditing company shall not receive payment based on a percentage of the amount recovered.

(b) Written report.--An entity conducting an audit under this act 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 90 days after the conclusion of the audit.

(2) A pharmacy shall be allowed at least 60 days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during 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, as provided for in section 6, whichever is later.

(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, including the appeal process as set forth in section 6.

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

(7) An entity conducting an audit shall provide a copy of the final audit report, after completion of any review process, to the plan sponsor.

Section 6. Appeal process.

The following shall apply:

(1) The National Council for Prescription Drug Programs (NCPDP) or any other recognized national industry standard shall be used to evaluate claims submission and product size disputes.

(2) An entity conducting an audit shall establish a written appeal process under which a pharmacy may appeal an unfavorable preliminary audit report to the entity.

(3) If, following the appeal, the entity finds that an unfavorable audit report or any portion of the report is unsubstantiated, the entity shall dismiss the audit report or the portion without the necessity of any further action.

Section 7. Extrapolation audits.

Notwithstanding any other provision in this act, 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 batch or group of claims not reviewed by the auditor.

Section 8. Third-party resources.

(a) Third-party resources.--An entity covered by this act

shall take all reasonable measures to ascertain the legal liability of any third parties, including health insurers, self-insured plans, group health plans as defined by section 607(1) of the Employee Retirement Income Security Act of 1974 (Public Law 93-406, 88 Stat. 829), service benefit plans, managed care organizations, pharmacy benefit managers, the Medicare program, other prescription drug plans or other parties that are by statute, contract or agreement legally responsible for payment for prescription drugs before claims become the liability of any prescription drug plan administered by the pharmacy benefit manager.

(b) Identification cards and claims processing systems.--Information regarding third-party resources identified pursuant to subsection (a) shall be included on identification cards issued by a PBM or prescription drug plan to persons eligible for prescription drug benefits and shall be included in all mechanized claims processing systems established by a PBM or prescription drug plan, including systems required under section 1903(r) of the Social Security Act (49 Stat. 620, 42 U.S.C. § 301 et seq.). Where information regarding third-party resources is made available to pharmacies on identification cards or through mechanized claims processing systems, a PBM may direct a pharmacy to submit claims for payment to the third parties prior to submission to the PBM or prescription drug plan, provided that this requirement shall not apply when a pharmacy has a reasonable basis to believe that a claim is not covered by available third-party resources based upon a diagnosis code or other information available to the pharmacy.

(c) Claims against pharmacies.--Provided that a pharmacy makes reasonable inquiries of recipients regarding the

availability of third-party resources, unless a pharmacy has actual knowledge regarding the availability of third-party resources available to a claimant for pharmacy benefits, a pharmacy is entitled to rely on information regarding the availability of third-party resources provided by a PBM, and shall not be liable to repay in whole or in part for any amounts for which any third party is liable. PBMs and prescription drug plans are hereby authorized to and shall pursue claims from the third-party resources. Upon the effective date of this act, this subsection shall apply to all pending and future claims against pharmacies asserted by PBMs or prescription drug plans, including claims relating to benefits provided to recipients prior to the effective date of this act.

(d) Applicability.--This section shall apply to agencies of the Commonwealth managing health care programs and their agents. This section shall also apply to other entities described in section 4 only to the extent that they engage in coordination of benefits between multiple plans. Subsection (c) shall apply to all section 4 entities covered by this act.

Section 9. Fraud.

(a) Exceptions.--Fraud shall not include the following:

(1) Payments for prescriptions where the proper pharmaceutical was delivered to the intended patient, who is eligible for benefits, in the prescribed amounts.

(2) Errors outlined in section 5(a)(5).

(b) Investigations.--Nothing in this act shall prevent investigations by the law enforcement agencies of the Commonwealth or the United States or use by entities under section 4 of collected data or other information to detect actual fraud by pharmacies or pharmacy personnel intended to

defraud prescription drug plans.

(c) Restrictions on audits.--The restrictions on audits in section 5(a)(10) do not apply once a pattern of systematic fraud has been established in order to allow for recovery of fraudulently obtained overpayments.

Section 10. Administration of this act by Commonwealth agencies.

Provisions of this act shall not apply to the extent determined by applicable Federal agencies to be contrary to Federal law or regulations or to disqualify the Commonwealth in whole or in part for Federal financial participation in Commonwealth health programs or other Federal benefits, subsidies or payments. However, the Commonwealth shall appeal any such determinations made by Federal agencies and attempt to obtain waivers or other agreements of understanding with Federal agencies in order to fully implement this act. To avoid the risk that the Commonwealth may be required to repay Federal financial participation or other benefits, subsidies or payments, the Commonwealth may request determinations from applicable Federal agencies regarding whether any provisions of this act violate Federal laws or regulations or disqualify the Commonwealth in whole or in part for Federal financial participation in Commonwealth health programs or other Federal benefits, subsidies or payments.

Section 11. Pharmacy Error Reduction Committee.

(a) Establishment.--The Pharmacy Error Reduction Committee is established to create a real-time, electronic pharmacy error reduction system for Commonwealth prescription drug programs and shall have as its purpose the reduction of prescription errors in order to save the Commonwealth money and reduce

administrative burdens on businesses. The system shall check multiple databases to ensure that the pharmacy filings contain the correct information. The system shall check each pharmacy claim for the following information: physician name, physician license number, name of prescription, prescription dosage, patient name, name of patient's insurance provider, patient's insurance identification number, as well as other information that will reduce errors and has been approved by a majority vote of the committee. If a pharmacy claim does not contain the correct information, the pharmacy error reduction system shall return the claim to the pharmacist for correction and resubmission.

(b) Membership.--The committee shall consist of:

(1) Two members of the State Board of Pharmacy elected by a majority of the board to serve on the committee.

(2) Two practicing pharmacists selected by the Governor from a list submitted by a State trade association that represents practicing pharmacists before the Department of Public Welfare, the Department of Aging, the General Assembly and other governmental bodies.

(3) Two practicing physicians selected by the Governor from a list submitted by a State trade association that represents all practicing physicians before the Department of Public Welfare, the Department of Aging, the General Assembly and other governmental bodies.

(4) The Secretary of Public Welfare or a designee, who shall serve as the chairperson of the committee.

(5) The commissioner of the Department of State's Bureau of Professional and Occupational Affairs or a designee.

(6) The Secretary of Aging or a designee.

(c) Powers and duties.--The committee shall:

(1) Hold meetings to discuss and develop an electronic pharmacy error reduction system.

(2) Consider issuing a request for proposals to develop software, programs and other items to create and implement the electronic pharmacy error reduction system or utilize existing departmental staff, equipment and technology to produce and implement the pharmacy error reduction system.

(3) Provide the electronic pharmacy error reduction system to pharmacies throughout this Commonwealth.

(4) Obtain and share information to develop and implement the electronic pharmacy error reduction system.

(d) Time period for completion of duties.--The committee shall complete its work within one year of the effective date of this section.

Section 12. Effective date.

This act shall take effect in 60 days.