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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1798 Session of 2007

INTRODUCED BY COHEN, ARGALL, CALTAGIRONE, FABRIZIO, FREEMAN, GALLOWAY, GEORGE, GRUCELA, HARKINS, JAMES, KENNEY, KIRKLAND, KORTZ, MELIO, MUNDY, MYERS, O'NEILL, PASHINSKI, PERZEL, RUBLEY, SABATINA, SHAPIRO, SIPTROTH, THOMAS, WALKO, YUDICHAK, KING, PETRI, STEIL, KOTIK, PARKER, WAGNER, MARSHALL AND McILVAINE SMITH, AUGUST 22, 2007

AS REPORTED FROM COMMITTEE ON HEALTH AND HUMAN SERVICES, HOUSE OF REPRESENTATIVES, AS AMENDED, SEPTEMBER 17, 2008

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. 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 any 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 ~~the onsite~~ AN audit shall give the pharmacy written notice at least two weeks prior to conducting ~~the~~ AN initial onsite audit for each audit cycle OR REQUESTING RECORDS FOR ANY 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 which involves clinical or professional judgment must be conducted by or in consultation with a ~~pharmacist licensed in this Commonwealth.~~ 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 thereto 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 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 SUBSECTION 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 covered by an audit may not exceed one year from the date the claim was submitted to or adjudicated by a managed care company, nonprofit hospital or medical service organization, insurance company, third-party payor, pharmacy benefit manager, a health program administered by a department of the Commonwealth or any entity that represents a company, group or department.~~ <—

(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 may 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) Each 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) Each 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 thereof is unsubstantiated, the entity shall dismiss the audit report or said 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.--~~A PBM~~ ENTITIES COVERED BY THIS SECTION 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 such 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 such 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. IN ADDITION, 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.

AS A GENERAL RULE, FRAUD SHALL NOT INCLUDE PAYMENTS FOR PRESCRIPTIONS WHERE THE PROPER PHARMACEUTICAL WAS DELIVERED TO

THE INTENDED PATIENT, WHO IS ELIGIBLE FOR BENEFITS, IN THE PRESCRIBED AMOUNTS. IN ADDITION, FRAUD SHALL NOT INCLUDE THOSE ERRORS OUTLINED IN SECTION 5(A)(5). NOTHING IN THIS ACT SHALL PREVENT INVESTIGATIONS BY THE LAW ENFORCEMENT AGENCIES OF THE COMMONWEALTH OR THE UNITED STATES. FURTHER, NOTHING IN THIS ACT PREVENTS THE SECTION 4 ENTITIES' USE OF COLLECTED DATA OR OTHER INFORMATION TO DETECT ACTUAL FRAUD BY PHARMACIES OR PHARMACY PERSONNEL INTENDED TO DEFRAUD PRESCRIPTION DRUG PLANS. 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 VIGOROUSLY APPEAL ANY SUCH DETERMINATIONS MADE BY APPLICABLE FEDERAL AGENCIES AND MAKE EVERY EFFORT 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 ~~9~~ 11. Effective date. <——

This act shall take effect in 60 days.