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THE GENERAL ASSEMBLY OF PENNSYLVANIA

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**SENATE BILL**

No. **831** Session of  
2013

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INTRODUCED BY ALLOWAY, ERICKSON, VULAKOVICH, WHITE, YUDICHAK,  
ARGALL, YAW AND SCARNATI, MAY 6, 2013

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REFERRED TO BANKING AND INSURANCE, MAY 6, 2013

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AN ACT

1 Providing for pharmacy audit procedures.

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

4 Section 1. Short title.

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

7 Section 2. Purpose and intent.

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

10 Section 3. Definitions.

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

14 "Pharmacy benefits manager" or "PBM." A person, business or  
15 other entity that performs pharmacy benefits management. The  
16 term includes a person or entity acting for a PBM in a  
17 contractual or employment relationship in the performance of

1 pharmacy benefits management for a managed care company,  
2 nonprofit hospital or medical service organization, insurance  
3 company, third-party payor or health program administered by a  
4 department of the Commonwealth.

5 Section 4. Scope of act.

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

12 Section 5. Procedures for conducting and reporting an audit.

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

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

17 (2) The entity conducting an audit shall give the  
18 pharmacy written notice at least 30 days prior to conducting  
19 an initial onsite audit for each audit cycle or requesting  
20 records for any audit conducted offsite, and such notice  
21 shall identify the prescriptions subject to the audit.

22 (3) The entity conducting the audit shall audit no more  
23 than 100 prescription records per audit, and the pharmacy's  
24 purchase orders or invoices shall not be subject to the  
25 audit.

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

1           (5) An audit that involves clinical or professional  
2 judgment must be conducted by or in consultation with a  
3 licensed Pennsylvania pharmacist applying only the  
4 applicable Federal or State law and regulations.

5           (6) A clerical or recordkeeping error, such as a  
6 typographical error, scrivener's error or computer error  
7 regarding a required document or record does not constitute  
8 fraud, and claims relating thereto shall be subject to  
9 neither recoupment nor criminal penalties without proof of  
10 intent to commit fraud. However, recoupment of any payment or  
11 overpayment made due to error, strictly limited to the amount  
12 of the payment or overpayment plus interest, is permissible  
13 in situations in which the pharmacy knew that services were  
14 not covered or were provided to an ineligible recipient and  
15 in which restitution of the amounts paid constitutes a proper  
16 remedy pursuant to 13 Pa.C.S. Div. 2 (relating to sales).

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

23           (8) Any legal prescription, complying with the Board of  
24 Pharmacy requirements, may be used to validate claims in  
25 connection with prescriptions, refills or changes in  
26 prescriptions. This shall include prescription records in  
27 electronic form or otherwise contained in digital media.

28           (9) A finding of an overpayment or underpayment must be  
29 based on the actual overpayment or underpayment and may not  
30 be projection based on the number of patients served having a

1 similar diagnosis or on the number of similar orders or  
2 refills for similar drugs. This subsection or any other  
3 section of this act does not prevent any entity from using  
4 its collected data to target audit resources or to detect  
5 fraud.

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

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

14 (12) The period of time covered by an audit may not go  
15 back in time more than six months from the scheduled date of  
16 the audit.

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

21 (14) The auditing company may not receive payment based  
22 on a percentage of the amount recovered.

23 (b) Written report.--An entity conducting an audit under  
24 this act shall provide the pharmacy with a written report of the  
25 audit and comply with the following requirements:

26 (1) The preliminary audit report must be delivered to  
27 the pharmacy or its corporate parent within 90 days after the  
28 initiation of the audit.

29 (2) A pharmacy shall be allowed at least 60 days  
30 following receipt of the preliminary audit report in which to

1 produce documentation to address any discrepancy found during  
2 the audit.

3 (3) A final audit report shall be delivered to the  
4 pharmacy or its corporate parent within 120 days after  
5 receipt of the preliminary audit report or final appeal, as  
6 provided for in section 6, whichever is later.

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

9 (5) Any recoupments of disputed funds shall only occur  
10 after final internal disposition of the audit, including the  
11 appeal process as set forth in section 6. Except with the  
12 consent of a pharmacy, no recoupment may be deducted against  
13 future remittance and any recoupment shall be invoiced to the  
14 pharmacy for payment.

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

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

19 Section 6. Audit parameters.

20 (a) General rule.--Audit parameters shall use consumer-  
21 oriented parameters based on manufacturer listings or  
22 recommendations as follows:

23 (1) When calculating days supply for drops,  
24 manufacturer-stated estimates of drops per ml shall take  
25 precedence over pharmacy benefit manager general guidelines.

26 (2) When calculating days supply for topical products,  
27 the pharmacist's judgment, based on communication with the  
28 patient or prescriber, shall take precedence.

29 (3) When the smallest manufacturer of a use package is  
30 dispensed, the patient should be charged only one copay,

1 regardless of actual days supply.

2 (4) When directions for use include variable dosing  
3 parameters, the highest prescribed dose must be used to  
4 calculate days supply, copay and allowable refill date and  
5 quantity.

6 (5) Manufacturer guidelines on beyond use dating must be  
7 used when calculating days supply, copay and allowable refill  
8 date and quantity.

9 (b) Reimbursable cost.--The retail pharmacy's usual and  
10 customary price for compounded medications shall be considered  
11 the reimbursable cost unless an alternate price is published in  
12 the provider contract and signed by both parties.

13 Section 7. Appeal process.

14 The following shall apply:

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

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

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

26 Section 8. Extrapolation audits.

27 Notwithstanding any other provision in this act, an entity  
28 conducting an audit under this act shall not use the accounting  
29 practice of extrapolation in calculating recoupments or  
30 penalties for audits. An extrapolation audit means an audit of a

1 sample of prescription drug benefit claims submitted by a  
2 pharmacy to the entity conducting the audit that is then used to  
3 estimate audit results for a larger batch or group of claims not  
4 reviewed by the auditor.

5 Section 9. Third-party resources.

6 (a) Third-party resources.--Entities covered by this section  
7 shall take all reasonable measures to ascertain the legal  
8 liability of any third parties, including health insurers, self-  
9 insured plans, group health plans as defined by section 607(1)  
10 of the Employee Retirement Income Security Act of 1974 (Public  
11 Law 93-406, 88 Stat. 829), service benefit plans, managed care  
12 organizations, pharmacy benefit managers, the Medicare program,  
13 other prescription drug plans or other parties that are by  
14 statute, contract or agreement legally responsible for payment  
15 for prescription drugs before claims become the liability of any  
16 prescription drug plan administered by the pharmacy benefit  
17 manager.

18 (b) Identification cards and claims processing systems.--  
19 Information regarding third-party resources identified pursuant  
20 to subsection (a) shall be included on identification cards  
21 issued by a PBM or prescription drug plan to persons eligible  
22 for prescription drug benefits and shall be included in all  
23 mechanized claims processing systems established by a PBM or  
24 prescription drug plan, including systems required under section  
25 1903(r) of the Social Security Act (49 Stat. 620, 42 U.S.C. §  
26 301 et seq.). Where information regarding third-party resources  
27 is made available to pharmacies on identification cards or  
28 through mechanized claims processing systems, a PBM may direct a  
29 pharmacy to submit claims for payment to such third parties  
30 prior to submission to the PBM or prescription drug plan,

1 provided that this requirement shall not apply when a pharmacy  
2 has a reasonable basis to believe that a claim is not covered by  
3 available third-party resources based upon a diagnosis code or  
4 other information available to the pharmacy.

5 (c) Claims against pharmacies.--Provided that a pharmacy  
6 makes reasonable inquiries of recipients regarding the  
7 availability of third-party resources, unless a pharmacy has  
8 actual knowledge regarding the availability of third-party  
9 resources available to a claimant for pharmacy benefits, a  
10 pharmacy is entitled to rely on information regarding the  
11 availability of third-party resources provided by a PBM and  
12 shall not be liable to repay in whole or in part for any amounts  
13 for which any third party is liable. PBMs and prescription drug  
14 plans are authorized to and shall pursue claims from such third-  
15 party resources. Upon the effective date of this act, this  
16 subsection shall apply to all pending and future claims against  
17 pharmacies asserted by PBMs or prescription drug plans,  
18 including claims relating to benefits provided to recipients  
19 prior to the effective date of this act.

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

26 Section 10. Fraud.

27 As a general rule, fraud shall not include payments for  
28 prescriptions where the proper pharmaceutical was delivered to  
29 the intended patient, who is eligible for benefits, in the  
30 prescribed amounts. In addition, fraud shall not include those

1 errors outlined in section 5(a)(5). Nothing in this act shall  
2 prevent investigations by the law enforcement agencies of the  
3 United States or the Commonwealth. Further, nothing in this act  
4 prevents the section 4 entities' use of collected data or other  
5 information to detect actual fraud by pharmacies or pharmacy  
6 personnel intended to defraud prescription drug plans. The  
7 restrictions on audits in section 5(a)(10) do not apply once a  
8 pattern of systematic fraud has been established in order to  
9 allow for recovery of fraudulently obtained overpayments.

10 Section 11. Administration of this act by Commonwealth  
11 agencies.

12 Provisions of this act shall not apply to the extent  
13 determined by applicable Federal agencies to be contrary to  
14 Federal law or regulations or to disqualify the Commonwealth in  
15 whole or in part for Federal financial participation in  
16 Commonwealth health programs or other Federal benefits,  
17 subsidies or payments. However, the Commonwealth shall  
18 vigorously appeal any such determinations made by applicable  
19 Federal agencies and make every effort to obtain waivers or  
20 other agreements of understanding with Federal agencies in order  
21 to fully implement this act. To avoid the risk that the  
22 Commonwealth may be required to repay Federal financial  
23 participation or other benefits, subsidies or payments, the  
24 Commonwealth may request determinations from applicable Federal  
25 agencies regarding whether any provisions of this act violate  
26 Federal laws or regulations or disqualify the Commonwealth in  
27 whole or in part for Federal financial participation in  
28 Commonwealth health programs or other Federal benefits,  
29 subsidies or payments.

30 Section 12. Effective date.

1        This act shall take effect in 60 days.