

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 946 Session of 2015

INTRODUCED BY BAKER, FABRIZIO, D. COSTA, STAATS, LONGIETTI, DAVIS, GIBBONS, PICKETT, PASHINSKI, CRUZ, GROVE, McNEILL, YOUNGBLOOD, M. K. KELLER, KILLION, P. COSTA, COHEN, THOMAS, EVERETT, CARROLL, FARRY, SCHLOSSBERG, PHILLIPS-HILL, M. DALEY, WARD, READSHAW, HARKINS, MURT, SAYLOR, GOODMAN, GALLOWAY, BARRAR, BOYLE, MICCARELLI, DeLUCA, NEUMAN, MATZIE, TOEPEL, WATSON, KNOWLES, O'BRIEN, SANTARSIERO, PETRI AND QUINN, AUGUST 18, 2015

AS REPORTED FROM COMMITTEE ON HEALTH, HOUSE OF REPRESENTATIVES, AS AMENDED, OCTOBER 19, 2015

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. Scope of act.

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

14 Section 3. Definitions.

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

4 "Audit." A review of one or more pharmacy records conducted  
5 by an auditing entity for payment for the provision of  
6 prescription or nonproprietary drugs or pharmacy services.

7 "Auditing entity." A person, company or government entity  
8 that performs a pharmacy audit, including a ~~payer~~ PLAN SPONSOR, <--  
9 pharmacy benefit manager, MANAGED CARE ORGANIZATION or third- <--  
10 party administrator.

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

13 "Department." The Department of Health of the Commonwealth.

14 "Health care practitioner." As defined in section 102 of the  
15 act of July 19, 1979 (P.L.130, No.48), known as the Health Care  
16 Facilities Act.

17 "Nonproprietary drug." As defined in section 2(7.1) of the  
18 act of September 27, 1961 (P.L.1700, No.699), known as the  
19 Pharmacy Act.

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

21 "Pharmacy benefits management." ~~Performing~~ ANY ENTITY THAT <--  
22 PERFORMS any of the following:

23 (1) The procurement of prescription drugs at a  
24 negotiated contracted rate for dispensation within this  
25 Commonwealth to covered individuals.

26 (2) The administration or management of prescription  
27 drug benefits provided by a covered entity for the benefit of  
28 covered individuals.

29 (3) The provision of any of the following in conjunction  
30 with the administration of pharmacy benefits:

- 1 (i) Mail service pharmacy.
- 2 (ii) Claims processing.
- 3 (iii) Retail network management.
- 4 (iv) Payment of claims to pharmacies for
- 5 prescription drugs dispensed to covered individuals via
- 6 retail or mail order pharmacy.
- 7 (v) Clinical formulary development and management
- 8 services, including, but not limited to, utilization
- 9 management and quality assurance programs.
- 10 (vi) Rebate contracting and administration.
- 11 (vii) Certain patient compliance, therapeutic
- 12 intervention and generic substitution programs.
- 13 (viii) Disease management programs.
- 14 (ix) Setting pharmacy reimbursement pricing and
- 15 methodologies, including maximum allowable cost, and
- 16 determining single or multiple source drugs.

17 "Pharmacy benefits manager" or "PBM." A person, business or  
18 other entity that performs pharmacy benefits management.

19 "Pharmacy record." Any record stored electronically or as a  
20 hard copy by a pharmacy that relates to the provision of  
21 prescription or nonproprietary drugs or pharmacy services or any  
22 other component of pharmacist care that is included in the  
23 practice of pharmacy.

24 "Pharmacy Services Administration Organization" or "PSAO."  
25 Any entity that contracts with pharmacies to assist with third-  
26 party payer interactions and can provide a variety of other  
27 administrative services. ~~Such administrative services vary, but~~ <--  
28 ADMINISTRATIVE SERVICES may include, BUT ARE NOT LIMITED TO, <--  
29 contracting with PBMs on behalf of pharmacies and managing  
30 pharmacies' claims payments from third-party payers.

1 "Plan sponsor." Any of the following that pays for or  
2 processes a claim for payment for prescription drugs or pharmacy  
3 services:

4 (1) A health insuring corporation.

5 (2) A person authorized to engage in the business of  
6 sickness and accident.

7 (3) A person or government entity providing coverage of  
8 prescription or nonproprietary drugs or pharmacy services to  
9 individuals on a self-insurance basis.

10 (4) A group health plan, as defined in 29 U.S.C. § 1167  
11 (relating to definitions and special rules).

12 (5) A service benefit plan, as referenced in 42 U.S.C. §  
13 1396a(a)(25) (relating to state plans for medical  
14 assistance).

15 (6) A Medicaid managed care organization that has  
16 entered into a contract with the Commonwealth.

17 (7) Any other person or government entity that is, by  
18 law, contract or agreement, responsible for paying or  
19 processing a claim for payment for the provision of  
20 prescription or nonproprietary drugs or pharmacy services.

21 Section 4. Procedures for conducting audits.

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

24 (1) The pharmacy contract between a PBM and a pharmacy,  
25 or alternatively, a PBM and a pharmacy's contracting  
26 representative or agent shall identify and describe in detail  
27 the audit procedures.

28 (2) The entity conducting an audit shall give the  
29 pharmacy written notice at least 30 days prior to conducting  
30 an onsite audit or requesting records for any audit conducted

1 offsite. The audit may be delayed 30 days at the request of  
2 the pharmacy, one time per year, and shall only be granted if  
3 there is good cause, including, but not limited to, a planned  
4 medical procedure or planned absence from work of a necessary  
5 pharmacist. If a delay is requested by the pharmacy, the  
6 pharmacy shall provide notice to the PBM 10 business days  
7 prior to the day the audit is to commence.

8 (3) The entity conducting the audit shall audit no more  
9 than 100 prescription records per onsite audit.

10 (4) A pharmacy may do any of the following when an audit  
11 is performed:

12 (i) Validate a pharmacy record by using an original  
13 or photocopied record of a hospital or health care  
14 practitioner for drugs or medicinal supplies written or  
15 transmitted electronically for purposes of validating the  
16 pharmacy record with respect to orders of prescription  
17 drugs.

18 (ii) Validate one or more claims for payment for the  
19 provision of prescription or nonproprietary drugs or  
20 pharmacy services by using either of the following:

21 (A) an original pharmacy record or photocopy of  
22 the record; or

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

29 (iii) Resubmit a disputed or denied claim for  
30 payment using any commercially reasonable method of

1 resubmission, including resubmission by facsimile, mail  
2 or electronic means, provided that the period of time  
3 when a claim may be resubmitted has not expired as  
4 mutually agreed upon by the contracting parties.

5 (5) An audit must be conducted applying only the  
6 applicable Federal or Pennsylvania laws and regulations.

7 (6) A clerical or recordkeeping error, such as a  
8 typographical error, scrivener's error or computer error  
9 regarding a required document or record does not constitute  
10 fraud, and claims relating thereto shall be subject to  
11 neither recoupment nor criminal penalties without proof of  
12 intent to commit fraud or absent an indication there was an  
13 error in dispensing the prescribed drug.

14 (7) The finding of an overpayment shall not include the  
15 dispensing fee amount. This provision specifically does not  
16 include the payment of multiple dispensing fees for the same  
17 prescription, exclusive of refills.

18 (8) The period of time covered by an audit may not be  
19 more than 12 months from the scheduled date of the audit.

20 (9) An onsite audit may not be initiated or scheduled  
21 during the first three business days of any month unless  
22 consented to by the pharmacy.

23 (10) The auditing entity may not receive payment, by  
24 contract, based on a percentage of the amount recovered.

25 (11) An entity conducting an audit under this act shall  
26 not use the accounting practice of extrapolation in  
27 calculating recoupments or penalties for audits. An  
28 extrapolation audit means an audit of a sample of  
29 prescription drug benefit claims submitted by a pharmacy to  
30 the entity conducting the audit that is then used to estimate

1 audit results for a larger group of claims not reviewed by  
2 the auditor.

3 (12) When calculating for days' supply for topical and  
4 ophthalmic products, the pharmacist's reasonable,  
5 professional judgment based on communication with the patient  
6 or prescriber shall take precedence.

7 (13) The auditing entity shall not recoup payment for a  
8 prescription which has been used by the patient in accordance  
9 with the prescriber's instructions even if the prescriber's  
10 instructions are different than the manufacturer's suggested  
11 use.

12 (14) When directions for use include variable dosing  
13 instructions, the highest prescribed dose must be used to  
14 calculate day's supply, copay and allowable refill date and  
15 quantity.

16 (15) The ~~retail~~ pharmacy's usual and customary price for <--  
17 compounded medications shall be considered the reimbursable  
18 cost unless the pricing methodology is published in the  
19 provider contract and mutually agreed upon by the contracting  
20 parties.

21 (16) A ~~retail~~ pharmacy shall be permitted to utilize <--  
22 information regarding the availability of third-party  
23 resources provided by a PBM and shall not be liable to repay  
24 any amount for which a third party is liable only if a ~~retail~~<--  
25 pharmacy has actual knowledge regarding the availability of  
26 third-party resources available to a claimant for pharmacy  
27 benefits. PBMs and prescription drug plans may pursue claims  
28 for such third-party resources.

29 (17) With the exception of overpayments, if a PBM  
30 approves a claim through adjudication, the auditor may not

1 retroactively deny or modify the claim based upon  
2 retroactively obtained ineligibility information, unless the  
3 claim was fraudulent.

4 (18) An auditor may not deny or reject any claim  
5 retroactively through audits in the event that the PBM or  
6 auditor has subsequently become aware of another payer  
7 responsible for payment of the claim following adjudication  
8 or payment of the claim.

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

12 (1) The preliminary audit report must be delivered to  
13 the pharmacy or its corporate parent within 60 days after the  
14 completion of the audit. The preliminary report shall include  
15 contact information for the individual who conducted the  
16 audit, including telephone number, facsimile number, e-mail  
17 and auditing firm, so that audit results, discrepancies and  
18 procedures can be reviewed. The preliminary audit report  
19 shall include, but is not limited to, claim level information  
20 for any discrepancy found and total dollar amount of claims  
21 subject to recovery.

22 (2) A pharmacy shall be allowed at least 60 days  
23 following receipt of the preliminary audit report to produce  
24 documentation to address any discrepancy found during the  
25 audit. This shall include prescriptions not initially  
26 provided in the audit.

27 (3) A final audit report shall be delivered to the  
28 pharmacy or its corporate parent within 120 days after  
29 receipt of the preliminary audit report or final appeal.

30 (4) The audit report must be signed and include the



1 signature of any pharmacist participating in the audit.

2 (5) Any recoupments of disputed funds shall only occur  
3 after final internal disposition of the audit. Any recoupment  
4 shall be provided in writing to the pharmacy for payment.

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

6 (7) Each entity conducting an audit shall provide a copy  
7 of the final audit report, after completion of any review  
8 process, to the plan sponsor. The final audit report may be  
9 delivered electronically.

10 Section 5. Appeals process.

11 (a) General rule.--An auditing entity shall establish a  
12 written appeals process under which a pharmacy may appeal an  
13 unfavorable final audit report to the entity.

14 (b) Adjudication.--The adjudication of a claim cannot be  
15 appealed through the audit process.

16 Section 6. ~~Fraud~~ LIMITATIONS. <--

17 (a) Exceptions.--Any rights derived from this act shall not  
18 apply to:

19 (1) Audits which are the result of a complaint to the  
20 PBM or Board of Pharmacy in which suspected fraudulent  
21 activity or other intentional and willful misrepresentation  
22 is evidenced by a physical review, review of claims data or  
23 statements or other investigative methods.

24 (2) Concurrent reviews or desk audits that occur within  
25 three business days of transmission of a claim where no  
26 chargeback or recoupment is demanded.

27 (b) Federal law.--This act does not supersede any audit  
28 requirements established by Federal law, including extrapolation  
29 audits when required.

30 Section 7. Enforcement.

1       The department shall have enforcement authority and shall  
2 take action or impose penalties to bring noncomplying entities  
3 into full compliance with this act, including the promulgation  
4 of any regulations necessary to carry out this act.

5 Section 8. Effective date.

6       This act shall take effect in 90 days.