

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 946 Session of 2015

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AS AMENDED ON THIRD CONSIDERATION, HOUSE OF REPRESENTATIVES, JULY 1, 2016

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, third-party payer, pharmacy  
10 benefits manager, a health program administered by a department  
11 of the Commonwealth or any entity that represents a company,  
12 group or department.

13 Section 3. Definitions.

14 The following words and phrases when used in this act shall

1 have the meanings given to them in this section unless the  
2 context clearly indicates otherwise:

3 "Auditing entity." A person, company or government entity  
4 that performs a pharmacy audit, including a plan sponsor,  
5 pharmacy benefit manager, managed care organization or third-  
6 party administrator.

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

9 "Department." The Insurance Department of the Commonwealth.

10 "Extrapolation." The practice of inferring a frequency of  
11 dollar amount of overpayments, underpayments, nonvalid claims or  
12 other errors on any portion of claims submitted, based on the  
13 frequency of dollar amount of overpayments, underpayments,  
14 nonvalid claims or other errors actually measured in a sample of  
15 claims.

16 "Health care practitioner." As defined in section 103 of the  
17 act of July 19, 1979 (P.L.130, No.48), known as the Health Care  
18 Facilities Act.

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

22 "Pharmacist." As defined in section 2(10) of the Pharmacy  
23 Act.

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

25 "Pharmacy audit." An audit, conducted on-site or remotely by  
26 or on behalf of an auditing entity of any records of a pharmacy  
27 for prescription or nonproprietary drugs dispensed by a pharmacy  
28 to beneficiaries of a health benefit plan. The term does not  
29 include either of the following:

30 (1) A concurrent review or remote audit that is

1 initiated within seven business days of the pharmacy's  
2 transmission of a claim to an auditing entity.

3 (2) A concurrent review or remote audit where no charge-  
4 back or recoupment is demanded by the auditing entity.

5 "Pharmacy benefits management." Any entity that performs any  
6 of the following:

7 (1) The procurement of prescription drugs at a  
8 negotiated contracted rate for dispensation within this  
9 Commonwealth to covered individuals.

10 (2) The administration or management of prescription  
11 drug benefits provided by a covered entity for the benefit of  
12 covered individuals.

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

15 (i) Mail-service pharmacy.

16 (ii) Claims processing.

17 (iii) Retail network management.

18 (iv) Payment of claims to pharmacies for  
19 prescription drugs dispensed to covered individuals via  
20 retail or mail-order pharmacy.

21 (v) Clinical formulary development and management  
22 services, including, but not limited to, utilization  
23 management and quality assurance programs.

24 (vi) Rebate contracting and administration.

25 (vii) Certain patient compliance, therapeutic  
26 intervention and generic substitution programs.

27 (viii) Disease management programs.

28 (ix) Setting pharmacy reimbursement pricing and  
29 methodologies, including maximum allowable cost, and  
30 determining single or multiple source drugs.

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

3 "Pharmacy record." Any record stored electronically or as a  
4 hard copy by a pharmacy that relates to the provision of  
5 prescription or nonproprietary drugs or pharmacy services or  
6 other component of pharmacist care that is included in the  
7 practice of pharmacy.

8 "Plan sponsor." Any of the following that pays for or  
9 processes a claim for payment for prescription drugs or pharmacy  
10 services:

11 (1) A health insuring corporation.

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

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

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

19 (5) A service benefit plan, as referenced in 42 U.S.C. §  
20 1396a(a)(25) (relating to state plans for medical  
21 assistance).

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

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

28 Section 4. Procedures for conducting pharmacy audits.

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

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

5           (2) Any information collected during a pharmacy audit  
6 shall be confidential by law, except that the auditing entity  
7 conducting the pharmacy audit may share the information with  
8 the pharmacy benefits manager and the plan sponsor, for which  
9 a pharmacy audit is being conducted.

10          (3) No auditing entity conducting a pharmacy audit shall  
11 solely compensate any of its employees or any contractor with  
12 which an auditing entity contracts to conduct a pharmacy  
13 audit, based on the amount claimed or the actual amount  
14 recouped by the pharmacy being audited.

15          (4) The entity shall provide the pharmacy being audited  
16 with at least 10 business days' prior written notice before  
17 conducting a pharmacy audit, unless both parties agree  
18 otherwise. The audit may be delayed for a period of up to 30  
19 days at the request of the pharmacy, one time per year, and  
20 shall only be granted if there is good cause, including, but  
21 not limited to, a planned medical procedure or planned  
22 absence from work of a necessary pharmacist. If a delay is  
23 requested by the pharmacy, the pharmacy shall provide notice  
24 to the PBM at least five business days prior to the day the  
25 audit is to commence.

26          (5) (Reserved).

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

1           (7) The entity shall accept paper or electronic  
2 signature logs that document the delivery of prescription or  
3 nonproprietary drugs and pharmacist services to a health plan  
4 beneficiary or the agent of the beneficiary.

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

9           (9) Any pharmacy audit that involves clinical judgment  
10 shall be conducted by or in consultation with a pharmacist.

11           (10) No pharmacy audit shall cover:

12                 (i) a period of more than 24 months after the date a  
13 claim was submitted by the pharmacy to the pharmacy  
14 benefits manager or plan sponsor unless a longer period  
15 is required by law; or

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

19           (11) No auditing entity may use extrapolation to  
20 calculate penalties or amounts to be charged back or recouped  
21 unless otherwise required by Federal requirements or Federal  
22 plans.

23           (12) No auditing entity shall include dispensing fees in  
24 the calculation of overpayments unless a prescription is  
25 considered a misfill. As used in this paragraph, "misfill"  
26 means a prescription that was not dispensed, a prescription  
27 error, a prescription where the prescriber denied the  
28 authorization request or a prescription where an extra  
29 dispensing fee was charged.

30           (13) A pharmacy may do any of the following when a

1 pharmacy audit is performed:

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

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

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

24 (1) The preliminary pharmacy audit report must be  
25 delivered to the pharmacy or its corporate parent within 60  
26 days after the completion of the pharmacy audit. The  
27 preliminary report shall include contact information for the  
28 individual who conducted the pharmacy audit, including  
29 telephone number, facsimile number, e-mail and auditing firm,  
30 so that audit results, discrepancies and procedures can be

1 reviewed. The preliminary pharmacy audit report shall  
2 include, but not be limited to, claim level information for  
3 any discrepancy found and total dollar amount of claims  
4 subject to recovery.

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

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

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

17 (5) No pharmacy shall be subject to a charge-back or  
18 recoupment for a clerical or recordkeeping error in a  
19 required document or record, including a typographical error,  
20 scrivener's error or computer error, unless the error  
21 resulted in overpayment to the pharmacy.

22 (6) No auditing entity conducting a pharmacy audit or  
23 person acting on behalf of the entity shall charge-back or  
24 recoup, ~~attempt to charge back or recoup or assess~~ or collect <--  
25 penalties from a pharmacy until the time period to file an  
26 appeal of a final pharmacy audit report has passed or the  
27 appeals process has been exhausted, whichever is later.

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

1 appeal.

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

5 Section 5. Appeals process.

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

9 (b) Adjudication.--The adjudication of a claim may not be  
10 appealed through the audit process.

11 Section 6. Limitations.

12 (a) General rule.--The provisions of this act shall not  
13 apply to an audit of pharmacy records when:

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

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

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

22 Section 7. Enforcement.

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

27 Section 8. Effective date.

28 This act shall take effect in 90 days.