

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, SAYLOR, GOODMAN, GALLOWAY, BARRAR, BOYLE, MICCARELLI, DeLUCA, NEUMAN, MATZIE, TOEPEL, WATSON, KNOWLES, O'BRIEN, SANTARSIERO, PETRI, QUINN, D. PARKER, DEASY, CUTLER AND BARBIN, AUGUST 18, 2015

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.