

1 SB383
2 137115-1
3 By Senators Bussman and Beasley
4 RFD: Small Business
5 First Read: 01-MAR-12

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8 SYNOPSIS: Existing law does not specifically provide
9 minimum and uniform standards and criteria for the
10 audit of pharmacy records.

11 This bill would establish minimum and
12 uniform standards and criteria for the audit of
13 pharmacy records by or on behalf of certain
14 entities.

15 This bill would prescribe the procedures for
16 conducting an audit.

17 This bill would provide for an appeal
18 process.

19 This bill would provide that an entity
20 conducting an audit may not use the accounting
21 practice of extrapolation in calculating
22 recoupments or penalties for audits.

23
24 A BILL
25 TO BE ENTITLED
26 AN ACT
27

1 Relating to audits of pharmacy records; to establish
2 minimum and uniform standards and criteria for the audit of
3 pharmacy records by or on behalf of certain entities; to
4 prescribe the procedures for conducting an audit; to provide
5 for an appeal process; and to provide that an entity
6 conducting an audit may not use the accounting practice of
7 extrapolation in calculating recoupments or penalties for
8 audits.

9 BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

10 Section 1. This act shall be known and may be cited
11 as "The Pharmacy Audit Integrity Act."

12 Section 2. The following words shall have the
13 following meanings as used in this act:

14 (1) HEALTH BENEFIT PLAN. Any individual or group
15 plan, employee welfare benefit plan, policy, or contract for
16 health care services issued, delivered, issued for delivery,
17 or renewed in this state by a health care insurer, health
18 maintenance organization, accident and sickness insurer,
19 fraternal benefit society, nonprofit hospital service
20 corporation, nonprofit medical service corporation, health
21 care service plan, or any other person, firm, corporation,
22 joint venture, or other similar business entity that pays for
23 insureds or beneficiaries in this state. The term includes,
24 but is not limited to, entities created pursuant to Article 6,
25 Chapter 4, Title 10, Code of Alabama 1975. A health benefit
26 plan located or domiciled outside of the State of Alabama is
27 deemed to be subject to this act if it receives, processes,

1 adjudicates, pays, or denies claims for health care services
2 submitted by or on behalf of patients, insureds, or
3 beneficiaries who reside in Alabama.

4 (2) PHARMACY. A place licensed by the Alabama State
5 Board of Pharmacy in which prescriptions, drugs, medicines,
6 medical devices, chemicals, and poisons are sold, offered for
7 sale, compounded, or dispensed and shall include all places
8 whose title may imply the sale, offering for sale,
9 compounding, or dispensing of prescriptions, drugs, medicines,
10 chemicals, or poisons.

11 (3) PHARMACY BENEFIT MANAGEMENT PLAN. An arrangement
12 for the delivery of pharmacist services in which a pharmacy
13 benefit manager undertakes to administer the payment or
14 reimbursement of any of the costs of pharmacist services for
15 an enrollee on a prepaid or insured basis that contains one or
16 more incentive arrangements intended to influence the cost or
17 level of pharmacist services between the plan sponsor and one
18 or more pharmacies with respect to the delivery of pharmacist
19 services and requires or creates benefit payment differential
20 incentives for enrollees to use under contract with the
21 pharmacy benefit manager.

22 (4) PHARMACY BENEFIT MANAGER. A business that
23 administers the prescription drug or device portion of
24 pharmacy benefit management plans or health insurance plans on
25 behalf of plan sponsors, insurance companies, unions, and
26 health maintenance organizations. The term includes a person
27 or entity acting for a pharmacy benefit manager in a

1 contractual or employment relationship in the performance of
2 pharmacy benefits management for a managed care company,
3 nonprofit hospital or medical service organization, insurance
4 company, or third-party payor.

5 (5) PHARMACIST SERVICES. Offering for sale,
6 compounding, or dispensing of prescriptions, drugs, medicines,
7 chemicals, or poisons pursuant to a prescription. Pharmacist
8 services also includes the sale or provision of, counseling
9 of, or fitting of medical devices, including prosthetics and
10 durable medical equipment.

11 Section 3. The purpose of this act is to establish
12 minimum and uniform standards and criteria for the audit of
13 pharmacy records by or on behalf of certain entities.

14 Section 4. This act shall apply to any audit of the
15 records of a pharmacy conducted by a managed care company,
16 nonprofit hospital or medical service organization, health
17 benefit plan, third-party payor, pharmacy benefit manager, a
18 health program administered by a department of the state, or
19 any entity that represents those companies, groups, or
20 department.

21 Section 5. (a) The entity conducting an audit shall
22 follow these procedures:

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

25 (2) The entity conducting the on-site or desk audit
26 shall give the pharmacy written notice at least two weeks
27 before conducting the desk audit or the initial on-site audit

1 for each audit cycle. The notice must include a documented
2 checklist of all items being audited and the manual, including
3 the name, date, and edition or volume, applicable to the
4 audit. This document shall serve as record for both the
5 pharmacy and the entity conducting the audit. On the day of
6 the on-site audit, the auditor shall initial each item that
7 was successfully audited. The pharmacy shall produce any items
8 not initialed by the auditor within 30 days of the on-site
9 audit. The auditor shall provide the pharmacy with a receipt
10 for records or copies of records that are taken from an
11 on-site audit.

12 (3) The entity conducting the on-site audit may not
13 interfere with the delivery of pharmacist services to a
14 patient and shall utilize every effort to minimize
15 inconvenience and disruption to pharmacy operations during the
16 audit process.

17 (4) An audit that involves clinical or professional
18 judgment shall be conducted by or in consultation with a
19 pharmacist licensed in the State of Alabama.

20 (5) The audit shall not consider as fraud any
21 clerical or record-keeping error, such as a typographical
22 error, scrivener's error, or computer error regarding a
23 required document or record; however, such errors may be
24 subject to recoupment. The pharmacy shall have the right to
25 submit amended claims to correct clerical or record-keeping
26 errors in lieu of recoupment, provided that the prescription
27 was dispensed according to prescription documentation

1 requirements set forth by the Alabama Pharmacy Act. Any fills
2 subsequent to the identification of such errors may not be
3 subject to recoupment. To the extent that an audit results in
4 the identification of any clerical or record-keeping errors
5 such as typographical errors, scrivener's errors, or computer
6 errors in a required document or record, the pharmacy shall
7 not be subject to recoupment of funds by the pharmacy benefits
8 manager unless the pharmacy benefits manager can provide proof
9 of intent to commit fraud or such error results in actual
10 financial harm to the pharmacy benefits manager, a health
11 insurance plan managed by the pharmacy benefits manager, or a
12 consumer. Any record-keeping errors resulting in financial
13 harm to the pharmacy benefits manager, health insurance plan
14 managed by the pharmacy benefits manager, or a consumer may
15 not include the cost of the drugs that were dispensed in
16 accordance with the prescriber's orders. A person shall not be
17 subject to criminal penalties for errors provided for in this
18 subsection without proof of intent to commit fraud.

19 (6) An entity conducting an audit shall not require
20 any documentation that is not required by state and federal
21 law or Alabama Medicaid.

22 (7) Unless superseded by state or federal law,
23 auditors shall only have access to previous audit reports on a
24 particular pharmacy conducted by the auditing entity for the
25 same pharmacy benefits manager, health plan, or insurer. An
26 auditing vendor contracting with multiple pharmacy benefits
27 managers or health insurance plans shall not use audit reports

1 or other information gained from an audit on a particular
2 pharmacy to conduct another audit for a different pharmacy
3 benefits manager or health insurance plan.

4 (8) Any audit findings shall be disclosed to the
5 health benefit plan.

6 (9) A pharmacy may use the records of a hospital,
7 physician, or other authorized practitioner of the healing
8 arts for drugs or medicinal supplies written or transmitted by
9 any means of communication for purposes of validating the
10 pharmacy record with respect to orders or refills of a legend
11 or narcotic drug.

12 (10) All costs associated with the audit shall be
13 the responsibility of the auditing entity with the exception
14 of Alabama Medicaid.

15 (11) A finding of an overpayment or an underpayment
16 may be a projection based on the number of patients served
17 having a similar diagnosis or on the number of similar orders
18 or refills for similar drugs, except that recoupment shall be
19 based on the actual overpayment or underpayment of actual
20 claims.

21 (12) A finding of an overpayment may not include the
22 cost of the drugs that were dispensed in accordance with the
23 prescriber's orders. A finding of an overpayment may not
24 include the dispensing fee amount unless a prescription was
25 not dispensed.

26 (13) Each pharmacy shall be audited under the same
27 standards and parameters as other similarly situated

1 pharmacies audited by the entity and must be audited under
2 rules applicable to the contractor and time period of the
3 prescription.

4 (14) Where not superseded by state or federal law,
5 the period covered by an audit may not exceed two years from
6 the date the claim was submitted to or adjudicated by a
7 managed care company, nonprofit hospital or medical service
8 organization, health benefit plan, third-party payor, pharmacy
9 benefit manager, a health program administered by a department
10 of the state, or any entity that represents those companies,
11 groups, or department, and in any event the audit period may
12 not exceed the time a pharmacy is allowed to resubmit a claim
13 pursuant to a contract. An audit may not be conducted six
14 months past the date the pharmacy benefit management plan
15 terminated its contract to adjudicate claims with a pharmacy
16 benefit manager, health plan administrator, or any other
17 entity representing those companies.

18 (15) An audit may not be initiated or scheduled
19 during the first five calendar days of any month, or day
20 immediately preceding and following a nationally recognized
21 holiday due to the high volume of prescriptions filled in the
22 pharmacy during that time unless otherwise consented to by the
23 pharmacy.

24 (b) The entity shall provide the pharmacy with a
25 written report of the audit and comply with the following
26 requirements:

1 (1) The preliminary audit report shall be delivered
2 to the pharmacy within 90 days after the conclusion of the
3 audit, with a reasonable extension to be granted upon request.

4 (2) A pharmacy shall be allowed at least 30 days
5 following receipt of the preliminary audit report in which to
6 produce documentation to address any discrepancy found during
7 the audit, with a reasonable extension to be granted upon
8 request.

9 (3) A final audit report shall be delivered to the
10 pharmacy within 180 days after receipt of the preliminary
11 audit report or final appeal, as provided for in Section 6,
12 whichever is later.

13 (4) The audit report shall be signed by the auditor.

14 (5) Recoupments of any disputed funds, or repayment
15 of funds to the entity by the pharmacy if permitted pursuant
16 to contractual agreement, shall occur after final internal
17 disposition of the audit, including the appeals process as set
18 forth in Section 6. If the identified discrepancy for an
19 individual audit exceeds twenty-five thousand dollars
20 (\$25,000), future payments in excess of that amount to the
21 pharmacy may be withheld pending finalization of the audit.

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

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

1 Section 6. (a) Each entity conducting an audit shall
2 establish a written appeals process under which a pharmacy may
3 appeal an unfavorable preliminary audit report to the entity.

4 (b) If, following the appeal, the entity finds that
5 an unfavorable audit report or any portion thereof is
6 unsubstantiated, the entity shall dismiss the audit report or
7 that portion without the necessity of any further action.

8 (c) If, following the appeal, any of the issues
9 raised in the appeal are not resolved to the satisfaction of
10 either party, that party may ask for mediation of those
11 unresolved issues. A certified mediator shall be chosen by
12 agreement of the parties from the mediators list maintained by
13 the Alabama Supreme Court. If an agreement cannot be made, the
14 pharmacy may designate the mediator from the list. The cost of
15 mediation shall be borne by agreement of the parties or by the
16 decision of the mediator.

17 Section 7. Notwithstanding any other provision in
18 this act, the entity conducting the audit may not use the
19 accounting practice of extrapolation in calculating
20 recoupments or penalties for audits. An extrapolation audit
21 means an audit of a sample of prescription drug benefit claims
22 submitted by a pharmacy to the entity conducting the audit
23 that is then used to estimate audit results for a larger batch
24 or group of claims not reviewed by the auditor. Future fills
25 or refills beyond the current claim date may not be subject to
26 recoupment due to an assumption of error under extrapolation
27 procedure.

1 Section 8. This act does not apply to any audit,
2 review, or investigation that involves alleged fraud, willful
3 misrepresentation, or abuse.

4 Section 9. This act shall become effective on the
5 first day of the third month following its passage and
6 approval by the Governor, or its otherwise becoming law.