

1 HB394  
2 137115-1  
3 By Representatives Beech and Johnson (R)  
4 RFD: Health  
5 First Read: 23-FEB-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  
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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.