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3 SENATE HEALTH AND HUMAN SERVICES COMMITTEE SUBSTITUTE FOR  
4 SB348

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9 SYNOPSIS: Existing law provides auditing procedures  
10 for pharmacy records by or on behalf of certain  
11 entities.

12 This bill would further provide auditing  
13 procedures for pharmacy records and would limit  
14 recoupment for certain errors by a pharmacy. The  
15 bill would specify that the procedures would not  
16 apply to the Alabama Medicaid Agency.

17  
18 A BILL  
19 TO BE ENTITLED  
20 AN ACT

21  
22 To amend Sections 34-23-181, 34-23-183, 34-23-184,  
23 34-23-185, and 34-23-186 of the Code of Alabama 1975, relating  
24 to auditing procedures for pharmacy records; to further  
25 provide for auditing procedures; to limit recoupment for  
26 certain errors by a pharmacy; and to specify that the  
27 procedures would not apply to the Alabama Medicaid Agency.

1 BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

2 Section 1. Sections 34-23-181, 34-23-183, 34-23-184,  
3 34-23-185, and 34-23-186 of the Code of Alabama 1975, are  
4 amended to read as follows:

5 "§34-23-181.

6 "The following words shall have the following  
7 meanings as used in this article:

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

25 "(2) PHARMACY. A place licensed by the Alabama State  
26 Board of Pharmacy in which prescriptions, drugs, medicines,  
27 medical devices, chemicals, and poisons are sold, offered for

1 sale, compounded, or dispensed and shall include all places  
2 whose title may imply the sale, offering for sale,  
3 compounding, or dispensing of prescriptions, drugs, medicines,  
4 chemicals, or poisons.

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

16 "(4) PHARMACY BENEFIT MANAGER. A business that  
17 administers the prescription drug or device portion of  
18 pharmacy benefit management plans or health insurance plans on  
19 behalf of plan sponsors, insurance companies, unions, and  
20 health maintenance organizations. The term includes a person  
21 or entity acting for a pharmacy benefit manager in a  
22 contractual or employment relationship in the performance of  
23 pharmacy ~~benefits~~ benefit management for a managed care  
24 company, nonprofit hospital or medical service organization,  
25 insurance company, or third-party payor.

26 "(5) PHARMACIST SERVICES. Offering for sale,  
27 compounding, or dispensing of prescriptions, drugs, medicines,

1 chemicals, or poisons pursuant to a prescription. Pharmacist  
2 services also includes the sale or provision of, counseling  
3 of, or fitting of medical devices, including prosthetics and  
4 durable medical equipment.

5 "§34-23-183.

6 "This article shall apply to any audit of the  
7 records of a pharmacy conducted by a managed care company,  
8 nonprofit hospital or medical service organization, health  
9 benefit plan, third-party payor, pharmacy benefit manager, a  
10 health program administered by a department of the state  
11 except the Alabama Medicaid Agency, or any entity that  
12 represents those companies, groups, or department.

13 "§34-23-184.

14 "(a) The entity conducting an audit shall follow  
15 these procedures:

16 "(1) The pharmacy contract shall identify and  
17 describe in detail the audit procedures.

18 "(2) The entity conducting the on-site audit shall  
19 give the pharmacy written notice at least two weeks before  
20 conducting the initial on-site audit for each audit cycle. If  
21 the pharmacy benefit manager does not include their auditing  
22 guidelines within their provider manual, then the notice must  
23 include a documented checklist of all items being audited and  
24 the manual, including the name, date, and edition or volume,  
25 applicable to the audit and auditing guidelines. For on-site  
26 audits a pharmacy benefit manager shall also provide a list of  
27 material that is copied or removed during the course of an

1 audit to the pharmacy. The pharmacy benefit manager may  
2 document this material on either a checklist or on an audit  
3 acknowledgement form. The pharmacy shall produce any items  
4 during the course of the audit or within 30 days of the  
5 on-site audit.

6 "(3) The entity conducting the on-site audit may not  
7 interfere with the delivery of pharmacist services to a  
8 patient and shall utilize every effort to minimize  
9 inconvenience and disruption to pharmacy operations during the  
10 audit process.

11 "(4) An audit that involves clinical or professional  
12 judgment shall be conducted by or in consultation with a  
13 licensed pharmacist.

14 "(5) The audit shall not consider as fraud any  
15 clerical or record-keeping error, such as a typographical  
16 error, scrivener's error, or computer error regarding a  
17 required document or record; however, such errors may be  
18 subject to recoupment, provided that a pharmacy shall not be  
19 subject to a charge-back or recoupment for a clerical or  
20 record-keeping error in a required document or record,  
21 including a typographical or computer error, unless the error  
22 resulted in overpayment to the pharmacy. The pharmacy shall  
23 have the right to submit amended claims through an online  
24 submission to correct clerical or record-keeping errors in  
25 lieu of recoupment of a claim where no actual financial harm  
26 to the patient or plan has occurred, provided that the  
27 prescription was dispensed according to prescription

1 documentation requirements set forth by the Alabama Pharmacy  
2 Act and within the plan limits. The pharmacy shall not be  
3 subject to recoupment of funds by the pharmacy ~~benefits~~  
4 benefit manager unless the pharmacy ~~benefits~~ benefit manager  
5 can provide proof of intent to commit fraud or such error  
6 results in actual financial harm to the pharmacy ~~benefits~~  
7 benefit manager, a health insurance plan managed by the  
8 pharmacy ~~benefits~~ benefit manager, or a consumer. A person  
9 shall not be subject to criminal penalties for errors provided  
10 for in this subsection without proof of intent to commit  
11 fraud, waste, or abuse.

12 "a. Any amount to be charged back or recouped due to  
13 overpayment shall not exceed the amount the pharmacy was  
14 overpaid.

15 "b. The auditing entity shall not include the  
16 dispensing fee in the calculation of an overpayment unless a  
17 prescription is considered a misfill. As used in this  
18 paragraph, misfill means a prescription that was not  
19 dispensed, a prescription in which the prescriber denied the  
20 authorization request, a prescription in which an additional  
21 dispensing fee was charged, or a prescription error.

22 "(6) An entity conducting an audit shall not require  
23 any documentation that is not required by state and federal  
24 law ~~or Alabama Medicaid~~. The information shall be considered  
25 to be valid if documented on the prescription, computerized  
26 treatment notes, pharmacy system, or other acceptable medical  
27 records.

1           "(7) Unless superseded by state or federal law,  
2           auditors shall only have access to previous audit reports on a  
3           particular pharmacy conducted by the auditing entity for the  
4           same pharmacy ~~benefits~~ benefit manager, health plan, or  
5           insurer. An auditing vendor contracting with multiple pharmacy  
6           ~~benefits~~ benefit managers or health insurance plans shall not  
7           use audit reports or other information gained from an audit on  
8           a particular pharmacy to conduct another audit for a different  
9           pharmacy ~~benefits~~ benefit manager or health insurance plan.

10           "(8) Audit results shall be disclosed to the health  
11           benefit plan in a manner pursuant to contract terms.

12           "(9) A pharmacy may use the records of a hospital,  
13           physician, or other authorized practitioner of the healing  
14           arts for drugs or medicinal supplies written or transmitted by  
15           any means of communication for the purposes of validating the  
16           pharmacy record with respect to orders or refills of a legend  
17           or narcotic drug.

18           "(10) If the pharmacy benefit manager or its  
19           representative conducts an audit, the sample size shall not be  
20           greater than 150 prescriptions, provided that a refill does  
21           not constitute a separate prescription for the purposes of  
22           this subdivision.

23           "~~(10)~~ (11) Reasonable costs associated with the  
24           audit shall be the responsibility of the auditing entity ~~with~~  
25           ~~the exception of Alabama Medicaid~~ if the claims sample exceeds  
26           100 unique prescription hard copies.

1           "~~(11)~~ (12) A finding of an overpayment or an  
2 underpayment may be a projection based on the number of  
3 patients served having a similar diagnosis or on the number of  
4 similar orders or refills for similar drugs, except that  
5 recoupment shall be based on the actual overpayment or  
6 underpayment of actual claims.

7           "~~(12)~~ (13) A finding of an overpayment may not  
8 include the cost of the drugs that were dispensed in  
9 accordance with the prescriber's orders, provided the  
10 prescription was dispensed according to prescription  
11 documentation requirements set forth by the Alabama Pharmacy  
12 Act and within the plan limits. A finding of an overpayment  
13 may not include the dispensing fee amount unless any of the  
14 following apply:

15           "a. A prescription was not actually dispensed.

16           "b. The prescriber denied authorization.

17           "c. The prescription dispensed was a medication  
18 error by the pharmacy.

19           "d. The identified overpayment is solely based on an  
20 extra dispensing fee.

21           "~~(13)~~ (14) Each pharmacy shall be audited under the  
22 same standards and parameters as other similarly situated  
23 pharmacies audited by the entity and must be audited under  
24 rules applicable to the contractor and time period of the  
25 prescription.

26           "~~(14)~~ (15) Where not superseded by state or federal  
27 law, the period covered by an audit may not exceed two years



1 from the date the claim was submitted to or adjudicated by a  
2 managed care company, nonprofit hospital or medical service  
3 organization, health benefit plan, third-party payor, pharmacy  
4 benefit manager, a health program administered by a department  
5 of the state, or any entity that represents those companies,  
6 groups, or department. An audit may not be conducted six  
7 months past the date the pharmacy benefit management plan  
8 terminated its contract to adjudicate claims with a pharmacy  
9 benefit manager, health plan administrator, or any other  
10 entity representing those companies.

11 ~~"(15)~~ (16) An audit may not be initiated or  
12 scheduled during the first five calendar days of any month.

13 "(b) The entity shall provide the pharmacy with a  
14 written report of the audit and comply with all of the  
15 following requirements:

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

19 "(2) A pharmacy shall be allowed at least 30 days  
20 following receipt of the preliminary audit report in which to  
21 produce documentation to address any discrepancy found during  
22 the audit, with a reasonable extension to be granted upon  
23 request.

24 "(3) A final audit report shall be delivered to the  
25 pharmacy within 180 days after receipt of the preliminary  
26 audit report or final appeal, as provided for in Section  
27 34-23-185, whichever is later.

1           "(4) The audit documents shall be signed by the  
2 auditors assigned to the audit. The acknowledgement or receipt  
3 shall be signed by the auditor and the audit report shall  
4 contain clear contact information of the representative of the  
5 auditing organization.

6           "(5) Recoupments of any disputed funds, or repayment  
7 of funds to the entity by the pharmacy if permitted pursuant  
8 to contractual agreement, shall occur after final internal  
9 disposition of the audit, including the appeals process as ~~set~~  
10 ~~forth~~ provided for in Section 34-23-185. If the identified  
11 discrepancy for an individual audit exceeds twenty-five  
12 thousand dollars (\$25,000), future payments in excess of that  
13 amount to the pharmacy may be withheld pending finalization of  
14 the audit.

15           "(6) Interest shall not accrue during the audit  
16 period.

17           "(7) Each entity conducting an audit shall provide a  
18 copy of the final audit report, after completion of any review  
19 process, to the plan sponsor in a manner pursuant to a  
20 contract.

21           "§34-23-185.

22           "(a) Each entity conducting an audit shall establish  
23 a written appeals process under which a pharmacy may appeal an  
24 unfavorable preliminary audit report to the entity.

25           "(b) ~~If, following the appeal,~~ Following the appeal,  
26 if the entity finds that an unfavorable audit report or any  
27 portion thereof is unsubstantiated, the entity shall dismiss

1 the audit report or that portion without the necessity of any  
2 further action.

3 "(c) ~~If, following the appeal,~~ Following the appeal,  
4 if any of the issues raised in the appeal are not resolved to  
5 the satisfaction of either party, that party may ask for  
6 mediation of those unresolved issues unless other remedies are  
7 granted under the terms of the contract. A certified mediator  
8 shall be chosen by agreement of the parties from the mediators  
9 list maintained by the Alabama Supreme Court. The cost of  
10 mediation shall be borne by agreement of the parties or by the  
11 decision of the mediator.

12 "§34-23-186.

13 "(a) Notwithstanding any other provision in this  
14 article or state or federal law, the entity conducting the  
15 audit may not use the accounting practice of extrapolation in  
16 calculating recoupments or penalties for audits. An  
17 extrapolation audit means an audit of a sample of prescription  
18 drug benefit claims submitted by a pharmacy to the entity  
19 conducting the audit that is then used to estimate audit  
20 results for a larger batch or group of claims not reviewed by  
21 the auditor. Future fills or refills beyond the current claim  
22 date may not be subject to recoupment due to an assumption of  
23 error under extrapolation procedure. The auditing entity shall  
24 not use extrapolation to calculate penalties or amounts to be  
25 charged back or recouped unless otherwise required by federal  
26 requirements or federal plans.

1                   "(b) The auditing entity conducting a pharmacy audit  
2                   shall not compensate an employee or contractor with which an  
3                   auditing entity contracts to conduct a pharmacy audit based on  
4                   the amount claimed or the actual amount recouped by the  
5                   pharmacy being audited."

6                   Section 2. This act shall become effective on the  
7                   first day of the third month following its passage and  
8                   approval by the Governor, or its otherwise becoming law.