- 1 HB394
- 2 140035-2
- 3 By Representatives Beech and Johnson (R)
- 4 RFD: Health
- 5 First Read: 23-FEB-12

1	<u>ENGROSSED</u>
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4	A BILL
5	TO BE ENTITLED
6	AN ACT
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8	Relating to audits of pharmacy records; to establish
9	minimum and uniform standards and criteria for the audit of
10	pharmacy records by or on behalf of certain entities; to
11	prescribe the procedures for conducting an audit; to provide
12	for an appeal process; and to provide that an entity
13	conducting an audit may not use the accounting practice of
14	extrapolation in calculating recoupments or penalties for
15	audits.
16	BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:
17	Section 1. This act shall be known and may be cited
18	as "The Pharmacy Audit Integrity Act."
19	Section 2. The following words shall have the
20	following meanings as used in this act:
21	(1) HEALTH BENEFIT PLAN. Any individual or group
22	plan, employee welfare benefit plan, policy, or contract for
23	health care services issued, delivered, issued for delivery,
24	or renewed in this state by a health care insurer, health
25	maintenance organization, accident and sickness insurer,
26	fraternal benefit society, nonprofit hospital service
27	corporation, nonprofit medical service corporation, health

care service plan, or any other person, firm, corporation, joint venture, or other similar business entity that pays for insureds or beneficiaries in this state. The term includes, but is not limited to, entities created pursuant to Article 6, Chapter 4, Title 10, Code of Alabama 1975. A health benefit plan located or domiciled outside of the State of Alabama is deemed to be subject to this act if it receives, processes, adjudicates, pays, or denies claims for health care services submitted by or on behalf of patients, insureds, or beneficiaries who reside in Alabama.

- (2) PHARMACY. A place licensed by the Alabama State Board of Pharmacy in which prescriptions, drugs, medicines, medical devices, chemicals, and poisons are sold, offered for sale, compounded, or dispensed and shall include all places whose title may imply the sale, offering for sale, compounding, or dispensing of prescriptions, drugs, medicines, chemicals, or poisons.
- (3) PHARMACY BENEFIT MANAGEMENT PLAN. An arrangement for the delivery of pharmacist services in which a pharmacy benefit manager undertakes to administer the payment or reimbursement of any of the costs of pharmacist services for an enrollee on a prepaid or insured basis that contains one or more incentive arrangements intended to influence the cost or level of pharmacist services between the plan sponsor and one or more pharmacies with respect to the delivery of pharmacist services and requires or creates benefit payment differential

incentives for enrollees to use under contract with the pharmacy benefit manager.

- (4) PHARMACY BENEFIT MANAGER. A business that administers the prescription drug or device portion of pharmacy benefit management plans or health insurance plans on behalf of plan sponsors, insurance companies, unions, and health maintenance organizations. The term includes a person or entity acting for a pharmacy benefit manager in a contractual or employment relationship in the performance of pharmacy benefits management for a managed care company, nonprofit hospital or medical service organization, insurance company, or third-party payor.
  - (5) PHARMACIST SERVICES. Offering for sale, compounding, or dispensing of prescriptions, drugs, medicines, chemicals, or poisons pursuant to a prescription. Pharmacist services also includes the sale or provision of, counseling of, or fitting of medical devices, including prosthetics and durable medical equipment.

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

Section 4. This act shall apply to any audit of the records of a pharmacy conducted by a managed care company, nonprofit hospital or medical service organization, health benefit plan, third-party payor, pharmacy benefit manager, a health program administered by a department of the state, or

any entity that represents those companies, groups, or department.

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

- (1) The pharmacy contract shall identify and describe in detail the audit procedures.
- (2) The entity conducting the on-site audit shall give the pharmacy written notice at least two weeks before conducting the initial on-site audit for each audit cycle. If the pharmacy benefit manager does not include their auditing guidelines within their provider manual, then the audit notice must include a documented checklist of all items being audited and the manual, including the name, date, and edition or volume, applicable to the audit and auditing guidelines. For on-site audits a pharmacy benefit manager shall also provide a list of material that is copied or removed during the course of an audit to the pharmacy. The pharmacy benefit manager may document this material on either a checklist or on an audit acknowledgement form. The pharmacy shall produce any items during the course of the audit or within 30 days of the on-site audit.
- (3) The entity conducting the on-site audit may not interfere with the delivery of pharmacist services to a patient and shall utilize every effort to minimize inconvenience and disruption to pharmacy operations during the audit process.

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

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- (5) The audit shall not consider as fraud any clerical or record-keeping error, such as a typographical error, scrivener's error, or computer error regarding a required document or record; however, such errors may be subject to recoupment. The pharmacy shall have the right to submit amended claims through an online submission to correct clerical or record-keeping errors in lieu of recoupment of a claim where no actual financial harm to the patient or plan has occurred, provided that the prescription was dispensed according to prescription documentation requirements set forth by the Alabama Pharmacy Act and within the plan limits. The pharmacy shall not be subject to recoupment of funds by the pharmacy benefits manager unless the pharmacy benefits manager can provide proof of intent to commit fraud or such error results in foreseeable financial or physical harm to the pharmacy benefits manager, a health insurance plan managed by the pharmacy benefits manager, or a consumer. A person shall not be subject to criminal penalties for errors provided for in this subsection without proof of intent to commit fraud, waste, or abuse.
- (6) An entity conducting an audit shall not require any documentation that is not required by state and federal law or Alabama Medicaid. The information shall be considered to be valid if documented on the prescription, computerized

treatment notes, pharmacy system, or other acceptable medical
records.

- (7) Unless superseded by state or federal law, auditors shall only have access to previous audit reports on a particular pharmacy conducted by the auditing entity for the same pharmacy benefits manager, health plan, or insurer. An auditing vendor contracting with multiple pharmacy benefits managers or health insurance plans shall not use audit reports or other information gained from an audit on a particular pharmacy to conduct another audit for a different pharmacy benefits manager or heath insurance plan.
- (8) Audit results shall be disclosed to the health benefit plan in a manner pursuant to contract terms.
- (9) A pharmacy may use the records of a hospital, physician, or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug.
- (10) Reasonable costs associated with the audit shall be the responsibility of the auditing entity with the exception of Alabama Medicaid if the claims sample exceeds 100 unique prescription hard copies.
- (11) A finding of an overpayment or an underpayment may be a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs, except that recoupment shall be

based on the actual overpayment or underpayment of actual
claims.

- (12) A finding of an overpayment may not include the cost of the drugs that were dispensed in accordance with the prescriber's orders, provided the prescription was dispensed according to prescription documentation requirements set forth by the Alabama Pharmacy Act and within the plan limits. A finding of an overpayment may not include the dispensing fee amount unless:
  - a. A prescription was not actually dispensed.
  - b. The prescriber denied authorization.
  - c. The prescription dispensed was a medication error by the pharmacy.
  - d. The identified overpayment is solely based on an extra dispensing fee.
  - (13) Each pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies audited by the entity and must be audited under rules applicable to the contractor and time period of the prescription.
  - (14) Where not superseded by state or federal law, the period covered by an audit may not exceed two years from the date the claim was submitted to or adjudicated by a managed care company, nonprofit hospital or medical service organization, health benefit plan, third-party payor, pharmacy benefit manager, a health program administered by a department of the state, or any entity that represents those companies,

- groups, or department. An audit may not be conducted six

  months past the date the pharmacy benefit management plan

  terminated its contract to adjudicate claims with a pharmacy

  benefit manager, health plan administrator, or any other

  entity representing those companies.
  - (15) An audit may not be initiated or scheduled during the first five calendar days of any month.

- (b) The entity shall provide the pharmacy with a written report of the audit and comply with the following requirements:
- (1) The preliminary audit report shall be delivered to the pharmacy within 90 days after the conclusion of the audit, with a reasonable extension to be granted upon request.
- (2) A pharmacy shall be allowed at least 30 days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during the audit, with a reasonable extension to be granted upon request.
- (3) A final audit report shall be delivered to the pharmacy within 180 days after receipt of the preliminary audit report or final appeal, as provided for in Section 6, whichever is later.
- (4) The audit documents shall be signed by the auditors assigned to the audit. The acknowledgement or receipt shall be signed by the auditor and the audit report shall contain clear contact information of the representative of the auditing organization.

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

- (6) Interest shall not accrue during the audit period.
- (7) Each entity conducting an audit shall provide a copy of the final audit report, after completion of any review process, to the plan sponsor in a manner pursuant to a contract.

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

- (b) If, following the appeal, the entity finds that an unfavorable audit report or any portion thereof is unsubstantiated, the entity shall dismiss the audit report or that portion without the necessity of any further action.
- (c) If, following the appeal, any of the issues raised in the appeal are not resolved to the satisfaction of either party, that party may ask for mediation of those unresolved issues unless other remedies are granted under the terms of the contract. A certified mediator shall be chosen by agreement of the parties from the mediators list maintained by

the Alabama Supreme Court. The cost of mediation shall be borne by agreement of the parties or by the decision of the mediator.

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

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

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

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3	House of Representatives
4 5 6 7	Read for the first time and re- ferred to the House of Representa- tives committee on Health 23-FEB-12
8 9 10	Read for the second time and placed on the calendar
11 12 13	Read for the third time and passed as amended
14 15 16	Greg Pappas Clerk