SB99

DA1KHNT-1

By Senators Stutts, Gudger, Beasley, Smitherman, Coleman, Singleton, Melson, Bell, Butler, Sessions, Williams, Price, Hatcher, Figures, Allen, Chesteen, Stewart, Kelley, Coleman-Madison, Roberts, Livingston

RFD: Banking and Insurance

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SYNOPSIS:

Pharmacy benefits managers are the intermediary between health insurance plans and their network pharmacies which process claims and determine the amount pharmacies are reimbursed for dispensing covered prescriptions. They deal directly with drug manufacturers by negotiating discounts or rebates on drug prices. Pharmacy benefits managers may also be affiliated with particular pharmacies that also participate in the network. Under existing law, they are licensed and regulated by the Department of Insurance.

This bill would expand oversight by the Department of Insurance by setting benchmarks for the amounts that pharmacy benefits managers reimburse pharmacies, and by regulating how they process claims, determine payment amounts, and use manufacturer rebates.

This bill would prohibit pharmacy benefits managers from requiring or influencing health insurance beneficiaries to purchase a particular variant of a prescription drug or only use certain pharmacies within a health plan network.

This bill would authorize a health insurance plan, a plan beneficiary, or a pharmacy to bring a

cause of action against a pharmacy benefits manager for damages due to a violation of this act.

This bill would also further regulate the audit of a pharmacy by a pharmacy benefits manager under The Pharmacy Audit Integrity Act by specifying the circumstances under which a pharmacy benefits manager may recoup funds from a pharmacy that was overpaid for claims.

A BILL

TO BE ENTITLED

AN ACT

Relating to pharmacy benefits managers; to amend Sections 27-45A-1, 27-54A-3, 27-45A-5, 27-45A-6, 27-45A-7, 27-45A-8, 27-45A-9, and 27-45A-10, Code of Alabama 1975; to further regulate pharmacy benefits managers in relation to health insurance plans, covered individuals, and plan network pharmacies; to add Section 27-45A-13 to the Code of Alabama 1975, to provide a civil action against pharmacy benefits managers for violations of this act and to provide remedies; to amend Sections 34-23-181 and 34-23-184, Code of Alabama 1975, to further regulate recoupment of funds from pharmacies pursuant to The Pharmacy Audit Integrity Act; and to make conforming changes.

BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

Section 1. Sections 27-45A-1, 27-45A-3, 27-45A-5,

27-45A-6, 27-45A-7, 27-45A-8, 27-45A-9, and 27-45A-10, Code of Alabama 1975, are amended to read as follows:

"§27-45A-1

This chapter shall be known as and may be cited as the Alabama Pharmacy Benefits Manager Licensure, ~~and~~ Regulation, and Accountability Act."

"§27-45A-3

For purposes of this chapter, the following words ~~shall~~ have the following meanings:

(1) BENEFICIARY. A covered individual who receives prescription drug benefits under a health benefit plan.

~~(1)~~ (2) CLAIMS PROCESSING SERVICES. The administrative services performed in connection with the processing and adjudicating of claims relating to pharmacist services that include any of the following:

a. Receiving payments for pharmacist services.

b. Making payments to pharmacists or pharmacies for pharmacist services.

c. Both paragraphs a. and b.

(3) CLIENT. An employer, employer group, health insurer, health benefit plan, or other payor that has a contract with a pharmacy benefits manager or PBM affiliate for pharmacy benefits services, including claims processing.

(4) COMMISSIONER. The Commissioner of the Department of Insurance of the State of Alabama.

~~(2)~~ (5) COVERED INDIVIDUAL. A member, policyholder, subscriber, enrollee, beneficiary, dependent, or other individual participating in a health benefit plan.

~~(3)~~(6) HEALTH BENEFIT PLAN. ~~A policy, contract, certificate, or agreement entered into, offered, or issued by a health insurer to provide, deliver, arrange for, pay for, or reimburse any of the costs of physical, mental, or behavioral health care services~~As defined in Section 34-23-181.

~~(4)~~(7) HEALTH INSURER. An entity subject to the insurance laws of this state and rules of the department, or subject to the jurisdiction of the department, that contracts or offers to contract to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services, including, but not limited to, a sickness and accident insurance company, a health maintenance organization operating pursuant to Chapter 21A, a nonprofit hospital or health service corporation, a health care service plan organized pursuant to Article 6, Chapter 20 of Title 10A, or any other entity providing a plan of health insurance, health benefits, or health services.

(8) IN-NETWORK PHARMACY. A pharmacy that fills a prescription for a beneficiary and which, either as an entity or in the name of an owner or employee, does not appear on the list of excluded individuals and entities maintained by the Office of Inspector General, U.S. Health and Human Services, pursuant to 42 U.S.C. § 1320a-7.

(9) NATIONAL AVERAGE DRUG ACQUISITION COST. The average acquisition cost of a drug product as determined by the Centers for Medicare & Medicaid Services (CMS) from survey data collected from retail community pharmacies nationwide.

~~(5)~~(10) OTHER PRESCRIPTION DRUG OR DEVICE SERVICES.

Services, other than claims processing services, provided directly or indirectly, whether in connection with or separate from claims processing services, including, but not limited to, any of the following:

a. Negotiating rebates, discounts, or other financial incentives and arrangements with drug companies.

b. Disbursing or distributing rebates.

c. Managing or participating in incentive programs or arrangements for pharmacist services.

d. Negotiating or entering into contractual arrangements with pharmacists or pharmacies, or both.

e. Developing formularies.

f. Designing prescription benefit programs.

g. Advertising or promoting services.

(11) PBM AFFILIATE. An entity, including a pharmacy, that, directly or indirectly, through one or more intermediaries, is affiliated with a pharmacy benefits manager in one of the following ways:

a. Owns, controls, or has an investment interest in a pharmacy benefits manager.

b. Owned, controlled by, or has an investment holder that is a pharmacy benefits manager.

c. Shares common ownership by another entity with a pharmacy benefits manager.

~~(6)~~(12) PHARMACIST. As defined in Section 34-23-1.

~~(7)~~(13) PHARMACIST SERVICES. Products, goods, and services, including the dispensing of prescription drugs, or any combination of products, goods, and services, provided as

a part of the practice of pharmacy.

~~(8)~~ (14) PHARMACY. As defined in Section 34-23-1.

(15) PHARMACY BENEFITS MANAGEMENT SERVICES. The term includes:

a. The management or administration of a plan or program pursuant to a health benefit plan that pays for, reimburses, or covers the cost of prescription drugs and medical devices.

b. Claims processing services and the adjudication of appeals or grievances related to prescription drug benefits.

~~(9)~~ (16) PHARMACY BENEFITS MANAGER. a. A person, including a wholly or partially owned or controlled subsidiary of a pharmacy benefits manager, that provides pharmacy benefits management services, claims processing services or other prescription drug or device services, or both, to covered individuals who are employed in or are residents of this state, for health benefit plans.

b. Pharmacy benefits manager does not include any of the following:

1. A healthcare facility licensed in this state.

2. A healthcare professional licensed in this state.

3. A consultant who only provides advice as to the selection or performance of a pharmacy benefits manager.

~~(10) PBM AFFILIATE. A pharmacy or pharmacist that, directly or indirectly, through one or more intermediaries, is owned or controlled by, or is under common control by, a pharmacy benefits manager.~~

~~(11)~~ (17) PRESCRIPTION DRUGS. Drugs covered by a health

benefit plan which are dispensed by an in-network pharmacy to a beneficiary. The term ~~Includes~~includes, but is not limited to, certain infusion, compounded, and long-term care prescription drugs. ~~The term does not include specialty drugs.~~

(18) REBATE. Any direct or indirect payment or concession, including a discount, administration fee, credit, incentive, or penalty that is made by a pharmaceutical manufacturer, its affiliate, subsidiary, or intermediary to a pharmacy benefits manager, a PBM affiliate, or a client, and which is associated in any way with claims administered by a pharmacy benefits manager under a health benefit plan.

~~(12)~~ (19) SPECIALTY DRUGS. Prescription medications that require special handling, administration, or monitoring and are used for the treatment of patients with serious health conditions requiring complex therapies, and that are eligible for specialty tier placement by the Centers for Medicare ~~and~~& Medicaid Services pursuant to 42 C.F.R. § 423.560.

(20) SPREAD PRICING. When a pharmacy benefits manager charges a client a price for prescription drugs which is higher than the amount the pharmacy benefits manager pays the pharmacy or pharmacist for the prescription drugs, including any post-sale or post-adjudication fees, discounts, or adjustments, provided that the post-sale or post-adjudication fees, discounts, or adjustments are not otherwise prohibited by law.

(21) STEERING. The term includes:

a. Directing, ordering, or requiring a beneficiary to use a specific pharmacy, including a PBM affiliate pharmacy,

for the purpose of filling a prescription or receiving pharmacist services.

b. Inducing a beneficiary to use a designated pharmacy, including a PBM affiliate pharmacy, by increasing costs to the health benefit plan or charging the beneficiary up to the full cost for a prescription drug if the beneficiary fails to use the pharmacy designated by the pharmacy benefits manager.

c. Advertising, marketing, or promoting a pharmacy, including a PBM affiliate pharmacy, over another in-network pharmacy.

d. Engaging in any practice that results in excluding, restricting, or inhibiting an in-network pharmacy from providing prescription drugs to beneficiaries under a health benefit plan, which may involve, but not be limited to, the use of credentialing or accreditation standards, day supply limitations, or delivery method limitations.

e. Engaging in any practice aimed at directly or indirectly influencing a pharmaceutical manufacturer to limit its distribution of a prescription drug to certain pharmacies or to restrict distribution of the drug to non-PBM affiliate pharmacies."

"§27-45A-5

(a) ~~The commissioner may adopt rules necessary to implement this chapter~~It shall be the responsibility of the commissioner to enforce this chapter and any conduct arising from any action taken by a pharmacy benefits manager or PBM affiliate pursuant to an audit conducted under Article 8, Chapter 23 of Title 34 which violates this chapter.

(b) The commissioner shall adopt rules necessary to implement and enforce this chapter, both independently and in conjunction with the conduct of an audit by a pharmacy benefits manager or PBM affiliate under Article 8 of Chapter 23 of Title 34.

(c) The commissioner shall set and impose civil penalties, of not less than one thousand dollars ($1,000) per violation for violations of this chapter, including conduct arising from an action taken by a pharmacy benefits manager or PBM affiliate pursuant to Article 8, Chapter 23 of Title 34 which violates this chapter.

~~(b)~~ (d) The powers and duties set forth in this chapter shall be in addition to all other authority of the commissioner.

~~(c)~~ (e) The commissioner shall enforce compliance with the requirements of this chapter and rules adopted thereunder.

~~(d)~~ (f)(1) The commissioner may examine or audit, including on an annual basis, any books and records of a pharmacy benefits manager providing claims processing services or other prescription drug or device services for a health benefit plan as may be deemed relevant and necessary by the commissioner to determine compliance with this chapter and Article 8 of Chapter 23 of Title 34.

(2) Examinations conducted by the commissioner shall be pursuant to the same examination authority of the commissioner relative to insurers as provided in Chapter 2, including, but not limited to, the confidentiality of documents and information submitted as provided in Section 27-2-24;

examination expenses shall be processed in accordance with Section 27-2-25; and pharmacy benefits managers shall have the same rights as insurers to request a hearing in accordance with Sections 27-2-28 et seq., and to appeal as provided in Section 27-2-32.

(3) The commissioner may contract the services of a third party to perform an audit under this subsection.

~~(c)~~ (g) The commissioner's examination expenses shall be collected from pharmacy benefits managers in the same manner as those collected from insurers."

"§27-45A-6

~~(a)~~ Nothing in this chapter is intended or shall be construed to do any of the following:

(1) Be in conflict with existing relevant federal law.

~~(2) Apply to any specialty drug.~~

~~(3)~~ (2) Impact the ability of a hospital to mandate its employees use of a hospital-owned pharmacy~~.~~

~~(b) The following provisions shall not apply to the administration by a person of any term, including prescription drug benefits, of a self-funded health benefit plan that is governed by the federal Employee Retirement Income Security Act of 1974, 29 U.S.C. §1001 et. seq.:~~

~~(1) Subdivisions (1) and (5) of Section 27-45A-8.~~

~~(2) Subdivisions (2), (3), (6), and (7) of Section 27-45A-10~~."

"§27-45A-7

~~Reserved~~A pharmacy benefits manager, either directly or through a PBM affiliate, when administering prescription drug

benefits on behalf of a health benefit plan, shall do all of the following:

(1) Reimburse every claim of an in-network pharmacy for the ingredient cost of a prescription drug in an amount greater than or equal to the sum of:

a. The National Average Drug Acquisition Cost for the drug on the day of claim adjudication or, in the case of a drug not listed on the National Average Drug Acquisition Cost index, the wholesale acquisition cost; plus

b. An amount equal to two percent of the applicable amount in paragraph a. or twenty-five dollars ($25), whichever is less.

(2) Pay an in-network pharmacy a professional dispensing fee that is greater than or equal to the current professional dispensing fee paid by the Medicaid Agency of the State of Alabama under Title XIX of the Social Security Act for dispensing a prescription drug.

(3) Uniformly and equally apply reimbursements pursuant to subdivisions (1) and (2) to all in-network pharmacies, including PBM affiliates, servicing a health benefit plan.

(4)a. Pass on to a client 100 percent of all rebates received, directly or indirectly, from a pharmaceutical manufacturer in connection with claims administered unless the client directs the pharmacy benefits manager or PBM affiliate to apply the rebates to purchases of prescription drugs by covered individuals at the point of sale.

b. Notwithstanding paragraph a., nothing shall be construed in this subdivision to allow a rebate from a

pharmaceutical manufacturer, directly or indirectly, to a pharmacy benefits manager, its PBM affiliate, or a client where otherwise prohibited by law.

(5) Reimburse an in-network pharmacy all amounts due for a prescription drug claim pursuant to subdivisions (1) and (2) according to the payment terms contained in the contract governing the pharmacy benefit manager or PBM affiliate."

"§27-45A-8

A pharmacy benefits manager may not do any of the following:

(1) Require a covered individual, as a condition of payment or reimbursement, to purchase pharmacist services, including, but not limited to, prescription drugs, exclusively through a mail-order pharmacy or ~~pharmacy benefits manager~~PBM affiliate.

(2) Prohibit or limit any covered individual from selecting an in-network pharmacy or pharmacist of his or her choice who meets and agrees to the terms and conditions, including reimbursements, in the pharmacy benefits manager's contract.

(3) Impose a monetary advantage or penalty under a health benefit plan that would affect a covered individual's choice of pharmacy among those pharmacies that have chosen to contract with the pharmacy benefits manager under the same terms and conditions, including reimbursements. For purposes of this subdivision, "monetary advantage or penalty" includes, but is not limited to, a higher copayment, a waiver of a copayment, a reduction in reimbursement services, a

requirement or limit on the number of days of a drug supply for which reimbursement will be allowed, or a promotion of one participating pharmacy over another by these methods.

(4)a. Use a covered individual's pharmacy services data collected pursuant to the provision of claims processing services for the purpose of soliciting, marketing, or referring the covered individual to a mail-order pharmacy or PBM affiliate.

b. This subdivision shall not limit a health benefit plan's use of pharmacy services data for the purpose of administering the health benefit plan.

~~c. This subdivision shall not prohibit a pharmacy benefits manager from notifying a covered individual that a less costly option for a specific prescription drug is available through a mail-order pharmacy or PBM affiliate, provided the notification shall state that switching to the less costly option is not mandatory. The commissioner, by rule, may determine the language of the notification authorized under this paragraph made by a pharmacy benefits manager to a covered individual.~~

(5) Require a covered individual to make a payment for a prescription drug at the point of sale in an amount that exceeds the ~~lessor~~lesser of the following:

a. The contracted cost share amount.

b. An amount an individual would pay for a prescription if that individual were paying without insurance.

(6) Charge a beneficiary more for a prescription drug than the amount of reimbursement made to the pharmacy or

pharmacist that dispenses the drug.

(7) Require a beneficiary to obtain a brand-name prescription drug when a lower cost, therapeutically equivalent version or an FDA-designated interchangeable biological product of the brand-name drug is available.

(8) Recoup any increased cost incurred for the dispensing fee required under Section 27-45A-7(2) by increasing the copayment, coinsurance, or deductible of the beneficiary.

(9) Otherwise seek to limit, control, or influence the utilization of pharmacist services by a covered individual or beneficiary through the practice of steering."

"§27-45A-9

(a) ~~For purposes of this section, client means a health insurer, payor, or health benefit plan.~~

~~(b)~~ If requested by a client under subsection (d), a pharmacy benefits manager shall prepare an annual report by June 1 which discloses all of the following with respect to that client:

(1) The aggregate amount of all rebates that the pharmacy benefits manager received from pharmaceutical manufacturers on behalf of the client.

(2) The aggregate amount of the rebates the pharmacy benefits manager received from pharmaceutical manufacturers that did not pass through to the client.

~~(3) If a pharmacy benefits manager or any consultant providing pharmacy benefits management services engages in spread pricing, the aggregated amount of the difference~~

~~between the amount paid by the client for prescription drugs and the actual amount paid to the pharmacy or pharmacist for pharmacist services. For purposes of this subdivision, "spread pricing" means the model of prescription drug reimbursement in which a pharmacy benefits manager charges a client a contracted price for prescription drugs, and the contract price for the prescription drugs differs from the amount the pharmacy benefits manager, directly or indirectly, pays the pharmacy or pharmacist for pharmacist services.~~

~~(c)~~ (b) Confidentiality of a report submitted under this section shall be governed by contract between the pharmacy benefits manager and the client.

~~(d)~~ (c) A pharmacy benefits manager shall annually notify all its clients in a timely manner that a report described in subsection (b) will be made available to the client by the pharmacy benefits manager if requested by the client."

"§27-45A-10

A pharmacy benefits manager may not do any of the following:

(1) Reimburse an in-network pharmacy or pharmacist in the state an amount less than the amount that the pharmacy benefits manager reimburses a ~~similarly situated~~ PBM affiliate for providing the same pharmacist services to covered individuals in the same health benefit plan.

(2) Deny a pharmacy or pharmacist the right to participate as a contract provider if the pharmacy or pharmacist meets and agrees to the terms and conditions,

including reimbursements, in the pharmacy benefits manager's contract.

(3) Impose credentialing standards on a pharmacist or pharmacy beyond or more onerous than the licensing standards set by the Alabama State Board of Pharmacy or charge a pharmacy a fee in connection with network enrollment, provided this subdivision shall not prohibit a pharmacy benefits manager from setting minimum requirements for participating in a pharmacy network.

(4) Prohibit a pharmacist or pharmacy from providing a client or covered individual specific information on the amount of the covered individual's cost share for the covered individual's prescription drug, the reimbursement amount or acquisition cost of a prescription drug, and the clinical efficacy of a more affordable alternative drug if one is available, or penalize a pharmacist or pharmacy for disclosing this information to a client or covered individual or for selling to a covered individual a more affordable alternative if one is available.

(5) Prohibit a pharmacist or pharmacy from offering and providing delivery services to a covered individual as an ancillary service of the pharmacy, provided all of the following requirements are met:

a. The pharmacist or pharmacy can demonstrate quality, stability, and safety standards during delivery.

b. The pharmacist or pharmacy does not charge any delivery or service fee to a pharmacy benefits manager or health insurer.

c. The pharmacist or pharmacy alerts the covered individual that he or she will be responsible for any delivery service fee associated with the delivery service, and that the pharmacy benefits manager or health insurer will not reimburse the delivery service fee.

(6) Charge or hold a pharmacist or pharmacy responsible for a fee or penalty relating to an audit conducted pursuant to The Pharmacy Audit Integrity Act, Article 8 of Chapter 23 of Title 34, provided this prohibition does not restrict recoupments made in accordance with the Pharmacy Audit Integrity Act.

(7) ~~Charge a pharmacist or pharmacy a point-of-sale or retroactive fee or otherwise recoup funds from a pharmacy in connection with claims for which the pharmacy has already been paid,~~Impose any fee or adjust a prescription drug claim at or after the time the claim for the drug is adjudicated that reduces the amount an in-network pharmacy is reimbursed pursuant to the requirements of Section 27-45A-7(1), including any fee that is not tied to a prescription drug claim, unless the ~~recoupment~~fee or adjustment is made pursuant to an audit conducted in accordance with the Pharmacy Audit Integrity Act.

(8) Impose any fee on an in-network pharmacy for claims processing services.

~~(8)~~ (9) Except for a drug reimbursed, directly or indirectly, by the Medicaid program, vary the amount a pharmacy benefits manager reimburses an entity for a drug, including each and every prescription medication that is eligible for specialty tier placement by the Centers for

Medicare and Medicaid Services pursuant to 42 C.F.R. § 423.560, regardless of any provision of law to the contrary, on the basis of whether:

a. The drug is subject to an agreement under 42 U.S.C. § 256b; or

b. The entity participates in the program set forth in 42 U.S.C. § 256b.

~~(9)~~ (10) If an entity participates, directly or indirectly, in the program set forth in 42 U.S.C. § 256b, do any of the following:

a. Assess a fee, charge-back, or other adjustment on the entity.

b. Restrict access to the pharmacy benefits manager's pharmacy network.

c. Require the entity to enter into a contract with a specific pharmacy to participate in the pharmacy benefits manager's pharmacy network.

d. Create a restriction or an additional charge on a patient who chooses to receive drugs from the entity.

e. Create any additional requirements or restrictions on the entity.

~~(10)~~ (11) Require a claim for a drug to include a modifier to indicate that the drug is subject to an agreement under 42 U.S.C. § 256b.

(12) Base or tie reimbursement for a prescription drug on outcomes, scores, or metrics relating to the pharmacy, the provision of pharmacist services, or a beneficiary, provided that the pharmacist or pharmacy provides pharmacist services

within the scope of practice as defined by law and professional standards.

(13) Impose any legal, financial, or other means of influence on a pharmacist to dispense a particular prescription drug or to practice pharmacy in a way that would be potentially harmful to a covered individual.

(14) Initiate a fraud, waste, or abuse investigation of a pharmacist or pharmacy under Article 8 of Chapter 23 of Title 34 without first notifying the pharmacist or pharmacy and receiving approval from the commissioner based upon an articulable suspicion of fraud, waste, or abuse.

(15) Impose a recoupment or charge back on a pharmacist or pharmacy pursuant to an audit under Article 8 of Chapter 23 of Title 34 which violates the conditions governing a recoupment or charge back under that article.

~~(11)~~ (16) Penalize or retaliate against a pharmacist or pharmacy for exercising rights under this chapter or the Pharmacy Audit Integrity Act.

(17) Practice spread pricing in this state."

Section 2. Section 27-45A-13 is added to the Code of Alabama 1975, to read as follows:

§27-45A-13

(a) Any pharmacy or pharmacist, health care provider, health insurer, covered individual, or beneficiary who is injured by any violation of this chapter, alone or in conjunction with an audit performed by a pharmacy benefits manager or PBM affiliate pursuant to Article 8 of Chapter 23 of Title 34, may bring a civil action against the pharmacy

benefits manager or PBM affiliate, for the remedies provided under this section.

(b) In any action brought under this section, the injured person may recover any of the following:

(1) Actual damages, including reimbursement for costs incurred due to reductions in payment, delays, or denials.

(2) No less than one thousand dollars ($1,000) per violation of this chapter, or treble the amount of actual damages, whichever is greater, if the pharmacy benefits manager or PBM affiliate is found to have knowingly or recklessly committed the violation.

(3) Injunctive relief upon a finding by the court that the pharmacy benefits manager or PBM affiliate has, or is about to, violate this chapter.

(4) Attorney fees and costs.

(c) No class action or joint action may be brought under this section unless each proposed class member or plaintiff has given notice of the prospective action to the pharmacy benefits manager or PBM affiliate and the pharmacy benefits manager or PBM affiliate is afforded 30 days to cure the alleged violation.

(d) An action under this section must be brought within two years from the date on which the alleged violation occurred or within one year of the discovery of the alleged violation, whichever period is longer.

Section 3. Sections 34-23-181 and 34-23-184, Code of Alabama 1975, are amended to read as follows:

"§34-23-181

The following words ~~shall~~ have the following meanings as used in this article:

(1) COMMISSIONER. The Commissioner of the Department of Insurance of the State of Alabama.

~~(1)~~(2) HEALTH BENEFIT PLAN. Any individual or group plan, employee welfare benefit plan, policy, or contract for health care services issued, delivered, issued for delivery, or renewed in this state by a health care insurer, health maintenance organization, accident and sickness insurer, fraternal benefit society, nonprofit hospital service 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 of Chapter 20 of Title 10A. A health benefit plan located or domiciled outside of the State of Alabama is deemed to be subject to this article 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)~~(3) 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)~~(4) PHARMACY ~~BENEFIT~~BENEFITS MANAGEMENT PLAN. An arrangement for the delivery of pharmacist services in which a pharmacy ~~benefit~~benefits 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~~benefits manager.

~~(4)~~(5) PHARMACY ~~BENEFIT~~BENEFITS MANAGER. A business that administers the prescription drug or device portion of pharmacy ~~benefit~~benefits 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~~benefits manager in a contractual or employment relationship in the performance of pharmacy ~~benefit~~benefits management for a managed care company, nonprofit hospital or medical service organization, insurance company, or third-party payor.

~~(5)~~(6) 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."

"§34-23-184

(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~~benefits manager does not include their auditing guidelines within their provider manual, then the 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~~benefits 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~~benefits 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.

(5) The audit shall not consider as fraud any clerical

or recordkeeping error, such as a typographical error, scrivener's error, or computer error regarding a required document or record~~;~~ subject to the provisions of subsection (b). ~~however, such errors may be subject to recoupment, provided that a pharmacy shall not be subject to a charge-back or recoupment for a clerical or recordkeeping error in a required document or record, including a typographical or computer error, unless the error resulted in overpayment to the pharmacy.~~ The pharmacy shall have the right to submit amended claims through an online submission to correct clerical or recordkeeping errors in lieu of recoupment of a claim pursuant to subsection (b) 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 benefit manager unless the pharmacy benefit manager can provide proof of intent to commit fraud or such error results in actual financial harm to the pharmacy benefit manager, a health insurance plan managed by the pharmacy benefit manager, or a consumer. A person~~A pharmacist or pharmacy shall not be subject to criminal penalties for errors provided for in this subsection without proof of intent to commit fraud, waste, or abuse.

~~a. Any amount to be charged back or recouped due to overpayment shall not exceed the amount the pharmacy was overpaid.~~

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

(6) An entity conducting an audit shall not require any documentation that is not required by state and federal law. 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 ~~benefit~~benefits manager, health plan, or insurer. An auditing vendor contracting with multiple pharmacy ~~benefit~~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 ~~benefit~~benefits manager or health 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 the purposes of validating the pharmacy record with respect to orders or refills of a legend

or narcotic drug.

(10) If the pharmacy ~~benefit~~benefits manager or its representative conducts an audit, the sample size shall comply with both of the following conditions:

a. ~~not be greater than~~Not exceed 150 prescriptions, provided that a refill does not constitute a separate prescription for the purposes of this subdivision.

b. The sample size shall not include prescriptions for brand-name or high-cost drugs at a rate that exceeds the percentage of brand-name or high-cost drugs in relation to all prescription drugs dispensed by the pharmacy during the period audited.

(11) Reasonable costs associated with the audit shall be the responsibility of the auditing entity if the claims sample exceeds 100 unique prescription hard copies.

(12) 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 pursuant to subsection (b) shall be based on the actual overpayment or underpayment of actual claims.

(13) 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 any of the following apply:

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.

(14) 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.

(15) A pharmacy benefits manager may not audit a pharmacy that is not a PBM affiliate as defined in Section 27-45A-3 more frequently than a pharmacy that is a PBM affiliate or use procedures when auditing a pharmacy which are different than those when auditing a pharmacy that is a PBM affiliate.

~~(15)~~ (16) 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~~benefits 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~~benefits management plan terminated its contract to adjudicate claims with a pharmacy ~~benefit~~benefits manager,

health plan administrator, or any other entity representing those companies.

~~(16)~~ (17) An audit may not be initiated or scheduled during the first five calendar days of any month.

(b)(1) An auditing entity has the right to charge back or recoup funds from a pharmacy when an audit discloses an overpayment at the expense of, or which financially harms, the auditing entity, or the beneficiary of a health benefit plan, due to one of the following:

a. Fraud.

b. Error, including a misfill. As used in this paragraph, a "misfill" means a prescription that was not dispensed, a prescription in which the prescriber denied the authorization request, a prescription in which an additional dispensing fee was charged, or a prescription error.

(2) Recoupment of an overpayment may not include the amount of the professional dispensing fee if the prescription was dispensed to the customer.

(3) Any amount to be recouped, or charged back, shall not exceed the amount the pharmacy was overpaid.

(4) If the auditing entity is a pharmacy benefits manager, the pharmacy benefits manager shall ensure that funds recouped pursuant to an audit shall be remitted to the health benefit plan or the beneficiary as provided under the terms of any contract governing pharmacy benefits management services as defined in Section 27-45A-3 or the pharmacy benefits management plan.

(5) If the auditing entity is a pharmacy benefits

manager claiming a recoupment or charge back, the pharmacy benefits manager shall notify the commissioner of its intent to recover the funds from the pharmacy at the time it delivers the preliminary audit report provided in subsection (c) to the pharmacy.

~~(b)~~ (c) The entity shall provide the pharmacy with a written report of the audit and comply with all of 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 34-23-185, 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 provided for in Section 34-23-185. 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 4. This act shall become effective on October 1, 2025.