- 1 SB483
- 2 169136-1
- 3 By Senator Marsh
- 4 RFD: Banking and Insurance
- 5 First Read: 19-MAY-15

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SYNOPSIS: This bill would amend the Pharmaceutical Insurance Coverage Chapter of the Alabama Insurance Code to provide further for the applicability of Chapter 45 of Title 27, Code of Alabama, to pharmacy benefit management administered by various health care plans, companies, and facilities; to provide for definitions, choice of pharmacy services, and contracting providers, void policies, non-mandated benefits and services; requirements of compliance; nonconforming policies; duty of Insurance Department to enforce, adoption of rules,

regulated activities; and violations.

This bill would add a new Article 3 to

Chapter 45 of Title 27, Code of Alabama, relating

to the administration of pharmaceutical insurance

coverage, including timely notice of changes in

terms of managers; reimbursement and payment;

cancellation procedures; denial of payment;

preservation of patient care; use of pharmacy data;

pricing of drugs; 90-day supply at retail; and synchronization of medication.

This bill would amend the Pharmacy Audit
Integrity Act to provide further for audit
procedures and reports regarding disclosure to a
pharmacy prior to changes in contract or audit
procedures; extension of time for producing audit
items; qualifications of licensed pharmacists
giving professional judgment; amended claims;
requirements for documentation; confidentiality and
limits on audit information; validation of pharmacy
records for changes of certain drugs authorized by
federal or state law; overpayments and recoupment
of excess payments; and claims adjudication.

17 TO BE ENTITLED

18 AN ACT

To amend Sections 27-45-1, 27-45-2, 27-45-3, 27-45-4, 27-45-5, 27-45-6, 27-45-7, 27-45-8, and 27-45-9, relating to Chapter 45 of Title 27 to provide further for the applicability of Chapter 45 of Title 27 to pharmacy benefit management plans and to provide for definitions, choice of pharmacy services, and contracting providers, void policies, non-mandated benefits and services; requirements of compliance; nonconforming policies; duty of Insurance

A BILL

1 Department to enforce, adoption of rules, regulated 2 activities; and violations; to add Article 3 to Chapter 45 of Title 27 consisting of Sections 27-45-30 to 27-45-38, 3 inclusive, Code of Alabama 1975, relating to the administration of pharmaceutical coverage, including timely 5 6 notice of changes in terms of managers; reimbursement and 7 payment; cancellation procedures; denial of payment; preservation of patient care; use of pharmacy data; pricing of 8 9 drugs; 90-day supply at retail; and synchronization of 10 medication; and to amend Section 34-23-184, Code of Alabama 1975, relating to audit and report procedures pursuant to the 11 12 Pharmacy Audit Integrity Act; to provide further for 13 disclosure of changes in pharmacy contract and audit 14 procedures; notice of on-site audits; qualifications of pharmacists giving professional judgment in audits; amended 15 claims; limits on audit documentation; confidentiality of 16 17 audit information; validation of pharmacy records for changes of certain drugs authorized by federal or state law; 18 overpayments and recoupment of excess payments, and claims 19 adjudication. 20 BE IT ENACTED BY THE LEGISLATURE OF ALABAMA: 21 22 Section 1. Sections 27-45-1, 27-45-2, 27-45-3, 27-45-4, 27-45-5, 27-45-6, 27-45-7, 27-45-8, and 27-45-9, Code 23 24 of Alabama 1975, are amended to read as follows: "\$27-45-1. 25 "This article shall apply to health insurance and 26

plans, employee benefit plans, health benefit plans, pharmacy

1	benefit management plans, administered by a managed care
2	company, nonprofit hospital or medical service organization,
3	health benefit plan, third-party payor, pharmacy benefit
4	manager, a health program administered by a department of the
5	state, or any entity that represents those companies, groups,
6	or departments providing for pharmaceutical services,
7	including without limitation, prescription drugs.
8	" §27-45-2.
9	"As used in this article, the following terms shall
10	have the respective meanings herein set forth, unless the
11	context shall otherwise require:
12	"(1) ALABAMA INSURANCE CODE. Title 27 of the Code of
13	Alabama 1975.
14	"(4) (2) COMMISSIONER and DEPARTMENT. Such terms,
15	respectively, shall have the meanings ascribed in Section
16	27-1-2 . The Commissioner of Insurance of this state.
17	" (5) (3) CONTRACTUAL OBLIGATION. Any obligation
18	under covered policies or employee benefit plans.
19	"(6) (4) COVERED POLICY OR PLAN. Any policy,
20	employee benefit plan. or contract within the scope of this
21	article.
22	"(5) DEPARTMENT. The Department of Insurance of this
23	<u>state.</u>
24	"(6) (12) DRUGS. All medical substances,
25	preparations, and devices recognized by the United States
26	Pharmacopoeia and National Formulary, or any revision thereof,
27	and all substances and preparations intended for external and

internal use in the cure, diagnosis, mitigation, treatment, or prevention of disease in man or animal and all substances and preparations other than food intended to affect the structure or any function of the body of man or animal.

"(7) (8) EMPLOYEE BENEFIT PLAN. Any plan, fund, or program heretofore or hereafter established or maintained by an employer or an employee organization, or by both, to the extent that such plan, fund, or program was established or is maintained for the purpose of providing for its participants or their beneficiaries, through the purchase of insurance or otherwise, pharmaceutical services, including, without limitation, prescription drugs.

"(8) 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 4 of Title 10. 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

Т	submitted by or on behalf of patients, insureds, or
2	beneficiaries who reside in Alabama.
3	" $\frac{(7)}{(9)}$ HEALTH INSURANCE POLICY. Any individual,
4	group, blanket, or franchise insurance policy, insurance
5	agreement, or group hospital service contract providing for
6	pharmaceutical services, including, without limitation,
7	prescription drugs, incurred as a result of accident or
8	sickness, or to prevent same.
9	" (2) <u>(10)</u> INSURER. Such term shall have the meaning
10	ascribed in Section 27-1-2. Every person engaged as
11	indemnitor, surety, or contractor in the business of entering
12	into contracts of insurance.
13	"(11) MAC. Maximum allowable cost.
14	" (3) <u>(12)</u> PERSON. Such term shall have the meaning
15	ascribed in Section 27-1-2. An individual, insurer, company,
16	association, organization, Lloyd's insurer, society,
17	reciprocal insurer or interinsurance exchange, partnership,
18	syndicate, business trust, corporation, and every legal
19	entity.
20	"(11) (13) PHARMACEUTICAL SERVICES. Services
21	ordinarily and customarily rendered by a pharmacy or
22	pharmacist, including, without limitation, the dispensing of
23	prescriptions, drugs, medicines, chemicals, or poisons
24	offering for sale, compounding, or dispensing or
25	prescriptions, drugs, medicines, chemicals, or poisons.
26	Pharmaceutical services also includes the sale or provision

of, counseling of, or fitting of medical devices, including
prosthetics and durable medical equipment.

"(9)(14) PHARMACIST. Any person licensed by the Alabama State Board of Pharmacy to practice the profession of pharmacy in the State of Alabama and whose license is in good standing.

"(10) (15) PHARMACY. A place licensed by the Alabama State Board of Pharmacy in which prescriptions, drugs, medicines, 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.

"(16) 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.

"(17) 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.

"(13) (18) PRESCRIPTION. Any order for drug or medical supplies, written or signed or transmitted by word of mouth, telephone, telegraph, closed circuit, television, or other means of communication by a legally competent practitioner, licensed by law to prescribe and administer such drugs and medical supplies intended to be filled, compounded, or dispensed by a pharmacist.

"\$27-45-3.

"No health insurance policy or employee benefit plan which is delivered, renewed, issued for delivery, or otherwise contracted for in this state shall:

"(1) Prevent any person who is a party to or
beneficiary of any such health insurance policy or employee
benefit plan from selecting the pharmacy or pharmacist of his
choice to furnish the pharmaceutical services, including
without limitation, prescription drugs, offered by said policy
or plan or interfere with said selection provided the pharmacy
or pharmacist is licensed to furnish such pharmaceutical
services in this state; or

"(2) Deny any pharmacy or pharmacist the right to participate as a contracting provider for such policy or plan provided the pharmacist is licensed to furnish pharmaceutical services, including without limitation, prescription drugs offered by said policy or plan.

"(a) No health insurance policy, employee benefit
plan, health benefit plan, or pharmacy benefit management plan
which is delivered, renewed, issued for delivery, or otherwise
contracted for in this state shall prevent any person who is a
party to or beneficiary of any such health insurance policy or
employee benefit plan from selecting the pharmacy or
pharmacist of his or her choice to furnish the pharmaceutical
services, including, without limitation, prescription drugs,
offered by the policy or plan or interfere with the selection
provided the pharmacy or pharmacist is licensed to furnish
such pharmaceutical services in this state.

"(b) No health insurance policy, employee benefit plan, health benefit plan, or pharmacy benefit management plan which is delivered, renewed, issued for delivery, or otherwise contracted for in this state shall deny any pharmacy or pharmacist the right to participate as a contracting provider for such policy or plan provided the pharmacist is licensed to furnish pharmaceutical services, including, without limitation, prescription drugs offered by the policy or plan.

"(c) A pharmacy benefit manager shall not mandate that a covered individual use a specific community pharmacy, mail order pharmacy, specialty pharmacy, or other pharmacy or

entity. Nor can the pharmacy benefit manager provide

incentives to beneficiaries or plan sponsors to encourage the

use of a specific pharmacy if only applicable to a pharmacy

benefit manager pharmacy.

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"(d) A pharmacy benefit manager may not require that a pharmacist or pharmacy participate in a network managed by the pharmacy benefit manager as a condition for the pharmacy to participate in another network managed by the same pharmacy benefit manager.

"(e) A pharmacy benefit manager may not exclude an otherwise qualified pharmacist or pharmacy from participation in a particular network provided that the pharmacist or pharmacy accepts the terms, conditions, and reimbursement rates of the pharmacy benefit manager offered to other in-network pharmacies, meets all applicable federal and state licensure and permit requirements, and has not been excluded from participation in any federal or state program.

"(f) A pharmacy benefit manager or entity shall not automatically enroll or disenroll a pharmacy in a contract or modify an existing agreement without written agreement of the pharmacist or pharmacy.

"(q) If a pharmacy benefit manager establishes a discount card network, the pharmacy benefit manager shall not require participation in the discount card network by a pharmacy in exchange for participation in the broader retail network. The pharmacy benefit manager shall allow a pharmacy to opt out of the discount card network and choose to only

1	participate	in	the	pharmacy	benefit	manager's	funded	retail
2	network.							

"(h) No pharmacy benefit manager or carrier offering a managed care plan shall transfer or request that a pharmacy provider transfer the prescription or prescriptions of a covered person, wholly or in part, to a different participating pharmacy provider than the provider selected by the covered person unless the participating pharmacy provider to whom the covered person's prescription is to be transferred has obtained signed documentation, oral authorization verified by electronic record, or the pharmacy provider is no longer a participating provider in the network.

"\$27-45-4.

"Any provision in a health insurance policy, or employee benefit plan, health benefit plan, or pharmacy benefit management plan which is delivered, renewed, issued for delivery, or otherwise contracted for in this state which is contrary to this article shall to the extent of such conflict be void.

"\$27-45-5.

"The provisions of this article do not mandate that any type of benefits for pharmaceutical services, including without limitation, prescription drugs, be provided by a health insurance policy, or an employee benefit plan, health benefit plan, or pharmacy benefit management plan.

"\$27-45-6.

1	"It shall be unlawful for any insurer or any person
2	to provide any health insurance policy, $\frac{\partial}{\partial x}$ employee benefit
3	plan, health benefit plan, or pharmacy benefit management plan
4	providing for pharmaceutical services, including $_{L}$ without
5	limitation, prescription drugs, that does not conform to the
6	provisions of this article.
7	" §27-45-7.
8	"The Commissioner of Insurance shall not approve for
9	sale in this state any health insurance policy $\underline{}$ or employee
10	benefit plan, health benefit plan, or pharmacy benefit
11	management plan providing for pharmaceutical services,
12	including, without limitation, prescription drugs, which does
13	not conform to the provisions of this article or to the
14	provisions of Sections 27-14-8 and 27-14-9.
15	" §27-45-8.
16	"(a) It shall be the duty and responsibility of the
17	Commissioner of Insurance to enforce the provisions of this
18	article.
19	"(b) The Commissioner of Insurance may adopt any
20	rules necessary for the implementation and administration of
21	this article.
22	"(c) The State Department of Insurance may adopt
23	rules to regulate the following activities of pharmacy benefit
24	managers:
25	"(1) Claims processing.
26	"(2) Pharmacy network management.

1	" <u>(3) Pharmacy discount card, employer sponsored</u>
2	plan, managed care Medicaid, and workers' compensation
3	management.
4	"(4) Payment of claims to pharmacies for
5	prescription drugs, medical devices, and durable medical
6	equipment dispensed to covered individuals.
7	"(5) Payment of claims to pharmacists for
8	pharmacist-provided services to covered individuals,
9	including, but not limited to, medication therapy management
10	services.
11	"(6) Clinical formulary development and management
12	services, including, but not limited to, utilization
13	management and quality assurance programs.
14	"(7) Rebate contracting and administration.
15	"(8) Conducting audits of contracted pharmacies.
16	"(9) Setting pharmacy reimbursement pricing and
17	methodologies, including MAC, and determining single source
18	and multiple source drugs.
19	"(10) Retention of any differential between what is
20	received from health plans as reimbursement for prescription
21	drugs or services and what is paid to pharmacies or
22	pharmacists by the pharmacy benefit manager for such drugs.
23	"\$27-45-9.
24	"Each willful violation of the provisions of this
25	article shall be nunishable as provided in Section 27-1-12

Τ	(a) The Commissioner of Insurance shall take action
2	or impose penalties to bring non-complying entities into full
3	compliance with this article.
4	"(b) Each willful violation of this title for which
5	a greater penalty is not provided by another provision of this
6	title or by other applicable laws of this state shall, in
7	addition to any applicable prescribed denial, suspension, or
8	revocation of certificate of authority or license, be
9	punishable as a misdemeanor, upon conviction, by a fine of not
10	more than five thousand dollar (\$5,000), or by imprisonment in
11	the county jail, or by sentence to hard labor for the county,
12	for a period not to exceed one year, or by both such fine and
13	imprisonment or hard labor in the discretion of the court.
14	Each instance of violation shall be considered a separate
15	offense.
16	"(c) Each violation of Sections 34-23-184,
17	34-23-185, or 34-23-186, or any combination thereof, by a
18	pharmacy benefit manager, person, or entity acting for a
19	pharmacy benefit manager shall be enforced subject to Section
20	27-45-9 for which a greater penalty is not provided by another
21	provision of this title or by other applicable laws of this
22	state."
23	Section 2. The following new Article 3 is added to
24	Chapter 45, Title 27, Code of Alabama 1975, to read as
25	follows:
26	Article 3.
27	Administration of Pharmaceutical Insurance Coverage.

1 \$27-45-30.

(a) Notice of any change in terms of a pharmacy benefit manager, including, but not limited to, drugs covered, pharmacist-provided services, reimbursement rates, copayments, and dosage quantity, shall be given to each enrolled pharmacy at least 30 days prior to the time it becomes effective.

(b) Pharmacy benefit manager must disclose at the time of contracting with a pharmacist and at least 30 days before any contract change: The terms of reimbursement; process for verifying benefits and beneficiary eligibility; dispute resolution; and audit appeals process and procedures for verifying drugs included on the formularies used by the pharmacy benefit manager.

§27-45-31.

Any agreement or contract entered into in this state between the pharmacy benefit manager and a pharmacy or pharmacist shall include a statement of the method and amount of reimbursement to the pharmacy or pharmacist for services rendered to persons enrolled in the program, the frequency of payment by the pharmacy benefit manager to the pharmacy or pharmacist for those services, and a method for the adjudication of complaints and the settlement of disputes between the contracting parties.

§27-45-32.

(a) The pharmacy benefit manager shall notify all pharmacies and pharmacists enrolled in the program of any cancellation of the coverage of benefits of any group enrolled

in the program at least 30 days prior to the effective date of such cancellation.

(b) When a program is terminated, all persons enrolled therein shall be so notified, and any person who intentionally uses a program identification card to obtain services from a pharmacy or pharmacist after having received notice of the cancellation of benefits shall be liable to the pharmacy benefit manager program administrator for all monies paid by the pharmacy benefit manager program administrator for any services received.

§27-45-33.

- (a) No pharmacy benefit manager shall deny payment to any pharmacy or pharmacist for covered pharmaceutical services, pharmacist-provided services, or prescription drug products rendered as a result of the misuse, fraudulent or illegal use of an identification card unless such identification card had expired, been noticeably altered, or the pharmacy or pharmacist was notified of the cancellation of such card.
- (b) No pharmacy benefit manager may withhold any payment to any pharmacy or pharmacist for covered pharmaceutical services, pharmacist-provided services, or prescription drug products beyond the time period specified in the payment schedule provisions of the agreement, except for individual claims for payment which have been returned to the pharmacy as incomplete or illegible. Such returned claims

shall be paid if resubmitted by the pharmacy to the pharmacy benefit manager with the appropriate corrections made.

\$27-45-34.

- (a) The pharmacy benefit manager shall not interfere with the exercise of professional responsibilities to a patient by a pharmacist and shall not take any retaliatory actions against a pharmacist or pharmacy because of the exercise of such responsibility such as terminate, suspend, or otherwise limit the participation of a pharmacy or pharmacist in a pharmacy benefit manager provider network or attempt to audit further claims submitted by the pharmacy or pharmacist. This includes recommendation of therapy change by the pharmacy or pharmacist applicable to federal or state law to therapy that is more appropriate to the patient health outcome or accessible to the patient.
- (b) The pharmacy benefit manager shall not interfere with the professional independence of a pharmacist or pharmacy or the prescribing health care provider.
- (c) The pharmacy benefit manager shall not engage in or interfere with the practice of medicine or intervene in the practice of medicine between a prescriber of medicine and the prescriber's patients. The pharmacy benefit manager shall not engage in the practice of medicine.
- (d) The pharmacy benefit manager may not request a therapeutic interchange or interfere directly with the care of the beneficiary.

(e) The pharmacy benefit manager may not directly solicit the prescriber, pharmacy, or individual beneficiary to make a therapeutic interchange or change in provider for health care services.

§27-45-35.

- (a) A pharmacy benefit manager may not use a pharmacy's usual and customary claims information for purposes other than determining reimbursement and may not sell, lease, or rent a pharmacy's customary information without the pharmacy's express written consent.
- (b) A pharmacy benefit manager may not contact covered individuals without express written permission of the health plan sponsor and the covered individual.
- (c) A pharmacy benefit manager may not transmit any personally identifiable utilization or claims data to a pharmacy owned by a pharmacy benefit manager if the patient has not voluntarily elected in writing to fill that particular prescription at the pharmacy benefit manager owned pharmacy.
- (d) Access to pharmacy or patient private banking information or other related materials is prohibited for providing proof of copayment during audit. Only use of pharmacy point of service records not eliciting confidential financial information is permitted to show collection of copayment.

\$27-45-36.

(a) A MAC shall be established for any drug with at least three or more A-rated therapeutically equivalent

multiple source drugs, as defined by the federal Food and Drug

Administration or generally available for purchase in this

state from a national or regional wholesaler.

- (b) MAC may be determined using comparable drug prices obtained from multiple nationally recognized comprehensive data sources, including wholesalers, drug file vendors, and pharmaceutical manufacturers for drugs that are nationally and locally available for purchase by multiple pharmacies in this state.
- (c) MAC shall be established for a product using only equivalent drugs as determined by the Federal Drug Administration (FDA).
- (d) For those drugs in which a MAC applies, the pharmacy benefit manager shall include in contracts with pharmacies information regarding which of the national compendia is used to obtain pricing data used in the calculation of MAC pricing and shall make MAC price adjustments at least twice a month and provide pharmacies with prompt notification of any changes or additions made to the MAC price list and MAC rates at that time, except when a price for a drug changes by more than 100 percent; in such cases, the MAC price adjustment for that drug shall be made within three business days of the change in price.
- (e) The pharmacy benefit manager shall provide a process to allow providers to submit identified claims per MAC appeal, containing National Drug Codes within the Generic Product Identifier, and shall allow pharmacy providers to

comment on, contest, or appeal the MAC rates and MAC list. The right to contest shall be limited in duration and provide for retroactive payment in the event it is determined that MAC pricing has been applied incorrectly. All inquiries to the pharmacy benefit manager concerning MAC lists, MAC rates, and pricing shall be acted upon and responded to within five business days.

- applicable MAC lists, including all in the price of drugs, available to network pharmacies upon request in a readily accessible and usable format that contains a complete list of the drug name, National Drug Code, size, per unit price, strength of drug, Generic Price Identifier, and Generic Code Number. In the event there are multiple MAC lists under the same contract, the contract shall identify which MAC lists are appropriately applicable.
- (g) A pharmacy benefit manager shall also include in contracts with pharmacies a process for no less than once a week updates to pharmacy product pricing files used to calculate prescription prices that will be used to reimburse pharmacies.
- (h) A pharmacy benefit manager shall provide a contractual commitment to deliver a particular average reimbursement rate for generic drugs. The average reimbursement rate for generic drugs shall be calculated using the actual amount paid to the pharmacy, including patient copays and reimbursements from pharmacy benefit managers but

excluding the dispensing fee. The average reimbursement rate for generic drugs shall not be calculated solely according to the amount allowed by the plan and shall include all generics dispensed, regardless of whether they are subject to MAC pricing. The pharmacy benefit manager shall disclose to the network pharmacy the methodology used in determining the average reimbursement rate for generic drugs.

(i) A pharmacy benefit manager may not charge a transaction fee for claims submissions provided in an electronic format by a health care provider.

§27-45-37.

- (a) A health plan must permit its enrollees to receive benefits, which may include a 90-day supply of covered prescription drugs, at any of its network community pharmacies. A health insurance policy or government program providing benefits for prescriptions may not impose on a covered individual utilizing a community pharmacy a copayment, deductible, fee, limitation on benefits, or other condition or requirement not otherwise imposed on the covered individual when using a mail order pharmacy.
- (b) Nothing in this section shall prohibit a pharmacist who is exercising his or her professional judgment from dispensing additional quantities of medication up to the total number of units authorized by the prescriber on the original prescription and any refills.

\$27-45-38.

- (a) All entities providing prescription drug

 coverage shall permit and apply a prorated daily cost-sharing

 rate to prescriptions that are dispensed by a pharmacy for

 less than a 30-day supply if the prescriber or pharmacist

 indicates the fill or refill could be in the best interest of

 the patient or is for the purpose of synchronizing the

 patient's chronic medications.
 - (b) No entity providing prescription drug coverage shall deny coverage for the dispensing of any drug prescribed for the treatment of a chronic illness that is made in accordance with a plan among the insured, the prescriber, and a pharmacist to synchronize the refilling of multiple prescriptions for the insured.
 - (c) No entity providing prescription drug coverage shall use payment structures incorporating prorated dispensing fees determined by calculation of the days' supply of medication dispensed. Dispensing fees shall be determined exclusively on the total number of prescriptions dispensed.

Section 3. Section 34-23-184 of the Code of Alabama 1975, is amended to read as follows:

"\$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. Changes in the pharmacy contract and audit procedures shall be disclosed to

the pharmacy 30 days prior to the effective date of the change.

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"(2) The entity conducting the on-site audit shall give the pharmacy written notice at least two weeks 30 days 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 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. The notice shall provide the specific prescriptions to be included in the audit. 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, with a reasonable extension to be granted upon request.

"(3) <u>a.</u> 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.

"b. The entity conducting the on-site audit shall be permitted to enter the prescription area of the pharmacy only when accompanied by a pharmacist employed by the pharmacy.

"(4) An audit that involves clinical or professional judgment shall be conducted by or in consultation with a licensed pharmacist <u>familiar with the pharmacy regulations of</u> the state in which the pharmacy is located.

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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 have the right to submit amended claims to correct clerical or record-keeping errors within 30 days of the initial audit notice. 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 actual financial 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.

1 "(6) An entity conducting an audit shall not require 2 pharmacists to perform duties in excess of, or any documentation that is not required in excess of requirements 3 defined by state and federal law or Alabama Medicaid. The information shall be considered to be valid if documented on 5 6 the prescription, computerized treatment notes, pharmacy system, or other acceptable medical records.

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"(7) Unless superseded Audit information shall remain confidential unless disclosure is required by state or federal law, auditors. Auditors shall only have access to previous audit reports on a particular pharmacy conducted by the auditing entity for the same pharmacy, 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. An auditor shall not use audit reports or other information gained from an audit on a particular pharmacy to conduct another audit for a separate pharmacy.

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

"b. Neither the agency conducting the audit nor its agents shall receive payment based on a percentage of the amount recovered. This section does not prevent the entity conducting the audit from charging or assessing the

1	responsible party, directly or indrectly, based on amounts
2	recouped unless the entity has a contract that explicitly
3	states the percentage charge or assessment to the plan sponsor
4	and a commission to an agent of the entity is not based
5	directly or indirectly on amounts recouped.
6	"c. The entity conducting the audit shall not base
7	compensation of any employees of the entity involved with the
8	audit process on a percentage of the amount recovered or audit
9	findings.
10	"(9) <u>a.</u> A pharmacy may use the records of a
11	hospital, physician, or other authorized practitioner of the
12	healing arts for drugs or medicinal supplies written or
13	transmitted by any means of communication for purposes of
14	validating the pharmacy record with respect to orders $\underline{\hspace{0.1cm}}$
15	refills, or changes to of a legend or narcotic drug authorized
16	by federal and state law.
17	"b. Validation of appropriate day's supply and drug
18	dosing must be based on manufacturer guidelines and
19	definitions or, in the case of topical products or titrated
20	products, the professional judgment of the pharmacist based
21	upon communication with the patient or prescriber.
22	"c. A pharmacy's usual and customary price for
23	medications is considered the reimbursable cost based on the
24	pricing methodology outlined in the contract unless an
25	alternative price is published in the provider contract and
26	signed by both parties.

"(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 as 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 prohibited. Recoupment shall be based on the actual overpayment or underpayment of actual claims. In the case of overpayment, the pharmacy may be subject to recoupment only following the correction of a claim, and the amount refunded shall be limited to the amount paid to the pharmacy minus the amount payable under the corrected claim. Recoupment of disputed funds shall not be allowed if based on requirements not defined in the contractual agreement plan, if limits are not clearly defined at the time of claim adjudication, or if the claim is not in compliance with federal or state law.

"(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 or claim adjudication.
 - "(14) Where not superseded by state or federal law, the period covered by an audit may not exceed two years six months 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) <u>a.</u> An audit may not be initiated or scheduled during the first $\frac{\text{five seven}}{\text{seven}}$ calendar days of any month.
 - "b. The entity conducting the audit shall not audit
 more than 40 prescriptions per audit selected by random
 process and duration of the audit shall not exceed four hours.

1	"c. An on-site audit may not be conducted at the
2	pharmacy more than one time per calendar year unless an
3	auditor has to return to complete an audit for each
4	third-party payor.

- "d. The pharmacy may reschedule the audit within 24 hours of receiving notice to a date no more than 14 days after the date proposed by the auditor. If the auditor is unable to reschedule within 14 days, the auditor will select and reschedule the audit for a date after the 14-day period.
- "(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 30 days after the conclusion of the audit, with a reasonable extension to be granted upon request, and shall contain claim level information for any discrepancy found and total dollar amount of claims subject to recovery.
- "(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 $\frac{180}{30}$ days after receipt of the preliminary audit report or final appeal, as provided for in Section 34-23-185, whichever is later.

"(4) <u>a.</u> 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.

"b. An exit interview to allow the pharmacy an opportunity to discuss, review, and respond to the audit findings put forth by the entity must be conducted at the end of an audit and at a time mutually agreed to by both parties.

"(5) <u>a.</u> 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 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.

"b. The entity may not recoup or offset any disputed funds until the pharmacy has an opportunity to review the findings and 30 days have elapsed after the date the final audit report has been delivered.

"c. Underpayments to the pharmacy must be remitted by the entity within 45 days after the appeals process has been exhausted and the final audit has been issued.

"d. Plan restrictions should be addressed during the claims adjudication process either though the rejection of the

Τ	claim or a rejection of the claim with direction to obtain a
2	prior authorization and may not be the basis of a
3	retrospective recoupment of a paid claim.
4	"e. With the exception of overpayments, if a PBM
5	approves a claim through adjudication, the PBM may not
6	retroactively deny or modify reimbursement based on
7	information accompanying the original claim or information
8	available to the PBM at the time of adjudication, unless the
9	claim was fraudulent, the pharmacy or pharmacist had been
10	reimbursed for the claim previously, or the services
11	reimbursed were not rendered by the pharmacy or pharmacist.
12	"f. A PBM may not require a pharmacy to agree to
13	recoupments deducted against future remittances and shall
14	invoice the pharmacy for payment if the pharmacy elects.
15	Recoupment may be deducted against future remittances without
16	mutual consent when the pharmacy is considered delinquent in
17	payment of the invoice per the contractual arrangement.
18	"g. A PBM may not recover payment of claims from the
19	pharmacy which is identified through the audit process to be
20	the responsibility of another payer. The PBM must reconcile
21	directly with the other payer for any monies owed without
22	requiring the pharmacy to reverse and rebill the original
23	claim in the retail setting.
24	"(6) Interest shall not accrue during the audit
25	period.
26	"(7) Each entity conducting an audit shall provide a
27	copy of the final audit report, after completion of any review

- 1 process, to the plan sponsor in a manner pursuant to a
- 2 contract."
- 3 Section 4. This act shall become effective on
- 4 October 1, 2015.