1	ENGROSSED HOUSE
2	BILL NO. 2677 By: Marti, Caldwell (Trey), Fugate, West (Tammy),
3	Dollens, Davis and Sneed of the House
4	and
5	McCortney of the Senate
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8	An Act relating to professions and occupations; amending 59 O.S. 2011, Section 356.2, which relates
9	to the Pharmacy Audit Integrity Act; modifying and expanding duties; prohibiting certain audits;
10	providing for discrepancies; requiring acceptance of certain evidence; requiring provision of certain
11	documents within specified time; providing audit requirements; modifying number of prescriptions to be
12	audited; requiring invoices; modifying audit report time periods; eliminating certain withholdings;
13	amending 59 O.S. 2011, Section 356.3, which relates to appeals process; clarifying when certain findings
14	are to be referred to the district attorney; clarifying scope of application; amending Section 3,
15 16	Chapter 263, O.S.L. 2014 (59 O.S. Supp. 2020, Section 359), which relates to information to be provided by
17	pharmacy benefits manager; removing exceptions; amending Section 4, Chapter 263, O.S.L. 2014, as amended by Section 8, Chapter 285, O.S.L. 2016 (59
18	O.S. Supp. 2020, Section 360), which relates to contractual duties to providers; modifying
19	reimbursement procedure; prohibiting placement of drugs on certain list, with exceptions; modifying
20	accreditation or licensing requirement; allowing certain entities to decline to provide services;
21	requiring provision of certain information; and declaring an emergency.
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24	BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

1SECTION 1.AMENDATORY59 O.S. 2011, Section 356.2, is2amended to read as follows:

3 Section 356.2 A. The entity conducting an audit of a pharmacy 4 shall:

Identify and <u>specifically</u> describe the audit <u>and appeal</u>
 procedures in the pharmacy contract. Unless otherwise agreed to in
 contract by both parties, prescription <u>Prescription</u> claim
 documentation and record-keeping requirements shall not exceed the
 requirements set forth by the Oklahoma Pharmacy Act or other
 applicable state or federal laws or regulations;

11 2. For an on-site audit, give Give the pharmacy written notice 12 by certified letter to the pharmacy and the pharmacy's contracting 13 agent, including identification of specific prescription numbers and 14 fill dates to be audited, at least two (2) weeks prior to conducting 15 the on-site audit, including, but not limited to, an on-site audit, 16 a desk audit, or a wholesale purchase audit, request for 17 documentation related to the dispensing of a prescription drug or 18 any reimbursed activity by a pharmacy provider; provided, however, 19 that wholesale purchase audits shall require a minimum of thirty 20 (30) days written notice. The pharmacy shall have the opportunity 21 to reschedule the audit no more than seven (7) days from the date 22 designated on the original audit notification;

3. For an on-site audit, not Not interfere with the delivery of
pharmacist services to a patient and shall utilize every reasonable

1 effort to minimize inconvenience and disruption to pharmacy
2 operations during the audit process;

4. Conduct any audit involving clinical or professional 3 4 judgment by means of or in consultation with a licensed pharmacist; 5 5. Not consider as fraud any clerical or record-keeping error, such as a typographical error, scrivener's error, or computer error 6 7 regarding a required document or record; however, including, but not limited to, a miscalculated day supply, incorrectly billed 8 9 prescription written date or prescription origin code, and such 10 errors may shall not be subject to recoupment. The pharmacy shall 11 have the right to submit amended claims electronically to correct 12 clerical or record-keeping errors in lieu of recoupment, provided 13 that the prescription was dispensed according to prescription 14 documentation requirements set forth by the Oklahoma Pharmacy Act. 15 To the extent that an audit results in the identification of any 16 clerical or record-keeping errors such as typographical errors, 17 scrivener's errors or computer errors in a required document or 18 record, the pharmacy shall not be subject to recoupment of funds by 19 the pharmacy benefits manager unless the pharmacy benefits manager 20 can provide proof of intent to commit fraud or such error results in 21 actual financial harm to the pharmacy benefits manager, a health 22 insurance plan managed by the pharmacy benefits manager or a 23 consumer. A person shall not be subject to criminal penalties for 24

1 errors provided for in this paragraph without proof of intent to
2 commit fraud;

6. Permit a pharmacy to 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;

8 7. Base a finding of an overpayment or underpayment on a
9 projection based on the number of patients served having similar
10 diagnoses or on the number of similar orders or refills for similar
11 drugs; provided, recoupment of claims shall be based on the actual
12 overpayment or underpayment of each identified claim. A projection
13 for overpayment or underpayment may be used to determine recoupment
14 as part of a settlement as agreed to by the pharmacy;

Not include the dispensing fee amount <u>or the actual invoice</u> <u>cost of the prescription dispensed</u> in a finding of an overpayment <u>audit recoupment</u> unless a prescription was not actually dispensed or a physician denied authorization or as otherwise agreed to by contract of a dispensing order;

9. 8. Audit each pharmacy under the same identical standards,
 regularity and parameters as other similarly situated pharmacies
 audited by the entity and all pharmacies owned or managed by the
 pharmacy benefits manager conducting or having conducted the audit;

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1 10.9. Not exceed two (2) years one (1) year from the date the 2 claim was submitted to or adjudicated by a managed care company, 3 nonprofit hospital or medical service organization, insurance 4 company, third-party payor, pharmacy benefits manager, a health 5 program administered by a department of this state, or any entity 6 that represents the companies, groups, or departments for the period 7 covered by an audit;

8 <u>11. 10.</u> Not schedule or initiate an audit during the first
9 seven (7) calendar days of any month due to the high volume of
10 prescriptions filled in the pharmacy during that time unless
11 otherwise consented to by the pharmacy; and

12 <u>12.</u> <u>11.</u> Disclose to any plan sponsor whose claims were included 13 in the audit any money recouped in the audit; and

14 <u>12. Not require pharmacists to break open packaging labeled</u> 15 <u>"for single-patient-use only". Packaging labeled "for single-</u> 16 <u>patient-use only" shall be deemed to be the smallest package size</u> 17 available.

B. <u>1. Any entity that conducts wholesale purchase review</u>
<u>during an audit of a pharmacist or pharmacy shall not require the</u>
<u>pharmacist or pharmacy to provide a full dispensing report.</u>
<u>Wholesaler invoice reviews shall be limited to verification of</u>
<u>purchase inventory specific to the pharmacy claims paid by the</u>
<u>health benefits plan or pharmacy benefits manager conducting the</u>
audit.

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1	2. Any e	ntity conducting an audit shall not identify or label a
2	prescription	claim as an audit discrepancy when:
3	<u>a.</u>	the National Drug Code for the dispensed drug is in a
4		quantity that is a subunit or multiple of the drug
5		purchased by the pharmacist or pharmacy as supported
6		by a wholesale invoice,
7	b.	the pharmacist or pharmacy dispensed the correct
8		quantity of the drug according to the prescription,
9		and
10	<u>C.</u>	the drug dispensed by the pharmacist or pharmacy
11		shares all but the last two digits of the National
12		Drug Code of the drug reflected on the supplier
13		invoice.
14	<u>3. An en</u>	tity conducting an audit shall accept as evidence,
15	<u>subject to va</u>	lidation, to support the validity of a pharmacy claim
16	related to a	dispensed drug:
17	<u>a.</u>	redacted copies of supplier invoices in the
18		pharmacist's or pharmacy's possession, or
19	b.	invoices and any supporting documents from any
20		supplier as authorized by federal or state law to
21		transfer ownership of the drug acquired by the
22		pharmacist or pharmacy.
23	4. An en	tity conducting an audit shall provide, no later than
24	five (5) busi	ness days after the date of a request by the pharmacist

1 or pharmacy, all supporting documents the pharmacist's or pharmacy's
2 purchase suppliers provided to the health benefits plan issuer or
3 pharmacy benefits manager.

<u>C.</u> A pharmacy may shall be allowed to provide the pharmacy's computerized patterned medical records or 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 supporting the pharmacy record with prespect to orders or refills of a legend or narcotic drug.

10 C. D. The entity conducting the audit shall not audit more than 11 seventy-five (75) fifty prescriptions, with specific date of 12 service, per initial audit calendar year. The annual limit to the 13 number of prescription claims audited shall be inclusive of all 14 audits, including any prescription-related documentation requests 15 from the health insurer, pharmacy benefits manager or any third-16 party company conducting audits on behalf of any health insurer or 17 pharmacy benefits manager during a calendar year.

D. E. If paper copies of records are requested by the entity
 conducting the audit, the entity shall pay twenty-five cents (\$0.25)
 per page to cover the costs incurred by the pharmacy. <u>The entity</u>
 <u>conducting the audit shall provide the pharmacy with accurate</u>
 <u>instructions, including any required form for obtaining</u>

23 reimbursement for the copied records.

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1 E. F. The entity conducting the audit shall provide the 2 pharmacy with a written report of the audit and shall: 3 1. Deliver a preliminary audit findings report to the pharmacy 4 and the pharmacy's contracting agent within ninety (90) forty-five 5 (45) calendar days after conclusion of conducting the audit; 2. Allow the pharmacy at least sixty (60) ninety (90) calendar 6 7 days following receipt of the preliminary audit findings report in which to produce documentation to address any discrepancy found 8 9 during the audit; provided, however, a pharmacy may request an 10 extension, not to exceed an additional sixty (60) forty-five (45) 11 calendar days; 12 3. Deliver a final audit findings report to the pharmacy and 13 the pharmacy's contracting agent signed by the auditor within one 14 hundred twenty (120) ten (10) calendar days after receipt of the 15 preliminary audit report or final appeal additional documentation 16 provided by the pharmacy, as provided for in Section 356.3 of this 17 title, whichever is later; 18 4. Recoup Allow the pharmacy to reverse and resubmit claims 19 electronically within thirty (30) days of receipt of the final audit 20 report in lieu of the auditing entity recouping discrepant claim 21 amounts from the pharmacy; 22 5. May not recoup any disputed funds until after final internal 23 disposition of the audit findings, including the appeals process as

24 provided for in Section 356.3 of this title. Unless otherwise

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agreed by the parties, future payments to the pharmacy may be
withheld pending finalization of the audit should the identified
discrepancy exceed Twenty-five Thousand Dollars (\$25,000.00); and
5. <u>6.</u> Not accrue interest during the audit and appeal period.
F. <u>G.</u> Each entity conducting an audit shall provide a copy of
the final audit results, and a final audit report upon request,
after completion of any review process to the plan sponsor.

8 G. H. 1. The full amount of any recoupment on an on-site audit 9 shall be refunded to the plan sponsor. Except as provided for in 10 paragraph 2 of this subsection, a charge or assessment for an audit 11 shall not be based, directly or indirectly, on amounts recouped.

12 2. This subsection does not prevent the entity conducting the 13 audit from charging or assessing the responsible party, directly or 14 indirectly, based on amounts recouped if both of the following 15 conditions are met:

a. the plan sponsor and the entity conducting the audit
have a contract that explicitly states the percentage
charge or assessment to the plan sponsor, and
b. a commission to an agent or employee of the entity
conducting the audit is not based, directly or
indirectly, on amounts recouped.

H. I. 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

1 manager, health plan or insurer. An auditing vendor contracting 2 with multiple pharmacy benefits managers or health insurance plans 3 shall not use audit reports or other information gained from an 4 audit on a particular pharmacy to conduct another audit for a 5 different pharmacy benefits manager or health insurance plan. 6 SECTION 2. AMENDATORY 59 O.S. 2011, Section 356.3, is

7 amended to read as follows:

8 Section 356.3 A. Each entity conducting an audit shall 9 establish a written appeals process under which a pharmacy may 10 appeal an unfavorable preliminary audit report and/or final audit 11 report to the entity.

B. Following an appeal, if the entity finds that an unfavorable audit report or any portion thereof is unsubstantiated, the entity shall dismiss the audit report or the unsubstantiated portion of the audit report without any further action.

C. Any final audit report, following the final audit appeal
period, with a finding of fraud or willful misrepresentation shall
be referred to the district attorney having proper jurisdiction or
the Attorney General for prosecution upon completion of the appeals
process.

D. This act does not apply to any audit, review or investigation that is initiated based on or that involves suspected or alleged fraud, willful mispresentation misrepresentation or abuse.

1 SECTION 3. AMENDATORY Section 3, Chapter 263, O.S.L.
2 2014 (59 O.S. Supp. 2020, Section 359), is amended to read as
3 follows:

Section 359. Unless otherwise provided by contract, a <u>A</u>
pharmacy benefits manager shall provide, upon request by the covered
entity, information regarding the difference in the amount paid to
providers for prescription services rendered to covered individuals
and the amount billed by the pharmacy benefits manager to the
covered entity or plan sponsor to pay for prescription services
rendered to covered individuals.

SECTION 4. AMENDATORY Section 4, Chapter 263, O.S.L.
2014, as amended by Section 8, Chapter 285, O.S.L. 2016 (59 O.S.
Supp. 2020, Section 360), is amended to read as follows:

Section 360. A. The pharmacy benefits manager shall, with respect to contracts between a pharmacy benefits manager and a provider, including a pharmacy service administrative organization:

17 1. Include in such contracts the <u>specific</u> sources utilized to 18 determine the maximum allowable cost (MAC) pricing of the pharmacy, 19 update MAC pricing at least every seven (7) calendar days, and 20 establish a process for providers to readily access the MAC list 21 specific to that provider;

22 2. In order to place a drug on the MAC list, ensure that the 23 drug is listed as "A" or "B" rated in the most recent version of the 24 FDA's Approved Drug Products with Therapeutic Equivalence

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Evaluations, also known as the Orange Book, or has an "NR" or "NA"
rating or a similar rating by a nationally recognized reference, and
the drug is generally available for purchase by pharmacies in the
state from national or regional wholesalers and is not obsolete;
3. Ensure dispensing fees are not included in the calculation
of MAC price reimbursement to pharmacy providers;

7 4. Provide a reasonable administration appeals procedure to allow a provider or, a provider's representative and a pharmacy 8 9 service administrative organization to contest reimbursement amounts 10 within ten (10) fourteen (14) business days of the final adjusted 11 payment date. The pharmacy benefits manager shall not prevent the 12 pharmacy or the pharmacy service administrative organization from 13 filing reimbursement appeals in an electronic batch format. The 14 pharmacy benefits manager must respond to a provider or, a 15 provider's representative and a pharmacy service administrative 16 organization who has have contested a reimbursement amount through 17 this procedure within ten (10) business days. The pharmacy benefits 18 manager must respond in an electronic batch format to reimbursement 19 appeals filed in an electronic batch format. The pharmacy benefits 20 manager shall not require a pharmacy or pharmacy services 21 administrative organization to log into a system to upload 22 individual claim appeals or to download individual appeal responses. 23 If a price update is warranted, the pharmacy benefits manager shall 24 make the change in the reimbursement amount, permit the challenging

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1 <u>dispensing</u> pharmacy to reverse and rebill the claim in question, and 2 make the reimbursement amount change <u>retroactive and</u> effective for 3 <u>each similarly</u> <u>all</u> contracted Oklahoma provider <u>providers</u>; and

4 5. If the a below-cost reimbursement appeal is denied, the PBM 5 shall provide the reason for the denial, including the National Drug Code number from the specific national or regional wholesalers where 6 7 the drug is generally available for purchase by pharmacies in the state at or the dispensing pharmacy at a price below the PBM's 8 9 reimbursement price. If the pharmacy benefits manager cannot 10 provide a specific national or regional wholesaler where the drug 11 can be purchased by the dispensing pharmacy at a price below the 12 pharmacy benefits manager's reimbursement price, the pharmacy 13 benefits manager shall immediately adjust the reimbursement amount, 14 permit the dispensing pharmacy to reverse and rebill the claim in 15 question, and make the reimbursement amount adjustment retroactive 16 and effective for all contracted providers.

B. The pharmacy benefits manager may <u>shall</u> not place a drug on a MAC list, unless there are at least two therapeutically equivalent, multiple-source drugs, or at least one generic drug available from only one manufacturer, generally available for purchase by network <u>dispensing retail</u> pharmacies from national or regional wholesalers.

C. The pharmacy benefits manager shall not require
 accreditation or licensing of providers, or any entity licensed or

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1	regulated by the State Board of Pharmacy, other than by the State
2	Board of Pharmacy or other state or federal government entity <u>as a</u>
3	condition for participation as a network provider.
4	D. A pharmacy or pharmacist may decline to provide the
5	pharmacist clinical or dispensing services to a patient or pharmacy
6	benefits manager if the pharmacy or pharmacist is to be paid less
7	than the pharmacy's cost for providing the pharmacist clinical or
8	dispensing services.
9	E. The pharmacy benefits manager shall provide a dedicated
10	telephone number, email address and names of the personnel with
11	decision-making authority regarding MAC appeals and pricing.
12	SECTION 5. It being immediately necessary for the preservation
13	of the public peace, health or safety, an emergency is hereby
14	declared to exist, by reason whereof this act shall take effect and
15	be in full force from and after its passage and approval.
16	Passed the House of Representatives the 10th day of February, 2021.
17	2021.
18	
19	Presiding Officer of the House of Representatives
20	or Representatives
21	Passed the Senate the day of, 2021.
22	
23	Presiding Officer of the Senate
24	riestaing officer of the senate