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                               STATE OF OKLAHOMA
 2
                  1st Session of the 57th Legislature (2019)
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    HOUSE BILL 2314
                                          By: Marti
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                                 AS INTRODUCED
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            An Act relating to the Pharmacy Audit Integrity Act;
            amending 59 O.S. 2011, Section 356.2, which relates
            to auditor duties; modifying types of audits;
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            modifying audit reports and results; amending 59 O.S.
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            2011, Section 356.3, which relates to appeals
            process; modifying requirements of final audit
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            report; amending Section 2, Chapter 263, O.S.L. 2014
            (59 O.S. Supp. 2018, Section 358), which relates to
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            Pharmacy Benefits Manager licensure; modifying
            licensure procedures; amending Section 3, Chapter
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            263, O.S.L. 2014 (59 O.S. Supp. 2018, Section 359),
            which relates to information to be provided by
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            Pharmacy Benefits Manager; removing exception;
            amending Section 4, Chapter 263, O.S.L. 2014, as
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            amended by Section 8, Chapter 285, O.S.L. 2016 (59
            O.S. Supp. 2018, Section 360), which relates to
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            contractual duties to providers; modifying
            reimbursement procedure; modifying accreditation or
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            licensing requirement; and providing an effective
            date.
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    BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:
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        SECTION 1.
                                       59 O.S. 2011, Section 356.2, is
                       AMENDATORY
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    amended to read as follows:
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        Section 356.2 A.
                           The entity conducting an audit of a pharmacy
    shall:
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1. Identify and describe the audit procedures in the pharmacy contract. Unless otherwise agreed to in contract by both parties, prescription 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;

- 2. For an en-site audit, including, but not limited to, an onsite audit, a desk audit, request for documentation related to the
 dispensing of a prescription drug or any reimbursed activity by a
 pharmacy provider, give the pharmacy written notice, by certified
 letter to the pharmacy and the pharmacy's contracting agent,
 including identification of prescription numbers to be audited, at
 least two (2) weeks prior to conducting the en-site audit. The
 pharmacy shall have the opportunity to reschedule the audit no more
 than seven (7) days from the date designated on the original audit
 notification;
- 3. For an on-site audit, not interfere with the delivery of pharmacist services to a patient and shall utilize every reasonable effort to minimize inconvenience and disruption to pharmacy operations during the audit process;
- 4. Conduct any audit involving clinical or professional judgment by means of or in consultation with a licensed pharmacist;
- 5. 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 to correct clerical or record-keeping errors in lieu of recoupment, provided that the prescription was dispensed according to prescription documentation requirements set forth by the Oklahoma Pharmacy Act. To the extent that an audit results in the identification of any clerical or record-keeping errors such as typographical errors, scrivener's errors or computer errors in a required document or record, 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 paragraph without proof of intent to 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;
- 7. Base a finding of an overpayment or underpayment on a projection based on the number of patients served having similar diagnoses or on the number of similar orders or refills for similar drugs; provided, recoupment of claims shall be based on the actual

overpayment or underpayment of each identified claim. A projection for overpayment or underpayment may be used to determine recoupment as part of a settlement as agreed to by the pharmacy;

- 8. Not include the dispensing fee amount or the actual invoice cost of the prescription dispensed in a finding of an overpayment unless a prescription was not actually dispensed or a physician denied authorization or as otherwise agreed to by contract;
- 9. Audit each pharmacy under the same identical standards, regularity and parameters as other similarly situated pharmacies and all pharmacies owned or operated by the Pharmacy Benefits Manager conducting or having conducted the audit audited by the entity;
- 10. Not exceed two (2) years one (1) year from the date the claim was submitted to or adjudicated by a managed care company, nonprofit hospital or medical service organization, insurance company, third-party payor, pharmacy benefits manager, a health program administered by a department of this state, or any entity that represents the companies, groups, or departments for the period covered by an audit;
- 11. Not schedule or initiate an audit during the first seven

 (7) calendar days of any month due to the high volume of

 prescriptions filled in the pharmacy during that time unless

 otherwise consented to by the pharmacy; and
- 12. Disclose to any plan sponsor whose claims were included in the audit any money recouped in the audit.

B. A pharmacy may 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 respect to orders or refills of a legend or narcotic drug.

- C. The entity conducting the audit shall not audit more than seventy-five (75) fifty prescriptions per initial annual audit.
- D. 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. The entity conducting the audit shall provide the pharmacy with an invoice form for the reimbursement of the copied records.
- E. The entity conducting the audit shall provide the pharmacy with a written report of the audit and shall:
- 1. Deliver a preliminary audit report to the pharmacy within ninety (90) calendar days after conclusion of the audit;
- 2. Allow the pharmacy at least sixty (60) calendar days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during the audit; provided, however, a pharmacy may request an extension, not to exceed an additional sixty (60) calendar days;
- 3. Deliver a final audit report to the pharmacy signed by the auditor within one hundred twenty (120) ninety (90) calendar days

after receipt of the preliminary audit report or final appeal, as provided for in Section 356.3 of this title, whichever is later;

- 4. Recoup any disputed funds after final internal disposition of the audit, including the appeals process as provided for in Section 356.3 of this title. Unless otherwise 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. Not accrue interest during the audit and appeal period.
- F. 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.
- G. 1. The full amount of any recoupment on an on-site audit shall be refunded to the plan sponsor. Except as provided for in paragraph 2 of this subsection, a charge or assessment for an audit shall not be based, directly or indirectly, on amounts recouped.
- 2. This subsection does not prevent the entity conducting the audit from charging or assessing the responsible party, directly or indirectly, based on amounts recouped if both of the following conditions are met:
 - 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. Unless superseded by state or federal law, auditors shall only have access to previous audit reports on a particular pharmacy conducted by the auditing entity for the same pharmacy benefits manager, health plan or insurer. An auditing vendor contracting with multiple pharmacy benefits managers or health insurance plans shall not use audit reports or other information gained from an audit on a particular pharmacy to conduct another audit for a different pharmacy benefits manager or health insurance plan.
- SECTION 2. AMENDATORY 59 O.S. 2011, Section 356.3, is amended to read as follows:
- Section 356.3 A. Each entity conducting an audit shall establish a written appeals process under which a pharmacy may appeal an unfavorable preliminary audit report and/or final audit 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 an appeal, 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.
- SECTION 3. AMENDATORY Section 2, Chapter 263, O.S.L. 2014 (59 O.S. Supp. 2018, Section 358), is amended to read as follows:
 - Section 358. A. In order to provide pharmacy benefits management or any of the services included under the definition of pharmacy benefits management in this state, a pharmacy benefits manager or any entity acting as one in a contractual or employment relationship for a covered entity shall first obtain a license from the Oklahoma Insurance Department, and the Department may charge a fee for such licensure.
 - B. The Department shall establish, by regulation, licensure procedures, required disclosures for pharmacy benefits managers (PBMs) and other rules as may be necessary for carrying out and enforcing the provisions of this act. The licensure procedures shall, at a minimum, include the completion of an application form that shall include the name and address of an agent for service of process, the payment of a requisite fee, and evidence of the procurement of a surety bond, and provide proof that all pharmacies,

owned by, managed by or contracted with the insurer or pharmacy

benefits manager, have been offered an identical contract and have

been audited at the identical standards, regularity and parameters

the previous thirty-six (36) months.

- C. The Department may subpoena witnesses and information. Its compliance officers may take and copy records for investigative use and prosecutions. Nothing in this subsection shall limit the Office of the Attorney General from using its investigative demand authority to investigate and prosecute violations of the law.
- D. The Department may suspend, revoke or refuse to issue or renew a license for noncompliance with any of the provisions hereby established or with the rules promulgated by the Department; for conduct likely to mislead, deceive or defraud the public or the Department; for unfair or deceptive business practices or for nonpayment of a renewal fee or fine. The Department may also levy administrative fines for each count of which a licensee has been convicted in a Department hearing.
- SECTION 4. AMENDATORY Section 3, Chapter 263, O.S.L. 2014 (59 O.S. Supp. 2018, Section 359), is amended to read as follows:
- Section 359. Unless otherwise provided by contract, a A

 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

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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.
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- 4 SECTION 5. AMENDATORY Section 4, Chapter 263, O.S.L.
- 5 | 2014, as amended by Section 8, Chapter 285, O.S.L. 2016 (59 O.S.
- 6 | Supp. 2018, Section 360), is amended to read as follows:

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- Section 360. A. The pharmacy benefits manager shall, with respect to contracts between a pharmacy benefits manager and a provider:
 - 1. Include in such contracts the sources utilized to determine the maximum allowable cost (MAC) pricing of the pharmacy, update MAC pricing at least every seven (7) calendar days, and establish a process for providers to readily access the MAC list specific to that provider;
 - 2. In order to place a drug on the MAC list, ensure that the drug is listed as "A" or "B" rated in the most recent version of the FDA's Approved Drug Products with Therapeutic Equivalence 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;

4. Provide a reasonable administration appeals procedure to allow a provider or a provider's representative to contest reimbursement amounts within ten (10) business days of the final adjusted payment date. The pharmacy benefits manager must respond to a provider or provider's representative who has contested a reimbursement amount through this procedure within ten (10) business days. If a price update is warranted, the pharmacy benefits manager shall make the change in the reimbursement amount, permit the challenging pharmacy to reverse and rebill the claim in question, and make the reimbursement amount change retroactive and effective for each similarly all contracted Oklahoma provider providers; and

- 5. If the <u>a below-cost</u> reimbursement appeal is denied, the PBM shall provide the reason for the denial, including the National Drug Code number from <u>the specific</u> national or regional wholesalers where the drug is generally available for purchase by pharmacies in the state at or below the PBM's reimbursement.
- B. The pharmacy benefits manager may shall 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 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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regulated by the Oklahoma State Board of Pharmacy other than by the
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    Oklahoma State Board of Pharmacy or other Oklahoma state or federal
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    government entity.
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        SECTION 6. This act shall become effective November 1, 2019.
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