ENGROSSED HOUSE
BILL NO. 2314

By: Marti, Davis and Townley of the House

and

McCortney of the Senate

An Act relating to the Pharmacy Audit Integrity Act; amending 59 O.S. 2011, Section 356.2, which relates to auditor duties; modifying and expanding duties; prohibiting certain audits; providing for discrepancies; requiring acceptance of certain evidence; requiring provision of certain documents within specified time; providing audit requirements; modifying number of prescriptions to be audited; requiring invoices; modifying audit report time periods; eliminating certain withholdings; amending 59 O.S. 2011, Section 356.3, which relates to appeals process; clarifying when certain findings are to be referred to the district attorney; clarifying scope of application; amending Section 3, Chapter 263, O.S.L. 2014 (59 O.S. Supp. 2019, Section 359), which relates to information to be provided by 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 O.S. Supp. 2019, Section 360), which relates to contractual duties to providers; modifying reimbursement procedure; prohibiting placement of drugs on certain list, with exceptions; modifying accreditation or licensing requirement; and providing an effective date.

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

SECTION 1. AMENDATORY 59 O.S. 2011, Section 356.2, is amended to read as follows:

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

1. Identify and describe the audit procedures in the pharmacy contract. ~~Unless otherwise agreed to in contract by both parties, prescription~~ 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 ~~on-site~~ audit, including, but not limited to, an on-site 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 ~~on-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~~, including, but not limited to, a miscalculated day supply of less than twenty-five percent (25%) error, prescription written date or prescription origin code, unless there is actual financial harm to the health insurer or patient, and such errors ~~may~~ shall not 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 ~~audited by the entity~~ and all pharmacies owned or managed by the pharmacy benefits manager conducting or having conducted the audit;

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; and

13. Not require pharmacists to break open packaging labeled "for single-patient-use only". Packaging labeled "for single-use only" shall be deemed to be the smallest package size available.

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

2. A health benefits plan issuer or pharmacy benefits manager shall reverse a finding of a discrepancy if:

a. the National Drug Code for the dispensed drug is in a quantity that is a subunit or multiple of the drug purchased by the pharmacist or pharmacy as supported by a wholesale invoice,

b. the pharmacist or pharmacy dispensed the correct quantity of the drug according to the prescription, and

c. the drug dispensed by the pharmacist or pharmacy shares all but the last two digits of the National Drug Code of the drug reflected on the supplier invoice.

3. A health benefits plan issuer or pharmacy benefits manager shall accept as evidence, subject to validation, to support the validity of a pharmacy claim related to a dispensed drug:

a. redacted copies of supplier invoices in the pharmacist's or pharmacy's possession, or

b. invoices and any supporting documents from any supplier as authorized by federal or state law to transfer ownership of the drug acquired by the pharmacist or pharmacy.

4. A health benefits plan issuer or pharmacy benefits manager shall provide, no later than five (5) business days after the date of a request by the pharmacist or pharmacy, any supporting documents the pharmacist's or pharmacy's suppliers provided to the health benefits plan issuer or pharmacy benefits manager.

C. 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.~~ D. The entity conducting the audit shall not audit more than ~~seventy-five (75)~~ fifty prescriptions, with specific date of service, per ~~initial~~ annual audit. The annual audit total shall be inclusive of all prescription-related documentation requests from the health insurer, pharmacy benefits manager or any third-party company conducting audits on behalf of the health insurer or 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. The entity conducting the audit shall provide the pharmacy with an invoice form for reimbursement of the copied records.

~~E.~~ F. 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)~~ forty-five (45) calendar days after conclusion of the audit;

2. Allow the pharmacy at least ~~sixty (60)~~ forty-five (45) 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)~~ forty-five (45) 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. Allow the pharmacy at least ninety (90) calendar days following receipt of the final audit report to produce documentation to address any discrepancy disputed in the final report; provided, however, a pharmacy may request an extension, not to exceed an additional ninety (90) calendar days;

5. 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.~~ 6. Not accrue interest during the audit and appeal period.

~~F.~~ G. 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.~~ H. 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:

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 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 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 ~~misprecentation~~ misrepresentation or abuse.

SECTION 3. AMENDATORY Section 3, Chapter 263, O.S.L. 2014 (59 O.S. Supp. 2019, 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 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. 2019, 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:

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~~ a below-cost reimbursement appeal is denied, the PBM shall provide the reason for the denial, including the National Drug Code number from the specific 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 regulated by the State Board of Pharmacy other than by the State Board of Pharmacy ~~or other state~~ or federal government entity.

SECTION 5. This act shall become effective November 1, 2020.

Passed the House of Representatives the 10th day of March, 2020.

_____
Presiding Officer of the House
of Representatives

Passed the Senate the ___ day of _____, 2020.

_____
Presiding Officer of the Senate