

An Act

ENROLLED HOUSE
BILL NO. 2677

By: Marti, Caldwell (Trey),
Fugate, West (Tammy),
Dollens, Davis and Sneed of
the House

and

McCortney, Bergstrom and
Garvin of the Senate

An Act relating to professions and occupations; amending 59 O.S. 2011, Section 356.2, which relates to the Pharmacy Audit Integrity Act; 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 2, Chapter 263, O.S.L. 2014 (59 O.S. Supp. 2020, Section 358), which relates to pharmacy benefits management; modifying reference; amending Section 3, Chapter 263, O.S.L. 2014 (59 O.S. Supp. 2020, 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. 2020, 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; allowing certain entities to decline to provide services; requiring provision of certain information; and declaring an emergency.

SUBJECT: Professions and occupations

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 specifically describe the audit and appeal 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, give~~ Give the pharmacy written notice by certified letter to the pharmacy and the pharmacy's contracting agent, including identification of specific prescription numbers and fill dates to be audited, at least two (2) weeks prior to conducting the on-site audit, including, but not limited to, an on-site audit, a desk audit, or a wholesale purchase audit, request for documentation related to the dispensing of a prescription drug or any reimbursed activity by a pharmacy provider; provided, however, that wholesale purchase audits shall require a minimum of thirty (30) days' written notice. 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~~ 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, incorrectly billed prescription written date or prescription origin code, and such errors may shall not~~ be subject to recoupment. The pharmacy shall have the right to submit amended claims electronically 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~~ audit recoupment 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;~~

~~10. 9. 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.~~ 10. 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.~~ 11. Disclose to any plan sponsor whose claims were included in the audit any money recouped in the audit; and

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

B. 1. Any entity 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. Any entity conducting an audit shall not identify or label a prescription claim as an audit discrepancy when:

- 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. An entity conducting an audit 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. An entity conducting an audit shall provide, no later than five (5) business days after the date of a request by the pharmacist or pharmacy, all supporting documents the pharmacist's or pharmacy's purchase suppliers provided to the health benefits plan issuer or pharmacy benefits manager.

C. 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 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 audit calendar year. The annual limit to the number of prescription claims audited shall be inclusive of all audits, including any prescription-related documentation requests from the health insurer, pharmacy benefits manager or any third-party company conducting audits on behalf of any 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 accurate instructions, including any required form for obtaining reimbursement for 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 findings report to the pharmacy and the pharmacy's contracting agent within ~~ninety (90)~~ forty-five (45) calendar days after conclusion of conducting the audit;

2. Allow the pharmacy at least ~~sixty (60)~~ ninety (90) calendar days following receipt of the preliminary audit findings 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 findings report to the pharmacy and the pharmacy's contracting agent signed by the auditor within ~~one hundred twenty (120)~~ ten (10) calendar days after receipt of ~~the preliminary audit report or final appeal~~ additional documentation provided by the pharmacy, as provided for in Section 356.3 of this title, ~~whichever is later~~;

4. ~~Recoup~~ Allow the pharmacy to reverse and resubmit claims electronically within thirty (30) days of receipt of the final audit report in lieu of the auditing entity recouping discrepant claim amounts from the pharmacy;

5. Not recoup any disputed funds until after final internal disposition of the audit findings, 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.~~ 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 ~~misrepresentation~~ misrepresentation or abuse.

SECTION 3. AMENDATORY Section 2, Chapter 263, O.S.L. 2014 (59 O.S. Supp. 2020, 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.

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~~ PBM has been convicted in a Department hearing.

SECTION 4. AMENDATORY Section 3, Chapter 263, O.S.L. 2014 (59 O.S. Supp. 2020, 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 5. 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:

1. Include in such contracts the specific 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 and a pharmacy service administrative organization to contest reimbursement amounts within ~~ten (10)~~ fourteen (14) business days of the final adjusted payment date. The pharmacy benefits manager shall not prevent the pharmacy or the pharmacy service administrative organization from filing reimbursement appeals in an electronic batch format. The pharmacy benefits manager must respond to a provider ~~or,~~ a provider's representative and a pharmacy service administrative organization who ~~has~~ have contested a reimbursement amount through this procedure within ten (10) business days. The pharmacy benefits manager must respond in an electronic batch format to reimbursement appeals filed in an electronic batch format. The pharmacy benefits manager shall not require a pharmacy or pharmacy services administrative organization to log into a system to upload individual claim appeals or to download individual appeal responses. If a price update is warranted, the pharmacy benefits manager shall make the change in the reimbursement amount, permit the ~~challenging~~ dispensing 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 the dispensing pharmacy at a price below the PBM's reimbursement price. If the pharmacy benefits manager cannot provide a specific national or regional wholesaler where the drug can be purchased by the dispensing pharmacy at a price below the pharmacy benefits manager's reimbursement price, the pharmacy benefits manager shall immediately adjust the reimbursement amount, permit the dispensing pharmacy to reverse and rebill the claim in question, and make the reimbursement amount adjustment retroactive and effective for all contracted providers.

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~~ dispensing retail 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 as a~~ condition for participation as a network provider.

D. A pharmacy or pharmacist may decline to provide the pharmacist clinical or dispensing services to a patient or pharmacy benefits manager if the pharmacy or pharmacist is to be paid less than the pharmacy's cost for providing the pharmacist clinical or dispensing services.

E. The pharmacy benefits manager shall provide a dedicated telephone number, email address and names of the personnel with decision-making authority regarding MAC appeals and pricing.

SECTION 6. It being immediately necessary for the preservation of the public peace, health or safety, an emergency is hereby declared to exist, by reason whereof this act shall take effect and be in full force from and after its passage and approval.

Passed the House of Representatives the 27th day of April, 2021.

Presiding Officer of the House
of Representatives

Passed the Senate the 22nd day of April, 2021.

Presiding Officer of the Senate

OFFICE OF THE GOVERNOR

Received by the Office of the Governor this _____

day of _____, 20_____, at _____ o'clock _____ M.

By: _____

Approved by the Governor of the State of Oklahoma this _____

day of _____, 20_____, at _____ o'clock _____ M.

Governor of the State of Oklahoma

OFFICE OF THE SECRETARY OF STATE

Received by the Office of the Secretary of State this _____

day of _____, 20_____, at _____ o'clock _____ M.

By: _____