SB1670 FA1 McEntireMa-TJ
4/24/2024 11:37:40 am

FLOOR AMENDMENT

HOUSE OF REPRESENTATIVES
State of Oklahoma

SPEAKER:

CHAIR:

I move to amend SB1670
Of the printed Bill

Page _____ Section _____ Lines _____
Of the Engrossed Bill

By striking the Title, the Enacting Clause, the entire bill, and by inserting in lieu thereof the following language:

AMEND TITLE TO CONFORM TO AMENDMENTS

Amendment submitted by: Marcus McEntire

Adopted: _____

_____
Reading Clerk

STATE OF OKLAHOMA

2nd Session of the 59th Legislature (2024)

FLOOR SUBSTITUTE
FOR ENGROSSED
SENATE BILL NO. 1670

By: McCortney, Prieto, Jett, Coleman, Hamilton, and Alvord of the Senate

and

McEntire of the House

FLOOR SUBSTITUTE

An Act relating to pharmacy benefits management; amending 59 O.S. 2021, Sections 356.1, 356.2, 356.3, 357, 358, and 360, which relate to the Pharmacy Audit Integrity Act and pharmacy reimbursement; providing for rule promulgation; modifying audit notice requirements; requiring notice and reporting to the Office of the Attorney General; providing for fines and fees; modifying definitions; requiring certain recouped funds from audit to be paid to patients first; making certain audits null and void; requiring certain notice to include certain declaration; modifying definition; modifying reimbursement appeal process; requiring reimbursement at certain rate under certain circumstances; updating statutory references; and declaring an emergency.

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

SECTION 1. AMENDATORY 59 O.S. 2021, Section 356.1, is amended to read as follows:

Section 356.1. A. For purposes of the Pharmacy Audit Integrity Act, "pharmacy benefits manager" or "PBM" ~~means a person, business, or other entity that performs pharmacy benefits management. The term includes a person or entity acting for a PBM in a contractual or employment relationship in the performance of pharmacy benefits management for a managed care company, nonprofit hospital, medical service organization, insurance company, third-party payor, or a health program administered by a department of this state~~ shall have the same meaning as in Section 6960 of Title 36 of the Oklahoma Statutes.

B. The purpose of the Pharmacy Audit Integrity Act is to establish minimum and uniform standards and criteria for the audit of pharmacy records by or on behalf of certain entities.

C. The Pharmacy Audit Integrity Act shall apply to any audit of the records of a pharmacy conducted by a managed care company, nonprofit hospital, 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 these companies, groups, or departments.

D. The Attorney General may promulgate rules to implement the provisions of the Pharmacy Audit Integrity Act.

SECTION 2. AMENDATORY 59 O.S. 2021, 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. 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. 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~~ fourteen (14) calendar days prior to conducting the 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'~~ calendar days' written notice. For an on-site audit, the audit date shall be the date the on-site audit occurs. For all other audit types, the audit date shall be the date the pharmacy provides the documentation requested in the audit notice. The pharmacy shall have the opportunity to reschedule the audit no more than seven (7) calendar days from the date designated on the original audit notification;

3. 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, including, but not limited to, a miscalculated day supply, incorrectly billed prescription written date or prescription origin code, and such errors 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. 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. 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. Not include the dispensing fee amount or the actual invoice cost of the prescription dispensed in a finding of an audit recoupment unless a prescription was not actually dispensed or a physician denied authorization of a dispensing order;

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

9. Not exceed 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;

10. Not schedule or initiate an audit during the first seven (7) calendar days of any month unless otherwise consented to by the pharmacy;

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; and

13. Upon recoupment of funds from a pharmacy, refund first to the patient the portion of the recovered funds that were originally paid by the patient, provided such funds were part of the recoupment.

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~~ calendar 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 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.

D. The entity conducting the audit shall not audit more than fifty prescriptions, with specific date of service, per 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.

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.

F. The entity conducting the audit shall:

1. Deliver a preliminary audit findings report to the pharmacy and the pharmacy's contracting agent within forty-five (45) calendar days of conducting the audit;

2. Allow the pharmacy at least 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 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 ten (10) calendar days after receipt of additional documentation provided by the pharmacy, as provided for in Section 356.3 of this title;

4. Allow the pharmacy to reverse and resubmit claims electronically within thirty (30) calendar 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 disposition of the audit findings, including the appeals process as provided for in Section 356.3 of this title; and

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

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.

H. 1. The full amount of any recoupment on an 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.

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 pharmacy to conduct another audit for a different pharmacy benefits manager or health insurance plan.

J. Sections A through I of this section shall not apply to any audit initiated based on or that involves fraud, willful misrepresentation, or abuse.

K. If the Attorney General, after notice and opportunity for hearing, finds that the entity conducting the audit failed to follow any of the requirements pursuant to the Pharmacy Audit Integrity Act, the audit shall be considered null and void. Any monies recouped from a null and void audit shall be returned to the affected pharmacy within fourteen (14) calendar days. Any violation

of this section by a pharmacy benefits manager or auditing entity shall be deemed a violation of the Pharmacy Audit Integrity Act.

SECTION 3. AMENDATORY 59 O.S. 2021, 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~~ For any audit initiated based on or that involves fraud, willful misrepresentation, or abuse, the auditing entity shall provide, in writing, at the time of the audit, a clear and conspicuous declaration to the pharmacy being audited that the audit is being conducted under suspicion of fraud, willful

misrepresentation, or abuse and a statement of facts that supports the reasonable suspicion.

E. Any entity conducting an audit that is based on or involves fraud, willful misrepresentation, or abuse shall provide to the Office of the Attorney General:

1. Notice at least two (2) calendar days prior to beginning performance of an audit pursuant to this section;

2. A preliminary report within thirty (30) calendar days of performing the audit pursuant to this section; and

3. A final report within thirty (30) calendar days following the closure of the final appeal period for an audit performed pursuant to this section.

F. The Attorney General, authorized employees, and examiners shall have access to any pharmacy benefit manager's files and records that may relate to an audit that is based on or involves fraud, willful misrepresentation, or abuse.

G. The Attorney General may levy a civil or administrative fine of not less than One Hundred Dollars ($100.00) and not greater than Ten Thousand Dollars ($10,000.00) for each violation of this section and assess any other penalty or remedy authorized by law.

SECTION 4. AMENDATORY 59 O.S. 2021, Section 357, is amended to read as follows:

Section 357. A. As used in ~~this act~~ Sections 357 through 360 of this title:

1. "Covered entity" means a nonprofit hospital or medical service organization, for-profit hospital or medical service organization, insurer, health ~~coverage~~ benefit plan ~~or~~, health maintenance organization~~; a~~, health program administered by the state in the capacity of ~~provider of~~ providing health coverage~~;~~, or an employer, labor union, or other ~~entity organized in the state~~ group of persons that provides health coverage to ~~covered individuals who are employed or reside in the~~ persons in this state. This term does not include a health benefit plan that provides coverage only for accidental injury, specified disease, hospital indemnity, disability income, or other limited benefit health insurance policies and contracts that do not include prescription drug coverage;

2. "Covered individual" means a member, participant, enrollee, contract holder or policy holder or beneficiary of a covered entity who is provided health coverage by the covered entity. A covered individual includes any dependent or other person provided health coverage through a policy, contract or plan for a covered individual;

3. "Department" means the ~~Oklahoma~~ Insurance Department;

4. "Maximum allowable cost" ~~or~~, "MAC", or "MAC list" means the list of drug products delineating the maximum per-unit reimbursement for multiple-source prescription drugs, medical product, or device;

5. "Multisource drug product reimbursement" (reimbursement) means the total amount paid to a pharmacy inclusive of any reduction in payment to the pharmacy, excluding prescription dispense fees;

6. "Office" means the Office of the Attorney General;

7. "Pharmacy benefits management" means a service provided to covered entities to facilitate the provision of prescription drug benefits to covered individuals within the state, including negotiating pricing and other terms with drug manufacturers and providers. Pharmacy benefits management may include any or all of the following services:

a. claims processing, retail network management and payment of claims to pharmacies for prescription drugs dispensed to covered individuals,

b. clinical formulary development and management services, or

c. rebate contracting and administration~~,~~

~~d. certain patient compliance, therapeutic intervention and generic substitution programs, or~~

~~e. disease management programs~~;

~~7.~~ 8. "Pharmacy benefits manager" or "PBM" means a person, business, or other entity that performs pharmacy benefits management. The term ~~includes~~ shall include a person or entity acting ~~for~~ on behalf of a PBM in a contractual or employment relationship in the performance of pharmacy benefits management for

a managed care company, nonprofit hospital, medical service organization, insurance company, third-party payor, or a health program administered by an agency or department of this state;

~~8.~~ 9. "Plan sponsor" means the employers, insurance companies, unions and health maintenance organizations or any other entity responsible for establishing, maintaining, or administering a health benefit plan on behalf of covered individuals; and

~~9.~~ 10. "Provider" means a pharmacy licensed by the State Board of Pharmacy, or an agent or representative of a pharmacy, including, but not limited to, the pharmacy's contracting agent, which dispenses prescription drugs or devices to covered individuals.

B. Nothing in the definition of pharmacy benefits management or pharmacy benefits manager in the Patient's Right to Pharmacy Choice Act, Pharmacy Audit Integrity Act, or Sections 357 through 360 of this title shall deem an employer a "pharmacy benefits manager" of its own self-funded health benefit plan, except, to the extent permitted by applicable law, where the employer, without the utilization of a third party and unrelated to the employer's own pharmacy:

a. negotiates directly with drug manufacturers,

b. processes claims on behalf of its members, or

c. manages its own retail network of pharmacies.

SECTION 5. AMENDATORY 59 O.S. 2021, 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~~ Title 59 of the Oklahoma Statutes. 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 or the Office of the Attorney General 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~~ an application or renewal fee or fine. The Department may also levy administrative fines for each count of which a PBM has been convicted in a Department hearing.

E. 1. The Office of the Attorney General, after notice and opportunity for hearing, may instruct the Insurance Commissioner that the PBM's license be censured, suspended, or revoked for conduct likely to mislead, deceive, or defraud the public or the State of Oklahoma; or for unfair or deceptive business practices, or for any violation of the Patient's Right to Pharmacy Choice Act, the Pharmacy Audit Integrity Act, or Sections 357 through 360 of this title. The Office of the Attorney General may also levy administrative fines for each count of which a PBM has been convicted following a hearing before the Attorney General. If the Attorney General makes such instruction, the Commissioner shall enforce the instructed action within thirty (30) calendar days.

2. In addition to or in lieu of any censure, suspension, or revocation of a license by the Commissioner, the Attorney General may levy a civil or administrative fine of not less than One Hundred Dollars ($100.00) and not greater than Ten Thousand Dollars

($10,000.00) for each violation of this subsection and/or assess any other penalty or remedy authorized by this section. For purposes of this section, each day a PBM fails to comply with an investigation or inquiry may be considered a separate violation.

F. The Attorney General may promulgate rules to implement the provisions of Sections 357 through 360 of this title.

SECTION 6. AMENDATORY 59 O.S. 2021, 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, 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, a provider's representative and a pharmacy service administrative organization to contest reimbursement amounts within fourteen (14) ~~business~~ calendar 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, a provider's representative and a pharmacy service administrative organization who have contested a reimbursement amount through this procedure within ten (10) ~~business~~ calendar 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 dispensing pharmacy to reverse and rebill the claim in question, and make the reimbursement amount change retroactive and effective for all contracted providers; and

5. If a below-cost reimbursement appeal is denied, the PBM shall provide the reason for the denial, including the National Drug Code (NDC) number from, and the name of, the specific national or

regional wholesalers doing business in this state where the drug is currently in stock and available for purchase by 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~~ If the NDC number provided by the pharmacy benefits manager is not available below the acquisition cost obtained from the pharmaceutical wholesaler from whom the dispensing pharmacy purchases the majority of the prescription drugs that are dispensed, 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 reimbursement appeal requirements in this section shall apply to all drugs, medical products, or devices reimbursed according to any payment methodology, including, but not limited to:

1. Average acquisition cost, including the National Average Drug Acquisition Cost;

2. Average manufacturer price;

3. Average wholesale price;

4. Brand effective rate or generic effective rate;

5. Discount indexing;

6. Federal upper limits;

7. Wholesale acquisition cost; and

8. Any other term that a pharmacy benefits manager or an insurer of a health benefit plan may use to establish reimbursement rates to a pharmacist or pharmacy for pharmacist services.

C. The pharmacy benefits manager shall not place a drug on a MAC list, unless there are at least two therapeutically equivalent, multiple-source drugs, generally available for purchase by dispensing retail pharmacies from national or regional wholesalers.

~~C.~~ D. In the event that a drug is placed on the FDA Drug Shortages Database, pharmacy benefits managers shall reimburse claims to pharmacies at no less than the wholesale acquisition cost for the specific NDC number being dispensed.

E. 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 federal government entity as a condition for participation as a network provider.

~~D.~~ F. 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.~~ G. 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 7. 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.

59-2-11041 TJ 04/23/24