PHARMACY BENEFIT MANAGER LICENSURE AND REGULATION ACT (EXCERPT)
Act 11 of 2022

550.838 Authorization to conduct audit; process and duties; written report; extrapolation audit prohibition; inapplicable to certain investigations; carrier pharmacy audits not impaired or superseded.

Sec. 28.

(1) Subject to this section, a carrier or a pharmacy benefit manager may conduct an audit of a pharmacy in this state. A carrier or a pharmacy benefit manager that conducts an audit of a pharmacy in this state shall do all of the following:

(a) In its pharmacy contract, identify and describe in detail the audit procedures, including the appeals process described in subdivision (m). A carrier or pharmacy benefit manager shall update its pharmacy contract and communicate any changes to the pharmacy as changes to the contract occur.

(b) Provide written notice to the pharmacy at least 2 weeks before initiating and scheduling the initial on-site audit for each audit cycle. If the pharmacy on average dispenses more than 600 prescriptions per week, a carrier or pharmacy benefit manager shall not initiate or schedule an audit under this subsection during the first 5 business days of a month without the express consent of the pharmacy. A carrier or pharmacy benefit manager shall be flexible in initiating and scheduling an audit at a time that is reasonably convenient to the pharmacy. Within 3 business days after the pharmacy receives notice of an on-site audit, the pharmacy may reschedule the audit to a date not more than 10 business days after the date proposed by the carrier or pharmacy benefit manager.

(c) Utilize every effort to minimize inconvenience and disruption to pharmacy operations during the audit process. A carrier or pharmacy benefit manager that conducts an audit of a pharmacy in this state shall not interfere with the delivery of pharmacy services to a patient.

(d) Conduct an audit that involves clinical or professional judgment by or in consultation with a pharmacist.

(e) Subject to the requirements of article 15 of the public health code, 1978 PA 368, MCL 333.16101 to 333.18838, for the purpose of validating a pharmacy record with respect to orders, refills, or changes in prescriptions, allow the use of either of the following:

(i) Hospital or physician records that are written or that are transmitted or stored electronically, including file annotations, document images, and other supporting documentation that is date- and time-stamped.

(ii) A prescription that complies with the requirements of the Michigan board of pharmacy created under section 17721 of the public health code, 1978 PA 368, MCL 333.17721, and federal law.

(f) Base any finding of an overpayment or underpayment on the actual overpayment or underpayment of claims.

(g) Subject to subsection (4), base any recoupment or payment adjustments of claims on a calculation that is reasonable and proportional in relation to the type of error detected.

(h) If there is a finding of an underpayment, reimburse the pharmacy as soon as possible after detection.

(i) Conduct its audit of the pharmacy under the same standards and parameters that the carrier or pharmacy benefit manager uses when auditing other similarly situated pharmacies.

(j) Audit only claims submitted or adjudicated within the 1-year period preceding the initiation of the audit unless a longer period is permitted under federal or state law.

(k) Not receive payment and not compensate the auditor based on the amount recovered.

(l) Not include the dispensing fee amount in a finding of an overpayment unless any of the following apply:

(i) The prescription was not dispensed. As used in this subparagraph, "dispense" means that term as defined in section 17703 of the public health code, 1978 PA 368, MCL 333.17703.

(ii) The prescription was not delivered to the patient. As used in this subparagraph, "deliver" means that term as defined in section 17703 of the public health code, 1978 PA 368, MCL 333.17703.

(iii) The prescriber denied prior authorization.

(iv) The prescription was a medication error by the pharmacy.

(v) The overpayment is solely based on an extra dispensing fee.

(m) Establish a written appeals process that includes a process to appeal preliminary audit reports and final audit reports prepared under this section. A pharmacy has 30 days after the pharmacy receives the final audit report to file an appeal under this section.

(n) Not limit the days' supply for unit-of-use items, such as topicals, drops, vials, and inhalants, beyond manufacturer recommendations.

(o) If the only commercially available package size exceeds the maximum days' supply, not use the dispensing of the package size as the basis for recoupment.

(p) If the only commercially available package size exceeds the maximum days' supply and the claim was affirmatively adjudicated, not recoup the claim as an early refill.

(q) In conducting an audit of wholesale invoices, all of the following:

(i) Not audit the claims of another carrier or pharmacy benefit manager.

(ii) Within 5 business days after a request by the audited pharmacy, provide supporting documentation provided to the carrier or pharmacy benefit manager by the audited pharmacy's suppliers.

(iii) Not utilize any of the following as a basis for recoupment:

(A) The national drug code for the dispensed drug is in a quantity that is a subunit or multiple of the purchased drug as reflected on a supporting wholesale invoice.

(B) The correct quantity dispensed is reflected on the audited pharmacy claim.

(C) The drug dispensed by the pharmacy on an audited pharmacy claim is identical to the labeler and product code section under the national drug code. A difference in the package code under the national drug code is not subject to recoupment.

(iv) Accept as evidence each of the following:

(A) Supplier invoices issued to the audited pharmacy before the date of dispensing the drug underlying the audited claim.

(B) Invoices issued to the audited pharmacy from any supplier permitted by law to transfer ownership of the drug acquired by the audited pharmacy, subject to validation by the supplier.

(C) Copies of supplier invoices in the possession of the audited pharmacy.

(2) Upon completion of an audit of a pharmacy, the carrier or pharmacy benefit manager shall do all of the following:

(a) Deliver a preliminary written audit report to the pharmacy not later than 60 days after the completion of the audit. The preliminary written audit report must include contact information for the person performing the audit and a description of the appeals process established under subsection (1)(m).

(b) Allow the pharmacy at least 30 days after its receipt of the preliminary written audit report under subdivision (a) to produce documentation to address any discrepancy found during the audit.

(c) If an appeal is not filed, deliver a final written audit report to the pharmacy within 90 days after the time described in subdivision (b) has elapsed. If an appeal is filed, deliver a final written audit report to the pharmacy within 90 days after the conclusion of the appeal.

(d) Except as otherwise provided in this section, recoup disputed money or overpayments or restore underpayments only after the final written audit report is delivered to the pharmacy under subdivision (c).

(3) Except as required by federal law, a carrier or pharmacy benefit manager shall not conduct an extrapolation audit in calculating recoupments, restoration, or penalties for an audit under this section. For the purposes of this subsection, "extrapolation audit" means an audit of a sample of prescription drug benefit claims submitted by a pharmacy to the carrier that is then used to estimate audit results for a larger batch or group of claims not reviewed during the audit.

(4) Any clerical or record-keeping error, including a typographical error, a scrivener's error, or a computer error, regarding a required document or record that is found during an audit under this section does not, on its face, constitute fraud. An error described in this subsection does not subject the individual involved to criminal penalties without proof of intent to commit fraud. To the extent that an audit results in the identification of a clerical or record-keeping error, including a typographical error, a scrivener's error, or a computer error, in a required document or record, the pharmacy is not subject to recoupment of money by the carrier or pharmacy benefit manager unless clerical error or record-keeping error surpasses the statistical threshold established by the Centers for Medicare and Medicaid Services or the carrier can provide proof of intent to commit fraud or the error results in actual financial harm to the carrier, pharmacy benefit manager, or a covered person or enrollee.

(5) This section does not apply to any of the following:

(a) An audit conducted to investigate fraud, willful misrepresentation, or abuse, including, but not limited to, investigative audits or audits conducted under any other statute that authorizes investigation relating to insurance fraud.

(b) An audit based on a criminal investigation.

(6) This section does not impair or supersede a provision regarding carrier pharmacy audits in the insurance code of 1956, 1956 PA 218, MCL 500.100 to 500.8302. If any provision of this section conflicts with a provision of the insurance code of 1956, 1956 PA 218, MCL 500.100 to 500.8302, with regard to carrier pharmacy audits, the provision in the insurance code of 1956, 1956 PA 218, MCL 500.100 to 500.8302, controls.

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