

**191—59.4(510B) Audits of pharmacies by pharmacy benefits managers.**

**59.4(1)** An audit of pharmacy records by a pharmacy benefits manager shall be conducted in accordance with the following:

*a.* The pharmacy benefits manager conducting the initial on-site audit must provide the pharmacy written notice at least ten business days prior to conducting any audit;

*b.* Any audit which involves clinical or professional judgment must be conducted by or in consultation with a pharmacist;

*c.* When a pharmacy benefits manager alleges an error in reimbursement has been made to a pharmacy, the pharmacy benefits manager shall provide the pharmacy sufficient documentation to determine the specific claims included in the alleged error;

*d.* A pharmacy may use the records of a hospital, physician or other authorized practitioner of the healing arts for prescription 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 drug dispensed pursuant to a prescription;

*e.* Each pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies audited by the pharmacy benefits manager;

*f.* The period covered by an audit may not exceed two years from the date on which the claim was submitted to or adjudicated by a managed care company, insurance company, third-party payor, or any pharmacy benefits manager that represents such entities;

*g.* Unless otherwise consented to by the pharmacy, an audit may not be initiated or scheduled during the first seven calendar days of any month due to the high volume of prescriptions filled during that time;

*h.* The preliminary audit report must be delivered to the pharmacy within 120 days after conclusion of the audit. A final written audit report shall be received by the pharmacy within six months of the preliminary audit report or final appeal, whichever is later;

*i.* A pharmacy shall be allowed at least 30 days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during an audit; and

*j.* If it is determined by the pharmacy benefits manager that an error in reimbursement to a pharmacy occurred, the following criteria apply:

(1) For each contract between the pharmacy benefits manager and the pharmacy existing on or after January 1, 2015, a pharmacy's usual and customary price for compounded medications is considered the reimbursable cost, unless the contract between the pharmacy benefits manager and the pharmacy specifically provides details for a pricing methodology for compounded medications.

(2) A finding of error in reimbursement must be based on the actual error in reimbursement and not be based on a projection of the number of patients served having a similar diagnosis or on a projection of the number of similar orders or refills for similar prescription drugs.

(3) Calculations of errors in reimbursement must not include dispensing fees unless prescriptions were not actually dispensed, the prescriber denied authorizations, the prescriptions dispensed were medication errors by the pharmacy, or the amounts of the dispensing fees were incorrect.

(4) Any clerical or record-keeping error of the pharmacy, including but not limited to a typographical error, scrivener's error, or computer error, regarding a required document or record shall not be considered fraud by the pharmacy under paragraph 59.6(3) "a" or under a pharmacy's contract with the pharmacy benefits manager.

(5) In the case of an error that has no actual financial harm to the patient or third-party payor, the pharmacy benefits manager shall not assess a charge against the pharmacy.

(6) If a pharmacy has entered into a corrective action plan with a pharmacy benefits manager, and if the pharmacy fails to comply with the corrective action plan in a manner that results in overpayments being made by the pharmacy benefits manager to the pharmacy, the pharmacy benefits manager may recover the overpaid amounts. For purposes of this paragraph, "corrective action plan" means an agreement entered into by a pharmacy benefits manager and a pharmacy which is intended to promote accurate submission and payment of pharmacy claims.

(7) During the audit period, interest on any outstanding balance shall not accrue for the pharmacy benefits manager or the pharmacy. For purposes of this rule, the audit period begins with the notice of the audit and ends with a final determination of the audit report.

**59.4(2)** Notwithstanding Iowa Code section 510B.7 and any other provision in this rule, the entity conducting the audit shall not use the accounting practice of extrapolation in calculating the recoupment or contractual penalty for an audit unless required by state or federal laws or regulations. The entity may not use the accounting practice of extrapolation in a manner more stringent than that required by state or federal laws or regulations.

**59.4(3)** Recoupment of any disputed funds shall occur only after final disposition of the audit, including the appeals process as set forth in subrules 59.4(4) and 59.4(5).

**59.4(4)** Each pharmacy benefits manager conducting an audit shall establish an appeals process under which a pharmacy may appeal an unfavorable preliminary audit report to the pharmacy benefits manager. The pharmacy benefits manager shall conduct a review of the unfavorable preliminary audit report. The cost of the audit review shall be paid by the pharmacy benefits manager. If, following the review, the pharmacy benefits manager finds that an unfavorable audit report or any portion thereof is unsubstantiated, the pharmacy benefits manager shall dismiss the unsubstantiated audit report or unsubstantiated portion of the audit report without the necessity of any further proceedings.

**59.4(5)** A pharmacy benefits manager shall establish a process for an independent third-party review of final audit findings. If, following the appeal of an audit report and upon conducting an audit review, the pharmacy benefits manager finds that an unfavorable audit report or any portion thereof is found to be substantiated, the pharmacy benefits manager shall notify the pharmacy in writing of its right to request an independent third-party review of the final audit findings and the process used to request such a review. If a pharmacy requests an independent third-party review of the final audit findings and the audit report is found to be substantiated, the cost of the third-party review shall be paid by the pharmacy. If a pharmacy requests an independent third-party review of the final audit findings and the audit report is found to be unsubstantiated, the cost of the third-party review shall be paid by the pharmacy benefits manager. If the reviewer finds partially in favor of both parties, the reviewer shall apportion the costs accordingly and each party will bear a portion of the costs of the review.

**59.4(6)** Rescinded IAB 4/27/16, effective 6/1/16.

**59.4(7)** Each pharmacy benefits manager conducting an audit shall, after completion of any review process, provide a copy of the final audit report to the third-party payor within ten business days of completing the report.

**59.4(8)** This rule shall not apply to any investigative audit which involves fraud, willful misrepresentation, abuse, or any other statutory provision which authorizes investigations relating to but not limited to insurance fraud.

[**ARC 1466C**, IAB 5/28/14, effective 7/2/14; **ARC 2518C**, IAB 4/27/16, effective 6/1/16; **ARC 6739C**, IAB 12/14/22, effective 1/1/23; **ARC 6890C**, IAB 2/8/23, effective 3/15/23]