CHAPTER 59
PHARMACY BENEFITS MANAGERS

191—59.1(510B) Purpose. The purpose of this chapter is to administer the provisions of Iowa Code chapter 510B relating to the regulation of pharmacy benefits managers.
[**ARC 1466C**, IAB 5/28/14, effective 7/2/14]

191—59.2(510B) Definitions. The terms defined in Iowa Code sections 510.11 and 510B.1 shall have the same meaning for the purposes of this chapter. The definitions contained in 191—Chapter 58, "Third-Party Administrators," and 191—Chapter 78, "Uniform Prescription Drug Information Card," of the Iowa Administrative Code are incorporated by reference. As used in this chapter:

"Clean claim" means a claim which is received by any pharmacy benefits manager for adjudication and which requires no further information, adjustment or alteration by the pharmacy or the covered individual in order to be processed and paid by the pharmacy benefits manager. A claim is a clean claim if it has no defect or impropriety, including any lack of substantiating documentation, or no particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this chapter. A clean claim includes a resubmitted claim with previously identified deficiencies corrected.

"Complaint" means a written communication expressing a grievance or an inquiry concerning a transaction between a pharmacy benefits manager and a pharmacy.

"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.

"Day" means a calendar day, unless otherwise defined or limited.

"Paid" means the later of either the day on which the payment is mailed by the pharmacy benefits manager or the day on which the electronic payment is processed by the pharmacy benefits manager's bank.

"Pharmacist" means "pharmacist" as defined in Iowa Code section 155A.3.

"Pharmacy" means "pharmacy" as defined in Iowa Code section 155A.3 and includes "pharmacist."
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191—59.3(510B) Timely payment of pharmacy claims.

59.3(1) All benefits payable under a pharmacy benefits management plan shall be paid as soon as feasible but within 20 days after receipt of a clean claim when the claim is submitted electronically and shall be paid within 30 days after receipt of a clean claim when the claim is submitted in paper format.

59.3(2) Payments to the pharmacy for clean claims are considered to be overdue and not timely if not paid within 20 or 30 days, whichever is applicable. If any clean claim is not timely paid, the pharmacy benefits manager must pay the pharmacy interest at the rate of 10 percent per annum commencing the day after any claim payment or portion thereof was due until the claim is finally settled or adjudicated in full.

59.3(3) Pharmacy benefits managers may demonstrate the date a claim is paid by a mail record or a bank statement.
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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 one week 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 59.5(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 covered entity, 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, errors that are a result of the pharmacy's failure to comply with such plan may be subject to recovery.

(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 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 penalties for audits 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) Any pharmacy's appeal or request for an independent third-party review of an audit report shall be considered a complaint and shall be included in the report required by subrule 59.7(2).

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 covered entity.

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.

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191—59.5(510B) Termination or suspension of contracts with pharmacies by pharmacy benefits managers.

59.5(1) A contract between a pharmacy benefits manager and a pharmacy shall include a provision describing notification procedures for contract termination. The contract shall require no less than 60 days' prior written notice by either party that wishes to terminate the contract.

59.5(2) Termination of a contract between a pharmacy benefits manager and a pharmacy or termination of a pharmacy from the network of the pharmacy benefits manager shall not release the pharmacy benefits manager from the obligation to make payments due to the pharmacy for contract-covered services rendered before the contract of the pharmacy was terminated.

59.5(3) The following apply to terminations or suspensions of contracts with pharmacies by pharmacy benefits managers:

a. If the pharmacy benefits manager has evidence that the pharmacy has engaged in fraudulent conduct or poses a significant risk to patient care or safety, the pharmacy benefits manager may immediately suspend the pharmacy from further performance under the contract only if written notice of the suspension and reasoning therefor is provided to the pharmacy, the covered entity and the commissioner.

b. A pharmacy shall not be terminated or suspended from the pharmacy benefits manager's provider network or otherwise penalized by a pharmacy benefits manager solely because the pharmacy files a complaint, grievance or appeal with any entity. A pharmacy benefits manager shall not imply or state that it may or will take action to cancel or limit a pharmacy's participation in a pharmacy benefits manager's provider network solely because the pharmacy files a complaint, grievance or appeal with any entity.

c. A pharmacy shall not be terminated from the network or suspended by a pharmacy benefits manager due to any disagreement with a decision of the pharmacy benefits manager to deny or limit benefits to covered individuals or due to any assistance provided to covered individuals by the pharmacy in obtaining reconsideration of a decision of the pharmacy benefits manager.

d. The pharmacy may request an independent third-party review of the final decision to terminate or suspend the contract between the pharmacy benefits manager and the pharmacy by filing with the pharmacy benefits manager a written request for an independent third-party review of the decision. This

written request must be filed with the pharmacy benefits manager within 30 days of receipt of the final termination or suspension decision.

e. Any request by a pharmacy for an independent third-party review of a termination or suspension decision shall be considered a complaint and included in the report required by subrule 59.7(2).

f. If a pharmacy requests an independent third-party review of a termination or suspension decision and the termination 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 a termination or suspension decision and the termination is found to be unsubstantiated, the cost of the third-party review shall be paid by the pharmacy benefits manager.

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191—59.6(510B) Price change. For purposes of Iowa Code section 510B.7(3), a pharmacy benefits manager may meet the requirements of having to adjust its payment to the pharmacy network provider consistent with a price increase within three business days of the price increase notification by a manufacturer or supplier by keeping a list of current prescription drugs and current maximum reimbursement amounts and by updating that list at least every three business days with any price increases. This list shall be made available to pharmacies and pharmacy network providers through a readily accessible and easily usable online format, or in some other readily accessible and easily usable format.

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191—59.7(510B) Complaints.

59.7(1) Each pharmacy benefits manager shall develop an internal system to record and report complaints. This system shall include but not be limited to the following information regarding each complaint from any pharmacy:

a. The reason for the complaint and factual documentation to support the complaint;

b. Contact name, address and telephone number of the pharmacy;

c. Prescription number;

d. Prescription reimbursement amount for any disputed claim;

e. Any disputed prescription claim payment date;

f. Covered entity benefits certificate; and

g. The final determination and outcome of the complaint.

59.7(2) A summary of all complaints received by the pharmacy benefits manager each calendar quarter shall be submitted to the commissioner within 30 days after the calendar quarter has ended. The summary shall include the following:

a. Name, address, telephone number and e-mail address for a contact person for the pharmacy benefits manager;

b. A summary of the information listed in paragraph 59.7(1)*"a,"* excluding documentation; and

c. The information listed in paragraphs 59.7(1)*"b," "d," "e,"* and *"g."*

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191—59.8(510,510B) Duty to notify commissioner of fraud. A covered entity that contracts with a pharmacy benefits manager to perform the covered entity's services shall require the pharmacy benefits manager to follow Iowa Code section 507E.6 in notifying the commissioner of any detection of fraud, including but not limited to prescription drug diversion activity. "Prescription drug diversion activity," for purposes of this rule, means the diversion of prescription drugs from legal and medically necessary uses to uses that are illegal and not medically authorized or necessary. A pharmacy benefits manager shall follow the fraud detection protocol developed by the covered entity or shall allow the covered entity to review and agree to the pharmacy benefits manager's protocol.

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191—59.9(507,510,510B) Commissioner examinations of pharmacy benefits managers.

59.9(1) Pharmacy benefits managers shall cooperate with the commissioner for the commissioner's administration of Iowa Code chapters 507, 510, and 510B and this chapter.

59.9(2) Pharmacy benefits managers shall maintain for five years the records necessary to demonstrate to the commissioner compliance with this chapter. Pharmacy benefits managers shall provide the commissioner easy accessibility to records for examination, audit and inspection to verify compliance with this chapter.

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191—59.10(505,507,507B,510,510B,514L) Failure to comply. Failure to comply with the provisions of this chapter or with Iowa Code chapters 510 and 510B, or failure to comply with 191—Chapters 58 and 78 or Iowa Code chapters 507 and 514L as they are relevant to the administration of this chapter or of Iowa Code chapters 510 and 510B, shall subject the pharmacy benefits manager to the penalties of Iowa Code chapter 507B.

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These rules are intended to implement Iowa Code chapters 17A, 505, 507, 510, 510B and 514L.

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*The September 17, 2008, effective date of subrules 59.6(3), 59.6(5) and 59.7(6) was delayed for 70 days by the Administrative Rules Review Committee at its meeting held September 9, 2008. At its meeting held October 14, 2008, the Committee voted to lift the delay, effective October 15, 2008.