CHAPTER 59
PHARMACY BENEFITS MANAGERS

191—59.1(510B,510C) Purpose. The purpose of this chapter is to administer the provisions of Iowa Code chapters 510, 510B and 510C relating to the regulation of pharmacy benefits managers.
[**ARC 1466C**, IAB 5/28/14, effective 7/2/14; **ARC 4578C**, IAB 7/31/19, effective 9/4/19; **ARC 6739C**, IAB 12/14/22, effective 1/1/23]

191—59.2(510B) Definitions. The terms defined in Iowa Code sections 510.11, 510B.1, and 510C.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," are incorporated by reference. As used in this chapter:

"Complaint" means a written communication from a pharmacy or the commissioner to a pharmacy benefits manager that makes an inquiry or expresses a grievance and includes, but is not limited to, the following:

1. A comment on, contest or appeal by a pharmacy of a pharmacy benefits manager's maximum allowable cost, maximum allowable cost list or other pricing methodology used to pay a pharmacy.
2. Any pharmacy's appeal or request for an independent third-party review of an audit report pursuant to subrules 59.4(4) and 59.4(5).
3. Any request by a pharmacy for an independent third-party review of a termination or suspension decision pursuant to paragraph 59.6(3)*"d."*
4. Any inquiries from the commissioner pursuant to subrule 59.8(3).

"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.
[**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]

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) A payment to the pharmacy for a clean claim is considered to be overdue and not timely if not paid within 20 or 30 days, whichever is applicable. If a 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) A pharmacy benefits manager may demonstrate the date a claim is paid by a mail record or a bank statement.

59.3(4) Pursuant to Iowa Code section 510B.4 and paragraph 59.4(1)*"j,"* a pharmacy benefits manager shall not retroactively reduce or increase reimbursement, through adjustment or reconciliation or any other means, of a clean claim paid to pharmacies.
[**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]

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]

191—59.5(510B) Disclosure of national compendia used. Rescinded **ARC 6739C**, IAB 12/14/22, effective 1/1/23.

191—59.6(510B) Termination or suspension of contracts with pharmacies by pharmacy benefits managers.

59.6(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.

59.6(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.

59.6(3) The following apply to a termination or suspension of a contract with a pharmacy by a pharmacy benefits manager:

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 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 third-party payor and the commissioner.

b. A pharmacy benefits manager shall neither take action, nor imply or state that it may or will take action, to decrease reimbursement or to terminate, suspend, cancel or limit a pharmacy's participation in a pharmacy benefits manager's provider network solely or mainly because the pharmacy files a complaint with any entity.

c. A pharmacy shall not be terminated or suspended from a network of a pharmacy benefits manager due to any disagreement with a decision of the pharmacy benefits manager to deny or limit

benefits to a covered person or due to any assistance provided to a covered person 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. 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.

[**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]

191—59.7(510B) Price change. Rescinded **ARC 6739C**, IAB 12/14/22, effective 1/1/23.

191—59.8(510B) Complaints.

59.8(1) *System to record complaints.* 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:

a. The reason for the complaint and any factual documentation submitted by the complainant 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 of fill;

f. Third-party payor benefits certificate;

g. The justification for final determination and outcome of the complaint, including but not limited to the section and language of the contract or provider manual that was used in making the determination;

h. The name of any pharmacy services administrative organization, if known by the pharmacy benefits manager, with which the pharmacy or the pharmacy benefits manager has a contract and that is involved in the matter; and

i. For complaints related to the maximum allowable cost or other pricing methodology used to pay a pharmacy, documentation demonstrating compliance with Iowa Code section 510B.8A as appropriate based on the nature of the complaint.

59.8(2) *Quarterly complaint summary.* A summary of all complaints received by the pharmacy benefits manager each calendar quarter shall be submitted to the commissioner, in a form and manner prescribed by the commissioner, within 30 days after the calendar quarter has ended. The summary shall include the following:

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

b. Information related to any pharmacy's appeal or request for an independent third-party review of an audit report pursuant to subrules 59.4(4) and 59.4(5);

c. Information related to any pharmacy's comment on or contest or appeal of a maximum allowable cost, maximum allowable cost list or other pricing methodology used to pay a pharmacy;

d. Information related to any request by a pharmacy for and the outcome of an independent third-party review of a termination or suspension decision pursuant to paragraph 59.6(3)*"d"*;

e. A summary of the information listed in paragraph 59.8(1)*"a,"* excluding documentation; and

f. The information listed in paragraphs 59.8(1)*"b," "c," "d," "e,"* and *"g."*

59.8(3) *Confidentiality.* The quarterly complaint summary shall be confidential pursuant to subrule 59.10(5).

59.8(4) *Inquiries and complaints from the commissioner.*

a. A pharmacy benefits manager shall comply with Iowa Code section 507B.4A(1) in responding promptly to an inquiry from the commissioner, including a complaint.

b. When responding to an inquiry or complaint from the commissioner, a pharmacy benefits manager shall include the Food and Drug Administration National Drug Code number, the names of the manufacturers of the prescription drugs that are related to the inquiry, and the names of any pharmaceutical wholesalers, if:

(1) The pharmacy benefits managers can determine that information from their records and other knowledge of the subject matter of the inquiry or complaint; or

(2) The commissioner has provided enough information in the inquiry or complaint for the pharmacy benefits manager to identify such facts.

[**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]

191—59.9(510,510B) Duty to notify commissioner of fraud. A third-party payor that contracts with a pharmacy benefits manager to perform the third-party payor'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 third-party payor or shall allow the third-party payor to review and agree to the pharmacy benefits manager's protocol.

[**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]

191—59.10(507,510,510B) Commissioner examinations of pharmacy benefits managers.

59.10(1) *Cooperation of pharmacy benefits managers with the commissioner.* A pharmacy benefits manager shall cooperate with the commissioner and comply with the commissioner's requests to aid with the commissioner's administration of Iowa Code chapters 507, 507B, 510, and 510B and this chapter, including cooperation and compliance with the commissioner in conducting an examination of a pharmacy benefits manager pursuant to Iowa Code chapter 507, and cooperation with the commissioner in conducting an investigation pursuant to Iowa Code chapter 507B.

59.10(2) *Maintenance of records.* A pharmacy benefits manager shall maintain the records necessary to demonstrate to the commissioner compliance with this chapter for the duration of any written agreement plus five years. A pharmacy benefits manager shall provide the commissioner easy accessibility to records for examination, audit and inspection to verify compliance with this chapter, including but not limited to all contracts and provider manuals governing pharmacies and pharmacy networks.

59.10(3) *Disclosure of payments received by the pharmacy benefits manager.*

a. The commissioner may request, and a pharmacy benefits manager shall disclose to the commissioner, the amount of all payments received by the pharmacy benefits manager, and the nature, type, and amounts of all other revenues that the pharmacy benefits manager receives.

b. For purposes of this subrule, "payments received by the pharmacy benefits manager" includes but is not limited to the aggregate amount of the following types of payments:

(1) A remuneration collected by the pharmacy benefits manager that is allocated to a third-party payor;

(2) An administrative fee collected from the manufacturer in consideration of an administrative service provided by the pharmacy benefits manager to the manufacturer; and

(3) Any other fee or amount collected by the pharmacy benefits manager from a manufacturer or other entity for a drug switch program, a formulary management program, a mail service pharmacy, educational support, data sales related to a covered person, or any other administrative function.

59.10(4) *Disclosure of pricing methodology used to pay a pharmacy.* The commissioner may require, and a pharmacy benefits manager shall submit to the commissioner, pursuant to Iowa Code section 510B.8A, information related to the pharmacy benefits manager's pricing methodology for maximum allowable cost or other pricing methodology used to pay a pharmacy.

59.10(5) *Confidentiality.* Information provided by a pharmacy benefits manager to the commissioner under this rule or under rule 191—59.8(510B) shall be deemed confidential under Iowa Code sections 22.7(2), 22.7(3), 22.7(6), 505.8(8), 505.8(9), 507.14, and 510B.10, as applicable.
[**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]

191—59.11(510B,510C) Pharmacy benefits manager annual report.

59.11(1) *Filing of annual report.* In addition to submitting the third-party administrator annual report required under rule 191—58.11(510), each pharmacy benefits manager shall submit to the commissioner on or before February 15 of each year the annual report required by Iowa Code section 510C.2 (PBM annual report). The pharmacy benefits manager shall follow the instructions and use the online submission form provided on the Iowa insurance division's website (iid.iowa.gov) to file the PBM annual report.

59.11(2) *Verification.* At least two officers of the pharmacy benefits manager shall certify in writing that they verified the accuracy of the PBM annual report.

59.11(3) *Electronic filing.* Each pharmacy benefits manager shall submit the PBM annual report electronically as set forth in the instructions, unless otherwise specifically authorized by the commissioner.

59.11(4) *Public access.* The commissioner shall publish on the Iowa insurance division's website (iid.iowa.gov) the nonconfidential information received in the PBM annual report.

59.11(5) *Completeness of PBM annual report.* All information required by the commissioner must be submitted before the PBM annual report shall be considered complete.

59.11(6) *Penalties.* A pharmacy benefits manager that fails to timely submit to the commissioner a complete PBM annual report shall pay a late fee of $100. If a pharmacy benefits manager fails to submit a complete PBM annual report by May 15, the pharmacy benefits manager shall be subject to penalties as set forth in rule 191—59.12(505,507,507B,510,510B,510C,514L).
[**ARC 4578C**, IAB 7/31/19, effective 9/4/19; **ARC 6739C**, IAB 12/14/22, effective 1/1/23]

191—59.12(505,507,507B,510,510B,510C,514L) Failure to comply. Failure to comply with the provisions of this chapter or with Iowa Code chapters 510, 510B and 510C 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 shall subject the pharmacy benefits manager to the penalties of Iowa Code chapter 507B. No provision of these rules or the Iowa Code chapters mentioned herein may be waived or modified by contract.
[**ARC 1466C**, IAB 5/28/14, effective 7/2/14; **ARC 2518C**, IAB 4/27/16, effective 6/1/16; **ARC 4578C**, IAB 7/31/19, effective 9/4/19; **ARC 6739C**, IAB 12/14/22, effective 1/1/23]

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