ARC 1295C

INSURANCE DIVISION[191]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)*"b."*

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code sections 507B.12 and 510B.3, the Iowa Insurance Division (the Division) hereby gives Notice of Intended Action to amend Chapter 59, "Pharmacy Benefits Managers," Iowa Administrative Code.

These amendments are proposed to implement and administer the provisions of Iowa Code chapters 507, 510, and 510B, which regulate examinations of insurance companies, third-party administrators, and pharmacy benefits managers, respectively.

The amendments to Chapter 59 set forth and clarify duties of insurers and pharmacy benefits managers. It is the intention of the Division that these amendments shall become effective April 23, 2014, and that insurers and pharmacy benefits managers must be in compliance with the amendments beginning April 23, 2014, except that pharmacy benefits managers must be in compliance with amended rule 191—59.3(510B) as set forth in that rule.

Any interested person may make written suggestions or comments on these proposed amendments until 4:30 p.m. on February 11, 2014. Such written comments should be directed to Rosanne Mead, Iowa Securities Bureau, Iowa Insurance Division, Two Ruan Center, 601 Locust Street, Fourth Floor, Des Moines, Iowa 50319-0065; fax (515)281-3059; e-mail rosanne.mead@iid.iowa.gov.

Also, there will be a public hearing on February 11, 2014, at 10 a.m., at the offices of the Insurance Division, Two Ruan Center, 601 Locust Street, Fourth Floor, Des Moines, Iowa, at which time persons may present their views about the amendments either orally or in writing. At the hearing, persons will be asked to give their names and addresses for the record.

Any person who intends to attend the public hearing and who has special requirements, such as those relating to hearing or mobility impairments, should contact the Division and advise of specific needs.

These rules are subject to waiver consistent with the waiver provisions provided for in 191—Chapter 4.

After review and analysis of this rule making, no impact on jobs has been found.

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

The following amendments are proposed.

ITEM 1. Amend rule 191—59.1(510B) as follows:

191—59.1(510B) Purpose. The purpose of this chapter is to administer the provisions of Iowa Code ~~Supplement~~ chapter 510B relating to the regulation of pharmacy benefits managers.

ITEM 2. Amend rule 191—59.2(510B) as follows:

191—59.2(510B) Definitions. The terms defined in Iowa Code ~~Supplement section~~ 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 ~~pharmacist or pharmacies~~ pharmacy or the ~~insured~~ 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 ~~or pharmacist~~.

"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 ~~check~~ 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."

ITEM 3. Amend rule 191—59.3(510B) as follows:

191—59.3(510B) Timely payment of pharmacy claims.

59.3(1) All benefits payable under a contract between a pharmacy benefits ~~management plan~~ manager and a pharmacy shall be paid as soon as feasible but within ~~20~~ 15 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 ~~or pharmacist~~ for clean claims are considered to be overdue if not paid within ~~20 or 30~~ 15 days~~, whichever is applicable~~. If any clean claim is not timely paid, the pharmacy benefits manager must pay the pharmacy ~~or pharmacist~~ 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) For each contract between a pharmacy benefits manager and a pharmacy, the pharmacy benefits manager must be in compliance with this rule no later than the first annual contract renewal on or after April 23, 2014, but no later than January 1, 2015, whichever occurs first. ~~Existing~~ For existing contracts between ~~clients~~ pharmacies and pharmacy benefits managers ~~shall comply with the requirement that clean claims be paid within 20 or 30 days, whichever is applicable, when such contracts are renegotiated on or after January 1, 2009, but no later than December 31, 2009~~, until the first annual contract renewal on or after April 23, 2014, but no later than January 1, 2015, whichever occurs first, all benefits shall be paid as soon as feasible but shall be paid 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. 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(4) Pharmacy benefits managers may demonstrate the date a claim is paid by a mail record or a bank statement.

ITEM 4. Rescind rule **191—59.4(510B)**.

ITEM 5. Renumber rules **191—59.5(510B)**, **191—59.6(510B)** and **191—59.7(510B)** as **191—59.7(510B)**, **191—59.4(510B)** and **191—59.5(510B)**, respectively.

ITEM 6. Amend renumbered rule 191—59.4(510B) as follows:

191—59.4(510B) ~~Auditing practices~~ Audits of pharmacies by pharmacy benefits managers.

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

a. and *b.* No change.

c. When a pharmacy benefits manager alleges an ~~overpayment~~ error in reimbursement has been made to a pharmacy ~~or pharmacist~~, the pharmacy benefits manager shall provide the pharmacy

~~or pharmacist~~ sufficient documentation to determine the specific claims included in the alleged ~~overpayment~~ 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 ~~legend or narcotic~~ 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 ~~companies, groups, or a department~~ entities;

g. to *i.* No change.

j. ~~The audit criteria set forth in this subrule shall apply only to audits of claims submitted for payment after December 31, 2008.~~ If it is determined by the pharmacy benefits manager that an error in reimbursement occurred, the following criteria apply:

(1) A pharmacy's usual and customary price for compounded medications is considered the reimbursable cost, unless the pricing methodology is outlined in the provider contract.

(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 nor 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 subrule 59.5(4) 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) Interest may not accrue during the audit period for either party. 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 ~~recuperation of~~ 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) ~~Recuperation~~ Recoupment of any disputed funds shall occur only after final disposition of the audit, including the appeals process as set forth in subrules ~~59.6(4)~~ 59.4(4) and ~~59.6(5)~~ 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 ~~appeal~~ 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 ~~said~~ unsubstantiated portion of the audit report without the necessity of any further proceedings.

59.4(5) A pharmacy benefits manager shall have a process for an independent third-party review of final audit findings. If, following the ~~final~~ 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 already have in place a process for an independent third-party review of the final audit findings. As part of the final appeal process of any~~

~~final adverse decision, 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 if the audit report is found to be substantiated, the cost of the third-party review shall be paid by the pharmacy, or if 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(6)~~ 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 ~~plan sponsor~~ covered entity.

~~59.4(7)~~ 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.

ITEM 7. Amend renumbered rule 191—59.5(510B) as follows:

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

59.5(1) A pharmacy ~~or pharmacist~~ shall not be terminated from the pharmacy benefits manager's provider network or otherwise penalized by a pharmacy benefits manager solely because of filing 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 of a pharmacy's filing of a complaint, grievance or appeal with any entity.

59.5(2) A pharmacy ~~or pharmacist~~ shall not be terminated from the network or penalized by a pharmacy benefits manager due to any disagreement with ~~the~~ a decision of the pharmacy benefits manager to deny or limit benefits to covered ~~persons~~ individuals or due to any assistance provided to covered ~~persons~~ individuals by the pharmacy ~~or pharmacist~~ in obtaining reconsideration of ~~the~~ a decision of the pharmacy benefits manager.

59.5(3) ~~Termination of contracts~~ Contracts 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(4) If the pharmacy benefits manager has evidence that the pharmacy ~~or pharmacist~~ has engaged in fraudulent conduct or poses a significant risk to patient care or safety, the pharmacy benefits manager may immediately suspend the pharmacy ~~or pharmacist~~ from further performance under the contract ~~provided~~ only if written notice of ~~termination~~ suspension is provided to the pharmacy ~~or pharmacist~~, the covered entity and the commissioner.

59.5(5) Termination of a contract between a pharmacy benefits manager and a pharmacy ~~or pharmacist~~ or termination of a pharmacy ~~or pharmacist~~ 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 ~~or pharmacist~~ for contract-covered services rendered before the contract of the pharmacy ~~or pharmacist~~ was terminated.

59.5(6) ~~Independent third-party review of termination decision.~~ The pharmacy ~~or pharmacist~~ may request an independent third-party review of the final decision to terminate the contract between the pharmacy benefits manager and the pharmacy ~~or pharmacist~~ 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 decision.

59.5(7) Any request by a pharmacy for an independent third-party review of a termination decision shall be considered a complaint and included in the report required by subrule 59.7(2).

59.5(8) If a pharmacy requests an independent third-party review of a termination decision, and if the termination is found to be substantiated, the cost of the third-party review shall be paid by the pharmacy,

or if the termination is found to be unsubstantiated, the cost of the third-party review shall be paid by the pharmacy benefits manager.

ITEM 8. Adopt the following **new** rule 191—59.6(510B):

191—59.6(510B) Notification of price change. For purposes of Iowa Code section 510B.7(3), the three business days for adjustments in payments shall be calculated from the day the pharmacy benefits manager becomes aware of a price change by a manufacturer or supplier. The pharmacy benefits manager shall immediately notify pharmacies and pharmacy network providers of the price change. This notification may be made by providing access for pharmacies and pharmacy network providers to an online price listing that includes current prices and the most recent price changes.

ITEM 9. Amend renumbered rule 191—59.7(510B) as follows:

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:

a. Complaints from ~~the~~ any pharmacy indicating the reason for the complaint and factual documentation to support the complaint;

~~*b. Contact name, address and telephone number of the pharmacy benefits manager;*~~

~~*c.*~~ *b.* ~~Contact~~ For each complaint, contact name, address and telephone number of the pharmacy;

~~*d.*~~ *c.* Prescription number;

~~*e.*~~ *d.* Prescription reimbursement amount for disputed ~~claim(s)~~ claims;

~~*f.*~~ *e.* Disputed prescription claim payment ~~date(s)~~ dates;

~~*g.*~~ *f.* ~~Plan~~ Covered entity benefits certificate.

59.7(2) A summary of all complaints ~~as outlined in subrule 59.5(1)~~ received by the pharmacy benefits manager shall be submitted to the commissioner on a quarterly basis within 30 days after the calendar quarter has ended. The summary shall include the name, address, telephone number and e-mail address for a contact person for the pharmacy benefits manager.

ITEM 10. Adopt the following **new** rule 191—59.8(510,510B):

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.

ITEM 11. Adopt the following **new** rule 191—59.9(507,510,510B):

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.

ITEM 12. Adopt the following **new** rule 191—59.10(505,507,507B,510,510B,514L):

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—Chapter 38 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.

ITEM 13. Amend **191—Chapter 59**, implementation sentence, as follows:

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