

INSURANCE DIVISION[191]

Adopted and Filed

Pursuant to the authority of Iowa Code section 510B.3, the Insurance Division hereby amends Chapter 59, “Pharmacy Benefits Managers,” Iowa Administrative Code.

Iowa Code chapter 510B provides for the Iowa Insurance Commissioner’s administration of the provisions of Iowa Code chapter 510B relating to the regulation of pharmacy benefits managers. The purposes of the amendments to Chapter 59 are to do the following:

1. Implement 2015 Iowa Acts, House File 395.
2. Incorporate the findings in *Pharm. Care Mgmt Ass’n v. Gerhart*, No. 4:14-CV-00345 (S.D. Iowa Feb. 18 and Sep. 8, 2015, appealed to the U.S. Court of Appeals for the Eighth Circuit, *PCMA v. Gerhart and Miller*, No. 15-3292). The Court did not enjoin the legislation, nor did it prohibit the promulgation of administrative rules related to the legislation.

3. Clarify duties of pharmacy benefits managers that will allow the Commissioner to administer Iowa Code chapter 510B. Pharmacy benefits managers are engaged to stand in the stead of insurers and other entities to administer and manage prescription drug benefits provided under the health insurance plans issued by the insurers and other entities. The Insurance Division has the duties to regulate and to supervise the conducting of the business of insurance in Iowa, pursuant to Iowa Code section 505.1. The Insurance Commissioner has general control, supervision, and direction over all insurance business transacted in the state, pursuant to Iowa Code section 505.8, and must provide assistance to the public and to consumers of insurance products in Iowa. The services provided by pharmacy benefits managers affect both the public (which includes pharmacies) and consumers of insurance products. Further, the services provided by pharmacy benefits managers not only contribute to the efficiency of how insurers administer the payment of benefits, but also contribute to insurance costs reflected in the rates charged by insurers to consumers of insurance. The Commissioner is required to review risks, costs and rates. (See, e.g., Iowa Code chapter 513C and sections 505.8(1), 505.8(19) and 514A.13.) The amendments provide means by which the Insurance Division and the Commissioner can obtain the information necessary to determine whether insurers, through their pharmacy benefits managers, are providing uniform, fair, administratively efficient and cost-efficient services to insurers, pharmacies and consumers.

Notice of Intended Action was published in the Iowa Administrative Bulletin on March 2, 2016, as **ARC 2433C**. A public hearing was held on March 22, 2016, at the offices of the Iowa Insurance Division, Two Ruan Center, 601 Locust Street, Fourth Floor, Des Moines, Iowa, and written comments were accepted through March 30, 2016. Comments were received. The following list summarizes the changes made to the amendments in response to public comment and Division review:

- A. The words “requests information” were removed from the definition of “complaint” in rule 191—59.2(510B).
- B. The first instance of the word “generic” was removed from the new definition of “maximum reimbursement amount,” and other clarifying changes were made to the definition.
- C. In the Notice, amended subrule 59.4(6), new subrule 59.5(3) and amended paragraph “e” of renumbered subrule 59.6(3) required pharmacy benefits managers to include certain items in the complaint summary of renumbered subrule 59.8(2). Those requirements have been moved to renumbered subrule 59.8(2). Consequently, subrule 59.4(6), which was proposed for amendment in the Notice, is now rescinded herein, new subrule 59.5(3) was not adopted, and paragraph “e” of renumbered subrule 59.6(3) is stricken. Cross references have been corrected accordingly.
- D. The word “formulary” was removed from new subrule 59.5(1) and renumbered rule 191—59.7(510B) and replaced with the words “therapeutically, pharmaceutically equivalent multiple-source prescription.”
- E. In new subrule 59.5(2), a reasonableness requirement was added to the appeal process requirement.

F. Proposed new subrule 59.8(3) has been renumbered as 59.8(4), and a new subrule 59.8(3) has been added to clarify the confidentiality of the quarterly complaint summaries.

G. The language of paragraph “h” of renumbered subrule 59.8(1) and paragraph “b” of new subrule 59.8(4) was changed so that a pharmacy benefits manager has to provide in a complaint report the name of a pharmacy services administration organization only when the pharmacy benefits manager has knowledge that a pharmacy services administration organization is involved in the matter that is the subject of the complaint.

H. Clarifying changes have been made to new paragraphs 59.10(4)“c” and “d” and subparagraph 59.10(4)“e”(1).

I. Changes have been made to new subrule 59.10(5) to clarify the confidentiality protections of pharmacy benefits managers’ information.

The Insurance Division received comments requesting delay of the effective date of these amendments, related both to the appeal of the case cited in paragraph “2” above and to the alleged short time until the effective date of the amendments. The Insurance Division is not changing the effective date from the one stated in the Notice.

- The Court opinion regarding *Pharm. Care Mgmt Ass’n v. Gerhart*, No. 4:14-CV-00345 (S.D. Iowa Feb. 18 and Sep. 8, 2015) is the law in effect at this time. As stated above, the Court did not enjoin the legislation nor the promulgation of rules related to it. The legislative bills which these rule amendments are clarifying were enacted in 2007, 2014 and 2015. The appeal of the case provides no reason to delay the adoption of these rule amendments.

- Iowa Code section 510B.3(6) gives the Commissioner the authority to adopt rules to administer Iowa Code chapter 510B. The Insurance Division has conducted several informal interactions with interested parties concerning preliminary drafts of what ultimately became these amendments. Interested parties have had ample opportunity to provide comments, which the Insurance Division has considered and taken into account as it has deemed appropriate. The Insurance Division is aware of no impediment to the interested parties being able to comply with these amendments by the effective date.

The Insurance Division’s waiver provisions in 191—Chapter 4 apply to this rule making.

These amendments will impose no fiscal impact to the State.

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

These amendments are intended to implement Iowa Code chapter 510B.

These amendments shall become effective June 1, 2016.

The following amendments are adopted.

ITEM 1. Rescind the definitions of “Clean claim,” “Corrective action plan” and “Pharmacist” in rule **191—59.2(510B)**.

ITEM 2. Amend rule **191—59.2(510B)**, definitions of “Complaint” and “Pharmacy,” as follows:

“Complaint” means a written communication expressing a grievance or an inquiry concerning a transaction between a pharmacy benefits manager and from a pharmacy- 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, as permitted by Iowa Code section 510B.8(3) and rule 191—59.5(510B), of a pharmacy benefits manager’s maximum reimbursement amount rate or maximum reimbursement amount list.

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).

“Pharmacy,” except as used in paragraph 59.4(1)“b,” means “pharmacy” as defined in Iowa Code section 155A.3 and includes “pharmacist,” as defined in Iowa Code section 155A.3, and a pharmacy services administrative organization while acting in its role as a representative of a pharmacist or pharmacy. For purposes of this definition, “pharmacy services administrative organization” means an entity that provides contracting services on behalf of pharmacies with payers and with pharmacy

benefits managers, consolidated reimbursement services for pharmacies, and other business support for pharmacies.

ITEM 3. Adopt the following **new** definition in rule **191—59.2(510B)**:

“Maximum reimbursement amount,” as defined in Iowa Code section 510B.1(6), includes but is not limited to any prices used by a pharmacy benefits manager for therapeutically, pharmaceutically equivalent multiple-source prescription drugs such as maximum allowable cost, federal upper limit pricing, generic effective rate pricing, or any other pricing strategies used by the pharmacy benefits manager.

ITEM 4. Adopt the following **new** subrule 59.3(4):

59.3(4) For purposes of this rule, “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.

ITEM 5. Amend paragraph **59.4(1)“b”** as follows:

b. Any audit which involves clinical or professional judgment must be conducted by or in consultation with a pharmacist as defined in Iowa Code section 155A.3;

ITEM 6. Amend subparagraphs **59.4(1)“j”(4)** and **(6)** as follows:

(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)~~ 59.6(3)“a” or under a pharmacy’s contract with the pharmacy benefits manager.

(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.~~ 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.

ITEM 7. Rescind and reserve subrule **59.4(6)**.

ITEM 8. Renumber rules **191—59.5(510B)** to **191—59.10(505,507,507B,510,510B,514L)** as **191—59.6(510B)** to **191—59.11(505,507,507B,510,510B,514L)**.

ITEM 9. Adopt the following **new** rule 191—59.5(510B):

191—59.5(510B) Disclosure of national compendia used.

59.5(1) Pursuant to Iowa Code section 510B.8(3), in each contract between a pharmacy benefits manager and a pharmacy beginning or renewed on or after July 1, 2016, a pharmacy benefits manager shall identify how and where pharmacies may find the names of the national compendia or other services the pharmacy benefits manager has used to obtain the pricing data incorporated in the calculation of the maximum reimbursement amounts for therapeutically, pharmaceutically equivalent multiple-source prescription drugs included in the list made available to pharmacies pursuant to rule 191—59.7(510B).

59.5(2) Pursuant to Iowa Code section 510B.8(3), a pharmacy benefits manager shall provide a process, reasonable in procedures and timing to both the pharmacy and the pharmacy benefits manager, to allow a pharmacy to comment on, contest or appeal a maximum reimbursement amount rate or maximum reimbursement amount list.

ITEM 10. Amend renumbered subrule 59.6(3) as follows:

59.6(3) The following apply to terminations or suspensions of contracts with pharmacies by pharmacy benefits managers:

a. No change.

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 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, grievance or appeal with any entity as defined in rule 191—59.2(510B), with any entity.

c. and *d.* No change.

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. 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.

ITEM 11. Amend renumbered rule 191—59.7(510B) as follows:

191—59.7(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~~ "price increase notification by a manufacturer or supplier" includes price changes made by national compendia or other services used by a pharmacy benefits manager which take into account, in whole or in part, price changes made by manufacturers or suppliers to help facilitate the development of a drug's maximum reimbursement amount to a pharmacy. A pharmacy benefits manager may comply with the requirements of Iowa Code section 510B.7(3) by keeping a list of current therapeutically, pharmaceutically equivalent multiple-source prescription drugs and current maximum reimbursement amounts for those therapeutically, pharmaceutically equivalent multiple-source prescription drugs and by updating that list at least every three business days with any price-increases maximum reimbursement amount changes. 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.

ITEM 12. Amend renumbered rule 191—59.8(510B) as follows:

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 ~~from any pharmacy~~:

a. The reason for the complaint and any factual documentation submitted by the complainant to support the complaint;

b. to *e.* No change.

f. Covered entity benefits certificate; ~~and~~

g. The final determination and outcome of the complaint;

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 of the complaint; and

i. For complaints related to a maximum reimbursement amount, documentation demonstrating compliance with subrule 59.5(1) and rule 191—59.7(510B).

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 within 30 days after the calendar quarter has ended. The summary shall include the following:

- a. No change.
- 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 reimbursement rate or maximum reimbursement amount list pursuant to subrule 59.5(2);
- 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";
- ~~b.~~ e. A summary of the information listed in paragraph ~~59.7(1)~~ 59.8(1) "a," excluding documentation; and
- ~~e.~~ f. The information listed in paragraphs ~~59.7(1)~~ 59.8(1) "b," "d," "e," and "g."

ITEM 13. Adopt the following **new** subrules 59.8(3) and 59.8(4):

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. Pharmacy benefits managers shall comply with Iowa Code section 507B.4A(1) in responding promptly to inquiries from the commissioner, including complaints.

b. When responding to inquiries and complaints from the commissioner, pharmacy benefits managers 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.

ITEM 14. Amend renumbered rule 191—59.10(507,510,510B) as follows:

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

59.10(1) *Cooperation of pharmacy benefits managers with the commissioner.* Pharmacy benefits managers shall cooperate with the commissioner ~~for~~ 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 examinations of pharmacy benefits managers pursuant to Iowa Code chapter 507, and cooperation with the commissioner in conducting investigations pursuant to Iowa Code chapter 507B.

59.10(2) *Maintenance of records.* 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 15. Adopt the following **new** subrules 59.10(3), 59.10(4) and 59.10(5):

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" means the aggregate amount of the following types of payments:

- (1) A remuneration collected by the pharmacy benefits manager which is allocated to a covered entity;
- (2) An administrative fee collected from the manufacturer in consideration of an administrative service provided by the pharmacy benefits manager to the manufacturer;

- (3) A pharmacy network fee; and
- (4) Any other fee or amount collected by the pharmacy benefits manager from a manufacturer or labeler for a drug switch program, a formulary management program, a mail service pharmacy, educational support, data sales related to a covered individual, or any other administrative function.

59.10(4) Disclosure of pricing methodology for maximum reimbursement amount.

a. The commissioner may require, and a pharmacy benefits manager shall submit to the commissioner, pursuant to Iowa Code section 510B.8, information related to the pharmacy benefits manager's pricing methodology for maximum reimbursement amounts.

b. "Disclosure," as used in Iowa Code section 510B.8(2), means the disclosure to the commissioner of the information the commissioner requires the pharmacy benefits manager to submit pursuant to Iowa Code section 510B.8(1).

c. Iowa Code section 510B.8(2) "a" permits pharmacy benefits managers to establish maximum reimbursement amounts, as defined in Iowa Code section 510B.1(6), for all multiple-source prescription drugs prescribed after the expiration of any generic exclusivity period. Any pricing methodology used by a pharmacy benefits manager for determining the maximum reimbursement amounts for multiple-source prescription drugs including but not limited to those prescribed after the expiration of any generic exclusivity period shall be disclosed to the commissioner, if the commissioner requires pursuant to Iowa Code sections 510B.8(1) and 510B.8(2).

d. Iowa Code section 510B.8(2) "b" permits pharmacy benefits managers to establish maximum reimbursement amounts, as defined in Iowa Code section 510B.1(6), for prescription drugs including, but not limited to, those with at least two or more A-rated therapeutically equivalent, multiple-source prescription drugs with a significant cost difference. Any pricing methodology used by a pharmacy benefits manager for determining the maximum reimbursement amounts for prescription drugs, including but not limited to those with at least two or more A-rated therapeutically equivalent, multiple-source prescription drugs with a significant cost difference, shall be disclosed to the commissioner, if the commissioner requires pursuant to Iowa Code sections 510B.8(1) and 510B.8(2).

e. A pharmacy benefits manager using data sources for determining maximum reimbursement amounts must comply with this paragraph "e."

(1) The pricing methodology for maximum reimbursement amounts that pharmacy benefits managers shall disclose to the commissioner, if the commissioner requires pursuant to Iowa Code sections 510B.8(1) and 510B.8(2), shall, pursuant to Iowa Code section 510B.8(2) "a" and "b," determine maximum reimbursement amounts by using comparable prescription drug prices that are:

1. Obtained from multiple nationally recognized comprehensive data sources including, for example, the U.S. Center for Medicare and Medicaid Services' national average drug acquisition cost, pharmaceutical wholesalers, prescription drug vendors, and pharmaceutical manufacturers for prescription drugs;

2. Nationally available; and

3. Available for purchase by multiple pharmacies in the state of Iowa.

(2) The sources listed in this paragraph and in Iowa Code section 510B.8(2) "c" as sources included among nationally recognized comprehensive data sources are examples of data sources that may be used by pharmacy benefits managers but are not the exclusive data sources that may be used and, if used, that must be disclosed when required by the commissioner.

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.3, as applicable.

ITEM 16. Amend **191—Chapter 59**, implementation sentence, as follows:
These rules are intended to implement Iowa Code chapters 17A, 505, 507, 507B, 510, 510B and 514L.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 4/27/16.