ARC 6825C

INSURANCE DIVISION[191]

Notice of Intended Action

Proposing rule making related to pharmacy benefits managers and providing an opportunity for public comment

The Insurance Division hereby proposes to amend Chapter 59, "Pharmacy Benefits Managers," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code chapters 510, 510B and 510C and 2022 Iowa Acts, House File 2384, section 22.

State or Federal Law Implemented

This rule making implements, in whole or in part, 2022 Iowa Acts, House File 2384.

Purpose and Summary

The proposed amendments update Chapter 59 to implement changes made in 2022 Iowa Acts, House File 2384, regarding pharmacy benefits managers. This proposed rule making adds new definitions for "brand-name drug," "generic drug," "ingredient costs," "prescription drug cost reimbursement fee," "specialty drug," and "wholesale acquisition cost." The proposed rule making also adds provisions regarding penalties and the pharmacy benefits manager annual report.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

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

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Division for a waiver of the discretionary provisions, if any, pursuant to 191—Chapter 4.

Public Comment

Any interested person may submit written or oral comments concerning this proposed rule making. Written or oral comments in response to this rule making must be received by the Division no later than 4:30 p.m. on February 2, 2023. Comments should be directed to:

Andria Seip
Iowa Insurance Division
1963 Bell Avenue, Suite 100
Des Moines, Iowa 50315
Phone: 515.654.6575
Email: andria.seip@iid.iowa.gov

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

February 2, 2023	1963 Bell Avenue, Suite 100
1 to 3 p.m.	Des Moines, Iowa

Persons who wish to make oral comments at the public hearing must submit a request to Angela Burke Boston prior to the public hearing to facilitate an orderly hearing. Persons will be asked to state their names for the record and to confine their remarks to the subject of this proposed rule making.

Any persons who intend to attend the public hearing and have special requirements, such as those related to hearing or mobility impairments, should contact Angela Burke Boston via email at angela.burke.boston@iid.iowa.gov or by telephone at 515.654.6543 and advise of specific needs.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making actions are proposed:

ITEM 1. Adopt the following **new** definitions of "Brand-name drug," "Generic drug," "Ingredient costs," "Prescription drug cost reimbursement fee," "Specialty drug" and "Wholesale acquisition cost" in rule **191—59.2(510B)**:

"Brand-name drug" means a prescription drug marketed under a proprietary name or registered trademark name, including a biological product. As used in this chapter, a brand-name drug is not a specialty or generic drug.

"Generic drug" means a prescription drug, whether identified by its chemical, proprietary or nonproprietary name, that is therapeutically equivalent to a brand-name drug in dosage, safety, strength, method of consumption, quality, performance and intended use. As used in this chapter, a generic drug is not a specialty or brand-name drug.

"Ingredient costs" means the costs of the component of the prescription drug for prescriptions dispensed. Ingredient costs do not include dispensing fees, copayments received by the pharmacy, service fees or any other type of reimbursement paid to the pharmacy by a pharmacy benefits manager.

"Prescription drug cost reimbursement fee" means the dollar amount reimbursed by a third-party payor to the pharmacy benefits manager for the ingredient costs of a prescription drug. The prescription drug cost reimbursement fee may be a type of third-party payor administrative service fee.

"Specialty drug" means a prescription drug that is prescribed for specialized treatment of chronic or rare afflictions; that requires special handling, administration, dispensing or monitoring; or that is a high-cost oral or injectable medication for nondiabetic use. As used in this chapter, a specialty drug is not a brand-name or generic drug.

"Wholesale acquisition cost" means the same as defined in 42 U.S.C. Section 1395w-3a(c)(6)(B).

ITEM 2. Adopt the following **new** subrule 59.8(5):

59.8(5) *Penalties.* A pharmacy benefits manager that fails to timely submit to the commissioner a complete quarterly complaint summary shall pay a late fee of $100. If a pharmacy benefits manager fails to submit a complete quarterly complaint summary within 45 days after the calendar quarter has ended, the pharmacy benefits manager shall be subject to penalties as set forth in rule 191—59.12(505,507,507B,510,510B,510C,514L).

ITEM 3. Renumber subrules **59.11(4)** to **59.11(6)** as **59.11(5)** to **59.11(7)**.

ITEM 4. Adopt the following **new** subrule 59.11(4):

59.11(4) *Report content.*

a. Reporting requirement elements.

(1) A pharmacy benefits manager shall provide information about all rebates which shall include but not be limited to any consideration, incentive, disbursement, discount, payment and any other pecuniary transaction that is provided directly or indirectly to the pharmacy benefits manager from a pharmaceutical manufacturer that adjusts the price of the wholesale acquisition cost of a prescription drug.

(2) An administrative service fee shall include but not be limited to any consideration, incentive, disbursement, payment and any other pecuniary transaction, other than a rebate, that is provided directly or indirectly to the pharmacy benefits manager from a pharmaceutical manufacturer.

(3) The aggregate dollar amount of a rebate shall be reported as the wholesale acquisition cost of a prescription drug minus the price negotiated by the pharmacy benefits manager for the same prescription drug.

(4) Aggregate dollar amounts reported shall be reported as gross aggregate dollar amounts using generally accepted accounting principles (GAAP).

(5) Information requested about pharmacies shall include any pharmacy services administrative organizations that may represent pharmacies.

(6) A third-party payor administrative service fee shall include but not be limited to any consideration, incentive, disbursement, payment and any other pecuniary transaction that is provided directly or indirectly to the pharmacy benefits manager from a third-party payor.

(7) A third-party payor administrative service fee, as defined by Iowa Code section 510C.1, shall not be reported as a benefit or incurred claim provided under a health benefit plan.

b. Information required under Iowa Code section 510C.2(1)*"a"* shall include:

(1) The aggregate dollar amount of all rebates received by the pharmacy benefits manager, either directly or indirectly through a proxy, contractor, subsidiary or parent company, for its business in Iowa.

(2) The aggregate dollar amount of all rebates received by the pharmacy benefits manager, either directly or indirectly through a proxy, contractor, subsidiary or parent company, for its business nationally.

(3) The rebate amounts received, based on the information reported in subparagraph 59.11(4)*"b"*(1), for each of the top prescription drugs for which the pharmacy benefits manager received the highest dollar amount of rebates from the pharmaceutical manufacturer.

1. Report the aggregate dollar amount of the rebate for each of the top prescription drugs reported pursuant to subparagraph 59.11(4)*"b"*(3).

2. Report the aggregate dollar amount of the rebate that was:

- Passed through to a third-party payor;
- Passed through to enrollees at the point of sale of a prescription drug; and
- Retained by the pharmacy benefits manager.

(4) The rebate amounts received, based on the information reported in subparagraph 59.11(4)*"b"*(1), for each of the top brand-name drugs prescribed for which the pharmacy benefits manager reimbursed the highest dollar amount based on ingredient costs to pharmacies for its business in Iowa. Brand-name drugs reported pursuant to this subparagraph shall exclude generic and specialty drugs.

1. Report the aggregate dollar amount of the rebate for each of the top brand-name drugs reported pursuant to this subparagraph.

2. Report the aggregate dollar amount of the rebate that was:

- Passed through to a third-party payor;
- Passed through to enrollees at the point of sale of a prescription drug; and
- Retained by the pharmacy benefits manager.

c. Information required under Iowa Code section 510C.2(1)*"b"* shall include:

(1) The aggregate dollar amount of all administrative fees received by the pharmacy benefits manager, either directly or indirectly through a proxy, contractor, subsidiary or parent company, for its business in Iowa.

(2) The aggregate dollar amount of all administrative fees received by the pharmacy benefits manager, either directly or indirectly through a proxy, contractor, subsidiary or parent company, for its business nationally.

d. Information required under Iowa Code section 510C.2(1)*"c"* shall include:

(1) The aggregate dollar amount of all third-party payor administrative service fees received by the pharmacy benefits manager, either directly or indirectly through a proxy, contractor, subsidiary or parent company, for its business in Iowa.

(2) The aggregate dollar amount of all third-party payor administrative service fees received by the pharmacy benefits manager, either directly or indirectly through a proxy, contractor, subsidiary or parent company, for its business nationally.

(3) The aggregate dollar amount of all prescription drug cost reimbursement fees received by the pharmacy benefits manager, either directly or indirectly through a proxy, contractor, subsidiary or parent company, for its business in Iowa.

(4) The aggregate dollar amount of all prescription drug cost reimbursement fees received by the pharmacy benefits manager, either directly or indirectly through a proxy, subsidiary or parent company, for its business nationally.

(5) The aggregate prescription drug reimbursement fee, based on the top prescription drugs reported in subparagraph 59.11(4)*"b"*(3), received for each drug that was:

1. Passed through to the pharmacies as reimbursement for the ingredient costs of prescriptions dispensed by the pharmacies.

2. Retained by the pharmacy benefits manager.

(6) The aggregate prescription drug reimbursement fee, based on the top prescription drugs reported in subparagraph 59.11(4)*"b"*(4), received for each drug that was:

1. Passed through to the pharmacies as reimbursement for the ingredient costs of prescriptions dispensed by the pharmacies.

2. Retained by the pharmacy benefits manager.

e. Information required under Iowa Code section 510C.2(1)*"d"* shall include:

(1) The aggregate dollar amount of all rebates received by the pharmacy benefits manager that it did not pass through to the third-party payor through its business in Iowa that is conducted either directly or indirectly through a proxy, contractor, subsidiary or parent company.

(2) The aggregate dollar amount of all rebates received by the pharmacy benefits manager that it did not pass through to the third-party payor through its business nationally that is conducted either directly or indirectly through a proxy, contractor, subsidiary or parent company.

f. Information required under Iowa Code section 510C.2(1)*"e"* shall include:

(1) The aggregate dollar amount of all administrative fees received by the pharmacy benefits manager that it did not pass through to the third-party payor through its business in Iowa that is conducted either directly or indirectly through a proxy, contractor, subsidiary or parent company.

(2) The aggregate dollar amount of all administrative fees received by the pharmacy benefits manager that it did not pass through to the third-party payor through its business nationally that is conducted either directly or indirectly through a proxy, contractor, subsidiary or parent company.