

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 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.

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.

[ARC 1466C, IAB 5/28/14, effective 7/2/14; ARC 2518C, IAB 4/27/16, effective 6/1/16]