CHAPTER 1113

PHARMACY BENEFITS MANAGERS, PHARMACIES, AND PRESCRIPTION DRUG BENEFITS

H.F. 2384

AN ACT relating to pharmacy benefits managers, pharmacies, and prescription drug benefits, and including effective date and applicability provisions.

Be It Enacted by the General Assembly of the State of Iowa:

DIVISION I
PHARMACY BENEFITS MANAGERS, PHARMACIES, AND PRESCRIPTION DRUG BENEFITS

Section 1. Section 507B.4, subsection 3, Code 2022, is amended by adding the following new paragraph:

NEW PARAGRAPH. *t. Pharmacy benefits managers.* Any violation of chapter 510B by a pharmacy benefits manager.

Sec. 2. Section 510B.1, Code 2022, is amended by striking the section and inserting in lieu thereof the following:

510B.1 Definitions.

As used in this chapter, unless the context otherwise requires:

1. *"Clean claim"* means a claim that has no defect or impropriety, including a lack of any required substantiating documentation, or other circumstances requiring special treatment, that prevents timely payment from being made on the claim.

2. *"Commissioner"* means the commissioner of insurance.

3. *"Cost-sharing"* means any coverage limit, copayment, coinsurance, deductible, or other out-of-pocket cost obligation imposed by a health benefit plan on a covered person.

4. *"Covered person"* means a policyholder, subscriber, or other person participating in a health benefit plan that has a prescription drug benefit managed by a pharmacy benefits manager.

5. *"Facility"* means an institution providing health care services or a health care setting, including but not limited to hospitals and other licensed inpatient centers, ambulatory surgical or treatment centers, skilled nursing centers, residential treatment centers, diagnostic, laboratory and imaging centers, and rehabilitation and other therapeutic health settings.

6. *"Health benefit plan"* means a policy, contract, certificate, or agreement offered or issued by a third-party payor to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services.

7. *"Health care professional"* means a physician or other health care practitioner licensed, accredited, registered, or certified to perform specified health care services consistent with state law.

8. *"Health care provider"* means a health care professional or a facility.

9. *"Health carrier"* means an entity subject to the insurance laws and regulations of this state, or subject to the jurisdiction of the commissioner, including an insurance company offering sickness and accident plans, a health maintenance organization, a nonprofit health service corporation, or a plan established pursuant to chapter 509A for public employees. *"Health carrier"* does not include any of the following:

a. The department of human services.

b. A managed care organization acting pursuant to a contract with the department of human services to administer the medical assistance program under chapter 249A or the healthy and well kids in Iowa (hawk-i) program under chapter 514I.

c. A policy or contract providing a prescription drug benefit pursuant to 42 U.S.C. ch. 7, subch. XVIII, part D.

d. A plan offered or maintained by a multiple employer welfare arrangement established under chapter 513D before January 1, 2022.

10. *"Maximum allowable cost"* means the maximum amount that a pharmacy will be reimbursed by a pharmacy benefits manager or a health carrier for a generic drug, brand-name drug, biologic product, or other prescription drug, and that may include any of the following:

a. Average acquisition cost.

b. National average acquisition cost.

c. Average manufacturer price.

d. Average wholesale price.

e. Brand effective rate.

f. Generic effective rate.

g. Discount indexing.

h. Federal upper limits.

i. Wholesale acquisition cost.

j. Any other term used by a pharmacy benefits manager or a health carrier to establish reimbursement rates for a pharmacy.

11. *"Maximum allowable cost list"* means a list of prescription drugs that includes the maximum allowable cost for each prescription drug and that is used, directly or indirectly, by a pharmacy benefits manager.

12. *"Pharmacist"* means the same as defined in section 155A.3.

13. *"Pharmacy"* means the same as defined in section 155A.3.

14. *"Pharmacy acquisition cost"* means the cost to a pharmacy for a prescription drug as invoiced by a wholesale distributor, and reduced by any discounts, rebates, or other price concessions applicable to the prescription drug that are not shown on the invoice and are known at the time that the pharmacy files an appeal with a pharmacy benefits manager.

15. *"Pharmacy benefits manager"* means a person who, pursuant to a contract or other relationship with a third-party payor, either directly or through an intermediary, manages a prescription drug benefit provided by the third-party payor.

16. *"Pharmacy benefits manager affiliate"* means a pharmacy or a pharmacist that directly or indirectly through one or more intermediaries, owns or controls, is owned and controlled by, or is under common ownership or control of, a pharmacy benefits manager.

17. *"Pharmacy network"* or *"network"* means pharmacies that have contracted with a pharmacy benefits manager to dispense or sell prescription drugs to covered persons of a health benefit plan for which the pharmacy benefits manager manages the prescription drug benefit.

18. *"Prescription drug"* means the same as defined in section 155A.3.

19. *"Prescription drug benefit"* means a health benefit plan providing for third-party payment or prepayment for prescription drugs.

20. *"Prescription drug order"* means the same as defined in section 155A.3.

21. *"Rebate"* means all discounts and other negotiated price concessions paid directly or indirectly by a pharmaceutical manufacturer or other entity, other than a covered person, in the prescription drug supply chain to a pharmacy benefits manager, and which may be based on any of the following:

a. A pharmaceutical manufacturer's list price for a prescription drug.

b. Utilization.

c. To maintain a net price for a prescription drug for a specified period of time for the pharmacy benefits manager in the event the pharmaceutical manufacturer's list price increases.

d. Reasonable estimates of the volume of a prescribed drug that will be dispensed by a pharmacy to covered persons.

22. *"Third-party payor"* means any entity other than a covered person or a health care provider that is responsible for any amount of reimbursement for a prescription drug benefit. *"Third-party payor"* includes health carriers and other entities that provide a plan of health insurance or health care benefits. *"Third-party payor"* does not include any of the following:

a. The department of human services.

b. A managed care organization acting pursuant to a contract with the department of human services to administer the medical assistance program under chapter 249A or the healthy and well kids in Iowa (hawk-i) program under chapter 514I.

c. A policy or contract providing a prescription drug benefit pursuant to 42 U.S.C. ch. 7, subch. XVIII, part D.

23. *"Wholesale distributor"* means the same as defined in section 155A.3.

Sec. 3. Section 510B.4, Code 2022, is amended to read as follows:

510B.4 Performance of duties — good faith — conflict of interest.

1. A pharmacy benefits manager shall ~~perform the pharmacy benefits manager's duties exercising~~ exercise good faith and fair dealing in the performance of ~~its~~ the pharmacy benefits manager's contractual obligations toward ~~the covered entity~~ a third-party payor.

2. A pharmacy benefits manager shall notify ~~the covered entity~~ a health carrier in writing of any activity, policy, practice ownership interest, or affiliation of the pharmacy benefits manager that presents any conflict of interest.

3. A pharmacy benefits manager shall act in the best interest of each third-party payor for whom the pharmacy benefits manager manages a prescription drug benefit provided by the third-party payor, and shall discharge its duties in accordance with applicable state and federal law.

Sec. 4. Section 510B.5, Code 2022, is amended to read as follows:

510B.5 Contacting covered ~~individual~~ persons — requirements.

A pharmacy benefits manager, unless authorized pursuant to the terms of its contract with a ~~covered entity~~ health carrier, shall not contact any covered ~~individual~~ person without the express written permission of the ~~covered entity~~ health carrier.

Sec. 5. Section 510B.6, Code 2022, is amended to read as follows:

510B.6 ~~Dispensing of substitute~~ Substitute prescription ~~drug for prescribed drug~~ drugs.

1. The following provisions shall apply ~~when~~ if a pharmacy benefits manager requests the dispensing of a substitute prescription drug for a ~~prescribed~~ drug ~~to~~ prescribed for a covered ~~individual~~ person:

a. The pharmacy benefits manager may request the substitution of a lower priced generic and therapeutically equivalent prescription drug for a higher priced ~~prescribed~~ prescription drug.

b. If the substitute prescription drug's net cost to the covered ~~individual~~ person or ~~covered entity~~ to the health carrier exceeds the cost of the ~~prescribed~~ prescription drug originally prescribed for the covered person, the substitution shall be made only for medical reasons that benefit the covered ~~individual~~ person.

2. A pharmacy benefits manager shall obtain the approval of the prescribing ~~practitioner~~ health care professional prior to requesting any substitution under this section.

3. A pharmacy benefits manager shall not substitute an equivalent prescription drug contrary to a prescription drug order that prohibits a substitution.

Sec. 6. Section 510B.7, Code 2022, is amended by striking the section and inserting in lieu thereof the following:

510B.7 Pharmacy networks.

A pharmacy benefits manager shall not assess, charge, or collect any form of remuneration that passes from a pharmacy or a pharmacist in a pharmacy network to the pharmacy benefits manager including but not limited to claim processing fees, performance-based fees, network participation fees, or accreditation fees.

Sec. 7. Section 510B.8, Code 2022, is amended by striking the section and inserting in lieu thereof the following:

510B.8 Prescription drugs — point of sale.

1. A covered person shall not be required to make a cost-sharing payment at the point of sale for a prescription drug in an amount that exceeds the total amount that the pharmacy at which the covered person fills the covered person's prescription drug order is reimbursed.

2. A pharmacy benefits manager shall not prohibit a pharmacy from disclosing the availability of a lower-cost prescription drug option to a covered person, or from selling a lower-cost prescription drug option to a covered person.

Sec. 8. NEW SECTION. **510B.8A Maximum allowable cost lists.**

1. Prior to placement of a particular prescription drug on a maximum allowable cost list, a pharmacy benefits manager shall ensure that all of the following requirements are met:

a. The particular prescription drug must be listed as therapeutically and pharmaceutically equivalent in the most recent edition of the publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations", published by the United States food and drug administration, otherwise known as the orange book.

b. The particular prescription drug must not be obsolete or temporarily unavailable.

c. The particular prescription drug must be available for purchase, without limitations, by all pharmacies in the state from a national or regional wholesale distributor that is licensed in the state.

2. For each maximum allowable cost list that a pharmacy benefits manager uses in the state, the pharmacy benefits manager shall do all of the following:

a. Provide each pharmacy in a pharmacy network reasonable access to the maximum allowable cost list to which the pharmacy is subject.

b. Update the maximum allowable cost list within seven calendar days from the date of an increase of ten percent or more in the pharmacy acquisition cost of a prescription drug on the list by one or more wholesale distributors doing business in the state.

c. Update the maximum allowable cost list within seven calendar days from the date of a change in the methodology, or a change in the value of a variable applied in the methodology, on which the maximum allowable cost list is based.

d. Provide a reasonable process for each pharmacy in a pharmacy network to receive prompt notice of all changes to the maximum allowable cost list to which the pharmacy is subject.

Sec. 9. NEW SECTION. **510B.8C Pharmacy benefits manager affiliates — reimbursement.**

A pharmacy benefits manager shall not reimburse any pharmacy located in the state in an amount less than the amount that the pharmacy benefits manager reimburses a pharmacy benefits manager affiliate for dispensing the same prescription drug as dispensed by the pharmacy. The reimbursement amount shall be calculated on a per unit basis based on the same generic product identifier or generic code number.

Sec. 10. NEW SECTION. **510B.8D Clean claims.**

After the date of receipt of a clean claim submitted by a pharmacy in a pharmacy network, a pharmacy benefits manager shall not retroactively reduce payment on the claim, either directly or indirectly except in the following circumstances:

1. The claim is found not to be a clean claim during the course of a routine audit.
2. The claim submission was fraudulent.
3. The claim submission was a duplicate submission of a claim for which the pharmacy had already received payment.

Sec. 11. Section 510B.9, Code 2022, is amended to read as follows:

510B.9 ~~Submission, approval, and use of prior~~ Prior authorization ~~form~~.

A pharmacy benefits manager shall ~~file with and have approved by the commissioner a single prior authorization form as provided in section 505.26~~ comply with all applicable prior authorization requirements pursuant to section 505.26. ~~A pharmacy benefits manager shall use the single prior authorization form as provided in section 505.26.~~

Sec. 12. Section 510B.10, Code 2022, is amended by striking the section and inserting in lieu thereof the following:

510B.10 Enforcement.

1. The commissioner may take any enforcement action under the commissioner's authority to enforce compliance with this chapter.

2. After notice and hearing, the commissioner may issue any order or impose any penalty pursuant to section 507B.7, and may suspend or revoke a pharmacy benefits manager's certificate of registration as a third-party administrator upon a finding that the pharmacy

benefits manager violated this chapter, or any applicable requirements pertaining to third-party administrators under chapter 510.

3. A pharmacy benefits manager shall be subject to the commissioner's authority to conduct an examination pursuant to chapter 507.

4. A pharmacy benefits manager is subject to the commissioner's authority to conduct a proceeding pursuant to chapter 507B. The procedures set forth in chapter 507B regarding proceedings shall apply to a proceeding related to a pharmacy benefits manager under this chapter.

5. A pharmacy benefits manager is subject to the commissioner's authority to conduct an examination, audit, or inspection pursuant to chapter 510 for third-party administrators. The procedures set forth in chapter 510 for third-party administrators shall apply to an examination, audit, or inspection of a pharmacy benefits manager under this chapter.

6. If the commissioner conducts an examination of a pharmacy benefits manager under chapter 507; a proceeding under chapter 507B; or an examination, audit, or inspection under chapter 510, all information received from the pharmacy benefits manager, and all notes, work papers, or other documents related to the examination, proceeding, audit, or inspection shall be confidential records pursuant to chapter 22 and shall be accorded the same confidentiality as notes, work papers, investigatory materials, or other documents related to the examination of an insurer as provided in section 507.14.

7. A violation of this chapter shall be an unfair or deceptive act or practice in the business of insurance pursuant to section 507B.4, subsection 3.

Sec. 13. NEW SECTION. **510B.11 Rules.**

The commissioner may adopt rules pursuant to chapter 17A to administer this chapter.

Sec. 14. NEW SECTION. **510B.12 Severability.**

If a provision of this chapter or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this chapter which can be given effect without the invalid provision or application, and to this end the provisions of this chapter are severable.

Sec. 15. REPEAL. Section 510B.3, Code 2022, is repealed.

Sec. 16. APPLICABILITY. This division of this Act applies to pharmacy benefits managers that manage a prescription drug benefit in the state on or after the effective date of this Act.

DIVISION II
PHARMACY BENEFITS MANAGER REPORTING

Sec. 17. Section 510C.1, Code 2022, is amended to read as follows:

510C.1 Definitions.

As used in this chapter unless the context otherwise requires:

1. *"Administrative fees"* means a fee or payment, other than a rebate, under a contract between a pharmacy benefits manager and a pharmaceutical drug manufacturer in connection with the pharmacy benefits manager's management of a ~~health carrier's~~ third-party payor's prescription drug benefit, that is paid by a pharmaceutical drug manufacturer to a pharmacy benefits manager or is retained by the pharmacy benefits manager.

2. *"Aggregate retained rebate percentage"* means the percentage of all rebates received by a pharmacy benefits manager that is not passed on to the pharmacy benefits manager's ~~health carrier~~ third-party payor clients.

3. *"Commissioner"* means the commissioner of insurance.

4. *"Covered person"* means the same as defined in section ~~514J.102~~ 510B.1.

5. *"Formulary"* means a complete list of prescription drugs eligible for coverage under a health benefit plan.

6. *"Health benefit plan"* means the same as defined in section ~~514J.102~~ 510B.1.

7. *"Health carrier"* means the same as defined in section ~~514J.102~~ 510B.1.

~~8. *"Health carrier administrative service fee"* means a fee or payment under a contract between a pharmacy benefits manager and a health carrier in connection with the pharmacy benefits manager's administration of the health carrier's prescription drug benefit that is paid by a health carrier to a pharmacy benefits manager or is otherwise retained by a pharmacy benefits manager.~~

~~9.~~ 8. *"Pharmacy benefits manager"* means ~~a person who, pursuant to a contract or other relationship with a health carrier, either directly or through an intermediary, manages a prescription drug benefit provided by the health carrier~~ the same as defined in section 510B.1.

~~10.~~ 9. *"Prescription drug benefit"* means ~~a health benefit plan providing for third-party payment or prepayment for prescription drugs~~ the same as defined in section 510B.1.

~~11.~~ 10. *"Rebate"* means ~~all discounts and other negotiated price concessions paid directly or indirectly by a pharmaceutical manufacturer or other entity, other than a covered person, in the prescription drug supply chain to a pharmacy benefits manager, and which may be based on any of the following:~~ the same as defined in section 510B.1.

~~*a.* A pharmaceutical manufacturer's list price for a prescription drug.~~

~~*b.* Utilization.~~

~~*c.* To maintain a net price for a prescription drug for a specified period of time for the pharmacy benefits manager in the event the pharmaceutical manufacturer's list price increases.~~

~~*d.* Reasonable estimates of the volume of a prescribed drug that will be dispensed by a pharmacy to covered persons.~~

11. *"Third-party payor"* means the same as defined in section 510B.1.

12. *"Third-party payor administrative service fee"* means a fee or payment under a contract between a pharmacy benefits manager and a third-party payor in connection with the pharmacy benefits manager's administration of the third-party payor's prescription drug benefit that is paid by a third-party payor to a pharmacy benefits manager or is otherwise retained by a pharmacy benefits manager.

Sec. 18. Section 510C.2, subsection 1, unnumbered paragraph 1, Code 2022, is amended to read as follows:

Each pharmacy benefits manager shall provide a report annually by February 15 to the commissioner that contains all of the following information regarding prescription drug benefits provided to covered persons of each ~~health carrier~~ third-party payor with whom the pharmacy benefits manager has contracted during the prior calendar year:

Sec. 19. Section 510C.2, subsection 1, paragraphs c, d, e, and g, Code 2022, are amended to read as follows:

c. The aggregate dollar amount of all ~~health carrier~~ third-party payor administrative service fees received by the pharmacy benefits manager.

d. The aggregate dollar amount of all rebates received by the pharmacy benefits manager that the pharmacy benefits manager did not pass through to the ~~health carrier~~ third-party payor.

e. The aggregate amount of all administrative fees received by the pharmacy benefits manager that the pharmacy benefits manager did not pass through to the ~~health carrier~~ third-party payor.

g. Across all ~~health carrier~~ third-party payor clients with whom the pharmacy benefits manager was contracted, the highest and the lowest aggregate retained rebate percentages.

Sec. 20. Section 510C.2, subsection 2, paragraph a, subparagraph (1), Code 2022, is amended to read as follows:

(1) The identity of a specific ~~health carrier~~ third-party payor.

Sec. 21. Section 510C.2, subsection 2, paragraph b, Code 2022, is amended to read as follows:

b. Information provided under this section by a pharmacy benefits manager to the commissioner that may reveal the identity of a specific ~~health carrier~~ third-party payor, the price charged by a specific pharmaceutical manufacturer for a specific prescription drug or

class of prescription drugs, or the amount of rebates provided for a specific prescription drug or class of prescription drugs shall be considered a confidential record and be recognized and protected as a trade secret pursuant to section 22.7, subsection 3.

DIVISION III
EMERGENCY RULEMAKING

Sec. 22. EMERGENCY RULES. The insurance division of the department of commerce may adopt emergency rules under section 17A.4, subsection 3, and section 17A.5, subsection 2, paragraph "b", to implement the provisions of this Act and the rules shall be effective immediately upon filing unless a later date is specified in the rules. Any rules adopted in accordance with this section shall also be published as a notice of intended action as provided in section 17A.4.

DIVISION IV
EFFECTIVE DATE

Sec. 23. EFFECTIVE DATE. This Act, being deemed of immediate importance, takes effect upon enactment.

Approved June 13, 2022