Senate File 2231

S-5158

Amend Senate File 2231 as follows:

1. By striking everything after the enacting clause and inserting:

<Section 1. Section 505.26, subsection 1, paragraph b, Code 2022, is amended to read as follows:

b. "Pharmacy benefits manager" means the same as defined in section ~~510B.1~~ 510C.1.

Sec. 2. 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. 3. 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. *"Health benefit plan"* means the same as defined in section 514J.102.

6. *"Health care professional"* means the same as defined in section 514J.102.

7. *"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, a plan established pursuant to chapter 509A for public employees, or any other entity providing a plan of health insurance, health care benefits, or health care services. "*Health carrier*" does not include the department of human services, or 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.

8. "*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.

9. "*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.

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

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

12. *"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.

13. *"Pharmacy benefits manager"* means the same as defined in section 510C.1.

14. *"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.

15. *"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.

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

17. *"Prescription drug benefit"* means the same as defined in section 510C.1.

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

19. *"Rebate"* means the same as defined in section 510C.1.

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

Sec. 4. 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

health carrier.

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 health carrier for whom the pharmacy benefits manager manages a prescription drug benefit provided by the health carrier, and shall discharge its duties in accordance with applicable state and federal law.

4. A pharmacy benefits manager, health carrier, or health benefit plan shall not discriminate against a pharmacy or a pharmacist with respect to participation, referral, reimbursement of a covered service, or indemnification if a pharmacist is acting within the scope of the pharmacist's license.

Sec. 5. 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. 6. 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. 7. Section 510B.7, Code 2022, is amended by striking the section and inserting in lieu thereof the following:

510B.7 Pharmacy networks.

1. A pharmacy located in the state shall not be prohibited from participating in a pharmacy network provided that the pharmacy accepts the same terms and conditions as the pharmacy benefits manager imposes on the pharmacies in the network.

2. 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. 8. 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.

3. Any amount paid by a covered person for a prescription drug purchased pursuant to this section shall be applied to any deductible imposed by the covered person's health benefit plan in accordance with the health benefit plan coverage documents.

4. A covered person shall not be prohibited from filling a prescription drug order at any pharmacy located in the state provided that the pharmacy accepts the same terms and conditions as the pharmacies participating in the covered person's health benefit plan's network.

5. Excluding incentives in value-based programs established by a health carrier or a pharmacy benefits manager to promote the use of higher quality pharmacies, a pharmacy benefits manager shall not impose different cost-sharing or additional fees on a covered person based on the pharmacy at which the covered person fills the covered person's prescription drug order.

6. A pharmacy benefits manager shall not require a covered person, as a condition of payment or reimbursement, to purchase pharmacy services, including prescription drugs, exclusively through a mail-order pharmacy.

7. *a.* For purposes of calculating a covered person's contribution toward the covered person's cost-sharing, a pharmacy benefits manager shall include all cost-sharing paid by the covered person and all cost-sharing paid by any other person on behalf of the covered person.

b. If application of paragraph "*a*" will result in health savings account ineligibility under section 223 of the Internal Revenue Code, paragraph "a" shall only apply to the covered person's deductible for a health savings account qualified-high deductible health plan after the covered person has satisfied the minimum deductible under section 223 of the Internal Revenue Code, except for items or services that are preventive

care, in which case, the requirement shall apply regardless of if the minimum deductible under section 223 of the Internal Revenue Code has been satisfied. For purposes of this section, *"preventive care"* means the same as under section 223(c)(2)(C) of the Internal Revenue Code.

c. Paragraph *"a"* shall not apply to cost-sharing paid by a covered person, or to cost-sharing paid by any other person on behalf of the covered person, for a specialty drug or for a prescription drug for which a medically appropriate A-rated generic equivalent or an interchangeable biological product is available to the covered person.

d. Paragraph *"a"* shall not apply to a state-regulated high-deductible health plan to the extent application of paragraph *"a"* will result in the state-regulated high-deductible health plan not qualifying as a high-deductible health plan under section 223 of the Internal Revenue Code.

e. If paragraph *"a"* conflicts with a federal law or a federal regulation as applied to a specific health carrier or to a specific circumstance, paragraph *"a"* shall apply to all health carriers and in all circumstances in which the federal law or federal regulation does not conflict.

Sec. 9. 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. 10. 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. 11. 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:

a. The claim is found not to be a clean claim during the

course of a routine audit.

b. The claim submission was fraudulent.

c. The claim submission was a duplicate submission of a claim for which the pharmacy had already received payment.

Sec. 12. NEW SECTION. **510B.8E Appeals and disputes.**

1. A pharmacy benefits manager shall provide a reasonable process to allow a pharmacy to appeal a maximum allowable cost or reimbursement rate for a specific prescription drug for any of the following reasons:

a. The pharmacy benefits manager violated section 510B.8A.

b. The maximum allowable cost or the reimbursement rate is below the pharmacy acquisition cost.

2. The appeal process must include all of the following:

a. A dedicated telephone number at which a pharmacy may contact the pharmacy benefits manager and speak directly with an individual involved in the appeal process.

b. A dedicated electronic mail address or internet site for the purpose of submitting an appeal directly to the pharmacy benefits manager.

c. A period of at least thirty business days after the date of a pharmacy's initial submission of a clean claim during which the pharmacy may initiate an appeal.

3. A pharmacy benefits manager shall respond to an appeal within seven business days after the date on which the pharmacy benefits manager receives the appeal.

a. If the pharmacy benefits manager grants a pharmacy's appeal, the pharmacy benefits manager shall do all of the following:

(1) Adjust the maximum allowable cost or the reimbursement rate of the prescription drug that is the subject of the appeal and provide the national drug code number that the adjustment is based on to the appealing pharmacy.

(2) Permit the appealing pharmacy to reverse and resubmit the claim that is the subject of the appeal.

(3) Make the adjustment pursuant to subparagraph (1)

applicable to all of the following:

(a) Each pharmacy that is under common ownership with the pharmacy that submitted the appeal.

(b) Each pharmacy in the state that demonstrates the inability to purchase the prescription drug for less than the established maximum allowable cost or reimbursement rate.

b. If the pharmacy benefits manager denies a pharmacy's appeal, the pharmacy benefits manager shall do all of the following:

(1) Provide the appealing pharmacy the national drug code number and the name of a wholesale distributor licensed pursuant to section 155A.17 from which the pharmacy can obtain the prescription drug at or below the maximum allowable cost or reimbursement rate.

(2) If the prescription drug identified by the national drug code number provided by the pharmacy benefits manager pursuant to subparagraph (1) is not available below the pharmacy acquisition cost from the wholesale distributor from whom the pharmacy purchases the majority of its prescription drugs for resale, the pharmacy benefits manager shall adjust the maximum allowable cost or the reimbursement rate above the appealing pharmacy's pharmacy acquisition cost, and permit the pharmacy to reverse and resubmit each claim affected by the pharmacy's inability to procure the prescription drug at a cost that is equal to or less than the previously appealed maximum allowable cost or the reimbursement rate.

Sec. 13. 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. 14. 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. 15. NEW SECTION. **510B.11 Rules.**

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

Sec. 16. 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. 17. REPEAL. Section 510B.3, Code 2022, is repealed.

Sec. 18. APPLICABILITY. 1. This Act applies to pharmacy benefits managers that manage a health carrier's prescription drug benefit in the state on or after the effective date of this Act.

2. The following applies to all health benefit plans delivered, issued for delivery, continued, or renewed in this state on or after January 1, 2023:

The section of this Act amending section 510B.8, subsection 7.>

MIKE KLIMESH