House File 489 - Introduced

HOUSE FILE 489
BY LUNDGREN

A BILL FOR

An Act relating to pharmacy benefit managers and health carriers and management of prescription drug benefits, and including applicability provisions.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. NEW SECTION. **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 benefit manager and a pharmaceutical drug manufacturer in connection with the pharmacy benefit manager's management of a health carrier's prescription drug benefit, that is paid by a pharmaceutical drug manufacturer to a pharmacy benefit manager or is retained by the pharmacy benefit manager.

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

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

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

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.

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

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

9. *"Pharmacy benefit 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.

10. *"Prescription drug benefit"* means a health benefit

plan providing for third-party payment or prepayment for prescription drugs.

11. *"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 benefit 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 benefit 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.

Sec. 2. NEW SECTION. **510C.2 Annual report to the commissioner.**

1. Each pharmacy benefit 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 with whom the pharmacy manager has contracted during the prior calendar year:

a. The aggregate dollar amount of all rebates received by the pharmacy benefit manager.

b. The aggregate dollar amount of all administrative fees received by the pharmacy benefit manager.

c. The aggregate dollar amount of all health carrier administrative service fees received by the pharmacy benefit manager.

d. The aggregate dollar amount of all rebates received by the pharmacy benefit manager that the pharmacy benefit manager did not pass through to the health carrier.

e. The aggregate amount of all administrative fees received

by the pharmacy benefit manager that the pharmacy benefit manager did not pass through to the health carrier.

f. The aggregate retained rebate percentage as calculated by dividing the dollar amount in paragraph *"d"* by the dollar amount in paragraph *"a"*.

g. Across all health carrier clients with whom the pharmacy manager was contracted, the highest and the lowest aggregate retained rebate percentages.

2. *a.* A pharmacy benefit manager shall provide the information pursuant to subsection 1 to the commissioner in a format approved by the commissioner that does not directly or indirectly disclose any of the following:

(1) The identity of a specific health carrier.

(2) The price charged by a specific pharmaceutical manufacturer for a specific prescription drug or for a class of prescription drugs.

(3) The amount of rebates provided for a specific prescription drug or class of prescription drugs.

b. Information provided under this section by a pharmacy benefit manager to the commissioner that may reveal the identity of a specific health carrier, 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.

3. The commissioner shall publish, within sixty calendar days of receipt, the nonconfidential information received by the commissioner on a publicly accessible internet site. The information shall be made available to the public in a format that complies with subsection 2, paragraph *"a"*.

Sec. 3. NEW SECTION. **510C.3 Formulary — public access.**

If a pharmacy benefit manager is contracted to manage the prescription drug benefit for a health carrier's health benefit

plan, the pharmacy benefit manager shall post all of the following for each health benefit plan on an internet site that is easily accessible to the public:

1. The health carrier's formulary.

2. Notice, at least ninety calendar days prior to implementation, of any of the following:

a. Any change to the health carrier's formulary.

b. The exclusion of a prescription drug from coverage by the health carrier, the health benefit plan, or the pharmacy benefit manager.

Sec. 4. NEW SECTION. **510C.4 Pharmacy and therapeutics committee.**

1. A pharmacy benefit manager that manages a health carrier's prescription drug benefit shall review the health carrier's formulary at least annually, utilizing an independent pharmacy and therapeutics committee that meets all of the following requirements:

a. Committee members must be practicing physicians, practicing pharmacists, or both, and must be licensed in this state.

b. Committee members must practice in various clinical specialty areas, and include high-volume specialists and specialists treating rare and orphan diseases, that represent the needs of the health carrier's covered persons.

c. The committee must meet at least quarterly.

d. Formulary development must be conducted in a transparent process and formulary decisions and rationale must be documented in writing. Any records and documents relating to the process shall be made available by the committee to the health carrier upon request, subject to the conditions in subsection 2.

e. One or more specialists with current clinical expertise who actively treat patients in a specific therapeutic area, including patients with the specific conditions within the therapeutic area, must participate in all formulary decisions

regarding each such therapeutic area and the specific conditions.

f. The committee shall base the committee's clinical decisions on the strength of scientific evidence, standards of practice, and nationally accepted treatment guidelines.

g. The committee shall consider whether a particular prescription drug has a clinically meaningful therapeutic advantage over other prescription drugs in terms of safety, effectiveness, or clinical outcome for patient populations who may be treated with the prescription drug.

h. The committee shall evaluate and analyze treatment protocols and procedures related to the health carrier's formulary.

i. The committee shall review formulary management activities, such as prior authorization, step therapy, quantity limits, generic substitutions, therapeutic interchange, and other prescription drug utilization management activities for all of the following:

(1) Clinical appropriateness.

(2) Consistency with industry standards.

(3) Consistency with patient and provider organization guidelines.

j. The committee shall review and provide a written report to the pharmacy benefit manager that addresses all of the following:

(1) The percentage of prescription drugs on the formulary that are subject to each of the types of utilization management described in paragraph "*i*".

(2) Rates of adherence and nonadherence to medicines by therapeutic area.

(3) Rates of abandonment of medicines by therapeutic area.

(4) Recommendations for improved adherence and reduced abandonment.

(5) Recommendations for improvement in formulary management practices consistent with patient and provider organization

guidelines, as well as other clinical guidelines, provided that the report shall be subject to the conditions in subsection 2.

k. The committee shall review and make a formulary decision on a prescription drug that is newly approved by the United States food and drug administration within ninety calendar days of the United States food and drug administration's approval of the prescription drug, or shall provide a clinical justification to the pharmacy benefit manager if the ninety-calendar-day time frame is not met.

l. The committee shall review procedures for the medical review and transitioning of a covered person who is new to a health benefit plan to appropriate formulary alternatives. The review must ensure that the procedures appropriately address situations involving a covered person who is stabilized on a prescription drug that is not on the health carrier's formulary, or that is on the health carrier's formulary but is subject to prior authorization, step therapy, or other utilization management requirements.

2. A pharmacy benefit manager, a pharmacy, or a therapeutic committee shall not publish or otherwise directly or indirectly disclose any confidential or proprietary information including but not limited to any information that reveals any of the following:

a. The identity of a specific health carrier.

b. The price charged by a specific pharmaceutical manufacturer for a specific prescription drug or class of prescription drugs.

c. The amount of rebates provided for a specific prescription drug or class of prescription drugs.

3. Information provided to or utilized by a pharmacy benefit manager and a pharmacy and therapeutics committee pursuant to subsection 1 shall be protected from disclosure as confidential and proprietary and shall not be a public record subject to disclosure under chapter 22.

Sec. 5. NEW SECTION. **510C.5 Rules.**

The commissioner of insurance shall adopt rules pursuant to chapter 17A as necessary to administer this chapter.

Sec. 6. NEW SECTION. **510C.6 Enforcement.**

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

Sec. 7. NEW SECTION. **510C.7 Applicability.**

This chapter is applicable to a health benefit plan that is delivered, issued for delivery, continued, or renewed in this state on or after January 1, 2020.

Sec. 8. NEW SECTION. **514M.1 Definitions.**

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

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

2. *"Cost sharing"* means any copayment, coinsurance, deductible, or other out-of-pocket expense requirement.

3. *"Covered person"* means the same as defined in section 514J.102.

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

5. *"Health carrier"* means the same as defined in section 514J.102.

6. *"Health carrier cost"* means the amount that a health carrier has contracted with a dispensing pharmacy to pay the dispensing pharmacy for a covered prescription drug, after accounting for rebates, and excluding a covered person's cost sharing.

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

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

9. *"Rebate"* means any of the following:

a. A negotiated price concession for a prescription drug that may accrue directly or indirectly to a health carrier during a health benefit plan coverage year from a

pharmaceutical manufacturer, a dispensing pharmacy, or from another entity in the prescription drug supply chain taking part in a transaction involving a pharmaceutical manufacturer's prescription drug and which may be based on any of the following:

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

(2) Patient outcomes.

(3) A reasonable estimate of price concessions necessary to maintain the net price of a prescription drug for the health carrier for a specified period of time in the event the pharmaceutical manufacturer's list price increases.

b. A reasonable estimate of fees and other administrative costs that are passed through to the health carrier by the pharmaceutical manufacturer.

10. *"Trade secret"* means the same as defined in section 550.2.

Sec. 9. NEW SECTION. **514M.2 Cost sharing — prescription drug benefit.**

1. If a health carrier provides prescription drug benefits to a covered person under a health benefit plan, the health carrier shall reduce any cost sharing requirement for a prescription drug for the covered person by an amount equal to the greater of the following:

a. A dollar amount that equals not less than fifty-one percent of the aggregate rebates received by the health carrier.

b. An amount that ensures that the covered person's cost sharing for the prescription drug does not exceed fifty-one percent of the health carrier's cost for the prescription drug.

2. A health carrier or health benefit plan may reduce a covered person's cost sharing by an amount greater than the amount required pursuant to subsection 1.

3. In complying with this section, a health carrier and the health carrier's agents shall not publish or otherwise

disclose, directly or indirectly, any information regarding the actual amount of rebates the health carrier receives for a specific prescription drug, from a specific pharmaceutical manufacturer, or from a specific pharmacy. Rebate information is a trade secret under chapter 550 and is a confidential record under section 22.7, subsection 3.

4. A health carrier shall have a written agreement with any third-party vendor or downstream entity requiring the third-party vendor or downstream entity to comply with subsection 3 if the third-party vendor or downstream entity receives or has access to the health carrier's rebate information in the course of performing any health care or administrative services on behalf of the health carrier.

Sec. 10. NEW SECTION. **514M.3 Rules.**

The commissioner of insurance shall adopt rules pursuant to chapter 17A as necessary to administer this chapter.

Sec. 11. NEW SECTION. **514M.4 Enforcement.**

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

Sec. 12. NEW SECTION. **514M.5 Applicability.**

This chapter is applicable to a health benefit plan that is delivered, issued for delivery, continued, or renewed in this state on or after January 1, 2020.

EXPLANATION

The inclusion of this explanation does not constitute agreement with the explanation's substance by the members of the general assembly.

This bill relates to pharmacy benefit managers, health carriers, and the management of prescription drug benefits.

The bill requires a pharmacy benefit manager to submit an annual report to the insurance commissioner that provides information on prescription drug prices and rebates received by the pharmacy benefit manager. The information is required to cover the prior calendar year and encompass prescription drug benefits provided to covered persons of each health carrier

with whom the pharmacy benefit manager was contracted during that calendar year. "Pharmacy benefits manager" is defined in the bill as a person who, pursuant to a contract or an employment relationship with a health carrier, either directly or through an affiliate or intermediary, manages a prescription drug benefit provided by the health carrier. The bill defines a "health carrier" as 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 Code chapter 509A for public employees, or any other entity providing a plan of health insurance, health care benefits, or health care services.

The commissioner is required to make the information provided by the pharmacy benefit managers available on a publicly accessible internet site. The bill prohibits the pharmacy benefits manager or the commissioner from providing the information in a manner that identifies a specific health carrier, a specific price charged by a pharmaceutical manufacturer, or the amount of rebates received by a pharmacy benefit manager for a specific drug or class of drug. If information submitted to the commissioner by the pharmacy benefits manager does contain any of these details, the information is deemed confidential and proprietary and is a confidential record pursuant to Code chapter 22.

For each health carrier's health benefit plan for which a pharmacy benefit manager is contracted to manage the prescription drug benefit, the bill requires the pharmacy benefit manager to publish the formulary on an internet site that is easily accessible to the public. The pharmacy benefit manager is also required to post any formulary changes, and a notification of any prescription drug that the health carrier, the health benefit plan, or the pharmacy benefit manager excludes from coverage, a minimum of 90 calendar days prior to

implementation of the formulary changes or prescription drug exclusions.

The bill requires a pharmacy benefit manager that manages a health carrier's prescription drug benefit to review the health carrier's formulary at least annually, utilizing an independent pharmacy and therapeutics committee. The requirements for the membership of the committee and the duties of the committee are detailed in the bill. Information provided to or utilized by the committee is confidential and proprietary and is a confidential record under Code chapter 22 and shall be recognized and protected as a trade secret pursuant to Code section 22.7, subsection 3.

The bill prohibits a health carrier from imposing a cost sharing requirement on a covered person for a prescription drug that exceeds an amount equal to the greater of either the dollar amount of 51 percent or more of the aggregate rebates received by the health carrier, or an amount that ensures that the covered person's cost sharing for the prescription drug shall not exceed 51 percent of the health carrier's cost for the prescription drug. "Covered person" is defined in the bill as a policyholder, subscriber, enrollee, or other individual participating in a health benefit plan.

A health carrier is prohibited from disclosing any information regarding the actual amount of rebates the health carrier received for a specific drug, or from a specific pharmaceutical manufacturer, or from a specific pharmacy in order to comply with the cost sharing requirement. Rebate information is protected as a trade secret and is a confidential record. A health carrier is also required to have an agreement with the health carrier's third-party vendors and downstream entities as necessary to ensure the information is protected as a trade secret.

The bill requires the commissioner of insurance to adopt rules as necessary to administer the provisions of the bill. The bill also allows the commissioner to take any action within

the commissioner's authority to enforce compliance with the provisions of the bill.

The bill is applicable to health benefit plans that are delivered, issued for delivery, continued, or renewed in this state on or after January 1, 2020.