House File 464 - Introduced

HOUSE FILE 464
BY MASCHER

A BILL FOR

An Act relating to price transparency and cost-sharing for prescription drugs, and including applicability provisions.

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

Section 1. NEW SECTION. **510D.1 Definitions.**

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

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

2. *"Dispenser"* means the same as defined in 21 U.S.C. §360eee(3).

3. *"Established name"* means the same as defined in 21 C.F.R. §299.4.

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

5. *"Pharmaceutical drug manufacturer"* or *"manufacturer"* means any person engaged in the business of producing, preparing, converting, processing, packaging, labeling, or distributing a prescription drug. *"Pharmaceutical drug manufacturer"* or *"manufacturer"* does not include a wholesale distributor or a dispenser.

6. *"Prescription drug"* means the same as defined in 21 U.S.C. §360eee(12).

7. *"Wholesale acquisition cost"* or *"cost"* means a manufacturer's list price for a prescription drug for wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

8. *"Wholesale distributor"* means the same as defined in 21 U.S.C. §360eee(29).

Sec. 2. NEW SECTION. **510D.2 Pharmaceutical drug manufacturers —— annual report.**

Each manufacturer shall provide an annual report by February 15 to the commissioner, in a format prescribed by the commissioner, that contains the current wholesale acquisition cost for each prescription drug manufactured by the manufacturer that was sold to a person in this state in the immediately preceding calendar year. Within thirty calendar

days of receipt, the commissioner shall publish the information received by the commissioner on a publicly accessible internet site.

Sec. 3. NEW SECTION. **510D.3 Wholesale acquisition cost increase — report.**

1. If a prescription drug sold to a person in this state has a wholesale acquisition cost of one hundred dollars or more for a thirty-day supply and the cost increases forty percent or more over the three preceding consecutive calendar years, or increases fifteen percent or more in the preceding calendar year, the manufacturer of the prescription drug shall file a report with the commissioner within thirty calendar days of the date on which the forty or the fifteen percent increase in the cost occurs. The report shall be in the form and manner prescribed by the commissioner and shall include all of the following information:

a. The established name of the prescription drug.

b. All brand names, generic names, proprietary names, and nonproprietary names for the prescription drug, as applicable.

c. The aggregate manufacturer-level research and development costs related to the prescription drug for the most recent calendar year for which third-party independent audit data for manufacturer-level research and development costs is available.

d. All established names, brand names, generic names, proprietary names, and nonproprietary names for each prescription drug manufactured by the manufacturer that received approval from the United States food and drug administration in the immediately preceding three consecutive calendar years.

e. All established names, brand names, generic names, proprietary names, and nonproprietary names for each prescription drug manufactured by the manufacturer for which a patent or exclusivity expired in the immediately preceding three consecutive calendar years.

f. A statement detailing the factor or factors that played

any role in the increase in cost of the prescription drug and an explanation for the factor or factors' impact on the increase in cost of the prescription drug.

2. All information and data a manufacturer submits to the commissioner must be consistent in detail and quality with the information and data submitted in the manufacturer's annual report filed with the United States securities and exchange commission on form 10-k.

3. *a.* Information provided by a pharmaceutical drug manufacturer to the commissioner pursuant to this section that may reveal any of the following as related to 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:

(1) The amount the manufacturer charges a specific health carrier, specific pharmacy benefit manager, or a specific dispenser.

(2) The dollar value of the rebates the manufacturer provides a specific health carrier, specific pharmacy benefit manager, or a specific dispenser.

(3) The identity of a specific health carrier, specific pharmacy benefit manager, or a specific dispenser.

b. Within sixty calendar days of receipt of the information pursuant to this section, the commissioner shall publish all nonconfidential information received by the commissioner on the same publicly accessible internet site referenced in section 510D.2.

Sec. 4. NEW SECTION. **510D.4 Rules.**

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

Sec. 5. NEW SECTION. **510D.5 Enforcement.**

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

Sec. 6. NEW SECTION. **510E.1 Definitions.**

As used in this chapter unless the context otherwise requires:

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

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

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

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

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

6. *"Pharmaceutical drug manufacturer"* or *"manufacturer"* means any person engaged in the business of producing, preparing, converting, processing, packaging, labeling, or distributing a prescription drug. *"Pharmaceutical drug manufacturer"* or *"manufacturer"* does not include a wholesale distributor or a dispenser.

7. *"Prescription drug"* means the same as defined in 21 U.S.C. §360eee(12).

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

9. *"Specialty drug"* means a prescription drug that a health carrier has designated as a specialty drug and that has either of the following characteristics:

a. The United States food and drug administration has designated the prescription drug an orphan drug.

b. The manufacturer of the prescription drug or the United States food and drug administration restricts distribution of the prescription drug to a limited number of distributors.

10. *"Utilization review"* means the same as defined in section 514F.7.

11. *"Utilization review organization"* means the same as defined in section 514F.7.

Sec. 7. NEW SECTION. **510E.2 Health carriers —— annual report.**

1. Each health carrier shall submit an annual report by February 1 to the commissioner, in the form and manner prescribed by the commissioner, that contains the following information for the immediately preceding calendar year, across all of the health carrier's health benefit plans that offer a prescription drug benefit:

a. The brand name of the twenty-five prescription drugs most frequently covered by the prescription drug benefits offered by the health carrier.

b. The percent increase in annual spending by the health carrier to provide all prescription drug benefits offered by the health carrier.

c. The percent increase in premiums paid by covered persons attributable to all prescription drug benefits offered by the health carrier.

d. The percentage of specialty drugs included in all prescription drug benefits offered by the health carrier that are subject to utilization review conducted by a utilization review organization.

e. The percent decrease in premiums paid by covered persons attributable to specialty drugs that are subject to utilization review conducted by a utilization review organization that are included in all prescription drug benefits offered by the health carrier.

2. Any information a health carrier provides to the commissioner pursuant to subsection 1 that may reveal any of the following shall be considered a confidential record, and be recognized and protected as a trade secret pursuant to section 22.7:

a. The identity of a specific health benefit plan.

b. The identity of the specific price charged by a specific manufacturer, pharmacy benefit manager, or dispenser for a specific prescription drug or class of prescription drugs.

c. The dollar value of the rebates a specific manufacturer, a specific pharmacy benefit manager, or a specific dispenser provides to the health carrier.

3. Prior to May 1 of each calendar year, the commissioner shall publish the nonconfidential data received by the commissioner pursuant to this section on the same publicly accessible internet site referenced in section 510D.2. The data shall be aggregated from all annual reports submitted pursuant to subsection 1, and the information shall be made available to the public in a format that complies with subsection 2.

Sec. 8. NEW SECTION. **510E.3 Rules.**

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

Sec. 9. NEW SECTION. **510E.4 Enforcement.**

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

Sec. 10. NEW SECTION. **514M.1 Definitions.**

1. *"Carrier"* means an entity subject to the insurance laws and regulations of this state, or subject to the jurisdiction of the commissioner, that offers at least one health plan in this state.

2. *"Cost-sharing requirement"* means any copayment, coinsurance, deductible, or other out-of-pocket expense obligation required of or on behalf of an enrollee in order for the enrollee to receive a specific health care service, including a prescription drug, covered by the enrollee's health plan.

3. *"Enrollee"* means an individual who is eligible to obtain health care services under a health plan.

4. *"Health care services"* means an item or service for the prevention, treatment, cure, or healing of an illness, injury, or physical disability.

5. *"Health plan"* means a policy, contract, certificate, or

agreement offered or issued by a carrier to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services.

6. "*Internal Revenue Code*" means the Internal Revenue Code as defined in section 422.3.

7. "*Person*" means a natural person, corporation, mutual company, unincorporated association, partnership, joint venture, limited liability corporation, trust, estate, foundation, not-for-profit organization, government or governmental subdivision, or government or governmental agency.

Sec. 11. NEW SECTION. **514M.2 Cost-sharing calculation.**

1. A carrier shall include all cost-sharing amounts paid by an enrollee, or by another person on behalf of the enrollee, as part of the carrier's calculation of an enrollee's contribution to the enrollee's applicable cost-sharing requirement. This requirement does not apply to cost-sharing amounts paid by an enrollee, or by another person on behalf of an enrollee, for a prescription drug for which a medically appropriate A-rated generic equivalent is available to the enrollee.

2. Subsection 1 shall not apply to a state-regulated high-deductible health plan to the extent it results in the plan's failure to qualify as a high-deductible health plan pursuant to section 223 of the Internal Revenue Code.

Sec. 12. NEW SECTION. **514M.3 Severability.**

If the provisions of subsection 1 conflict with a federal law or regulation as applied to a specific carrier or in a specific circumstance, the provisions shall remain in full force and effect for all carriers and in all circumstances in which the federal conflict does not exist.

Sec. 13. NEW SECTION. **514M.4 Applicability.**

This chapter applies to all health plans delivered, issued for delivery, continued, or renewed in this state on or after January 1, 2022.

Sec. 14. RETROACTIVE APPLICABILITY.

1. The section of this Act that requires a pharmaceutical

drug manufacturer to submit an annual report to the commissioner containing the current wholesale acquisition cost for each of the manufacturer's prescription drugs is retroactively applicable to all manufacturers that manufactured any prescription drug that is sold to a person in this state on or after January 1, 2021.

2. The section of this Act that requires a pharmaceutical drug manufacturer to submit a report to the commissioner containing information related to an increase in the wholesale acquisition cost of a prescription drug manufactured by the manufacturer is retroactively applicable to all manufacturers that manufactured any prescription drug that is sold to a person in this state on or after January 1, 2021.

3. The section of this Act that requires a health carrier to submit an annual report to the commissioner related to all of the health carrier's health benefit plans that offer a prescription drug benefit is retroactively applicable to all health benefit plans providing for third-party payment or prepayment of health or medical expenses that provide a prescription drug benefit that have been delivered, issued for delivery, continued, or renewed in this state on or after January 1, 2021.

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 price transparency and cost-sharing for prescription drugs.

The bill requires a manufacturer to file an annual report with the commissioner of insurance (commissioner) that discloses the wholesale acquisition cost for all prescription drugs manufactured by the manufacturer that were sold to a person in this state in the immediately preceding calendar year. The first report that is due covers all prescription drugs sold to a person in this state on or after January 1, 2021. "Wholesale acquisition cost" or "cost" is defined in the

bill as the manufacturer's list price for a prescription drug for wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data. Within 30 calendar days of receipt, the commissioner is required to publish this information from the annual reports on a publicly accessible internet site.

If a prescription drug sold to a person in this state has a cost of $100 or more for a 30-day supply and the cost increases 40 percent or more over the three preceding calendar years, or increases 15 percent or more in the preceding calendar year, the manufacturer of the prescription drug must file a report with the commissioner within 30 calendar days of the date on which the 40 or 15 percent increase in cost occurs. This requirement is applicable to all manufacturers that manufactured prescription drugs that are sold to a person in this state on or after January 1, 2021. The report must include the information detailed in the bill. Certain information provided by a manufacturer, as detailed in the bill, is considered a confidential record and is required to be protected as a trade secret. Within 60 calendar days of receipt, the commissioner is required to publish the nonconfidential information on the same publicly accessible internet site on which the manufacturer's annual report information is published.

The bill requires each health carrier to submit an annual report by February 1 to the commissioner that contains information as detailed in the bill across all of the health carrier's health benefit plans. This requirement is applicable to all health benefit plans providing for third-party payment or prepayment of health or medical expenses that provide a prescription drug benefit that have been delivered, issued for delivery, continued, or renewed in this state on or after

January 1, 2021. "Health carrier" is defined in the bill 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. Certain information provided by a health carrier, as detailed in the bill, is considered a confidential record and must be protected as a trade secret. Prior to May 1 of each year, the commissioner must publish the nonconfidential data received by the commissioner on the same publicly accessible internet site on which the manufacturers' information is published. The data must be aggregated from the annual reports submitted by all health carriers.

The bill directs the commissioner to adopt rules as necessary to administer the requirements outlined in the bill and allows the commissioner to take any action within the commissioner's authority to enforce compliance with the manufacturer and health carrier reporting requirements outlined in the bill.

The bill also requires a carrier to include all cost-sharing amounts paid by an enrollee of a health plan, or by another person on behalf of an enrollee, as part of the carrier's calculation of an enrollee's contribution to the enrollee's applicable cost-sharing requirement. "Cost-sharing requirement" is defined in the bill as any copayment, coinsurance, deductible, or other out-of-pocket expense obligation required of or on behalf of an enrollee in order for the enrollee to receive a specific health care service, including a prescription drug, covered by the enrollee's health plan. This requirement applies to all health plans delivered, issued for delivery, continued, or renewed in this state on or after January 1, 2022. The bill excludes state-regulated

high-deductible health plans (HDHP) from the requirement if it will result in the plan not qualifying as an HDHP under section 223 of the Internal Revenue Code. The bill also prohibits application of the requirement to a carrier or a circumstance in a manner that will conflict with a federal law or a federal regulation.