House File 526 - Introduced

HOUSE FILE 526
BY COMMITTEE ON COMMERCE

(SUCCESSOR TO HSB 46)

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 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 percent 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.

g. The aggregate manufacturer-level direct and administrative costs related to marketing and advertising of the prescription drug for the immediately preceding calendar year.

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 Summary enforcement.**

1. Upon a determination by the commissioner that a manufacturer or manufacturer's agent has engaged, is engaging, or is about to engage in any act or practice in violation of this chapter, a rule adopted by the commissioner, or an order issued by the commissioner under this chapter, the commissioner may do any of the following:

a. Issue a summary order, including a brief statement of findings of fact and conclusions of law, and direct the manufacturer or manufacturer's agent to cease and desist from engaging in the act or practice.

b. Take other affirmative action that in the judgment of the commissioner is necessary to ensure that the manufacturer or manufacturer's agent comply with this chapter, and rules adopted and orders issued by the commissioner under this chapter.

2. *a.* A manufacturer or manufacturer's agent that has been issued a summary order under this section may contest the order by filing a request for a contested case proceeding and hearing as provided in chapter 17A, and in accordance with rules adopted by the commissioner. The manufacturer or manufacturer's agent shall have at least thirty calendar days from the date that the summary order is issued to file the request. If a hearing is not timely requested, the summary order shall be final by operation of law.

b. Section 17A.18A shall not apply to a summary order issued under this section.

c. A summary order issued pursuant to this section shall remain effective from the date of issuance unless overturned by a final decision of a presiding officer or by a final judgment of the court.

3. A manufacturer or manufacturer's agent violating a summary order issued under this section shall be deemed in contempt of that order. The commissioner may petition the district court to enforce the order as certified by

the commissioner. The district court shall adjudge the manufacturer or manufacturer's agent in contempt of the order if the court finds after hearing that the manufacturer or manufacturer's agent is not in compliance with the order. The court may assess a civil penalty against the manufacturer or manufacturer's agent of not more than one thousand dollars per day for each day that the manufacturer or manufacturer's agent is in violation of the order. A civil penalty collected pursuant to this section shall be deposited as provided in section 505.7. The court may issue further orders as the court deems appropriate.

Sec. 6. NEW SECTION. **510D.6 Enforcement after hearing.**

1. If, after a hearing and contested case proceeding pursuant to section 510D.5, subsection 2, the commissioner determines that a manufacturer or a manufacturer's agent violated this chapter, a rule adopted by the commissioner, or an order issued by the commissioner under this chapter, the commissioner shall reduce the findings to writing and shall issue and cause to be served upon the manufacturer or the manufacturer's agent all of the following:

a. A copy of the commissioner's findings.

b. An order requiring the manufacturer or the manufacturer's agent to cease and desist from violating this chapter, a rule adopted by the commissioner, or an order issued by the commissioner under this chapter.

2. The commissioner may take other affirmative action that in the judgment of the commissioner is necessary to ensure that the manufacturer or the manufacturer's agent complies with this chapter. The commissioner may also, at the commissioner's discretion, order payment of a civil penalty of not more than five thousand dollars for each violation of this chapter by the manufacturer or the manufacturer's agent.

3. A manufacturer or a manufacturer's agent that violates an order of the commissioner, and while such order is in effect, may, after notice and hearing and upon order of the

commissioner, be subject to a civil penalty of not more than ten thousand dollars for each violation of the commissioner's order. A manufacturer or a manufacturer's agent violating an order issued by the commissioner under this section shall be deemed in contempt of the order. A civil penalty collected pursuant to this subsection shall be deposited as provided in section 505.7.

4. A manufacturer or a manufacturer's agent may seek judicial review of an action of the commissioner pursuant to chapter 17A. To the extent that a decision or order of the commissioner is affirmed in a judicial review proceeding, the court shall issue an order directing that the manufacturer or the manufacturer's agent complies with the terms of the commissioner's decision or order.

5. If the period for judicial review of an order of the commissioner has expired and no petition for judicial review has been filed, upon request of the commissioner, the attorney general shall proceed in the district court to enforce the order of the commissioner. The court shall issue an order directing that the manufacturer or the manufacturer's agent comply with the terms of the commission's order.

6. Upon request of the commissioner, the attorney general shall petition the district court to enforce an order as certified by the commissioner. The district court shall adjudge a manufacturer or a manufacturer's agent in contempt of the commissioner's order if the court finds after hearing that the manufacturer or the manufacturer's agent is not in compliance with the commissioner's order. For each day of noncompliance, the court may order a civil penalty of not more than one thousand dollars against the manufacturer or the manufacturer's agent and may issue further orders as the court deems appropriate.

Sec. 7. 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. *"Dispenser"* means the same as defined in 21 U.S.C. §360eee(3).

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

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

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

7. *"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.

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

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

10. *"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.

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

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

Sec. 8. NEW SECTION. **510E.2 Health carriers — annual**

report.

1. *a.* Each health carrier shall submit an annual report by February 15 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:

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

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

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

(4) 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.

(5) 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.

b. An authorized insurer or an authorized third-party administrator that administers a multiple employer welfare arrangement pursuant to section 507A.4, subsection 9, paragraph *"a"*, subparagraph (1), shall submit the report required in paragraph *"a"* on behalf of the multiple employer welfare arrangement that the authorized insurer or the authorized third-party administrator administers.

2. Any information a health carrier provides, or an authorized insurer or an authorized third-party administrator provides on behalf of a multiple employer welfare arrangement,

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, subsection 3:

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. 9. NEW SECTION. **510E.3 Rules.**

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

Sec. 10. NEW SECTION. **510E.4 Summary enforcement.**

1. Upon a determination by the commissioner that a health carrier or a health carrier's agent has engaged, is engaging, or is about to engage in any act or practice in violation of this chapter, a rule adopted by the commissioner, or an order issued by the commissioner under this chapter, the commissioner may do any of the following:

a. Issue a summary order, including a brief statement of findings of fact and conclusions of law, and direct the health carrier or health carrier's agent to cease and desist from engaging in the act or practice.

b. Take other affirmative action that in the judgment of the commissioner is necessary to ensure that the health

carrier or health carrier's agent comply with this chapter, and rules adopted and orders issued by the commissioner under this chapter.

2. *a.* A health carrier or health carrier's agent that has been issued a summary order under this section may contest the order by filing a request for a contested case proceeding and hearing as provided in chapter 17A, and in accordance with rules adopted by the commissioner. The health carrier or health carrier's agent shall have at least thirty calendar days from the date that the summary order is issued to file the request. If a hearing is not timely requested, the summary order shall be final by operation of law.

b. Section 17A.18A shall not apply to a summary order issued under this section.

c. A summary order issued pursuant to this section shall remain effective from the date of issuance unless overturned by a final decision of a presiding officer or by a final judgment of the court.

3. A health carrier or health carrier's agent violating a summary order issued under this section shall be deemed in contempt of that order. The commissioner may petition the district court to enforce the order as certified by the commissioner. The district court shall adjudge the health carrier or health carrier's agent in contempt of the order if the court finds after hearing that the health carrier or health carrier's agent is not in compliance with the order. The court may assess a civil penalty against the health carrier or health carrier's agent of not more than one thousand dollars per day for each day that the health carrier or health carrier's agent is in violation of the order. A civil penalty collected pursuant to this section shall be deposited as provided in section 505.7. The court may issue further orders as the court deems appropriate.

Sec. 11. NEW SECTION. **510E.5 Enforcement after hearing.**

1. If, after a hearing and contested case proceeding

pursuant to section 510E.4, subsection 2, the commissioner determines that a health carrier or a health carrier's agent violated this chapter, a rule adopted by the commissioner, or an order issued by the commissioner under this chapter, the commissioner shall reduce the findings to writing and shall issue and cause to be served upon the health carrier or the health carrier's agent all of the following:

a. A copy of the commissioner's findings.

b. An order requiring the health carrier or the health carrier's agent to cease and desist from violating this chapter, a rule adopted by the commissioner, or an order issued by the commissioner under this chapter.

2. The commissioner may take other affirmative action that in the judgment of the commissioner is necessary to ensure that a health carrier or a health carrier's agent complies with this chapter. The commissioner may also, at the commissioner's discretion, order payment of a civil penalty of not more than five thousand dollars for each violation of this chapter by a health carrier or a health carrier's agent.

3. A health carrier or a health carrier's agent that violates an order of the commissioner, and while such order is in effect, may, after notice and hearing and upon order of the commissioner, be subject to a civil penalty of not more than ten thousand dollars for each violation of the commissioner's order. A health carrier or a health carrier's agent that violates an order issued by the commissioner under this section shall be deemed in contempt of the order. A civil penalty collected pursuant to this subsection shall be deposited as provided in section 505.7.

4. A health carrier or a health carrier's agent may seek judicial review of an action of the commissioner pursuant to chapter 17A. To the extent that a decision or order of the commissioner is affirmed in a judicial review proceeding, the court shall issue an order directing that the health carrier or the health carrier's agent comply with the terms of the

commissioner's decision or order.

5. If the period for judicial review of an order of the commissioner has expired and no petition for judicial review has been filed, upon request of the commissioner, the attorney general shall proceed in the district court to enforce the order of the commissioner. The court shall issue an order directing that the health carrier or the health carrier's agent comply with the terms of the commission's order.

6. Upon request of the commissioner, the attorney general shall petition the district court to enforce an order as certified by the commissioner. The district court shall adjudge a health carrier or a health carrier's agent in contempt of the commissioner's order if the court finds after hearing that the health carrier or the health carrier's agent is not in compliance with the commissioner's order. For each day of noncompliance, the court may order a civil penalty of not more than one thousand dollars against a health carrier or a health carrier's agent and may issue further orders as the court deems appropriate.

Sec. 12. 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. *"Interchangeable biological product"* means the same as defined in section 155A.3.

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

8. *"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.

9. *"Specialty drug"* means the same as defined in section 510E.1.

Sec. 13. NEW SECTION. **514M.2 Cost-sharing calculation.**

1. A carrier shall include all cost-sharing amounts paid by an enrollee, or need-based payments paid 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 specialty drug or a prescription drug for which a medically appropriate A-rated generic equivalent or an interchangeable biological product 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.

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

Sec. 14. NEW SECTION. **514M.3 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. 15. 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 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 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 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. "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 the 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 15 to the commissioner that contains information as detailed in the bill across all of the health carrier's health benefit plans. An authorized insurer or an authorized third-party administrator that administers a

multiple employer welfare arrangement must submit the required report on behalf of the multiple employer welfare arrangement that the insurer or the third-party administrator administers. 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. As detailed in the bill, certain information provided by a health carrier, or an authorized insurer or an authorized third-party administrator on behalf of a multiple employer welfare arrangement, 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. The bill details the commissioner's authority, and the process to enforce that authority, for manufacturers', manufacturers' agents', health carriers' or health carriers' agents' violations of a provision of the bill, a rule adopted by the commissioner, or of an order issued by the commissioner.

The bill also allows the commissioner, or the court, to order payment of penalties for certain violations as outlined

in the bill. Manufacturers, manufacturer's agents, health carriers, and health carrier's agents may request a contested case proceeding, or seek judicial review of an action of the commissioner, in certain circumstances as detailed 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. This does not apply to cost-sharing incurred for a specialty drug or a prescription drug for which an A-rated generic equivalent or an interchangeable biological product is available. "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 to a circumstance in a manner that will conflict with a federal law or a federal regulation.