

House File 2253 - Introduced

HOUSE FILE 2253

BY LUNDGREN

A BILL FOR

1 An Act relating to price transparency for prescription drugs
2 sold in this state, and including applicability provisions.
3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

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

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

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

5 2. "*Dispenser*" means the same as defined in 21 U.S.C.
6 §360eee(3).

7 3. "*Established name*" means the same as defined in 21 C.F.R.
8 299.4.

9 4. "*Health benefit plan*" means the same as defined in
10 514J.102.

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

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

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

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

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

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

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

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

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

17 a. The established name of the prescription drug.

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

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

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

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

35 f. A statement detailing the factor or factors that played

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

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

9 3. *a.* Information provided by a pharmaceutical drug
10 manufacturer to the commissioner pursuant to this section
11 that may reveal any of the following as related to a specific
12 prescription drug or class of prescription drugs shall
13 be considered a confidential record, and be recognized
14 and protected as a trade secret pursuant to section 22.7,
15 subsection 3:

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

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

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

24 *b.* Within sixty calendar days of receipt of the information
25 pursuant to this section, the commissioner shall publish all
26 nonconfidential information received by the commissioner on the
27 same publicly accessible internet site referenced in section
28 510D.2.

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

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

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

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

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

2 As used in this chapter unless the context otherwise
3 requires:

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

5 2. "*Covered person*" means the same as defined in section
6 514J.102.

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

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

11 5. "*Health carrier*" means the same as defined in section
12 514J.102.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

27 2. Any information a health carrier provides to the
28 commissioner pursuant to subsection 1 that may reveal any of
29 the following shall be considered a confidential record, and be
30 recognized and protected as a trade secret pursuant to section
31 22.7:

32 a. The identity of a specific health benefit plan.

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

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

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

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

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

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

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

19 Sec. 10. APPLICABILITY.

20 1. The section of the Act that requires a pharmaceutical
21 drug manufacturer to submit an annual report to the
22 commissioner containing the current wholesale acquisition cost
23 for each of the manufacturer's prescription drugs is applicable
24 to all manufacturers that manufactured any prescription drug
25 that is sold to a person in this state on or after January 1,
26 2021.

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

34 3. The section of the Act that requires a health carrier
35 to submit an annual report to the commissioner related to all

1 of the health carrier's health benefit plans that offer a
2 prescription drug benefit is applicable to all health benefit
3 plans providing for third-party payment or prepayment of health
4 or medical expenses that provide a prescription drug benefit
5 that have been delivered, issued for delivery, continued, or
6 renewed in this state on or after January 1, 2021.

7 EXPLANATION

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

10 This bill relates to price transparency for prescription
11 drugs sold in this state.

12 The bill requires a manufacturer to file an annual report
13 with the commissioner of insurance (commissioner) that
14 discloses the wholesale acquisition cost for all prescription
15 drugs manufactured by the manufacturer that were sold to a
16 person in this state in the immediately preceding calendar
17 year. "Wholesale acquisition cost" or "cost" is defined in the
18 bill as the manufacturer's list price for a prescription drug
19 for wholesalers or direct purchasers in the United States, not
20 including prompt pay or other discounts, rebates, or reductions
21 in price, for the most recent month for which the information
22 is available, as reported in wholesale price guides or other
23 publications of drug or biological pricing data. Within 30
24 calendar days of receipt, the commissioner is required to
25 publish this information from the annual reports on a publicly
26 accessible internet site.

27 If a prescription drug sold to a person in this state has a
28 cost of \$100 or more for a 30-day supply and the cost increases
29 40 percent or more over three consecutive calendar years, or
30 increases 15 percent or more in a single calendar year, the
31 manufacturer of the prescription drug must file a report with
32 the commissioner within 30 calendar days of the date on which
33 the 40 or 15 percent increase in cost occurs. This requirement
34 is applicable to all manufacturers that manufactured
35 prescription drugs that are sold to a person in this state

1 on or after January 1, 2021. The report must include the
2 information detailed in the bill. Certain information provided
3 by a manufacturer, as detailed in the bill, is considered a
4 confidential record and is required to be protected as a trade
5 secret. Within 60 calendar days of receipt, the commissioner
6 is required to publish the nonconfidential information on
7 the same publicly accessible internet site on which the
8 manufacturer's annual report information is published.

9 The bill requires each health carrier to submit an annual
10 report by February 1 to the commissioner that contains
11 information as detailed in the bill across all of the health
12 carrier's health benefit plans. This requirement is applicable
13 to all health benefit plans providing for third-party payment
14 or prepayment of health or medical expenses that provide a
15 prescription drug benefit that have been delivered, issued
16 for delivery, continued, or renewed in this state on or after
17 January 1, 2021. "Health carrier" is defined in the bill as an
18 entity subject to the insurance laws and regulations of this
19 state, or subject to the jurisdiction of the commissioner,
20 including an insurance company offering sickness and accident
21 plans, a health maintenance organization, a nonprofit health
22 service corporation, a plan established pursuant to Code
23 chapter 509A for public employees, or any other entity
24 providing a plan of health insurance, health care benefits,
25 or health care services. Certain information provided by
26 a health carrier, as detailed in the bill, is considered a
27 confidential record and must be protected as a trade secret.
28 Prior to May 1 of each year, the commissioner must publish the
29 nonconfidential data received by the commissioner on the same
30 publicly accessible internet site on which the manufacturers'
31 information is published. The data must be aggregated from the
32 annual reports submitted by all health carriers.

33 The bill directs the commissioner to adopt rules as
34 necessary to administer the requirements outlined in the
35 bill and allows the commissioner to take any action within

1 the commissioner's authority to enforce compliance with the
2 requirements outlined in the bill.