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## **SENATE** STATE OF MINNESOTA NINETY-THIRD SESSION

## S.F. No. 5329

DATE	D-PG	OFFICIAL STATUS
04/04/2024	13379	Introduction and first reading Referred to Health and Human Services

1.1	A bill for an act
1.2 1.3 1.4 1.5 1.6 1.7	relating to health; modifying reporting requirements for drug price increases; modifying commissioner of health posting requirements relating to prescription drug price information; exempting the commissioner of health from rulemaking requirements under chapter 14; modifying pharmacy benefit manager reporting requirements for certain prescription drugs; amending Minnesota Statutes 2023 Supplement, section 62J.84, subdivisions 3, 6, 10, 11, 13, 15.
1.8	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:
1.9 1.10	Section 1. Minnesota Statutes 2023 Supplement, section 62J.84, subdivision 3, is amended to read:
1.11	Subd. 3. Prescription drug price increases reporting. (a) Beginning January 1, 2022,
1.12	a drug manufacturer must submit to the commissioner the information described in paragraph
1.13	(b) for each prescription drug for which the price was \$100 or greater for a 30-day supply
1.14	or for a course of treatment lasting less than 30 days and:
1.15	(1) for brand name drugs where there is an increase of ten percent or greater in the price
1.16	over the previous 12-month period or an increase of 16 percent or greater in the price over
1.17	the previous 24-month period; and
1.18	(2) for generic or biosimilar drugs where there is an increase of 50 percent or greater in
1.19	the price over the previous 12-month period.
1.20	(b) For each of the drugs described in paragraph (a), the manufacturer shall submit to
1.21	the commissioner no later than 60 days after the price increase goes into effect, in the form
1.22	and manner prescribed by the commissioner, the following information, if applicable:

- 2.1 (1) the description and price of the drug and the net increase, expressed as a percentage,
- 2.2 with the following listed separately:
- 2.3 (i) the national drug code;
- 2.4 (ii) the product name;
- 2.5 (iii) the dosage form;
- 2.6 (iv) the strength; and
- 2.7 (v) the package size;
- 2.8 (2) the factors that contributed to the price increase;
- 2.9 (3) the name of any generic version of the prescription drug available on the market;
- 2.10 (4) the year the prescription drug was introduced for sale in the United States;
- 2.11 (4)(5) the introductory price of the prescription drug when it was introduced for sale in
- 2.12 the United States and the price of the drug on the last day of each of the five calendar years
- 2.13 preceding the price increase;
- 2.14 (5) (6) the direct costs incurred during the previous 12-month period by the manufacturer
- 2.15 that are associated with the prescription drug, listed separately:
- 2.16 (i) to manufacture the prescription drug;
- 2.17 (ii) to market the prescription drug, including advertising costs; and
- 2.18 (iii) to distribute the prescription drug;
- 2.19 (7) the number of units of the prescription drug sold during the previous 12-month period;
- 2.20 (6) (8) the total sales revenue for the prescription drug during the previous 12-month 2.21 period;
- 2.22 (9) the total rebate payable amount accrued for the prescription drug during the previous
  2.23 12-month period;
- 2.24 (7) (10) the manufacturer's net profit attributable to the prescription drug during the 2.25 previous 12-month period;
- 2.26 (8) (11) the total amount of financial assistance the manufacturer has provided through
  2.27 patient prescription assistance programs during the previous 12-month period, if applicable;
- 2.28 (9)(12) any agreement between a manufacturer and another entity contingent upon any 2.29 delay in offering to market a generic version of the prescription drug;

3.1	(10) (13) the patent expiration date of the prescription drug if it is under patent;
3.2	(11) (14) the name and location of the company that manufactured the drug;
3.3	(12)(15) if a brand name prescription drug, the highest price paid for the prescription
3.4	drug during the previous calendar year in the ten countries, excluding the United States,
3.5	that charged the highest single price for the prescription drug; and
3.6	(13) (16) if the prescription drug was acquired by the manufacturer during the previous
3.7	12-month period, all of the following information:
3.8	(i) price at acquisition;
3.9	(ii) price in the calendar year prior to acquisition;
3.10	(iii) name of the company from which the drug was acquired;
3.11	(iv) date of acquisition; and
3.12	(v) acquisition price.
3.13	(c) The manufacturer may submit any documentation necessary to support the information
3.14	reported under this subdivision.
3.15	Sec. 2. Minnesota Statutes 2023 Supplement, section 62J.84, subdivision 6, is amended
3.16	to read:
3.17	Subd. 6. Public posting of prescription drug price information. (a) The commissioner
3.18	shall post on the department's website, or may contract with a private entity or consortium
3.19	that satisfies the standards of section 62U.04, subdivision 6, to meet this requirement, the
3.20	following information:
3.21	(1) a list of the prescription drugs reported under subdivisions 3, 4, and 11 to 14 and the
3.22	manufacturers of those prescription drugs;
3.23	(2) a list of reporting entities under subdivisions 3, 4, and 11 to 14; and
3.24	(2) (3) information reported to the commissioner under subdivisions 3, 4, and 11 to 14,
3.25	aggregated in a manner that does not allow the determination of individual contract terms
2.24	1 1 1 1
3.26	when applicable.
3.26 3.27	when applicable. (b) The information must be published in an easy-to-read format and in a manner that
3.27	(b) The information must be published in an easy-to-read format and in a manner that
3.27 3.28	(b) The information must be published in an easy-to-read format and in a manner that identifies the information that is disclosed on a per-drug basis and must not be aggregated

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as introduced

(c) The commissioner shall not post to the department's website or a private entity 4.1 contracting with the commissioner shall not post any information described in this section 4.2 if the information is not public data under section 13.02, subdivision 8a; or is trade secret 4.3 information under section 13.37, subdivision 1, paragraph (b); or is trade secret information 4.4 pursuant to the Defend Trade Secrets Act of 2016, United States Code, title 18, section 4.5 1836, as amended. If a reporting entity believes information should be withheld from public 4.6 disclosure pursuant to this paragraph, the reporting entity must clearly and specifically 4.7 identify that information and describe the legal basis in writing when the reporting entity 4.8 submits the information under this section. If the commissioner disagrees with the reporting 4.9 entity's request to withhold information from public disclosure, the commissioner shall 4.10 provide the reporting entity written notice that the information will be publicly posted 30 4.11 days after the date of the notice. 4.12

(d) If the commissioner withholds any information from public disclosure pursuant to 4.13 this subdivision, the commissioner shall post to the department's website a report describing 4.14 the nature of the information and the commissioner's basis for withholding the information 4.15 from disclosure. 4.16

(e) To the extent the information required to be posted under this subdivision is collected 4.17 and made available to the public by another state, by the University of Minnesota, or through 4.18 an online drug pricing reference and analytical tool, the commissioner may reference the 4.19 availability of this drug price data from another source including, within existing 4.20 appropriations, creating the ability of the public to access the data from the source for 4.21 purposes of meeting the reporting requirements of this subdivision. 4.22

Sec. 3. Minnesota Statutes 2023 Supplement, section 62J.84, subdivision 10, is amended 4.23 to read: 4.24

Subd. 10. Notice of prescription drugs of substantial public interest. (a) No later than 4.25 January 31, 2024, and quarterly thereafter, the commissioner shall produce and post on the 4.26 department's website a list of prescription drugs that the commissioner determines to represent 4.27 4.28 a substantial public interest and for which the commissioner intends to request data under subdivisions 11 to 14, subject to paragraph (c). The commissioner shall base its inclusion 4.29 of prescription drugs on any information the commissioner determines is relevant to providing 4.30 greater consumer awareness of the factors contributing to the cost of prescription drugs in 4.31 the state, and the commissioner shall consider drug product families that include prescription 4.32 4.33 drugs:

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(1) that triggered reporting under subdivision 3 or 4 during the previous calendar quarter;

5.1 (2) for which average claims paid amounts exceeded 125 percent of the price as of the
5.2 claim incurred date during the most recent calendar quarter for which claims paid amounts
5.3 are available; or

5.4 (3) that are identified by members of the public during a public comment process.

(b) Not sooner than 30 days after publicly posting the list of prescription drugs under
paragraph (a), the department shall notify, via email, reporting entities registered with the
department of the requirement to report under subdivisions 11 to 14.

5.8 (c) The commissioner must not designate more than 500 prescription drugs as having a
5.9 substantial public interest in any one notice.

5.10 (d) Notwithstanding subdivision 16 of this section, the commissioner is exempt from
5.11 chapter 14, including section 14.386, in implementing this subdivision.

5.12 **EFFECTIVE DATE.** This section is effective the day following final enactment.

5.13 Sec. 4. Minnesota Statutes 2023 Supplement, section 62J.84, subdivision 11, is amended
5.14 to read:

- 5.15 Subd. 11. Manufacturer prescription drug substantial public interest reporting. (a)
  5.16 Beginning January 1, 2024, a manufacturer must submit to the commissioner the information
  5.17 described in paragraph (b) for any prescription drug:
- 5.18 (1) included in a notification to report issued to the manufacturer by the department5.19 under subdivision 10;
- 5.20 (2) which the manufacturer manufactures or repackages;

5.21 (3) for which the manufacturer sets the wholesale acquisition cost; and

5.22 (4) for which the manufacturer has not submitted data under subdivision 3 during the5.23 120-day period prior to the date of the notification to report.

5.24 (b) For each of the drugs described in paragraph (a), the manufacturer shall submit to

5.25 the commissioner no later than 60 days after the date of the notification to report, in the

5.26 form and manner prescribed by the commissioner, the following information, if applicable:

- 5.27 (1) a description of the drug with the following listed separately:
- 5.28 (i) the national drug code;
- 5.29 (ii) the product name;
- 5.30 (iii) the dosage form;

6.1	(iv) the strength; and
6.2	(v) the package size;
6.3	(2) the price of the drug product on the later of:
6.4	(i) the day one year prior to the date of the notification to report;
6.5	(ii) the introduced to market date; or
6.6	(iii) the acquisition date;
6.7	(3) the price of the drug product on the date of the notification to report;
6.8	(4) the year the prescription drug was introduced for sale in the United States;
6.9	(4) (5) the introductory price of the prescription drug when it was introduced for sale in
6.10	the United States and the price of the drug on the last day of each of the five calendar years
6.11	preceding the date of the notification to report;
6.12	(5) (6) the direct costs incurred during the 12-month period prior to the date of the
6.13	notification to report by the manufacturers that are associated with the prescription drug,
6.14	listed separately:
6.15	(i) to manufacture the prescription drug;
6.16	(ii) to market the prescription drug, including advertising costs; and
6.17	(iii) to distribute the prescription drug;
6.18	(6) (7) the number of units of the prescription drug sold during the 12-month period
6.19	prior to the date of the notification to report;
6.20	(7) (8) the total sales revenue for the prescription drug during the 12-month period prior
6.21	to the date of the notification to report;
6.22	(8) (9) the total rebate payable amount accrued for the prescription drug during the
6.23	12-month period prior to the date of the notification to report;
6.24	(9) (10) the manufacturer's net profit attributable to the prescription drug during the
6.25	12-month period prior to the date of the notification to report;
6.26	(10) (11) the total amount of financial assistance the manufacturer has provided through
6.27	patient prescription assistance programs during the 12-month period prior to the date of the
6.28	notification to report, if applicable;
6.29	(11) (12) any agreement between a manufacturer and another entity contingent upon
6.30	any delay in offering to market a generic version of the prescription drug;

7.1	(12) (13) the patent expiration date of the prescription drug if the prescription drug is
7.2	under patent;
7.3	(13) (14) the name and location of the company that manufactured the drug;
7.4	(14) (15) if the prescription drug is a brand name prescription drug, the ten countries
7.5	other than the United States that paid the highest prices for the prescription drug during the
7.6	previous calendar year and their prices; and
7.7	(15) (16) if the prescription drug was acquired by the manufacturer within a 12-month
7.8	period prior to the date of the notification to report, all of the following information:
7.9	(i) the price at acquisition;
7.10	(ii) the price in the calendar year prior to acquisition;
7.11	(iii) the name of the company from which the drug was acquired;
7.12	(iv) the date of acquisition; and
7.13	(v) the acquisition price.
7.14	(c) The manufacturer may submit any documentation necessary to support the information
7.15	reported under this subdivision.
7.16	Sec. 5. Minnesota Statutes 2023 Supplement, section 62J.84, subdivision 13, is amended
7.17	to read:
7.18	Subd. 13. PBM prescription drug substantial public interest reporting. (a) Beginning
7.19	January 1, 2024, a PBM must submit to the commissioner the information described in
7.20	paragraph (b) for any prescription drug included in a notification to report issued to the
7.21	PBM by the department under subdivision 10.
7.22	(b) For each of the drugs described in paragraph (a), the PBM shall submit to the
7.23	commissioner no later than 60 days after the date of the notification to report, in the form
7.24	and manner prescribed by the commissioner, the following information, if applicable:
7.25	(1) a description of the drug with the following listed separately:
7.26	(i) the national drug code;
7.27	(ii) the product name;
7.28	(iii) the dosage form;
7.29	(iv) the strength; and

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8.1	(2) the number of pricing units of the drug product filled for which the PBM administered
8.2	claims during the 12-month period prior to the date of the notification to report;
8.3	(3) the total reimbursement amount accrued and payable to pharmacies for pricing units
8.4	of the drug product filled for which the PBM administered claims during the 12-month
8.5	period prior to the date of the notification to report;
8.6	(4) the total reimbursement or administrative fee amount, or both, accrued and receivable
8.7	from payers for pricing units of the drug product filled for which the PBM administered
8.8	claims during the 12-month period prior to the date of the notification to report;
8.9	(5) the total administrative fee amount accrued and receivable from payers for pricing
8.10	units of the drug product filled for which the PBM administered claims during the 12-month
8.11	period prior to the date of the notification to report;
8.12	(5) (6) the total rebate receivable amount accrued by the PBM for the drug product
8.13	during the 12-month period prior to the date of the notification to report; and
8.14	(6) (7) the total rebate payable amount accrued by the PBM for the drug product during
8.15	the 12-month period prior to the date of the notification to report.
8.16	(c) The PBM may submit any documentation necessary to support the information
8.17	reported under this subdivision.
8.18	Sec. 6. Minnesota Statutes 2023 Supplement, section 62J.84, subdivision 15, is amended
8.19	to read:
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8.20	Subd. 15. Registration requirements. Beginning Effective January 1, 2024, a reporting
8.21	entity subject to this chapter shall register, or update existing registration information, with
8.22	the department in a form and manner prescribed by the commissioner by January 30 of each
8.23	year.