

1.1 Senator moves to amend S.F. No. 2477 as follows:

1.2 Page 1, after line 7, insert:

1.3 "Section 1. Minnesota Statutes 2024, section 13.7191, subdivision 4, is amended to read:

1.4 Subd. 4. **Insurance holding company systems; various insurance data.** Disclosure
1.5 of information obtained by the commissioner of commerce or health under section 60D.18,
1.6 60D.19, or 60D.20 is governed by section 60D.22.

1.7 Sec. 2. Minnesota Statutes 2024, section 60D.15, subdivision 3, is amended to read:

1.8 Subd. 3. **Commissioner.** The term "commissioner" means the commissioner of commerce
1.9 or, for the purposes of regulating health maintenance organizations, the commissioner of
1.10 health, the relevant commissioner's deputies, or the Commerce or Health Department, as
1.11 appropriate.

1.12 Sec. 3. Minnesota Statutes 2024, section 60D.21, subdivision 1, is amended to read:

1.13 Subdivision 1. **Power of commissioner.** Subject to the limitation contained in this section
1.14 and in addition to the powers that the commissioner has under chapter 60A or this chapter
1.15 relating to the examination of insurers, the commissioner shall also have the power to
1.16 examine an insurer registered under section 60D.19 and its affiliates to ascertain the financial
1.17 condition of the insurer, including the enterprise risk to the insurer by the ultimate controlling
1.18 party, or by an entity or combination of entities within the insurance holding company
1.19 system, or by the insurance holding company system on a consolidated basis.

1.20 Sec. 4. Minnesota Statutes 2024, section 60D.21, subdivision 3, is amended to read:

1.21 Subd. 3. **Expenses.** Each registered insurer producing for examination records, books,
1.22 and papers pursuant to subdivision 1 is liable for and shall pay the expense of the examination
1.23 in accordance with section 60A.03 or 62D.14.

1.24 Sec. 5. Minnesota Statutes 2024, section 60D.23, is amended to read:

1.25 **60D.23 RULES.**

1.26 Subdivision 1. **Commissioner of commerce.** The commissioner of commerce may
1.27 adopt the rules and orders that are necessary to carry out the provisions of this chapter.

1.28 Subd. 2. **Commissioner of health.** The commissioner of health may adopt rules and
1.29 orders that are necessary to carry out the provisions of this chapter as they relate to health

2.1 maintenance organizations. Health maintenance organizations are subject to and must comply
2.2 with the provisions of Minnesota Rules, chapter 2720, applicable to insurers, unless the
2.3 commissioner of health adopts rules for health maintenance organizations under this
2.4 subdivision."

2.5 Page 5, after line 25, insert:

2.6 "Sec. 14. Minnesota Statutes 2024, section 62D.221, subdivision 1, is amended to read:

2.7 Subdivision 1. **Insurance provisions applicable to health maintenance**
2.8 **organizations.** Health maintenance organizations are subject to sections 60A.135, 60A.136,
2.9 60A.137, 60A.16, and 60A.161, ~~60D.17, 60D.18, and 60D.20~~ and must comply with the
2.10 provisions of these sections applicable to insurers. ~~In applying these sections to health~~
2.11 ~~maintenance organizations, "commissioner" means the commissioner of health. Health~~
2.12 ~~maintenance organizations are subject to Minnesota Rules, chapter 2720, as applicable to~~
2.13 ~~sections 60D.17, 60D.18, and 60D.20, and must comply with the provisions of chapter 2720~~
2.14 ~~applicable to insurers, unless the commissioner of health adopts rules to implement this~~
2.15 ~~subdivision.~~

2.16 Sec. 15. Minnesota Statutes 2024, section 62J.461, subdivision 3, is amended to read:

2.17 Subd. 3. **Reporting by covered entities to the commissioner.** (a) Each 340B covered
2.18 entity shall report to the commissioner by April 1 of each year the following information
2.19 for transactions conducted by the 340B covered entity or on its behalf, and related to its
2.20 participation in the federal 340B program for the previous calendar year:

2.21 (1) the aggregated acquisition cost for prescription drugs obtained under the 340B
2.22 program;

2.23 (2) the aggregated payment amount received for drugs obtained under the 340B program
2.24 and dispensed or administered to patients;

2.25 (i) that are net of the contracted price for insurance claims payments; and

2.26 (ii) that reflect the portion of payment received from grants, cash, or other payment types
2.27 that relate to the dispensing or administering of drugs obtained under the 340B program;

2.28 (3) the number of pricing units dispensed or administered for prescription drugs described
2.29 in clause (2); and

2.30 (4) the aggregated payments made:

2.31 (i) to contract pharmacies to dispense drugs obtained under the 340B program;

3.1 (ii) to any other entity that is not the covered entity and is not a contract pharmacy for
3.2 managing any aspect of the covered entity's 340B program; and

3.3 (iii) for ~~all~~ other internal, direct expenses related to administering the 340B program
3.4 with a detailed description of the direct costs included.

3.5 The information under clauses (2) and (3) must be reported by payer type, including but
3.6 not limited to commercial insurance, medical assistance, MinnesotaCare, and Medicare, in
3.7 the form and manner prescribed by the commissioner.

3.8 (b) For covered entities that are hospitals, the information required under paragraph (a),
3.9 clauses (1) to (3), must also be reported at the national drug code level for the 50 most
3.10 frequently dispensed or administered drugs by the facility under the 340B program.

3.11 (c) Data submitted to the commissioner under paragraphs (a) and (b) are classified as
3.12 nonpublic data, as defined in section 13.02, subdivision 9.

3.13 Sec. 16. Minnesota Statutes 2024, section 62J.461, subdivision 4, is amended to read:

3.14 Subd. 4. **Enforcement and exceptions.** (a) Any ~~health care~~ covered entity subject to
3.15 reporting under this section that fails to provide data in the form and manner prescribed by
3.16 the commissioner is subject to the levy of a fine ~~paid to the commissioner~~ of up to \$500 for
3.17 each day the data are past due. Any fine levied against the entity under this subdivision is
3.18 subject to the contested case and judicial review provisions of sections 14.57 ~~and~~ to 14.69.

3.19 (b) The commissioner may grant an entity an extension of or exemption from the reporting
3.20 obligations under this ~~subdivision~~ section, upon a showing of good cause by the entity.

3.21 Sec. 17. Minnesota Statutes 2024, section 62J.461, subdivision 5, is amended to read:

3.22 Subd. 5. **Reports to the legislature.** By November 15, 2024, and by November 15 of
3.23 each year thereafter, the commissioner shall submit to the chairs and ranking minority
3.24 members of the legislative committees with jurisdiction over health care finance and policy,
3.25 a report that aggregates the data submitted under subdivision 3, paragraphs (a) and (b). ~~The~~
3.26 ~~following information must be included in the report~~ For all 340B entities whose net 340B
3.27 revenue constitutes a significant share, as determined by the commissioner, of all net 340B
3.28 revenue across all 340B covered entities in Minnesota, the following information must also
3.29 be included in the report:

3.30 (1) the information submitted under subdivision 2; and

4.1 (2) for each 340B entity identified in subdivision 2, that entity's 340B net revenue as
4.2 calculated using the data submitted under subdivision 3, paragraph (a), with net revenue
4.3 being subdivision 3, paragraph (a), clause (2), less the sum of subdivision 3, paragraph (a),
4.4 clauses (1) and (4).

4.5 For all other entities, the data in the report must be aggregated to the entity type or groupings
4.6 of entity types in a manner that prevents the identification of an individual entity and any
4.7 entity's specific data value reported for an individual data element.

4.8 Sec. 18. Minnesota Statutes 2024, section 62J.51, subdivision 19a, is amended to read:

4.9 Subd. 19a. **Uniform explanation of benefits document.** "Uniform explanation of
4.10 benefits ~~document~~" means either the document associated with and explaining the details
4.11 of a group purchaser's claim adjudication for services rendered or its electronic equivalent
4.12 under section 62J.581, which is sent to a patient.

4.13 Sec. 19. Minnesota Statutes 2024, section 62J.581, is amended to read:

4.14 **62J.581 STANDARDS FOR MINNESOTA UNIFORM HEALTH CARE**
4.15 **REIMBURSEMENT DOCUMENTS.**

4.16 Subdivision 1. **Minnesota uniform remittance advice.** All group purchasers shall
4.17 provide a uniform claim payment/advice transaction to health care providers when a claim
4.18 is adjudicated. The uniform claim payment/advice transaction shall comply with section
4.19 62J.536, subdivision 1, paragraph (b), and rules adopted under section 62J.536, subdivision
4.20 2.

4.21 Subd. 2. **Minnesota uniform explanation of benefits document.** (a) All group
4.22 purchasers shall provide a uniform explanation of benefits ~~document~~ to health care patients
4.23 when an explanation of benefits ~~document~~ is provided as otherwise required or permitted
4.24 by law. The uniform explanation of benefits ~~document~~ shall comply with the standards
4.25 prescribed in this section.

4.26 (b) Notwithstanding paragraph (a), this section does not apply to group purchasers not
4.27 included as covered entities under United States Code, title 42, sections 1320d to 1320d-8,
4.28 as amended from time to time, and the regulations promulgated under those sections.

4.29 Subd. 3. **Scope.** For purposes of sections 62J.50 to 62J.61, the ~~uniform claim~~
4.30 ~~payment/advice transaction and~~ uniform explanation of benefits ~~document~~ format specified
4.31 in subdivision 4 shall apply to all health care services delivered by a health care provider
4.32 or health care provider organization in Minnesota, regardless of the location of the payer.

5.1 Health care services not paid on an individual claims basis, such as capitated payments, are
5.2 not included in this section. A health plan company is excluded from the requirements in
5.3 ~~subdivisions 1 and~~ subdivision 2 if they comply with section 62A.01, subdivisions 2 and
5.4 3.

5.5 Subd. 4. **Specifications.** (a) The uniform explanation of benefits document shall be
5.6 provided by use of a paper document conforming to the specifications in this section or its
5.7 electronic equivalent under paragraph (b).

5.8 (b) Group purchasers may make the uniform explanation of benefits available in a version
5.9 that can be accessed by health care patients electronically if:

5.10 (1) the group purchaser making the uniform explanation of benefits available
5.11 electronically provides health care patients the ability to choose whether to receive paper,
5.12 electronic, or both paper and electronic versions of their uniform explanation of benefits;

5.13 (2) the group purchaser provides clear, readily accessible information and instructions
5.14 for the patient to communicate their choice; and

5.15 (3) health care patients not responding to the opportunity to make a choice will receive
5.16 at a minimum a paper uniform explanation of benefits.

5.17 (c) The commissioner, after consulting with the Administrative Uniformity Committee,
5.18 shall specify the data elements and definitions for the paper uniform explanation of benefits
5.19 document. ~~The commissioner and the Administrative Uniformity Committee must consult~~
5.20 ~~with the Minnesota Dental Association and Delta Dental Plan of Minnesota before requiring~~
5.21 ~~under this section the use of a paper document for the uniform explanation of benefits~~
5.22 ~~document or the uniform claim payment/advice transaction for dental care services. Any~~
5.23 electronic version of the uniform explanation of benefits must use the same data elements
5.24 and definitions as the paper uniform explanation of benefits.

5.25 ~~Subd. 5. **Effective date.** The requirements in subdivisions 1 and 2 are effective June 30,~~
5.26 ~~2007. The requirements in subdivisions 1 and 2 apply regardless of when the health care~~
5.27 ~~service was provided to the patient.~~

5.28 Sec. 20. Minnesota Statutes 2024, section 62J.84, subdivision 2, is amended to read:

5.29 Subd. 2. **Definitions.** (a) For purposes of this section, the terms defined in this subdivision
5.30 have the meanings given.

5.31 (b) "Biosimilar" means a drug that is produced or distributed pursuant to a biologics
5.32 license application approved under United States Code, title 42, section 262(K)(3).

6.1 (c) "Brand name drug" means a drug that is produced or distributed pursuant to:

6.2 (1) a new drug application approved under United States Code, title 21, section 355(c),
6.3 except for a generic drug as defined under Code of Federal Regulations, title 42, section
6.4 447.502; or

6.5 (2) a biologics license application approved under United States Code, title 42, section
6.6 262(a)(c).

6.7 (d) "Commissioner" means the commissioner of health.

6.8 (e) "Generic drug" means a drug that is marketed or distributed pursuant to:

6.9 (1) an abbreviated new drug application approved under United States Code, title 21,
6.10 section 355(j);

6.11 (2) an authorized generic as defined under Code of Federal Regulations, title 42, section
6.12 447.502; or

6.13 (3) a drug that entered the market the year before 1962 and was not originally marketed
6.14 under a new drug application.

6.15 (f) "Manufacturer" means a drug manufacturer licensed under section 151.252.

6.16 (g) "New prescription drug" or "new drug" means a prescription drug approved for
6.17 marketing by the United States Food and Drug Administration (FDA) for which no previous
6.18 wholesale acquisition cost has been established for comparison.

6.19 (h) "Patient assistance program" means a program that a manufacturer offers to the public
6.20 in which a consumer may reduce the consumer's out-of-pocket costs for prescription drugs
6.21 by using coupons, discount cards, prepaid gift cards, manufacturer debit cards, or by other
6.22 means.

6.23 (i) "Prescription drug" or "drug" has the meaning provided in section 151.441, subdivision
6.24 8.

6.25 (j) "Price" means the wholesale acquisition cost as defined in United States Code, title
6.26 42, section 1395w-3a(c)(6)(B).

6.27 (k) "30-day supply" means the total daily dosage units of a prescription drug
6.28 recommended by the prescribing label approved by the FDA for 30 days. If the
6.29 FDA-approved prescribing label includes more than one recommended daily dosage, the
6.30 30-day supply is based on the maximum recommended daily dosage on the FDA-approved
6.31 prescribing label.

7.1 (l) "Course of treatment" means the total dosage of a single prescription for a prescription
7.2 drug recommended by the FDA-approved prescribing label. If the FDA-approved prescribing
7.3 label includes more than one recommended dosage for a single course of treatment, the
7.4 course of treatment is the maximum recommended dosage on the FDA-approved prescribing
7.5 label.

7.6 (m) "Drug product family" means a group of one or more prescription drugs that share
7.7 a unique generic drug description or nontrade name and dosage form.

7.8 ~~(n) "Individual salable unit" means the smallest container of product introduced into~~
7.9 ~~commerce by the manufacturer or repackager that is intended by the manufacturer or~~
7.10 ~~repackager for individual sale to a dispenser.~~

7.11 ~~(n)~~ (n) "National drug code" means the three-segment code maintained by the federal
7.12 Food and Drug Administration that includes a labeler code, a product code, and a package
7.13 code for a drug product and that has been converted to an 11-digit format consisting of five
7.14 digits in the first segment, four digits in the second segment, and two digits in the third
7.15 segment. A three-segment code shall be considered converted to an 11-digit format when,
7.16 as necessary, at least one "0" has been added to the front of each segment containing less
7.17 than the specified number of digits such that each segment contains the specified number
7.18 of digits.

7.19 ~~(p)~~ (o) "Pharmacy" or "pharmacy provider" means a community/outpatient pharmacy
7.20 as defined in Minnesota Rules, part 6800.0100, subpart 2, that is also licensed as a pharmacy
7.21 by the Board of Pharmacy under section 151.19.

7.22 ~~(p)~~ (p) "Pharmacy benefit manager" or "PBM" means an entity licensed to act as a
7.23 pharmacy benefit manager under section 62W.03.

7.24 ~~(q)~~ (q) "Pricing unit" means the smallest dispensable amount of a prescription drug
7.25 product that could be dispensed or administered.

7.26 ~~(r)~~ (r) "Rebate" means a discount, chargeback, or other price concession that affects the
7.27 price of a prescription drug product, regardless of whether conferred through regular
7.28 aggregate payments, on a claim-by-claim basis at the point of sale, as part of retrospective
7.29 financial reconciliations, including reconciliations that also reflect other contractual
7.30 arrangements, or by any other method. "Rebate" does not mean a bona fide service fee as
7.31 defined in Code of Federal Regulations, title 42, section 447.502.

7.32 ~~(s)~~ (s) "Reporting entity" means any manufacturer, pharmacy, pharmacy benefit manager,
7.33 wholesale drug distributor, or any other entity required to submit data under this section.

8.1 ~~(t)~~ (t) "Wholesale drug distributor" or "wholesaler" means an entity that:
8.2 ~~(1)~~ is licensed to act as a wholesale drug distributor under section 151.47; ~~and~~
8.3 ~~(2)~~ distributes prescription drugs, for which it is not the manufacturer, to persons or
8.4 entities, or both, other than a consumer or patient in the state.

8.5 Sec. 21. Minnesota Statutes 2024, section 62J.84, subdivision 3, is amended to read:

8.6 Subd. 3. **Prescription drug price increases reporting.** (a) Beginning January 1, 2022,
8.7 a drug manufacturer must submit to the commissioner the information described in paragraph
8.8 (b) for each prescription drug for which the price was \$100 or greater for a 30-day supply
8.9 or for a course of treatment lasting less than 30 days ~~and~~:

8.10 ~~(1)~~ for brand name drugs where there is an increase of ten percent or greater in the price
8.11 over the previous 12-month period or an increase of 16 percent or greater in the price over
8.12 the previous 24-month period; ~~and~~

8.13 ~~(2)~~ for generic or biosimilar drugs where there is an increase of 50 percent or greater in
8.14 the price over the previous 12-month period.

8.15 (b) For each of the drugs described in paragraph (a), the manufacturer shall submit to
8.16 the commissioner no later than 60 days after the price increase goes into effect, in the form
8.17 and manner prescribed by the commissioner, the following information, if applicable:

8.18 (1) the description and price of the drug and the net increase, expressed as a percentage,
8.19 with the following listed separately:

8.20 (i) the national drug code;

8.21 (ii) the product name;

8.22 (iii) the dosage form;

8.23 (iv) the strength; and

8.24 (v) the package size;

8.25 (2) the factors that contributed to the price increase;

8.26 (3) the name of any generic version of the prescription drug available on the market;

8.27 (4) the year the prescription drug was introduced for sale in the United States;

8.28 ~~(4)~~ (5) the introductory price of the prescription drug when it was introduced for sale in
8.29 the United States and the price of the drug on the last day of each of the five calendar years
8.30 preceding the price increase;

- 9.1 ~~(5)~~ (6) the direct costs incurred during the previous 12-month period by the manufacturer
- 9.2 that are associated with the prescription drug, listed separately:
- 9.3 (i) to manufacture the prescription drug;
- 9.4 (ii) to market the prescription drug, including advertising costs; and
- 9.5 (iii) to distribute the prescription drug;
- 9.6 (7) the number of units of the prescription drug sold during the previous 12-month period;
- 9.7 ~~(6)~~ (8) the total sales revenue for the prescription drug during the previous 12-month
- 9.8 period;
- 9.9 (9) the total rebate payable amount accrued for the prescription drug during the previous
- 9.10 12-month period;
- 9.11 ~~(7)~~ (10) the manufacturer's net profit attributable to the prescription drug during the
- 9.12 previous 12-month period;
- 9.13 ~~(8)~~ (11) the total amount of financial assistance the manufacturer has provided through
- 9.14 patient prescription assistance programs during the previous 12-month period, if applicable;
- 9.15 ~~(9)~~ (12) any agreement between a manufacturer and another entity contingent upon any
- 9.16 delay in offering to market a generic version of the prescription drug;
- 9.17 ~~(10)~~ (13) the patent expiration date of the prescription drug if it is under patent;
- 9.18 ~~(11)~~ (14) the name and location of the company that manufactured the drug;
- 9.19 ~~(12)~~ (15) if a brand name prescription drug, the highest price paid for the prescription
- 9.20 drug during the previous calendar year in the ten countries, excluding the United States,
- 9.21 that charged the highest single price for the prescription drug; and
- 9.22 ~~(13)~~ (16) if the prescription drug was acquired by the manufacturer during the previous
- 9.23 12-month period, all of the following information:
- 9.24 (i) price at acquisition;
- 9.25 (ii) price in the calendar year prior to acquisition;
- 9.26 (iii) name of the company from which the drug was acquired;
- 9.27 (iv) date of acquisition; and
- 9.28 (v) acquisition price.
- 9.29 (c) The manufacturer may submit any documentation necessary to support the information
- 9.30 reported under this subdivision.

10.1 Sec. 22. Minnesota Statutes 2024, section 62J.84, subdivision 6, is amended to read:

10.2 Subd. 6. **Public posting of prescription drug price information.** (a) The commissioner
10.3 shall post on the department's website, or may contract with a private entity or consortium
10.4 that satisfies the standards of section 62U.04, subdivision 6, to meet this requirement, the
10.5 following information:

10.6 (1) a list of the prescription drugs reported under subdivisions 3, 4, and 11 to 14 and the
10.7 manufacturers of those prescription drugs; ~~and~~

10.8 (2) a list of reporting entities that reported prescription drug price information under
10.9 subdivisions 3, 4, and 11 to 14; and

10.10 ~~(2)~~ (3) information reported to the commissioner under subdivisions 3, 4, and 11 to 14,
10.11 aggregated on a per-drug basis in a manner that does not allow the identification of a reporting
10.12 entity that is not the manufacturer of the drug.

10.13 (b) The information must be published in an easy-to-read format and in a manner that
10.14 identifies the information that is disclosed on a per-drug basis and must not be aggregated
10.15 in a manner that prevents the identification of the prescription drug.

10.16 (c) The commissioner shall not post to the department's website or a private entity
10.17 contracting with the commissioner shall not post any information described in this section
10.18 if the information is not public data under section 13.02, subdivision 8a; or is trade secret
10.19 information under section 13.37, subdivision 1, paragraph (b); or is trade secret information
10.20 pursuant to the Defend Trade Secrets Act of 2016, United States Code, title 18, section
10.21 1836, as amended. If a reporting entity believes information should be withheld from public
10.22 disclosure pursuant to this paragraph, the reporting entity must clearly and specifically
10.23 identify that information and describe the legal basis in writing when the reporting entity
10.24 submits the information under this section. If the commissioner disagrees with the reporting
10.25 entity's request to withhold information from public disclosure, the commissioner shall
10.26 provide the reporting entity written notice that the information will be publicly posted 30
10.27 days after the date of the notice.

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

10.32 (e) To the extent the information required to be posted under this subdivision is collected
10.33 and made available to the public by another state, by the University of Minnesota, or through

11.1 an online drug pricing reference and analytical tool, the commissioner may reference the
11.2 availability of this drug price data from another source including, within existing
11.3 appropriations, creating the ability of the public to access the data from the source for
11.4 purposes of meeting the reporting requirements of this subdivision.

11.5 Sec. 23. Minnesota Statutes 2024, section 62J.84, subdivision 10, is amended to read:

11.6 Subd. 10. **Notice of prescription drugs of substantial public interest.** (a) No later than
11.7 January 31, 2024, and quarterly thereafter, the commissioner shall produce and post on the
11.8 department's website a list of prescription drugs that the commissioner determines to represent
11.9 a substantial public interest and for which the commissioner intends to request data under
11.10 subdivisions 11 to 14, subject to paragraph (c). The commissioner shall base its inclusion
11.11 of prescription drugs on any information the commissioner determines is relevant to providing
11.12 greater consumer awareness of the factors contributing to the cost of prescription drugs in
11.13 the state, and the commissioner shall consider drug product families that include prescription
11.14 drugs:

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

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

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

11.20 (b) Not sooner than 30 days after publicly posting the list of prescription drugs under
11.21 paragraph (a), the department shall notify, via email, reporting entities registered with the
11.22 department of:

11.23 (1) the requirement to report under subdivisions 11 to 14; and

11.24 (2) the reporting period for which data must be provided.

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

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

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

12.1 Sec. 24. Minnesota Statutes 2024, section 62J.84, subdivision 11, is amended to read:

12.2 Subd. 11. **Manufacturer prescription drug substantial public interest reporting.** (a)
12.3 Beginning January 1, 2024, a manufacturer must submit to the commissioner the information
12.4 described in paragraph (b) for any prescription drug:

12.5 (1) included in a notification to report issued to the manufacturer by the department
12.6 under subdivision 10;

12.7 (2) which the manufacturer manufactures or repackages;

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

12.9 (4) for which the manufacturer has not submitted data under subdivision 3 during the
12.10 120-day period prior to the date of the notification to report.

12.11 (b) For each of the drugs described in paragraph (a), the manufacturer shall submit to
12.12 the commissioner no later than 60 days after the date of the notification to report, in the
12.13 form and manner prescribed by the commissioner, the following information, if applicable:

12.14 (1) a description of the drug with the following listed separately:

12.15 (i) the national drug code;

12.16 (ii) the product name;

12.17 (iii) the dosage form;

12.18 (iv) the strength; and

12.19 (v) the package size;

12.20 (2) the price of the drug product on the later of:

12.21 (i) the day one year prior to the date of the notification to report;

12.22 (ii) the introduced to market date; or

12.23 (iii) the acquisition date;

12.24 (3) the price of the drug product on the date of the notification to report;

12.25 (4) the year the prescription drug was introduced for sale in the United States;

12.26 ~~(4)~~ (5) the introductory price of the prescription drug when it was introduced for sale in
12.27 the United States and the price of the drug on the last day of each of the five calendar years
12.28 preceding the date of the notification to report;

- 13.1 ~~(5)~~ (6) the direct costs incurred during the ~~12-month period prior to the date of reporting~~
13.2 period specified in the notification to report by the manufacturers that are associated with
13.3 the prescription drug, listed separately:
- 13.4 (i) to manufacture the prescription drug;
- 13.5 (ii) to market the prescription drug, including advertising costs; and
- 13.6 (iii) to distribute the prescription drug;
- 13.7 ~~(6)~~ (7) the number of units of the prescription drug sold during the ~~12-month period~~
13.8 prior to the date of reporting period specified in the notification to report;
- 13.9 ~~(7)~~ (8) the total sales revenue for the prescription drug during the ~~12-month period prior~~
13.10 to the date of reporting period specified in the notification to report;
- 13.11 ~~(8)~~ (9) the total rebate payable amount accrued for the prescription drug during the
13.12 ~~12-month period prior to the date of reporting period specified in the notification to report~~;
- 13.13 ~~(9)~~ (10) the manufacturer's net profit attributable to the prescription drug during the
13.14 ~~12-month period prior to the date of reporting period specified in the notification to report~~;
- 13.15 ~~(10)~~ (11) the total amount of financial assistance the manufacturer has provided through
13.16 patient prescription assistance programs during the ~~12-month period prior to the date of~~
13.17 reporting period specified in the notification to report, if applicable;
- 13.18 ~~(11)~~ (12) any agreement between a manufacturer and another entity contingent upon
13.19 any delay in offering to market a generic version of the prescription drug;
- 13.20 ~~(12)~~ (13) the patent expiration date of the prescription drug if the prescription drug is
13.21 under patent;
- 13.22 ~~(13)~~ (14) the name and location of the company that manufactured the drug;
- 13.23 ~~(14)~~ (15) if the prescription drug is a brand name prescription drug, the ten countries
13.24 other than the United States that paid the highest prices for the prescription drug during the
13.25 previous calendar year and their prices; and
- 13.26 ~~(15)~~ (16) if the prescription drug was acquired by the manufacturer within a ~~12-month~~
13.27 period prior to the date of the reporting period specified in the notification to report, all of
13.28 the following information:
- 13.29 (i) the price at acquisition;
- 13.30 (ii) the price in the calendar year prior to acquisition;
- 13.31 (iii) the name of the company from which the drug was acquired;

14.1 (iv) the date of acquisition; and

14.2 (v) the acquisition price.

14.3 (c) The manufacturer may submit any documentation necessary to support the information
14.4 reported under this subdivision.

14.5 Sec. 25. Minnesota Statutes 2024, section 62J.84, subdivision 12, is amended to read:

14.6 Subd. 12. **Pharmacy prescription drug substantial public interest reporting.** (a)
14.7 Beginning January 1, 2024, a pharmacy must submit to the commissioner the information
14.8 described in paragraph (b) for any prescription drug:

14.9 (1) included in a notification to report issued to the pharmacy by the department under
14.10 subdivision 10; and

14.11 (2) that the pharmacy dispensed in Minnesota or mailed to a Minnesota address.

14.12 (b) For each of the drugs described in paragraph (a), the pharmacy shall submit to the
14.13 commissioner no later than 60 days after the date of the notification to report, in the form
14.14 and manner prescribed by the commissioner, the following information, if applicable:

14.15 (1) a description of the drug with the following listed separately:

14.16 (i) the national drug code;

14.17 (ii) the product name;

14.18 (iii) the dosage form;

14.19 (iv) the strength; and

14.20 (v) the package size;

14.21 (2) the number of units of the drug acquired during the ~~12-month period prior to the date~~
14.22 ~~of reporting period specified in the notification to report;~~

14.23 (3) the total spent before rebates by the pharmacy to acquire the drug during the ~~12-month~~
14.24 ~~period prior to the date of~~ reporting period specified in the notification to report;

14.25 (4) the total rebate receivable amount accrued by the pharmacy for the drug during the
14.26 ~~12-month period prior to the date of~~ reporting period specified in the notification to report;

14.27 (5) the number of pricing units of the drug dispensed by the pharmacy during the
14.28 ~~12-month period prior to the date of~~ reporting period specified in the notification to report;

15.1 (6) the total payment receivable by the pharmacy for dispensing the drug including
15.2 ingredient cost, dispensing fee, and administrative fees during the ~~12-month period prior~~
15.3 ~~to the date of~~ reporting period specified in the notification to report;

15.4 (7) the total rebate payable amount accrued by the pharmacy for the drug during the
15.5 ~~12-month period prior to the date of~~ reporting period specified in the notification to report;
15.6 and

15.7 (8) the average cash price paid by consumers per pricing unit for prescriptions dispensed
15.8 where no claim was submitted to a health care service plan or health insurer during the
15.9 ~~12-month period prior to the date of~~ reporting period specified in the notification to report.

15.10 (c) The pharmacy may submit any documentation necessary to support the information
15.11 reported under this subdivision.

15.12 (d) The commissioner may grant extensions, exemptions, or both to compliance with
15.13 the requirements of paragraphs (a) and (b) by small or independent pharmacies, if compliance
15.14 with paragraphs (a) and (b) would represent a hardship or undue burden to the pharmacy.
15.15 The commissioner may establish procedures for small or independent pharmacies to request
15.16 extensions or exemptions under this paragraph.

15.17 Sec. 26. Minnesota Statutes 2024, section 62J.84, subdivision 13, is amended to read:

15.18 Subd. 13. **PBM prescription drug substantial public interest reporting.** (a) Beginning
15.19 January 1, 2024, a PBM must submit to the commissioner the information described in
15.20 paragraph (b) for any prescription drug:

15.21 (1) included in a notification to report issued to the PBM by the department under
15.22 subdivision 10; and

15.23 (2) for which the PBM fulfilled pharmacy benefit management duties for Minnesota
15.24 residents.

15.25 (b) For each of the drugs described in paragraph (a), the PBM shall submit to the
15.26 commissioner no later than 60 days after the date of the notification to report, in the form
15.27 and manner prescribed by the commissioner, the following information, if applicable:

15.28 (1) a description of the drug with the following listed separately:

15.29 (i) the national drug code;

15.30 (ii) the product name;

15.31 (iii) the dosage form;

16.1 (iv) the strength; and

16.2 (v) the package size;

16.3 (2) the number of pricing units of the drug product filled ~~for which the PBM administered~~
16.4 ~~claims during the 12-month period prior to the date of~~ reporting period specified in the
16.5 notification to report;

16.6 (3) the total reimbursement amount accrued and payable to pharmacies for pricing units
16.7 of the drug product filled ~~for which the PBM administered claims during the 12-month~~
16.8 ~~period prior to the date of~~ reporting period specified in the notification to report;

16.9 (4) the total reimbursement ~~or administrative fee amount, or both,~~ accrued and receivable
16.10 from payers for pricing units of the drug product filled ~~for which the PBM administered~~
16.11 ~~claims during the 12-month period prior to the date of~~ reporting period specified in the
16.12 notification to report;

16.13 (5) the total administrative fee amount accrued and receivable from payers for pricing
16.14 units of the drug product filled during the reporting period specified in the notification to
16.15 report;

16.16 ~~(5)~~ (6) the total rebate receivable amount accrued by the PBM for the drug product
16.17 during the ~~12-month period prior to the date of~~ reporting period specified in the notification
16.18 to report; and

16.19 ~~(6)~~ (7) the total rebate payable amount accrued by the PBM for the drug product during
16.20 the ~~12-month period prior to the date of~~ reporting period specified in the notification to
16.21 report.

16.22 (c) The PBM may submit any documentation necessary to support the information
16.23 reported under this subdivision.

16.24 Sec. 27. Minnesota Statutes 2024, section 62J.84, subdivision 14, is amended to read:

16.25 Subd. 14. **Wholesale drug distributor prescription drug substantial public interest**
16.26 **reporting.** (a) Beginning January 1, 2024, a wholesale drug distributor that distributes
16.27 prescription drugs, for which it is not the manufacturer, to persons or entities, or both, other
16.28 than a consumer or patient in the state, must submit to the commissioner the information
16.29 described in paragraph (b) for any prescription drug:

16.30 (1) included in a notification to report issued to the wholesale drug distributor by the
16.31 department under subdivision 10-; and

16.32 (2) that the wholesale drug distributor distributed within or into Minnesota.

17.1 (b) For each of the drugs described in paragraph (a), the wholesale drug distributor shall
17.2 submit to the commissioner no later than 60 days after the date of the notification to report,
17.3 in the form and manner prescribed by the commissioner, the following information, if
17.4 applicable:

17.5 (1) a description of the drug with the following listed separately:

17.6 (i) the national drug code;

17.7 (ii) the product name;

17.8 (iii) the dosage form;

17.9 (iv) the strength; and

17.10 (v) the package size;

17.11 (2) the number of units of the drug product acquired by the wholesale drug distributor
17.12 during the ~~12-month period prior to the date of~~ reporting period specified in the notification
17.13 to report;

17.14 (3) the total spent before rebates by the wholesale drug distributor to acquire the drug
17.15 product during the ~~12-month period prior to the date of~~ reporting period specified in the
17.16 notification to report;

17.17 (4) the total rebate receivable amount accrued by the wholesale drug distributor for the
17.18 drug product during the ~~12-month period prior to the date of~~ reporting period specified in
17.19 the notification to report;

17.20 (5) the number of units of the drug product sold by the wholesale drug distributor during
17.21 the ~~12-month period prior to the date of~~ reporting period specified in the notification to
17.22 report;

17.23 (6) gross revenue from sales in the United States generated by the wholesale drug
17.24 distributor for ~~this~~ the drug product during the ~~12-month period prior to the date of~~ reporting
17.25 period specified in the notification to report; and

17.26 (7) total rebate payable amount accrued by the wholesale drug distributor for the drug
17.27 product during the ~~12-month period prior to the date of~~ reporting period specified in the
17.28 notification to report.

17.29 (c) The wholesale drug distributor may submit any documentation necessary to support
17.30 the information reported under this subdivision.

18.1 Sec. 28. Minnesota Statutes 2024, section 62J.84, subdivision 15, is amended to read:

18.2 Subd. 15. **Registration requirements.** ~~Beginning~~ Effective January 1, ~~2024~~ 2026, a
18.3 reporting entity subject to this chapter shall register, or update existing registration
18.4 information, with the department in a form and manner prescribed by the commissioner by
18.5 January 30 of each year.

18.6 Sec. 29. Minnesota Statutes 2024, section 62K.10, subdivision 2, is amended to read:

18.7 Subd. 2. ~~Primary care; mental health services; general hospital services~~ Time and
18.8 distance standards. ~~The maximum travel distance or time shall be the lesser of 30 miles~~
18.9 ~~or 30 minutes to the nearest provider of each of the following services: primary care services,~~
18.10 ~~mental health services, and general hospital services~~ Health carriers must meet the time and
18.11 distance standards under Code of Federal Regulations, title 45, section 155.1050.

18.12 Sec. 30. Minnesota Statutes 2024, section 62K.10, subdivision 5, is amended to read:

18.13 Subd. 5. **Waiver.** (a) A health carrier may apply to the commissioner of health for a
18.14 waiver of the requirements in subdivision 2 ~~or 3~~ if it is unable to meet the statutory
18.15 requirements. A waiver application must be submitted on a form provided by the
18.16 commissioner, must be accompanied by an application fee of \$500 for each application to
18.17 waive the requirements in subdivision 2 ~~or 3~~ for one or more provider types per county, and
18.18 must:

18.19 (1) demonstrate with specific data that the requirement of subdivision 2 ~~or 3~~ is not
18.20 feasible in a particular service area or part of a service area; and

18.21 (2) include specific information as to the steps that were and will be taken to address
18.22 the network inadequacy, and, for steps that will be taken prospectively to address network
18.23 inadequacy, the time frame within which those steps will be taken.

18.24 (b) The commissioner shall establish guidelines for evaluating waiver applications,
18.25 standards governing approval or denial of a waiver application, and standards for steps that
18.26 health carriers must take to address the network inadequacy and allow the health carrier to
18.27 meet network adequacy requirements within a reasonable time period. The commissioner
18.28 shall review each waiver application using these guidelines and standards and shall approve
18.29 a waiver application only if:

18.30 (1) the standards for approval established by the commissioner are satisfied; and

18.31 (2) the steps that were and will be taken to address the network inadequacy and the time
18.32 frame for taking these steps satisfy the standards established by the commissioner.

19.1 (c) If, in its waiver application, a health carrier demonstrates to the commissioner that
 19.2 there are no providers of a specific type or specialty in a county, the commissioner may
 19.3 approve a waiver in which the health carrier is allowed to address network inadequacy in
 19.4 that county by providing for patient access to providers of that type or specialty via telehealth,
 19.5 as defined in section 62A.673, subdivision 2.

19.6 (d) The waiver shall automatically expire after one year. Upon or prior to expiration of
 19.7 a waiver, a health carrier unable to meet the requirements in subdivision 2 ~~or 3~~ must submit
 19.8 a new waiver application under paragraph (a) and must also submit evidence of steps the
 19.9 carrier took to address the network inadequacy. When the commissioner reviews a waiver
 19.10 application for a network adequacy requirement which has been waived for the carrier for
 19.11 the most recent one-year period, the commissioner shall also examine the steps the carrier
 19.12 took during that one-year period to address network inadequacy, and shall only approve a
 19.13 subsequent waiver application that satisfies the requirements in paragraph (b), demonstrates
 19.14 that the carrier took the steps it proposed to address network inadequacy, and explains why
 19.15 the carrier continues to be unable to satisfy the requirements in subdivision 2 ~~or 3~~.

19.16 (e) Application fees collected under this subdivision shall be deposited in the state
 19.17 government special revenue fund in the state treasury.

19.18 Sec. 31. Minnesota Statutes 2024, section 62K.10, subdivision 6, is amended to read:

19.19 Subd. 6. **Referral centers.** ~~Subdivisions~~ Subdivision 2 and 3 shall not apply if an enrollee
 19.20 is referred to a referral center for health care services. A referral center is a medical facility
 19.21 that provides highly specialized medical care, including but not limited to organ transplants.
 19.22 A health carrier or preferred provider organization may consider the volume of services
 19.23 provided annually, case mix, and severity adjusted mortality and morbidity rates in
 19.24 designating a referral center.

19.25 Sec. 32. **REPEALER.**

19.26 Minnesota Statutes 2024, section 62K.10, subdivision 3, is repealed."

19.27 Renumber the sections in sequence and correct the internal references

19.28 Amend the title accordingly