Bill Summary

H.F. 294

First engrossment

Subject	**Prescription Drug Price Reporting and Benefit Transparency**
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Overview

This bill establishes requirements for reporting and maintaining prescription drug prices and requirements for transparency of prescription drug benefits. Article 1 requires health carriers to file drug formularies with the commissioner of commerce, requires drug manufacturers to report price and other information for certain drugs, and prohibits price increases for formulary drugs subject to reporting. Article 2 modifies requirements for electronic prescribing, establishes requirements for health plan companies to make available formularies and related benefit information, and establishes requirements for formulary changes made by health plan companies.

Article 1: Reporting and Maintaining Prescription Drug Prices

This article requires health carriers to include health plan prescription drug formulary information when filing premium rates. The article also requires drug manufacturers to report drug price and other information for certain drugs and prohibits manufacturers from increasing the price of those drugs for the next calendar year, if they are included in a health plan formulary that has been approved by the commissioner of commerce. The article also expands the scope of an existing report to the legislature on drug price transparency and makes the failure by a manufacturer to comply with reporting and price stabilization requirements grounds for civil penalties or disciplinary action.

Section	Description - Article 1: Reporting and Maintaining Prescription Drug Prices
1	**Filing.** Amends § 62A.02, subd. 1. Requires health carriers to include the health plan's prescription drug formulary, when filing premium rates with the commissioner of commerce. Requires proposed revisions to the formulary to be filed with the commissioner by August 1 of the application year.

Section	Description - Article 1: Reporting and Maintaining Prescription Drug Prices

2 **Definitions.**

Amends § 62J.84, subd. 2. Applies the definitions in this subdivision (related to prescription drug transparency reporting) to § 62J.841. Also specifies that "manufacturer" does not include an entity licensed as a drug manufacturer solely because it repackages or relabels drugs.

3 **Public posting of prescription drug price information.**

Amends § 62J.84, subd. 6. Requires the commissioner of health to post drug pricing and related information reported under § 62J.841, subd. 2, on the agency website. Also provides that the prohibition on posting trade secret information does not apply to this drug pricing and related information, reported under § 62J.841, subd. 2, paragraph (e), if that information is classified by the manufacturer as trade secret information. (This information is classified as public data under paragraph (e) of that subdivision; paragraph (e) also prohibits a manufacturer from classifying the information reported as trade secret information.)

4 **Consultation.**

Amends § 62J.84, subd. 7. Allows the commissioner to consult with a private entity or consortium for assistance in collecting and posting the drug pricing and related information collected under § 62J.841. (Under current law, the commissioner may consult with this entity or consortium to implement prescription drug transparency reporting.)

5 **Enforcement and penalties.**

Amends § 62J.84, subd. 8. Allows the commissioner of health to impose civil penalties on manufacturers for:

1) failing to submit timely reports or notices as required by section 62J.841;
2) failing to provide information required by section 62J.841;
3) providing inaccurate or incomplete information under section 62J.841; and
4) classifying drug price and other information submitted under section 62J.841 as trade secret information or increasing the wholesale acquisition cost for drugs subject to price reporting and included in a health plan formulary, for the next calendar year.

Also makes conforming changes.

6 **Legislative report.**

Amends § 62J.84, subd. 9. Modifies requirements for the annual report to the legislature related to drug transparency, to:

Section	Description - Article 1: Reporting and Maintaining Prescription Drug Prices

1) include reporting related to section 62J.841; and
2) require the commissioner to assess whether reporting promotes pricing transparency for health carriers, assists health carriers in managing drug costs, and assists health carriers and other payers in limiting formulary changes due to cost increases during a coverage year.

7 **Reporting prescription drug prices; formulary development and price stability.**

Adds § 62J.841.

Subd. 1. Definitions. Defines the following terms: average wholesale price, national drug code, wholesale acquisition cost, and unit.

Subd. 2. Price reporting. (a) Requires drug manufacturers, beginning July 31, 2024, and each July 31 thereafter, to report the information in paragraph (b) for each drug with a wholesale acquisition cost of $100 or more (for a 30-day supply or course of treatment lasting less than 30 days), for the next calendar year.

(b) Requires manufacturers to report a drug's:

1) national drug code, labeler code, and manufacturer name associated with the labeler code;
2) brand name, if applicable;
3) generic name, if applicable;
4) wholesale acquisition cost (WAC) for one unit;
5) measure that constitutes a WAC unit;
6) average wholesale price; and
7) status as brand name or generic.

(c) Requires the effective date of the information in (b) to be included in the report to the commissioner.

(d) Requires a manufacturer to report information in the form and manner specified by the commissioner.

(e) Classifies the information reported under this subdivision as public data not on individuals, and prohibits manufacturers from classifying the information as trade secret.

(f) Provides that the failure of a manufacturer to report required information is grounds for disciplinary action by the Board of Pharmacy.

Section	Description - Article 1: Reporting and Maintaining Prescription Drug Prices
	Subd. 3. Public posting of prescription drug price information. Requires the commissioner, by October 1 of each year, beginning October 1, 2024, to post the information reported under subdivision 2 on the department's website. **Subd. 4. Price change.** (a) If a drug is subject to price reporting under subdivision 2 and has been included in a health plan formulary that has been approved by the commissioner of commerce, allows the manufacturer to increase the WAC of that drug for the next calendar year only after providing the commissioner with at least 90 days' written notice. (b) States that a manufacturer's failure to comply with paragraph (a) is grounds for disciplinary action by the Board of Pharmacy.
8	**Grounds for disciplinary action.** Amends § 151.071, subd. 2. Classifies the failure of a drug manufacturer to comply with the requirements of § 62J.841 (drug price reporting and prohibition on certain drug price changes) as grounds for disciplinary action by the Board of Pharmacy.

Article 2: Prescription Drug Benefit Transparency

This article modifies standards for electronic prescribing, requires health plan companies to make available formulary and related benefit information at least 30 days before annual renewal dates, and establishes requirements for formulary changes made by health plan companies.

Section	Description – Article 2: Prescription Drug Benefit Transparency
1	**Definitions.** Amends § 62J.497, subd. 1. Adds definitions of NCPDP Real-Time Prescription Benefit Standard, pharmacy benefit manager, and real-time prescription benefit tool to the statute governing the electronic prescription drug program.
2	**Standards for electronic prescribing.** Amends § 62J.497, subd. 3. In a subdivision establishing standards for electronic prescribing, a new paragraph (f) requires group purchasers and pharmacy benefit managers to use a real-time prescription benefit tool that complies with the NCPDP Real-Time Prescription Benefit Standard and that notifies a prescriber of at least the listed information for a prescribed drug. This section is effective January 1, 2024.

Section	Description – Article 2: Prescription Drug Benefit Transparency

3 **Prescription drug benefit transparency and management.**

Adds § 62Q.83.

Subd. 1. Definitions. Defines the following terms for this section: drug, enrollee contract term, formulary, health plan company, and prescription.

Subd. 2. Prescription drug benefit disclosure. Paragraph (a) requires a health plan company that provides prescription drug coverage and uses a formulary to make the plan's formulary and related benefit information available at least 30 days before annual renewal dates.

Paragraph (b) requires formularies to be organized and disclosed consistent with the most recent version of the United States Pharmacopeia's Model Guidelines.

Paragraph (c) requires the specific enrollee benefit terms, including cost-sharing and expected out-of-pocket costs, to be identified for each item or category of items on the formulary.

Subd. 3. Formulary changes. Paragraph (a) allows a health plan company, at any time during a contract term, to expand its formulary, reduce copayments or coinsurance, or move a drug to a benefit category that reduces an enrollee's cost.

Paragraph (b) allows a health plan company to remove a brand name drug from the formulary or place a brand name drug in a benefit category that increases the enrollee's cost if the health plan company also adds a generic or multisource brand name drug rated as therapeutically equivalent, or a biologic drug rated as interchangeable, that is at a lower cost to the enrollee. The health plan company must also provide at least 60 days' notice before making this change.

Paragraph (c) allows a health plan company to change utilization review requirements or move drugs to a benefit category that increases an enrollee's cost during the contract term with at least 60 days' notice. Specifies that these changes do not apply to enrollees currently taking these drugs for the duration of the enrollees' contract terms.

Paragraph (d) allows a health plan company to remove a drug from the plan's formulary if the drug has been deemed unsafe by the Food and Drug Administration or withdrawn by the FDA or the product manufacturer, or when an independent source of research, clinical guidelines, or evidence-based standards issues drug-specific warnings or recommends changes in drug use.

Section	Description – Article 2: Prescription Drug Benefit Transparency

Subd. 4. Not severable. States that this section is not severable from article 1 of this act. If any provision in article 1 is void for any reason, this section is void also.

This section is effective January 1, 2024, and applies to health plans offered, sold, issued, or renewed on or after that date.