MN HOUSE RESEARCH

Bill Summary

H.F. 1718

First engrossment

Subject	Board of Pharmacy
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Overview

This bill makes clarifying changes to the Pharmacy Practice Act, chapter 151, modifies licensing for wholesale distributors, and creates licensure for third-party logistics providers.

Summary

Section	Description
1	**Central service pharmacy.** Amends § 151.01, subd. 31. Clarifies the definition of "central service pharmacy."
2	**Compounding.** Amends § 151.01, subd. 35. Clarifies that for mixing or reconstituting a drug according to a product's label or manufacturer directions, the label must be approved by the FDA or manufacturer must be licensed.
3	**Syringe services provider.** Amends § 151.01 by adding subd. 42. Adds definition for "syringe services provider."
4	**Application fees.** Amends § 151.065, subd. 1. Modifies application fees by removing drug wholesalers and adding third-party logistics providers, and removing drug manufacturer application fees.

Section	Description
5	**Annual renewal fees.** Amends § 151.065, subd. 3. Modifies annual renewal fees by removing drug wholesalers and adding third-party logistics providers, and removing drug manufacturer renewal fees.
6	**Reinstatement fees.** Amends § 151.065, subd. 6. Modifies license reinstatement fees by adding third-party logistics providers.
7	**Grounds for disciplinary action.** Amends § 151.071, subd. 2. Updates terminology; adds provision to actions that constitute fee splitting addressing price setting arrangements between pharmacies and physicians, and pharmacies and veterinarians.
8	**Location.** Amends § 151.15, subd. 1. Makes clarifying change; allows a licensed pharmacist or pharmacist intern working within a hospital to receive a prescription order and access the hospital pharmacy's processing system through secure and encrypted electronic means to process the order.
9	**Receipt of emergency prescription orders.** Amends § 151.15 by adding subd. 5. Adds subdivision allowing a pharmacist to accept a prescription drug order when not present in a pharmacy, in specified circumstances.
10	**Processing of emergency prescription orders.** Amends § 151.15 by adding subd. 6. Adds subdivision outlining the required processes for accepting and filling a prescription under subdivision 5, in emergency circumstances.
11	**Pharmacy licensure requirements.** Amends § 151.19, subd. 1. Clarifies provision related to inspection prior to pharmacy licensure. ▪ Specifies that pharmacy licensing requirements do not apply to manufacturers, wholesale drug distributors, and logistics providers who distribute home dialysis supplies and devices, if: o the manufacturer leases or owns the licensed manufacturing or wholesaling facility from which the dialysate or devices will be delivered;

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- the dialysis supplies meet certain specifications;
- the supplies are only delivered pursuant to physician's order by a Minnesota licensed pharmacy;
- the entity keeps records for at least three years, available to the board upon request; and
- the entity delivers the supplies directly to a patient with end-stage renal disease or the patient's designee, for dialysis, or to a health care provider or institution, for the same purpose.

12 **Sale of federally restricted medical gases.**

Amends § 151.19, subd. 3.

Clarifies provision related to inspection prior to medical gas distributor registration.

13 **Requirements.**

Amends § 151.252, subd. 1.

Clarifies provision related to inspection prior to drug manufacturing facility licensure.

14 **Outsourcing facility.**

Amends § 151.252, subd. 1a.

Clarifies provisions related to inspection of outsourcing facilities for initial licensure or renewal.

15 **Payment to practitioner; reporting.**

Amends § 151.252, subd. 3.

Adds outsourcing facilities to the requirement for an annual report to the board.

16 **Emergency veterinary compounding.**

Amends § 151.253 by adding subd. 4.

Allows a pharmacist working within a pharmacy licensed as a veterinary pharmacy to compound and provide a drug to a veterinarian without a patient-specific prescription when:

1) the compounded drug is needed in an emergency situation;
2) timely access to a compounding pharmacy is not available;
3) no suitable commercially manufactured drug exists to treat the animal, or there is a shortage of the drug;
4) the compounded drug will be administered by a veterinarian or employee, or dispensed in an amount not to exceed a 10-day supply;

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5) the pharmacy has selected the sterile or nonsterile compounding license category; and
6) the pharmacy is registered by the DEA when providing compounded products containing controlled substances.

17 **Citation.**

Amends § 151.32. Modifies citation and title of the Pharmacy Practice Act.

18 **Generally.**

Amends § 151.40, subd. 1.

Modifies list of persons who may possess, control, manufacture, sell, furnish, dispense, or otherwise dispose of hypodermic syringes or needles. Adds syringe service providers and their employees; persons self-administering drugs pursuant to a prescription or practitioner direction; persons disposing of needles for certain programs; and persons who sell, possess, or handle hypodermic syringes or needles.

19 **Sales of limited quantities of clean needles and syringes.**

Amends § 151.40, subd. 2. Clarifies provisions governing the sale of hypodermic needles or syringes. Removes provision prohibiting a pharmacy from advertising needles for retail sale.

20 **Scope.**

Amends § 151.43. Modifies cross-reference and specifies that the sections apply to persons operating as third-party logistics providers.

21 **Definitions.**

Proposes coding for § 151.441.

Defines the following terms for the purposes of sections 151.43 to 151.51:

- "Dispenser"
- "Disposition"
- "Distribute" or "distribution"
- "Manufacturer"
- "Medical convenience kit"
- "Package"
- "Prescription drug"
- "Product"
- "Repackager"
- "Third-party logistics provider"
- "Transaction"
- "Wholesale distribution"

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	▪ "Wholesale distributor"
22	**Prohibited drug purchases or receipt.** Amends § 151.46. Adds licensed third-party logistics providers to those prohibited from dispensing or distributing drugs directly to patients.
23	**Generally.** Amends § 151.47, subd. 1. Removes requirements for wholesale drug distributors. Requires manufacturers, repackagers, wholesale distributors, and dispensers to comply with requirements in federal law.
24	**Licensing.** Amends § 151.47 by adding subd. 1a. Paragraph (a) specifies that the board will license wholesale distributors, engaged in wholesale distribution, consistent with federal law. Paragraph (b) prohibits a person to act as a wholesale distributor unless licensed by the board. Paragraph (c) requires application for a license to be made in a manner specified by the board. Paragraph (d) requires agreement to operate in compliance with state and federal law in order to be licensed. Paragraph (e) requires a wholesale distributor facility in another state to prove licensure or registration with the FDA or the state in which the facility is located, in order to be licensed in Minnesota. Paragraph (f) requires a license for each separate facility. Paragraph (g) requires an inspection for licensure. Paragraph (h) specifies additional conditions for wholesale distributor licensure. Paragraph (i) specifies that employees of wholesale distributors do not need to be licensed. Paragraph (j) authorizes and requires fingerprint-based criminal background checks for facility managers or designated representatives.

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Paragraph (k) prohibits a licensed wholesaler from being owned by or employing individuals who have been convicted of certain felonies or who have violated federal law or certain state licensure requirements.

Paragraph (m) requires a $100,000 surety bond prior to licensing a wholesale distributor that is not government-owned and operated, and a $25,000 surety bond for an applicant with gross receipts under $10,000,000.

Paragraph (n) allows for waiver of the bond requirement in certain circumstances.

Paragraph (o) specifies the purpose of the surety bond.

Paragraph (p) specifies that a single surety bond satisfies the requirement for all wholesale distributor facilities under common ownership.

25 **Third-party logistics provider requirements.**

Proposes coding for § 151.471.

Subd. 1. Generally. Requires third-party logistics providers to comply with applicable federal law.

Subd. 2. Licensing. Requires board licensure for third-party logistics provider, consistent with federal law. Specifies licensing requirements.

26 **Repealer.**

Repeals sections 151.42, 151.44, 151.49, 151.50, 151.51, and 151.55, relating to wholesale drug distribution licensing and the cancer drug repository program.