

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	<p>Central service pharmacy. Amends § 151.01, subd. 31.</p> <p>Clarifies the definition of “central service pharmacy.”</p>
2	<p>Compounding. Amends § 151.01, subd. 35.</p> <p>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.</p>
3	<p>Syringe services provider. Amends § 151.01 by adding subd. 42.</p> <p>Adds definition for “syringe services provider.”</p>
4	<p>Application fees. Amends § 151.065, subd. 1.</p> <p>Modifies application fees by removing drug wholesalers and adding third-party logistics providers, and removing drug manufacturer application fees.</p>

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5	<p>Annual renewal fees. Amends § 151.065, subd. 3.</p> <p>Modifies annual renewal fees by removing drug wholesalers and adding third-party logistics providers, and removing drug manufacturer renewal fees.</p>
6	<p>Reinstatement fees. Amends § 151.065, subd. 6.</p> <p>Modifies license reinstatement fees by adding third-party logistics providers.</p>
7	<p>Grounds for disciplinary action. Amends § 151.071, subd. 2.</p> <p>Updates terminology; adds provision to actions that constitute fee splitting addressing price setting arrangements between pharmacies and physicians, and pharmacies and veterinarians.</p>
8	<p>Location. Amends § 151.15, subd. 1.</p> <p>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.</p>
9	<p>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.</p>
10	<p>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.</p>
11	<p>Pharmacy licensure requirements. Amends § 151.19, subd. 1.</p> <p>Clarifies provision related to inspection prior to pharmacy licensure.</p> <ul style="list-style-type: none">▪ Specifies that pharmacy licensing requirements do not apply to manufacturers, wholesale drug distributors, and logistics providers who distribute home dialysis supplies and devices, if:<ul style="list-style-type: none">○ the manufacturer leases or owns the licensed manufacturing or wholesaling facility from which the dialysate or devices will be delivered;

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	<ul style="list-style-type: none">○ 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	<p>Sale of federally restricted medical gases. Amends § 151.19, subd. 3.</p> <p>Clarifies provision related to inspection prior to medical gas distributor registration.</p>
13	<p>Requirements. Amends § 151.252, subd. 1.</p> <p>Clarifies provision related to inspection prior to drug manufacturing facility licensure.</p>
14	<p>Outsourcing facility. Amends § 151.252, subd. 1a.</p> <p>Clarifies provisions related to inspection of outsourcing facilities for initial licensure or renewal.</p>
15	<p>Payment to practitioner; reporting. Amends § 151.252, subd. 3.</p> <p>Adds outsourcing facilities to the requirement for an annual report to the board.</p>
16	<p>Emergency veterinary compounding. Amends § 151.253 by adding subd. 4.</p> <p>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:</p> <ul style="list-style-type: none">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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	<ul style="list-style-type: none">5) the pharmacy has selected the sterile or nonsterile compounding license category; and6) the pharmacy is registered by the DEA when providing compounded products containing controlled substances.
17	<p>Citation. Amends § 151.32. Modifies citation and title of the Pharmacy Practice Act.</p>
18	<p>Generally. Amends § 151.40, subd. 1.</p> <p>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.</p>
19	<p>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.</p>
20	<p>Scope. Amends § 151.43. Modifies cross-reference and specifies that the sections apply to persons operating as third-party logistics providers.</p>
21	<p>Definitions. Proposes coding for § 151.441.</p> <p>Defines the following terms for the purposes of sections 151.43 to 151.51:</p> <ul style="list-style-type: none">▪ “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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22	<ul style="list-style-type: none"><li data-bbox="451 268 781 296">▪ “Wholesale distributor” <p>Prohibited drug purchases or receipt. Amends § 151.46.</p> <p>Adds licensed third-party logistics providers to those prohibited from dispensing or distributing drugs directly to patients.</p>
23	<p>Generally. Amends § 151.47, subd. 1.</p> <p>Removes requirements for wholesale drug distributors. Requires manufacturers, repackagers, wholesale distributors, and dispensers to comply with requirements in federal law.</p>
24	<p>Licensing. Amends § 151.47 by adding subd. 1a.</p> <p>Paragraph (a) specifies that the board will license wholesale distributors, engaged in wholesale distribution, consistent with federal law.</p> <p>Paragraph (b) prohibits a person to act as a wholesale distributor unless licensed by the board.</p> <p>Paragraph (c) requires application for a license to be made in a manner specified by the board.</p> <p>Paragraph (d) requires agreement to operate in compliance with state and federal law in order to be licensed.</p> <p>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.</p> <p>Paragraph (f) requires a license for each separate facility.</p> <p>Paragraph (g) requires an inspection for licensure.</p> <p>Paragraph (h) specifies additional conditions for wholesale distributor licensure.</p> <p>Paragraph (i) specifies that employees of wholesale distributors do not need to be licensed.</p> <p>Paragraph (j) authorizes and requires fingerprint-based criminal background checks for facility managers or designated representatives.</p>

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	<p>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.</p> <p>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.</p> <p>Paragraph (n) allows for waiver of the bond requirement in certain circumstances.</p> <p>Paragraph (o) specifies the purpose of the surety bond.</p> <p>Paragraph (p) specifies that a single surety bond satisfies the requirement for all wholesale distributor facilities under common ownership.</p>
25	<p>Third-party logistics provider requirements.</p> <p>Proposes coding for § 151.471.</p> <p>Subd. 1. Generally. Requires third-party logistics providers to comply with applicable federal law.</p> <p>Subd. 2. Licensing. Requires board licensure for third-party logistics provider, consistent with federal law. Specifies licensing requirements.</p>
26	<p>Repealer.</p> <p>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.</p>



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