HOUSE RESEARCH

Bill Summary

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Subject: Pharmacy regulation; compounding

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Overview

This bill changes licensing requirements for pharmacies, drug manufacturers, and wholesale drug distributors.

Section

1 **Pharmacy licensure requirements.** Amends §151.19, subd. 1. Paragraph (a) requires pharmacies to be licensed by the board.

Paragraph (b) requires applications to be made in a manner specified by the board.

Paragraph (c) requires all licensed pharmacies to comply with federal laws and state laws and rules related to operation of a pharmacy. Requires out-of-state pharmacies dispensing drugs to residents of Minnesota to comply with federal laws related to operation of a pharmacy.

Paragraph (d) provides that an out-of-state pharmacy must provide proof of licensure or registration by the state in which it is physically located before the board will issue a license.

Paragraph (e) provides that a separate license is required for each pharmacy at which any portion of the dispensing process occurs for drugs dispensed to residents of Minnesota.

Paragraph (f) prohibits the board from issuing a pharmacy license unless the pharmacy passes an inspection. For out-of-state pharmacies, a report issued by the regulatory authority of the state in which the pharmacy is located satisfies this requirement.

Paragraph (g) lists the requirements that must be met by an out-of-state pharmacy in order to be licensed or have its license renewed.

Section

2 **Sale of federally restricted medical gases.** Amends §151.19, subd. 3. Paragraph (a) provides that unless licensed as a pharmacy or a practitioner, a person or establishment must be registered by the board before selling or distributing federally restricted medical gases.

Paragraph (b) requires a person or establishment seeking registration to submit an application in a manner specified by the board.

Paragraph (c) provides that medical gas distributors must comply with federal laws and state laws and rules. Requires out-of-state distributors that distribute medical gases for residents of this state to comply with federal laws.

Paragraph (d) provides that an out-of-state distributor must provide proof of licensure or registration by the state in which it is physically located before the board will issue a license.

Paragraph (e) requires a separate registration for each distributor located in the state and for each facility located outside of the state from which medical gases are distributed to residents of this state.

Paragraph (f) prohibits the board from issuing a registration unless the distributor passes an inspection. For an out-of-state distributor, a report issued by the regulatory authority of the state in which the distributor is located satisfies the inspection requirement.

3 **Licensing of drug manufacturers; fees; prohibitions.** Creates §151.252.

Subd. 1. Requirements. Paragraph (a) requires manufacturers to be licensed by the board.

Paragraph (b) requires applications to be made in a manner specified by the board.

Paragraph (c) requires licensed manufacturers to comply with federal law and state law and rules.

Paragraph (d) provides that manufacturers that are required to be registered pursuant to federal law must be registered before they can be licensed by the board. Allows the board to establish standards for the licensure of manufacturers that are not required to be registered by federal law.

Paragraph (e) provides that out-of-state manufacturers must be licensed or registered by the state in which they are physically located. Allows the board to establish standards for the licensure of a manufacturer that is not required to be licensed or registered by the state in which it is located.

Paragraph (f) requires a separate license for each facility where manufacturing occurs.

Paragraph (g) prohibits the board from issuing a license unless the manufacturer passes an inspection. For an out-of-state manufacturer, a report issued by the regulatory authority of the state in which the facility is located or by the USFDA satisfied the inspection requirement.

Section

Subd. 2. Prohibition. Makes it unlawful for a manufacturer to sell legend drugs to anyone located in this state except as provided in this chapter.

4 **Research.** Amends §151.37, subd. 4. Adds paragraph (b). Allows a pharmacy to dispense drugs for use by patients enrolled in a bona fide research study being conducted pursuant to an investigational new drug application or that has been approved by an institutional review board. Provides that dispensing research drugs is not compounding, manufacturing, or the sale of a drug at wholesale.

5 **Requirements.** Amends §151.47, subd. 1. Makes technical changes. Adds that wholesale drug distributors must be licensed or registered by the state in which it is physically located. Allows the board to establish standards for the licensure of a drug wholesaler if licensure or registration is not required by the state in which the wholesaler is located.

Adds that a separate license is required for each wholesale distribution facility from which drugs are shipped into the state or to which drugs are reverse distributed.

Adds that a distribution facility must pass an inspection before the board will issue a license. For out-of-state facilities, an inspection report issued by the regulatory authority of the state in which the facility is located will satisfy this requirement.

6 **Prohibition.** Amends §151.47, by adding subdivision 3. Makes it unlawful for a wholesale distributor to sell drugs to anyone located in the state or to receive drugs in reverse distribution from anyone located within the state except as provided in this chapter.

7 **License renewal application procedures.** Amends §151.49. Makes technical changes.

8 **Repealer.** Repeals §§151.19, subd. 2 (nonresident pharmacies; registration and fees); 151.25 (registration of manufacturers); 151.45 (wholesale drug distributor advisory task force); 151.47, subd. 2 (wholesale drug distributor licensing requirements); and 151.48 (out-of-state wholesale drug distributor licensing).