MN HOUSE RESEARCH

Bill Summary

H.F. 182

As Introduced

Subject	Prescription Drug Repository Program
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Overview

This bill directs the Board of Pharmacy to establish a drug repository program. The program would allow individuals without prescription drug coverage to obtain donated prescription drugs and medical supplies from a central or local repository, if the drug or medical supply has been prescribed for the individual. The central repository must be a wholesale distributor; health care facilities such as physician offices and hospitals may elect to accept donations and serve as local repositories. A repository may charge the individual a handling fee of up to 250 percent of the Medical Assistance dispensing fee. Health care facilities, nursing and assisted living facilities, pharmacies, drug wholesalers, and drug manufacturers may donate drugs and medical supplies under the program.

Summary

Section	Description
1	**Prescription drug repository program.** Adds § 151.555.

Subd. 1. Definitions. Defines the following terms: central repository; distribute; donor; drug; health care facility; local repository; medical supplies; original, sealed, unopened, tamper-evident packaging; and practitioner.

"Central repository" means a wholesale distributor that meets certain requirements and enters into a contract with the Board of Pharmacy.

"Donor" means a health care facility, skilled nursing facility, assisted living facility meeting certain requirements, pharmacy, drug wholesaler, or drug manufacturer.

"Health care facility" means a physician's office or health care clinic, hospital, pharmacy, or nonprofit community clinic.

"Local repository" means a health care facility that elects to accept donated drugs and meets certain requirements.

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Subd. 2. Establishment. Requires the Board of Pharmacy to establish, by January 1, 2020 (as amended), a drug repository program through which donors may donate a drug or medical supply, to be used by eligible individuals. Requires the board to contract with a central repository to implement and administer the program.

Subd. 3. Central repository requirements. Requires the board to select a wholesale drug distributor to act as central repository using a request for proposal process. Specifies related requirements.

Subd. 4. Local repository requirements. In order to serve as a local repository, requires a health care facility to agree to comply with all federal and state requirements related to the drug repository program, drug storage, and dispensing, and maintain any required state license or registration. Specifies application requirements. Provides that participation as a drug repository is voluntary and specifies the process to be used to withdraw from participation.

Subd. 5. Individual eligibility and application requirements. (a) In order to participate in the program, requires an individual to submit an application form to the local repository that attests that the individual: (1) is a state resident; (2) is uninsured, has no prescription drug coverage, or is underinsured; (3) acknowledges that the drugs or medical supplies received may have been donated; and (4) consents to a waiver of child resistant packaging requirements. Requires the local repository to issue eligible individuals with an identification card that is valid for one year, can be used at any local repository, and may be reissued upon expiration. Requires the local repository to send a copy of the application form to the central repository. Requires the board to make available on its Web site an application form and the format for the identification card.

Subd. 6. Standards and procedure. (a) Allows a donor to donate to the central repository or a local repository prescription drugs and medical supplies that meet specified requirements.

(b) Specifies requirements for prescriptions drugs to be eligible for donation.

(c) Specifies requirements for medical supplies to be eligible for donation.

(d) Requires the board to develop a drug repository donor form, which must accompany each donation. Specifies requirements for the form and requires the form to be available on the board's Web site.

(e) Allows donated drugs and supplies to be shipped or delivered to the central repository or a local repository. Requires the drugs and supplies to be inspected by the pharmacist or other practitioner designated by the repository to accept donations. Prohibits the use of a drop box to deliver or accept donations.

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(f) Requires the central repository and local repository to inventory all drugs and supplies that are donated, and specifies related requirements.

Subd. 7. Standards and procedures for inspecting and storing donated prescription drugs and supplies. (a) Specifies requirements for the pharmacist or authorized practitioner to follow when inspecting all donated drugs and supplies.

(b) Specifies storage requirements for donated drugs and supplies.

(c) Requires the central repository and local repositories to dispose of all drugs and supplies not suitable for donation in compliance with applicable federal and state requirements related to hazardous waste.

(d) Requires shipments or deliveries of controlled substances or drugs that can only be dispensed to a patient registered with the drug's manufacturer to be documented by the central or local repository, and returned immediately to the donor or donor's representative that provided the drugs.

(e) Requires each repository to develop drug and medical supply recall policies and procedures, and specifies related requirements.

(f) Specifies record keeping requirements related to donated drugs and supplies that are destroyed.

Subd. 8. Dispensing requirements. (a) Allows donated drugs and supplies to be dispensed if they are prescribed by a practitioner for the eligible individual. Specifies related requirements.

(b) Requires the visual inspection of a drug or supply for adulteration, misbranding, tampering, and expiration, and prohibits dispensing or administering of drugs meeting these criteria.

(c) Requires individuals to sign a drug repository recipient form and specifies form requirements.

Subd. 9. Handling fees. (a) Allows a repository to charge an individual receiving a drug or supply a handling fee of no more than 250 percent of the MA dispensing fee.

(b) Prohibits a repository from receiving MA or MinnesotaCare reimbursement for a drug or supply provided through the program.

Subd. 10. Distribution of donated drugs and supplies. (a) Allows the central repository and local repositories to distribute donated drugs and supplies to other repositories.

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(b) Requires a local repository that elects not to participate to transfer all donated drugs and supplies to the central repository, and provide copies of the donor forms at the time of the transfer.

Subd. 11. Forms and record-keeping requirements. (a) Specifies forms that must be available on the board's Web site.

(b) Requires all records to be maintained by a repository for at least five years, and maintained pursuant to all applicable practice acts.

(c) Requires data collected by the program from local repositories to be submitted quarterly or upon request of the central repository.

(d) Requires the central repository to submit reports to the board as required by contract or upon request.

Subd. 12. Liability. (a) Provides that manufacturers are not subject to criminal or civil liability for causes of action related to: (1) alteration of a drug or supply by a party not under the control of the manufacturer; or (2) failure of a party not under the control of the manufacturer to communicate product or consumer information or the expiration date of a donated drug or supply.

(b) Provides civil immunity for a health care facility, pharmacist, practitioner, or donor related to participation in the program and also prohibits a health-related licensing board from taking disciplinary action. States that immunity does not apply if the act or omission involves reckless, wanton, or intentional misconduct, or malpractice unrelated to the quality of the drug or supply.

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