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S.F. No. 223

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01/17/2019	109	Introduction and first reading Referred to Health and Human Services Finance and Policy

A bill for an act

relating to health; establishing a prescription drug repository program; proposing coding for new law in Minnesota Statutes, chapter 151.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. **[151.555] PRESCRIPTION DRUG REPOSITORY PROGRAM.**

Subdivision 1. **Definitions.** (a) For the purposes of this section, the terms defined in this subdivision have the meanings given.

(b) "Central repository" means a wholesale distributor that meets the requirements under subdivision 3 and enters into a contract with the Board of Pharmacy in accordance with this section.

(c) "Distribute" means to deliver, other than by administering or dispensing.

(d) "Donor" means:

(1) a health care facility as defined in this subdivision;

(2) a skilled nursing facility licensed under chapter 144A;

(3) an assisted living facility registered under chapter 144D where there is centralized storage of drugs and 24-hour on-site licensed nursing coverage provided seven days a week;

(4) a pharmacy licensed under section 151.19, and located either in the state or outside the state;

(5) a drug wholesaler licensed under section 151.47; or

(6) a drug manufacturer licensed under section 151.252.

(e) "Drug" means any prescription drug that has been approved for medical use in the United States, is listed in the United States Pharmacopoeia or National Formulary, and meets the criteria established under this section for donation. This definition includes cancer drugs and antirejection drugs, but does not include controlled substances, as defined in section 152.01, subdivision 4, or a prescription drug that can only be dispensed to a patient registered with the drug's manufacturer in accordance with federal Food and Drug Administration requirements.

(f) "Health care facility" means:

(1) a physician's office or health care clinic where licensed practitioners provide health care to patients;

(2) a hospital licensed under section 144.50;

(3) a pharmacy licensed under section 151.19 and located in Minnesota; or

(4) a nonprofit community clinic, including a federally qualified health center; a rural health clinic; public health clinic; or other community clinic that provides health care utilizing a sliding fee scale to patients who are low-income, uninsured, or underinsured.

(g) "Local repository" means a health care facility that elects to accept donated drugs and medical supplies and meets the requirements of subdivision 4.

(h) "Medical supplies" or "supplies" means any prescription and nonprescription medical supply needed to administer a prescription drug.

(i) "Original, sealed, unopened, tamper-evident packaging" means packaging that is sealed, unopened, and tamper-evident, including a manufacturer's original unit dose or unit-of-use container, a repackager's original unit dose or unit-of-use container, or unit-dose packaging prepared by a licensed pharmacy according to the standards of Minnesota Rules, part 6800.3750.

(j) "Practitioner" has the meaning given in section 151.01, subdivision 23, except that it does not include a veterinarian.

Subd. 2. **Establishment.** By January 1, 2019, the Board of Pharmacy shall establish a drug repository program, through which donors may donate a drug or medical supply for use by an individual who meets the eligibility criteria specified under subdivision 5. The board shall contract with a central repository that meets the requirements of subdivision 3 to implement and administer the prescription drug repository program.

Subd. 3. **Central repository requirements.** (a) The board shall publish a request for proposal for participants who meet the requirements of this subdivision and are interested in acting as the central repository for the drug repository program. The board shall follow all applicable state procurement procedures in the selection process.

(b) To be eligible to act as the central repository, the participant must be a wholesale drug distributor located in Minnesota, licensed pursuant to section 151.47, and in compliance with all applicable federal and state statutes, rules, and regulations.

(c) The central repository shall be subject to inspection by the board pursuant to section 151.06, subdivision 1.

Subd. 4. **Local repository requirements.** (a) To be eligible for participation in the drug repository program, a health care facility must agree to comply with all applicable federal and state laws, rules, and regulations pertaining to the drug repository program, drug storage, and dispensing. The facility must also agree to maintain in good standing any required state license or registration that may apply to the facility.

(b) A local repository may elect to participate in the program by submitting the following information to the central repository on a form developed by the board and made available on the board's Web site:

(1) the name, street address, and telephone number of the health care facility and any state-issued license or registration number issued to the facility, including the issuing state agency;

(2) the name and telephone number of a responsible pharmacist or practitioner who is employed by or under contract with the health care facility; and

(3) a statement signed and dated by the responsible pharmacist or practitioner indicating that the health care facility meets the eligibility requirements under this section and agrees to comply with this section.

(c) Participation in the drug repository program is voluntary. A local repository may withdraw from participation in the drug repository program at any time by providing written notice to the central repository on a form developed by the board and made available on the board's Web site. The central repository shall provide the board with a copy of the withdrawal notice within ten business days from the date of receipt of the withdrawal notice.

Subd. 5. **Individual eligibility and application requirements.** (a) To be eligible for the drug repository program, an individual must submit to a local repository an intake application form that is signed by the individual and attests that the individual:

(1) is a resident of Minnesota;

(2) is uninsured, has no prescription drug coverage, or is underinsured;

(3) acknowledges that the drugs or medical supplies to be received through the program may have been donated; and

(4) consents to a waiver of the child-resistant packaging requirements of the federal Poison Prevention Packaging Act.

(b) Upon determining that an individual is eligible for the program, the local repository shall furnish the individual with an identification card. The card shall be valid for one year from the date of issuance and may be used at any local repository. A new identification card may be issued upon expiration once the individual submits a new application form.

(c) The local repository shall send a copy of the intake application form to the central repository by regular mail, facsimile, or secured e-mail within ten days from the date the application is approved by the local repository.

(d) The board shall develop and make available on the board's Web site an application form and the format for the identification card.

Subd. 6. **Standards and procedures for accepting donations of drugs and supplies.** (a) A donor may donate prescription drugs or medical supplies to the central repository or a local repository if the drug or supply meets the requirements of this section as determined by a pharmacist or practitioner who is employed by or under contract with the central repository or a local repository.

(b) A prescription drug is eligible for donation under the drug repository program if the following requirements are met:

(1) the donation is accompanied by a drug repository donor form described under paragraph (d) that is signed by an individual who is authorized by the donor to attest to the donor's knowledge in accordance with paragraph (d);

(2) the drug's expiration date is at least six months after the date the drug was donated. If a donated drug bears an expiration date that is less than six months from the donation date, the drug may be accepted and distributed if the drug is in high demand and can be dispensed for use by a patient before the drug's expiration date;

(3) the drug is in its original, sealed, unopened, tamper-evident packaging that includes the expiration date. Single-unit-dose drugs may be accepted if the single-unit-dose packaging is unopened;

(4) the drug or the packaging does not have any physical signs of tampering, misbranding, deterioration, compromised integrity, or adulteration;

(5) the drug does not require storage temperatures other than normal room temperature as specified by the manufacturer or United States Pharmacopoeia, unless the drug is being donated directly by its manufacturer, a wholesale drug distributor, or a pharmacy located in Minnesota; and

(6) the prescription drug is not a controlled substance.

(c) A medical supply is eligible for donation under the drug repository program if the following requirements are met:

(1) the supply has no physical signs of tampering, misbranding, or alteration and there is no reason to believe it has been adulterated, tampered with, or misbranded;

(2) the supply is in its original, unopened, sealed packaging;

(3) the donation is accompanied by a drug repository donor form described under paragraph (d) that is signed by an individual who is authorized by the donor to attest to the donor's knowledge in accordance with paragraph (d); and

(4) if the supply bears an expiration date, the date is at least six months later than the date the supply was donated. If the donated supply bears an expiration date that is less than six months from the date the supply was donated, the supply may be accepted and distributed if the supply is in high demand and can be dispensed for use by a patient before the supply's expiration date.

(d) The board shall develop the drug repository donor form and make it available on the board's Web site. The form must state that to the best of the donor's knowledge the donated drug or supply has been properly stored and that the drug or supply has never been opened, used, tampered with, adulterated, or misbranded.

(e) Donated drugs and supplies may be shipped or delivered to the premises of the central repository or a local repository, and shall be inspected by a pharmacist or an authorized practitioner who is employed by or under contract with the repository and who has been designated by the repository to accept donations. A drop box must not be used to deliver or accept donations.

(f) The central repository and local repository shall inventory all drugs and supplies donated to the repository. For each drug, the inventory must include the drug's name, strength, quantity, manufacturer, expiration date, and the date the drug was donated. For each medical

supply, the inventory must include a description of the supply, its manufacturer, the date the supply was donated, and, if applicable, the supply's brand name and expiration date.

Subd. 7. **Standards and procedures for inspecting and storing donated prescription drugs and supplies.** (a) A pharmacist or authorized practitioner who is employed by or under contract with the central repository or a local repository shall inspect all donated prescription drugs and supplies before the drug or supply is dispensed to determine, to the extent reasonably possible in the professional judgment of the pharmacist or practitioner, that the drug or supply is not adulterated or misbranded, has not been tampered with, is safe and suitable for dispensing, and meets the requirements for donation. The pharmacist or practitioner who inspects the drugs or supplies shall sign an inspection record stating that the requirements for donation have been met. If a local repository receives drugs and supplies from the central repository, the local repository does not need to reinspect the drugs and supplies.

(b) The central repository and local repositories shall store donated drugs and supplies in a secure storage area under environmental conditions appropriate for the drug or supply being stored. Donated drugs and supplies may not be stored with nondonated inventory. If donated drugs or supplies are not inspected immediately upon receipt, a repository must quarantine the donated drugs or supplies separately from all dispensing stock until the donated drugs or supplies have been inspected and (1) approved for dispensing under the program; (2) disposed of pursuant to paragraph (c); or (3) returned to the donor pursuant to paragraph (d).

(c) The central repository and local repositories shall dispose of all prescription drugs and medical supplies that are not suitable for donation in compliance with applicable federal and state statutes, regulations, and rules concerning hazardous waste.

(d) In the event that controlled substances or prescription drugs that can only be dispensed to a patient registered with the drug's manufacturer are shipped or delivered to a central or local repository for donation, the shipment delivery must be documented by the repository and returned immediately to the donor or the donor's representative that provided the drugs.

(e) Each repository must develop drug and medical supply recall policies and procedures. If a repository receives a recall notification, the repository shall destroy all of the drug or medical supply in its inventory that is the subject of the recall and complete a record of destruction form in accordance with paragraph (f). If a drug or medical supply that is the subject of a Class I or Class II recall has been dispensed, the repository shall immediately notify the recipient of the recalled drug or medical supply. A drug that potentially is subject

to a recall need not be destroyed if its packaging bears a lot number and that lot of the drug is not subject to the recall. If no lot number is on the drug's packaging, it must be destroyed.

(f) A record of destruction of donated drugs and supplies that are not dispensed under subdivision 8, are subject to a recall under paragraph (e), or are not suitable for donation shall be maintained by the repository for at least five years. For each drug or supply destroyed, the record shall include the following information:

(1) the date of destruction;

(2) the name, strength, and quantity of the drug destroyed; and

(3) the name of the person or firm that destroyed the drug.

Subd. 8. **Dispensing requirements.** (a) Donated drugs and supplies may be dispensed if the drugs or supplies are prescribed by a practitioner for use by an eligible individual and are dispensed by a pharmacist or practitioner. A repository shall dispense drugs and supplies to eligible individuals in the following priority order: (1) individuals who are uninsured; (2) individuals with no prescription drug coverage; and (3) individuals who are underinsured. A repository shall dispense donated prescription drugs in compliance with applicable federal and state laws and regulations for dispensing prescription drugs, including all requirements relating to packaging, labeling, record keeping, drug utilization review, and patient counseling.

(b) Before dispensing or administering a drug or supply, the pharmacist or practitioner shall visually inspect the drug or supply for adulteration, misbranding, tampering, and date of expiration. Drugs or supplies that have expired or appear upon visual inspection to be adulterated, misbranded, or tampered with in any way must not be dispensed or administered.

(c) Before a drug or supply is dispensed or administered to an individual, the individual must sign a drug repository recipient form acknowledging that the individual understands the information stated on the form. The board shall develop the form and make it available on the board's Web site. The form must include the following information:

(1) that the drug or supply being dispensed or administered has been donated and may have been previously dispensed;

(2) that a visual inspection has been conducted by the pharmacist or practitioner to ensure that the drug or supply has not expired, has not been adulterated or misbranded, and is in its original, unopened packaging; and

(3) that the dispensing pharmacist, the dispensing or administering practitioner, the central repository or local repository, the Board of Pharmacy, and any other participant of

the drug repository program cannot guarantee the safety of the drug or medical supply being dispensed or administered and that the pharmacist or practitioner has determined that the drug or supply is safe to dispense or administer based on the accuracy of the donor's form submitted with the donated drug or medical supply and the visual inspection required to be performed by the pharmacist or practitioner before dispensing or administering.

Subd. 9. **Handling fees.** (a) The central or local repository may charge the individual receiving a drug or supply a handling fee of no more than 250 percent of the medical assistance program dispensing fee for each drug or medical supply dispensed or administered by that repository.

(b) A repository that dispenses or administers a drug or medical supply through the drug repository program shall not receive reimbursement under the medical assistance program or the MinnesotaCare program for that dispensed or administered drug or supply.

Subd. 10. **Distribution of donated drugs and supplies.** (a) The central repository and local repositories may distribute drugs and supplies donated under the drug repository program to other participating repositories for use pursuant to this program.

(b) A local repository that elects not to dispense donated drugs or supplies must transfer all donated drugs and supplies to the central repository. A copy of the donor form that was completed by the original donor under subdivision 6 must be provided to the central repository at the time of transfer.

Subd. 11. **Forms and record-keeping requirements.** (a) The following forms developed for the administration of this program shall be utilized by the participants of the program and shall be available on the board's Web site:

(1) intake application form described under subdivision 5;

(2) local repository participation form described under subdivision 4;

(3) local repository withdrawal form described under subdivision 4;

(4) drug repository donor form described under subdivision 6;

(5) record of destruction form described under subdivision 7; and

(6) drug repository recipient form described under subdivision 8.

(b) All records, including drug inventory, inspection, and disposal of donated prescription drugs and medical supplies must be maintained by a repository for a minimum of five years. Records required as part of this program must be maintained pursuant to all applicable practice acts.

(c) Data collected by the drug repository program from all local repositories shall be submitted quarterly or upon request to the central repository. Data collected may consist of the information, records, and forms required to be collected under this section.

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

Subd. 12. **Liability.** (a) The manufacturer of a drug or supply is not subject to criminal or civil liability for injury, death, or loss to a person or to property for causes of action described in clauses (1) and (2). A manufacturer is not liable for:

(1) the intentional or unintentional alteration of the drug or supply by a party not under the control of the manufacturer; or

(2) the failure of a party not under the control of the manufacturer to transfer or communicate product or consumer information or the expiration date of the donated drug or supply.

(b) A health care facility participating in the program, a pharmacist dispensing a drug or supply pursuant to the program, a practitioner dispensing or administering a drug or supply pursuant to the program, or a donor of a drug or medical supply is immune from civil liability for an act or omission that causes injury to or the death of an individual to whom the drug or supply is dispensed and no disciplinary action by a health-related licensing board shall be taken against a pharmacist or practitioner so long as the drug or supply is donated, accepted, distributed, and dispensed according to the requirements of this section. This 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 medical supply.