

**SENATE
STATE OF MINNESOTA
NINETIETH SESSION**

S.F. No. 2562

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OFFICIAL STATUS
Introduction and first reading
Referred to Health and Human Services Finance and Policy

1.1 A bill for an act
1.2 relating to health care; creating a drug repository program; proposing coding for
1.3 new law in Minnesota Statutes, chapter 151; repealing Minnesota Statutes 2016,
1.4 section 151.55.

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

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

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

1.9 (b) "Central repository" means a wholesale distributor that meets the requirements under
1.10 subdivision 4 and enters into a contract with the Board of Pharmacy in accordance with this
1.11 section.

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

1.13 (d) "Donor" means:

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

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

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

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

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

1.21 (6) a drug manufacturer licensed under section 151.252.

2.1 (e) "Drug" means any prescription drug that has been approved for medical use in the
2.2 United States, is listed in the United States Pharmacopoeia or National Formulary, and
2.3 meets the criteria established under this section for donation. This definition includes cancer
2.4 drugs and antirejection drugs, but does not include controlled substances, as defined in
2.5 section 152.01, subdivision 4.

2.6 (f) "Health care facility" means:

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

2.9 (2) a hospital licensed under section 144.50;

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

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

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

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

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

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

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

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

3.1 (c) The central repository shall be subject to inspection by the board pursuant to section
3.2 151.06, subdivision 1.

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

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

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

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

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

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

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

3.27 (1) is a resident of Minnesota;

3.28 (2) is uninsured or is underinsured and has no prescription drug coverage for the drug
3.29 prescribed;

3.30 (3) acknowledges that the drugs to be received through the program may have been
3.31 donated; and

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

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

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

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

4.12 **Subd. 6. Standards and procedures for accepting donations of drugs and supplies.**

4.13 (a) A donor may donate prescription drugs or medical supplies to the central repository or
4.14 a local repository if the drug or supply meets the requirements of this section as determined
4.15 by a pharmacist or practitioner who is employed by or under contract with the central
4.16 repository or a local repository.

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

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

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

4.26 (3) the drug is in its original, sealed, unopened, tamper-evident packaging that includes
4.27 the drug's lot number and expiration date. Single-unit-dose drugs may be accepted if the
4.28 single-unit-dose packaging is unopened;

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

4.31 (5) the drug does not require storage temperatures other than normal room temperature
4.32 as specified by the manufacturer or United States Pharmacopoeia, unless the drug is being

5.1 donated directly by its manufacturer, a wholesale drug distributor, or a pharmacy located
5.2 in Minnesota; and

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

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

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

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

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

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

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

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

5.26 (f) The central repository and local repository shall inventory all drugs and supplies
5.27 donated to the repository. For each drug, the inventory must include the drug's name, strength,
5.28 quantity, manufacturer, lot number, expiration date, and the date the drug was donated. For
5.29 each medical supply, the inventory must include a description of the supply, its manufacturer,
5.30 the date the supply was donated, and, if applicable, the supply's brand name, lot number,
5.31 and expiration date.

5.32 Subd. 7. Standards and procedures for inspecting and storing donated prescription
5.33 drugs and supplies. (a) A pharmacist or authorized practitioner who is employed by or

6.1 under contract with the central repository or a local repository shall inspect all donated
6.2 prescription drugs and supplies to determine, to the extent reasonably possible in the
6.3 professional judgment of the pharmacist or practitioner, that the drug or supply is not
6.4 adulterated or misbranded, has not been tampered with, is safe and suitable for dispensing,
6.5 and meets the requirements for donation. The pharmacist or practitioner who inspects the
6.6 drugs shall sign an inspection record stating that the requirements for donation have been
6.7 met. If a local repository receives drugs and supplies from the central repository, the local
6.8 repository does not need to reinspect the drugs and supplies.

6.9 (b) The central repository and local repositories shall store donated drugs and supplies
6.10 in a secure storage area under environmental conditions appropriate for the drug or supply
6.11 being stored. Donated drugs and supplies may not be stored with nondonated inventory. If
6.12 donated drugs or supplies are not inspected immediately upon receipt, a repository must
6.13 quarantine the donated drugs or supplies separately from all dispensing stock until the
6.14 donated drugs or supplies have been inspected and approved for dispensing under the
6.15 program.

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

6.19 (d) In the event that controlled substances are shipped or delivered to a central or local
6.20 repository for donation, the shipment delivery must be documented by the repository and
6.21 returned immediately to the donor or the donor's representative that provided the drugs.

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

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

6.32 (1) the date of destruction;

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

7.1 (3) the name of the person or firm that destroyed the drug; and

7.2 (4) the source of the drugs or supplies destroyed.

7.3 Subd. 8. **Dispensing requirements.** (a) Donated drugs and supplies may be dispensed
7.4 if the drugs or supplies are prescribed by a practitioner for use by an eligible individual and
7.5 are dispensed by a pharmacist or practitioner. A repository shall dispense donated prescription
7.6 drugs in compliance with applicable federal and state laws and regulations for dispensing
7.7 prescription drugs, including all requirements relating to packaging, labeling, record keeping,
7.8 drug utilization review, and patient counseling.

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

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

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

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

7.22 (3) that the dispensing pharmacist, the dispensing or administering practitioner, the
7.23 central repository or local repository, the Board of Pharmacy, and any other participant of
7.24 the drug repository program cannot guarantee the safety of the drug or medical supply being
7.25 dispensed or administered and that the pharmacist or practitioner has determined that the
7.26 drug or supply is safe to dispense or administer based on the accuracy of the donor's form
7.27 submitted with the donated drug or medical supply and the visual inspection required to be
7.28 performed by the pharmacist or practitioner before dispensing or administering.

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

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

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

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

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

8.14 (1) intake application form described under subdivision 5;

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

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

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

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

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

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

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

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

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

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

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

9.6 (b) A health care facility participating in the program, a pharmacist dispensing a drug
 9.7 or supply pursuant to the program, a practitioner dispensing or administering a drug or
 9.8 supply pursuant to the program, or a donor of a drug or medical supply is immune from
 9.9 civil liability for an act or omission that causes injury to or the death of an individual to
 9.10 whom the drug or supply is dispensed and no disciplinary action by a health-related licensing
 9.11 board shall be taken against a pharmacist or practitioner so long as the drug or supply is
 9.12 donated, accepted, distributed, and dispensed according to the requirements of this section.
 9.13 This immunity does not apply if the act or omission involves reckless, wanton, or intentional
 9.14 misconduct, or malpractice unrelated to the quality of the drug or medical supply.

9.15 Sec. 2. **REPEALER.**

9.16 Minnesota Statutes 2016, section 151.55, is repealed.

151.55 CANCER DRUG REPOSITORY PROGRAM.

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

(b) "Board" means the Board of Pharmacy.

(c) "Cancer drug" means a prescription drug that is used to treat:

(1) cancer or the side effects of cancer; or

(2) the side effects of any prescription drug that is used to treat cancer or the side effects of cancer.

(d) "Cancer drug repository" means a medical facility or pharmacy that has notified the board of its election to participate in the cancer drug repository program.

(e) "Cancer supply" or "supplies" means prescription and nonprescription cancer supplies needed to administer a cancer drug.

(f) "Dispense" has the meaning given in section 151.01, subdivision 30.

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

(h) "Donor" means an individual and not a drug manufacturer or wholesale drug distributor who donates a cancer drug or supply according to the requirements of the cancer drug repository program.

(i) "Medical facility" means an institution defined in section 144.50, subdivision 2.

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

(k) "Pharmacist" has the meaning given in section 151.01, subdivision 3.

(l) "Pharmacy" means any pharmacy registered with the Board of Pharmacy according to section 151.19, subdivision 1.

(m) "Practitioner" has the meaning given in section 151.01, subdivision 23.

(n) "Prescription drug" means a legend drug as defined in section 151.01, subdivision 17.

(o) "Side effects of cancer" means symptoms of cancer.

(p) "Single-unit-dose packaging" means a single-unit container for articles intended for administration as a single dose, direct from the container.

(q) "Tamper-evident unit dose packaging" means a container within which a drug is sealed so that the contents cannot be opened without obvious destruction of the seal.

Subd. 2. **Establishment.** The Board of Pharmacy shall establish and maintain a cancer drug repository program, under which any person may donate a cancer drug or supply for use by an individual who meets the eligibility criteria specified under subdivision 4. Under the program, donations may be made on the premises of a medical facility or pharmacy that elects to participate in the program and meets the requirements specified under subdivision 3.

Subd. 3. **Requirements for participation by pharmacies and medical facilities.** (a) To be eligible for participation in the cancer drug repository program, a pharmacy or medical facility must be licensed and in compliance with all applicable federal and state laws and administrative rules.

(b) Participation in the cancer drug repository program is voluntary. A pharmacy or medical facility may elect to participate in the cancer drug repository program by submitting the following information to the board, in a form provided by the board:

(1) the name, street address, and telephone number of the pharmacy or medical facility;

(2) the name and telephone number of a pharmacist who is employed by or under contract with the pharmacy or medical facility, or other contact person who is familiar with the pharmacy's or medical facility's participation in the cancer drug repository program; and

(3) a statement indicating that the pharmacy or medical facility meets the eligibility requirements under paragraph (a) and the chosen level of participation under paragraph (c).

(c) A pharmacy or medical facility may fully participate in the cancer drug repository program by accepting, storing, and dispensing or administering donated drugs and supplies, or may limit its participation to only accepting and storing donated drugs and supplies. If a pharmacy or facility chooses to limit its participation, the pharmacy or facility shall distribute any donated drugs to a fully participating cancer drug repository according to subdivision 8.

(d) A pharmacy or medical facility may withdraw from participation in the cancer drug repository program at any time upon notification to the board. A notice to withdraw from participation may be given by telephone or regular mail.

Subd. 4. **Individual eligibility requirements.** Any Minnesota resident who is diagnosed with cancer is eligible to receive drugs or supplies under the cancer drug repository program. Drugs and supplies shall be dispensed or administered according to the priority given under subdivision 6, paragraph (d).

Subd. 5. **Donations of cancer drugs and supplies.** (a) Any one of the following persons may donate legally obtained cancer drugs or supplies to a cancer drug repository, if the drugs or supplies meet the requirements under paragraph (b) or (c) as determined by a pharmacist who is employed by or under contract with a cancer drug repository:

(1) an individual who is 18 years old or older; or

(2) a pharmacy, medical facility, drug manufacturer, or wholesale drug distributor, if the donated drugs have not been previously dispensed.

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

(1) the donation is accompanied by a cancer drug repository donor form described under paragraph (d) that is signed by the person making the donation or that person's authorized representative;

(2) the drug's expiration date is at least six months later than the date that the drug was donated;

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

(4) the drug is not adulterated or misbranded.

(c) Cancer supplies are eligible for donation under the cancer drug repository program only if the following requirements are met:

(1) the supplies are not adulterated or misbranded;

(2) the supplies are in their original, unopened, sealed packaging; and

(3) the donation is accompanied by a cancer drug repository donor form described under paragraph (d) that is signed by the person making the donation or that person's authorized representative.

(d) The cancer drug repository donor form must be provided by the board and shall 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. The board shall make the cancer drug repository donor form available on the Board of Pharmacy's Web site.

(e) Controlled substances and drugs and supplies that do not meet the criteria under this subdivision are not eligible for donation or acceptance under the cancer drug repository program.

(f) Drugs and supplies may be donated on the premises of a cancer drug repository to a pharmacist designated by the repository. A drop box may not be used to deliver or accept donations.

(g) Cancer drugs and supplies donated under the cancer drug repository program must be stored in a secure storage area under environmental conditions appropriate for the drugs or supplies being stored. Donated drugs and supplies may not be stored with nondonated inventory.

Subd. 6. **Dispensing requirements.** (a) Drugs and supplies must be dispensed by a licensed pharmacist pursuant to a prescription by a practitioner or may be dispensed or administered by a practitioner according to the requirements of chapter 151 and within the practitioner's scope of practice.

(b) Cancer drugs and supplies shall be visually inspected by the pharmacist or practitioner before being dispensed or administered for adulteration, misbranding, 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 may not be dispensed or administered.

(c) Before a cancer drug or supply may be dispensed or administered to an individual, the individual must sign a cancer drug repository recipient form provided by the board acknowledging that the individual understands the information stated on the form. The form shall 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 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 cancer drug repository, the Board of Pharmacy, and any other participant of the cancer drug repository program cannot guarantee the safety of the drug or 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 supply and the visual inspection required to be performed by the pharmacist or practitioner before dispensing or administering.

The board shall make the cancer drug repository form available on the Board of Pharmacy's Web site.

(d) Drugs and supplies shall only be dispensed or administered to individuals who meet the eligibility requirements in subdivision 4 and in the following order of priority:

(1) individuals who are uninsured;

(2) individuals who are enrolled in medical assistance, MinnesotaCare, Medicare, or other public assistance health care; and

(3) all other individuals who are otherwise eligible under subdivision 4 to receive drugs or supplies from a cancer drug repository.

Subd. 7. **Handling fees.** A cancer drug 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 cancer drug or supply dispensed or administered.

Subd. 8. **Distribution of donated cancer drugs and supplies.** (a) Cancer drug repositories may distribute drugs and supplies donated under the cancer drug repository program to other repositories if requested by a participating repository.

(b) A cancer drug repository that has elected not to dispense donated drugs or supplies shall distribute any donated drugs and supplies to a participating repository upon request of the repository.

(c) If a cancer drug repository distributes drugs or supplies under paragraph (a) or (b), the repository shall complete a cancer drug repository donor form provided by the board. The completed form and a copy of the donor form that was completed by the original donor under subdivision 5 shall be provided to the fully participating cancer drug repository at the time of distribution.

Subd. 9. **Resale of donated drugs or supplies.** Donated drugs and supplies may not be resold.

Subd. 10. **Record-keeping requirements.** (a) Cancer drug repository donor and recipient forms shall be maintained for at least five years.

(b) A record of destruction of donated drugs and supplies that are not dispensed under subdivision 6 shall be maintained by the dispensing 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 cancer drug destroyed;
- (3) the name of the person or firm that destroyed the drug; and
- (4) the source of the drugs or supplies destroyed.

Subd. 11. **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 medical facility or pharmacy 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 cancer drug or supply as defined in subdivision 1 is immune from civil liability for an act or omission that causes injury to or the death of an individual to whom the cancer drug or supply is dispensed and no disciplinary action 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 cancer drug or supply.

151.55 CANCER DRUG REPOSITORY PROGRAM.

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

(b) "Board" means the Board of Pharmacy.

(c) "Cancer drug" means a prescription drug that is used to treat:

(1) cancer or the side effects of cancer; or

(2) the side effects of any prescription drug that is used to treat cancer or the side effects of cancer.

(d) "Cancer drug repository" means a medical facility or pharmacy that has notified the board of its election to participate in the cancer drug repository program.

(e) "Cancer supply" or "supplies" means prescription and nonprescription cancer supplies needed to administer a cancer drug.

(f) "Dispense" has the meaning given in section 151.01, subdivision 30.

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

(h) "Donor" means an individual and not a drug manufacturer or wholesale drug distributor who donates a cancer drug or supply according to the requirements of the cancer drug repository program.

(i) "Medical facility" means an institution defined in section 144.50, subdivision 2.

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

(k) "Pharmacist" has the meaning given in section 151.01, subdivision 3.

(l) "Pharmacy" means any pharmacy registered with the Board of Pharmacy according to section 151.19, subdivision 1.

(m) "Practitioner" has the meaning given in section 151.01, subdivision 23.

(n) "Prescription drug" means a legend drug as defined in section 151.01, subdivision 17.

(o) "Side effects of cancer" means symptoms of cancer.

(p) "Single-unit-dose packaging" means a single-unit container for articles intended for administration as a single dose, direct from the container.

(q) "Tamper-evident unit dose packaging" means a container within which a drug is sealed so that the contents cannot be opened without obvious destruction of the seal.

Subd. 2. **Establishment.** The Board of Pharmacy shall establish and maintain a cancer drug repository program, under which any person may donate a cancer drug or supply for use by an individual who meets the eligibility criteria specified under subdivision 4. Under the program, donations may be made on the premises of a medical facility or pharmacy that elects to participate in the program and meets the requirements specified under subdivision 3.

Subd. 3. **Requirements for participation by pharmacies and medical facilities.** (a) To be eligible for participation in the cancer drug repository program, a pharmacy or medical facility must be licensed and in compliance with all applicable federal and state laws and administrative rules.

(b) Participation in the cancer drug repository program is voluntary. A pharmacy or medical facility may elect to participate in the cancer drug repository program by submitting the following information to the board, in a form provided by the board:

(1) the name, street address, and telephone number of the pharmacy or medical facility;

(2) the name and telephone number of a pharmacist who is employed by or under contract with the pharmacy or medical facility, or other contact person who is familiar with the pharmacy's or medical facility's participation in the cancer drug repository program; and

(3) a statement indicating that the pharmacy or medical facility meets the eligibility requirements under paragraph (a) and the chosen level of participation under paragraph (c).

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(c) A pharmacy or medical facility may fully participate in the cancer drug repository program by accepting, storing, and dispensing or administering donated drugs and supplies, or may limit its participation to only accepting and storing donated drugs and supplies. If a pharmacy or facility chooses to limit its participation, the pharmacy or facility shall distribute any donated drugs to a fully participating cancer drug repository according to subdivision 8.

(d) A pharmacy or medical facility may withdraw from participation in the cancer drug repository program at any time upon notification to the board. A notice to withdraw from participation may be given by telephone or regular mail.

Subd. 4. **Individual eligibility requirements.** Any Minnesota resident who is diagnosed with cancer is eligible to receive drugs or supplies under the cancer drug repository program. Drugs and supplies shall be dispensed or administered according to the priority given under subdivision 6, paragraph (d).

Subd. 5. **Donations of cancer drugs and supplies.** (a) Any one of the following persons may donate legally obtained cancer drugs or supplies to a cancer drug repository, if the drugs or supplies meet the requirements under paragraph (b) or (c) as determined by a pharmacist who is employed by or under contract with a cancer drug repository:

(1) an individual who is 18 years old or older; or

(2) a pharmacy, medical facility, drug manufacturer, or wholesale drug distributor, if the donated drugs have not been previously dispensed.

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

(1) the donation is accompanied by a cancer drug repository donor form described under paragraph (d) that is signed by the person making the donation or that person's authorized representative;

(2) the drug's expiration date is at least six months later than the date that the drug was donated;

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

(4) the drug is not adulterated or misbranded.

(c) Cancer supplies are eligible for donation under the cancer drug repository program only if the following requirements are met:

(1) the supplies are not adulterated or misbranded;

(2) the supplies are in their original, unopened, sealed packaging; and

(3) the donation is accompanied by a cancer drug repository donor form described under paragraph (d) that is signed by the person making the donation or that person's authorized representative.

(d) The cancer drug repository donor form must be provided by the board and shall 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. The board shall make the cancer drug repository donor form available on the Board of Pharmacy's Web site.

(e) Controlled substances and drugs and supplies that do not meet the criteria under this subdivision are not eligible for donation or acceptance under the cancer drug repository program.

(f) Drugs and supplies may be donated on the premises of a cancer drug repository to a pharmacist designated by the repository. A drop box may not be used to deliver or accept donations.

(g) Cancer drugs and supplies donated under the cancer drug repository program must be stored in a secure storage area under environmental conditions appropriate for the drugs or supplies being stored. Donated drugs and supplies may not be stored with nondonated inventory.

Subd. 6. **Dispensing requirements.** (a) Drugs and supplies must be dispensed by a licensed pharmacist pursuant to a prescription by a practitioner or may be dispensed or administered by a practitioner according to the requirements of chapter 151 and within the practitioner's scope of practice.

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(b) Cancer drugs and supplies shall be visually inspected by the pharmacist or practitioner before being dispensed or administered for adulteration, misbranding, 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 may not be dispensed or administered.

(c) Before a cancer drug or supply may be dispensed or administered to an individual, the individual must sign a cancer drug repository recipient form provided by the board acknowledging that the individual understands the information stated on the form. The form shall 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 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 cancer drug repository, the Board of Pharmacy, and any other participant of the cancer drug repository program cannot guarantee the safety of the drug or 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 supply and the visual inspection required to be performed by the pharmacist or practitioner before dispensing or administering.

The board shall make the cancer drug repository form available on the Board of Pharmacy's Web site.

(d) Drugs and supplies shall only be dispensed or administered to individuals who meet the eligibility requirements in subdivision 4 and in the following order of priority:

(1) individuals who are uninsured;

(2) individuals who are enrolled in medical assistance, MinnesotaCare, Medicare, or other public assistance health care; and

(3) all other individuals who are otherwise eligible under subdivision 4 to receive drugs or supplies from a cancer drug repository.

Subd. 7. **Handling fees.** A cancer drug 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 cancer drug or supply dispensed or administered.

Subd. 8. **Distribution of donated cancer drugs and supplies.** (a) Cancer drug repositories may distribute drugs and supplies donated under the cancer drug repository program to other repositories if requested by a participating repository.

(b) A cancer drug repository that has elected not to dispense donated drugs or supplies shall distribute any donated drugs and supplies to a participating repository upon request of the repository.

(c) If a cancer drug repository distributes drugs or supplies under paragraph (a) or (b), the repository shall complete a cancer drug repository donor form provided by the board. The completed form and a copy of the donor form that was completed by the original donor under subdivision 5 shall be provided to the fully participating cancer drug repository at the time of distribution.

Subd. 9. **Resale of donated drugs or supplies.** Donated drugs and supplies may not be resold.

Subd. 10. **Record-keeping requirements.** (a) Cancer drug repository donor and recipient forms shall be maintained for at least five years.

(b) A record of destruction of donated drugs and supplies that are not dispensed under subdivision 6 shall be maintained by the dispensing 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 cancer drug destroyed;

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

(4) the source of the drugs or supplies destroyed.

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Subd. 11. **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 medical facility or pharmacy 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 cancer drug or supply as defined in subdivision 1 is immune from civil liability for an act or omission that causes injury to or the death of an individual to whom the cancer drug or supply is dispensed and no disciplinary action 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 cancer drug or supply.