

MINNESOTA BOARD OF PHARMACY GUIDELINES ADDRESSING THE CANCER DRUG REPOSITORY PROGRAM; MINNESOTA STATUTE 151.55

INTRODUCTION

- The 2005 Minnesota State Legislature passed and Governor Tim Pawlenty signed the cancer drug repository program.
- The Minnesota Board of Pharmacy has been designated by statute to safely establish and maintain a cancer drug repository program.
- Participation in the cancer drug repository program is voluntary.
- Enclosed is a copy of Minnesota Statute 151.55 cancer drug repository program.
- Enclosed are the Minnesota Board of Pharmacy guidelines for the cancer drug repository program.
- Enclosed are the three forms required to comply with the cancer drug repository program statutory language.

MINNESOTA BOARD OF PHARMACY

- The pharmacist responsible for a cancer drug repository program must submit policies and procedures to the Minnesota Board of Pharmacy for review and appropriate actions.
- The submitted policies and procedures must completely address Minnesota Statute 151.55 and the Minnesota Board of Pharmacy guidelines for the cancer drug repository program
- The Minnesota Board of Pharmacy cannot grant a variance to a federal regulation or a Minnesota statute.

GUIDELINES ADDRESSING THE CANCER DRUG REPOSITORY PROGRAM

The cancer drug repository program policies and procedures must address all the provisions of Minnesota Statute 151.55, including use of the three required forms: the participation form, the donation form and the recipient form. (Enclosed)

The cancer drug repository program policies and procedures must address all the following Minnesota Board of Pharmacy guidelines.

- 1) The policies and procedures must address the participation limit a pharmacy or medical facility chooses and how a partially participating repository will distribute any donated drugs or supplies to a fully participating cancer drug repository. See Minnesota Statute 151.55, subdivision 3.
- 2) All required forms must be maintained for at least five years.
- 3) The policies and procedures pertaining to individual eligibility must address how Minnesota Statute 151.55, subdivision 4, requirements will be met, including identification as a Minnesota resident who has been diagnosed with cancer.
- 4) Policies and procedures must address the donations of cancer drugs and supplies and all the elements of Minnesota Statute 151.55, subdivision 5, including that the donor must be 18 years of age or older and that only if the donated drugs have not been previously dispensed can a pharmacy, medical facility, drug manufacturer, or drug wholesaler donate.
- 5) A pharmacist, who is employed by or under contract with a cancer drug repository, must determine that the donated drugs or supplies meet all the requirements of the Minnesota Statute 151.55, including that the drug's expiration date must be least six months later than the date the drug was donated; the drug must be in its original manufacturer's unopened, tamper-evident, unit-dose packaging, including lot number and expiration date and the drug must not be adulterated or misbranded. The person making the donation or the person's authorized representative, shall affirm, with a signature on the cancer drug repository donation form, that the donated drugs and supplies were properly stored, never opened, never used and never tampered with, adulterated or misbranded.
- 6) Controlled substances cannot be part of the cancer drug repository program.
- 7) Recommend that donated drugs and supplies with special storage or handling requirements only be accepted if donors are able to provide documentation that the special storage or handling requirements have been met.
- 8) Pharmacists and practitioners need to review the dispensing requirements in Minnesota Statute 151.55, subdivision 6, and address these in the policies and procedures.

- 9) The cancer drug repository program recipient form [enclosed] must be addressed in the policies and procedures including all elements of Minnesota Statute 151.55, subdivision 6. These include the recipient's right to know that the drugs have been previously dispensed, have not expired, have not been adulterated or misbranded and that the drugs are in their original manufacturer's unopened, tamper-evident, unit-dose packaging. It must be made clear to the recipient that they are making a decision about their treatment, not merely signing a form. (Informed Consent)
- 10) Policies and procedures for the distribution of donated drugs and supplies to other drug repositories need to be established that address Minnesota Statute 151.55, subdivision 8, including the use of the cancer drug repository program donor form.
- 11) The policies and procedures must follow the Minnesota Statute 151.55, which states that donated drugs and supplies may not be resold.
- 12) Drugs used in the cancer drug repository program must be stored separately from the rest of the pharmacy's stock.
- 13) Recommend a monthly inspection of all cancer drug repository program drugs. This inspection should include checking the expiration date, checking the security of the storage area, and a reconciliation of all the cancer drug repository program drugs and supplies.
- 14) Cancer drug repository program prescriptions must be filed separately or the pharmacy must have an auditable record system that identifies all necessary information for the cancer drug repository program.
- 15) All dispensed cancer drug repository program drugs must be verified, have a drug utilization review performed, and be dispensed by a pharmacist or by a practitioner, according to the requirements of Minnesota Statutes Chapter 151 and within the practitioner's scope of practice.
- 16) All cancer drug repository program drugs must be entered on the patient's profile and the profile must indicate that the drug was obtained through the cancer drug repository program.
- 17) All drugs dispensed in the cancer drug repository program must be labeled according to Minnesota Rule 6800.3400.
- 18) All patient-counseling requirements will apply to all drugs dispensed in the cancer drug repository program.
- 19) There must be a recall procedure for the cancer drug repository program drugs including documentation of all recalls.

- 20) Recommend a failure mode and effect analysis “FMEA” and a quality improvement “QI” system that addresses the cancer drug repository program, Minnesota Statute 151.55, and the cancer drug repository program policies and procedures.
- 21) Recommend being fully aware of federal regulations, especially those FDA regulations involving drug adulteration and drug misbranding along with the potential penalties for violations of these regulations.
- 22) Review Minnesota Statute 151.35 on drug adulteration and Minnesota Statute 151.36 on drug misbranding.
- 23) Must comply with the Minnesota Hazardous Waste Rule, Chapter 7045, as enforceable by the Minnesota Pollution Control Agency [MPCA] and other authorized state agencies. For information contact the MPCA at 1-800-657-3864 or www.pca.state.mn.us. All these records must be kept for at least five years.
- 24) All Minnesota Board of Pharmacy statutes and rules must be complied with.
- 25) Suggest seeking opinions from your legal counsel, risk management, and liability carrier before implementing.
- 26) All drugs used in the cancer drug repository program should be easily auditable and every dose accounted for. See below for recommended entries for a perpetual inventory logbook.

Suggested information to be contained in a perpetual inventory logbook.

1. Name of drug;
2. Quantity of the drug
3. Expiration date of the drug;
4. Lot number of the drug;
5. Name of person who accepted the drug from the donor;
6. Name of the person who donated the drug;
7. Name of the person to whom the drug was originally prescribed;
8. Name of the person to whom the drug was dispensed;
9. Date the drug was dispensed;
10. Name of the prescribing practitioner who wrote the prescription for the drug to be dispensed under the cancer drug repository program;
11. Name of the medical facility or pharmacy to which the drug was distributed;
12. Date the drug was distributed to another cancer drug repository;
13. Date of destruction or disposal of the drug;
14. Whether a handling fee was charged and the amount of any such fee.

CANCER DRUG REPOSITORY PROGRAM NOTICE OF PARTICIPATION OR WITHDRAWAL

Completion of this form meets the notification requirement for participation in, or withdrawal from, the Cancer Drug Repository Program under Minnesota Statute 151.55. Complete and submit this form to the following address. Questions about completing this form may be directed to 651-201-2825. This form must be maintained for at least five years

Minnesota Board of Pharmacy
Cancer Drug Repository Program
2829 University Avenue SE #530
Minneapolis, Minnesota 55414
OR FAX TO
651-201-2837

NOTICE OF PARTICIPATION PHARMACY OR MEDICAL FACILITY

A pharmacy or medical facility may fully participate in the cancer drug repository program by accepting, storing and dispensing donated drugs and supplies or may limit its participation to only accepting and storing donated drugs and medical supplies. Check one of the following:

- Full Participation (Will dispense drugs and supplies.) Partial Participation (WILL NOT dispense drugs and supplies.)

Name -- Pharmacy or Medical Facility	Telephone Number
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Address

City	State	Zip Code
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Name -- Pharmacist	License Number	Telephone Number
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I certify that the above named facility is licensed in the State of Minnesota and is in compliance with all State and Federal laws and administrative rules.

SIGNATURE -- Pharmacist	Date Signed
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NOTICE OF WITHDRAWAL PHARMACY OR MEDICAL FACILITY
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Name -- Pharmacy or Medical Facility	Telephone Number
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Address

City	State	Zip Code
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As of (enter date) _____ the pharmacy or medical facility identified above, will no longer be participating in the Cancer Drug Repository Program.

SIGNATURE -- Pharmacist	Date Signed
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CANCER DRUG REPOSITORY PROGRAM DONATION, TRANSFER AND DESTRUCTION RECORD

Completion of this form meets the requirements under Minnesota Statute 151.55 for donating drugs and supplies, for distribution of drugs or supplies to a participating repository and for destruction of drugs or supplies under the Cancer Drug Repository Program. This form must be maintained for at least five years.

Questions about completing this form may be directed to 651-201-2825.

DONATION INFORMATION

Name -- Donor (print or type)	Date Donated
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Name -- Pharmacy or Medical Facility Receiving Donation

Name -- Medication or Medical Supply

Medication Strength	Expiration Date	Lot Number	Quantity Donated
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I certify that the above named drug or supply was stored as recommended by the manufacturer and that the drug or supply has never been opened, used, tampered with, adulterated, or misbranded.

SIGNATURE -- Donor or Designee	Date Signed
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Name of Pharmacist accepting donation	License number of pharmacist
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DISTRIBUTION OF DONATED DRUG OR MEDICAL SUPPLY TO A PARTICIPATING REPOSITORY

A COPY of the original donation form must accompany this form for all distributions between participating repositories

Name -- Pharmacy or Medical Facility Receiving Drug or Medical Supply	Date Distributed
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Quantity of Medication or Description of Medical Supply Distributed

DESTRUCTION OR DISPOSAL INFORMATION
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Name, Strength and Quantity

Source of Drug or Medical Supply

Name of Person or Firm Destroying or Disposing of Drug or Medical Supply
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CANCER DRUG REPOSITORY PROGRAM RECIPIENT RECORD

Completion of this form meets the requirements under Minnesota Statute 151.55 for dispensing or administering drugs and medical supplies to recipients who meet the eligibility requirements of the Cancer Drug Repository Program. This form must be maintained for at least five years.

Questions about completing this form may be directed to 651-201-2825.

RECIPIENT INFORMATION

Name -- Recipient (print or type)	Date Received
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Name -- Medication or Medical Supply

Medication Strength	Expiration Date	Lot Number	Quantity Received
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I certify that I am a Minnesota Resident and that I understand that the above named drug or supply I am receiving has been donated, may have been previously dispensed, and has potentially been stored in a non-controlled environment. I understand 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 manufacturer's unopened packaging. I understand that the dispensing pharmacist, the 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.

SIGNATURE -- Recipient	Date Signed
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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, general assistance medical care, 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.

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