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130.25 Sec. 2. [151.55] [CANCER DRUG REPOSITORY PROGRAM.]
130.26 Subdivision 1. [DEFINITIONS.] (a) For the purposes of this
130.27 section, the terms defined in this subdivision have the meanings
130.28 given.
130.29 (b) "Board" means the Board of Pharmacy.
130.30 (c) "Cancer drug" means a prescription drug that is used to
130.31 treat:
130.32 (1) cancer or the side effects of cancer; or
130.33 (2) the side effects of any prescription drug that is used
130.34 to treat cancer or the side effects of cancer.
130.35 (d) "Cancer drug repository" means a medical facility or
130.36 pharmacy that has notified the board of its election to
131.1 participate in the cancer drug repository program.
131.2 (e) "Cancer supply" or "supplies" means prescription and
131.3 nonprescription cancer supplies needed to administer a cancer
131.4 drug.
131.5 (f) "Dispense" has the meaning given in section 151.01,
131.6 subdivision 30.
131.7 (g) "Distribute" means to deliver, other than by
131.8 administering or dispensing.
131.9 (h) "Donor" means an individual and not a drug manufacturer
131.10 or wholesale drug distributor who donates a cancer drug or
131.11 supply according to the requirements of the cancer drug
131.12 repository program.
131.13 (i) "Medical facility" means an institution defined in
131.14 section 144.50, subdivision 2.
131.15 (j) "Medical supplies" means any prescription and
131.16 nonprescription medical supply needed to administer a cancer
131.17 drug.
131.18 (k) "Pharmacist" has the meaning given in section 151.01,
131.19 subdivision 3.
131.20 (l) "Pharmacy" means any pharmacy registered with the Board
131.21 of Pharmacy according to section 151.19, subdivision 1.
131.22 (m) "Practitioner" has the meaning given in section 151.01,
131.23 subdivision 23.
131.24 (n) "Prescription drug" means a legend drug as defined in
131.25 section 151.01, subdivision 17.
131.26 (o) "Side effects of cancer" means symptoms of cancer.
131.27 (p) "Single-unit-dose packaging" means a single-unit
131.28 container for articles intended for administration as a single
131.29 dose, direct from the container.
131.30 (q) "Tamper-evident unit dose packaging" means a container
131.31 within which a drug is sealed so that the contents cannot be
131.32 opened without obvious destruction of the seal.
131.33 Subd. 2. [ESTABLISHMENT.] The Board of Pharmacy shall
131.34 establish and maintain a cancer drug repository program, under
131.35 which any person may donate a cancer drug or supply for use by
131.36 an individual who meets the eligibility criteria specified under
132.1 subdivision 4. Under the program, donations may be made on the
132.2 premises of a medical facility or pharmacy that elects to
132.3 participate in the program and meets the requirements specified
132.4 under subdivision 3.

132.5 Subd. 3. [REQUIREMENTS FOR PARTICIPATION BY PHARMACIES AND
132.6 MEDICAL FACILITIES.] (a) To be eligible for participation in the
132.7 cancer drug repository program, a pharmacy or medical facility
132.8 must be licensed and in compliance with all applicable federal
132.9 and state laws and administrative rules.

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

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

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

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

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

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

133.1 Subd. 4. [INDIVIDUAL ELIGIBILITY REQUIREMENTS.] Any
133.2 Minnesota resident who is diagnosed with cancer is eligible to
133.3 receive drugs or supplies under the cancer drug repository
133.4 program. Drugs and supplies shall be dispensed or administered
133.5 according to the priority given under subdivision 6, paragraph
133.6 (d).

133.7 Subd. 5. [DONATIONS OF CANCER DRUGS AND SUPPLIES.] (a) Any
133.8 one of the following persons may donate legally obtained cancer
133.9 drugs or supplies to a cancer drug repository, if the drugs or
133.10 supplies meet the requirements under paragraph (b) or (c) as
133.11 determined by a pharmacist who is employed by or under contract
133.12 with a cancer drug repository:

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

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

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

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

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

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

133.30 (4) the drug is not adulterated or misbranded.

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

133.34 (1) the supplies are not adulterated or misbranded;

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

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

134.5 (d) The cancer drug repository donor form must be provided
134.6 by the board and shall state that to the best of the donor's
134.7 knowledge the donated drug or supply has been properly stored
134.8 and that the drug or supply has never been opened, used,
134.9 tampered with, adulterated, or misbranded. The board shall make
134.10 the cancer drug repository donor form available on the Board of
134.11 Pharmacy's Web site.

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

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

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

134.25 Subd. 6. [DISPENSING REQUIREMENTS.] (a) Drugs and supplies
134.26 must be dispensed by a licensed pharmacist pursuant to a
134.27 prescription by a practitioner or may be dispensed or
134.28 administered by a practitioner according to the requirements of
134.29 chapter 151 and within the practitioner's scope of practice.

134.30 (b) Cancer drugs and supplies shall be visually inspected
134.31 by the pharmacist or practitioner before being dispensed or
134.32 administered for adulteration, misbranding, and date of
134.33 expiration. Drugs or supplies that have expired or appear upon
134.34 visual inspection to be adulterated, misbranded, or tampered
134.35 with in any way may not be dispensed or administered.

134.36 (c) Before a cancer drug or supply may be dispensed or
135.1 administered to an individual, the individual must sign a cancer
135.2 drug repository recipient form provided by the board
135.3 acknowledging that the individual understands the information
135.4 stated on the form. The form shall include the following
135.5 information:

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

135.8 (2) that a visual inspection has been conducted by the
135.9 pharmacist or practitioner to ensure that the drug has not
135.10 expired, has not been adulterated or misbranded, and is in its

135.11 original, unopened packaging; and
135.12 (3) that the dispensing pharmacist, the dispensing or
135.13 administering practitioner, the cancer drug repository, the
135.14 Board of Pharmacy, and any other participant of the cancer drug
135.15 repository program cannot guarantee the safety of the drug or
135.16 supply being dispensed or administered and that the pharmacist
135.17 or practitioner has determined that the drug or supply is safe
135.18 to dispense or administer based on the accuracy of the donor's
135.19 form submitted with the donated drug or supply and the visual
135.20 inspection required to be performed by the pharmacist or
135.21 practitioner before dispensing or administering.
135.22 The board shall make the cancer drug repository form available
135.23 on the Board of Pharmacy's Web site.
135.24 (d) Drugs and supplies shall only be dispensed or
135.25 administered to individuals who meet the eligibility
135.26 requirements in subdivision 4 and in the following order of
135.27 priority:
135.28 (1) individuals who are uninsured;
135.29 (2) individuals who are enrolled in medical assistance,
135.30 general assistance medical care, MinnesotaCare, Medicare, or
135.31 other public assistance health care; and
135.32 (3) all other individuals who are otherwise eligible under
135.33 subdivision 4 to receive drugs or supplies from a cancer drug
135.34 repository.
135.35 Subd. 7. [HANDLING FEES.] A cancer drug repository may
135.36 charge the individual receiving a drug or supply a handling fee
136.1 of no more than 250 percent of the medical assistance program
136.2 dispensing fee for each cancer drug or supply dispensed or
136.3 administered.
136.4 Subd. 8. [DISTRIBUTION OF DONATED CANCER DRUGS AND
136.5 SUPPLIES.] (a) Cancer drug repositories may distribute drugs and
136.6 supplies donated under the cancer drug repository program to
136.7 other repositories if requested by a participating repository.
136.8 (b) A cancer drug repository that has elected not to
136.9 dispense donated drugs or supplies shall distribute any donated
136.10 drugs and supplies to a participating repository upon request of
136.11 the repository.
136.12 (c) If a cancer drug repository distributes drugs or
136.13 supplies under paragraph (a) or (b), the repository shall
136.14 complete a cancer drug repository donor form provided by the
136.15 board. The completed form and a copy of the donor form that was
136.16 completed by the original donor under subdivision 5 shall be
136.17 provided to the fully participating cancer drug repository at
136.18 the time of distribution.
136.19 Subd. 9. [RESALE OF DONATED DRUGS OR SUPPLIES.] Donated
136.20 drugs and supplies may not be resold.
136.21 Subd. 10. [RECORD-KEEPING REQUIREMENTS.] (a) Cancer drug
136.22 repository donor and recipient forms shall be maintained for at
136.23 least five years.
136.24 (b) A record of destruction of donated drugs and supplies
136.25 that are not dispensed under subdivision 6 shall be maintained
136.26 by the dispensing repository for at least five years. For each
136.27 drug or supply destroyed, the record shall include the following
136.28 information:
136.29 (1) the date of destruction;
136.30 (2) the name, strength, and quantity of the cancer drug
136.31 destroyed;

136.32 (3) the name of the person or firm that destroyed the drug;
136.33 and
136.34 (4) the source of the drugs or supplies destroyed.
136.35 Subd. 11. [LIABILITY.] (a) The manufacturer of a drug or
136.36 supply is not subject to criminal or civil liability for injury,
137.1 death, or loss to a person or to property for causes of action
137.2 described in clauses (1) and (2). A manufacturer is not liable
137.3 for:
137.4 (1) the intentional or unintentional alteration of the drug
137.5 or supply by a party not under the control of the manufacturer;
137.6 or
137.7 (2) the failure of a party not under the control of the
137.8 manufacturer to transfer or communicate product or consumer
137.9 information or the expiration date of the donated drug or supply.
137.10 (b) A medical facility or pharmacy participating in the
137.11 program, a pharmacist dispensing a drug or supply pursuant to
137.12 the program, a practitioner dispensing or administering a drug
137.13 or supply pursuant to the program, or a donor of a cancer drug
137.14 or supply as defined in subdivision 1 is immune from civil
137.15 liability for an act or omission that causes injury to or the
137.16 death of an individual to whom the cancer drug or supply is
137.17 dispensed and no disciplinary action shall be taken against a
137.18 pharmacist or practitioner so long as the drug or supply is
137.19 donated, accepted, distributed, and dispensed according to the
137.20 requirements of this section. This immunity does not apply if
137.21 the act or omission involves reckless, wanton, or intentional
137.22 misconduct, or malpractice unrelated to the quality of the
137.23 cancer drug or supply.
137.24 [EFFECTIVE DATE.] This section is effective August 1, 2005.