

PUBLIC HEALTH CODE (EXCERPT)
Act 368 of 1978

333.17780 Cancer drug repository program.

Sec. 17780.

(1) The board shall establish and maintain a cancer drug repository program that would allow a person to donate a cancer drug or supply for use by an individual who meets the eligibility criteria specified under subsection (7). The board shall establish program guidelines, policies, and procedures addressing the cancer drug repository program. Under the cancer drug repository program, donations may be made on the premises of a health facility or pharmacy that elects to participate in the program and meets the requirements specified under subsection (2).

(2) Any health facility or pharmacy that is licensed and in compliance with all federal and state laws, rules, and regulations is eligible to participate in the cancer drug repository program. Participation in the cancer drug repository program is voluntary and a pharmacy or health 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. A pharmacy or health facility may choose to fully participate in the cancer drug repository program by accepting, storing, and dispensing or administering donated drugs and supplies or the pharmacy or health facility may limit its participation to only accepting and storing donated drugs and supplies. If a pharmacy or health facility chooses to limit its participation, the pharmacy or health facility shall distribute any donated drugs to a fully participating cancer drug repository in accordance with subsection (8). A pharmacy or health facility that elects to participate in the cancer drug repository program shall submit the following information to the board in a form provided by the board that includes, at a minimum, each of the following:

(a) The name, street address, and telephone number of the pharmacy or health facility.

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

(c) A statement indicating that the pharmacy or health facility is licensed in this state and in compliance with all federal and state laws, rules, and regulations and the chosen level of participation in the cancer drug repository program.

(3) An individual who is at least 18 years of age may donate legally obtained cancer drugs or supplies to a cancer drug repository. If the donated drugs have not been previously dispensed, a pharmacy, health facility, manufacturer, or wholesale distributor may also donate cancer drugs or supplies to a cancer drug repository. Donated drugs or supplies are acceptable for donation if they are determined to be eligible by a pharmacist who is employed by or under contract with a cancer drug repository as follows:

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

(i) The donation is accompanied by a cancer drug repository donor form that is provided by the board and states that to the best of the donor's knowledge the donated drug has been properly stored and that the drug has never been opened, used, tampered with, adulterated, or misbranded. The board shall make the cancer drug repository donor form available on the board's website. The form shall be signed by the person making the donation or that person's authorized representative.

(ii) The drug's expiration date is at least 6 months later than the date the drug was donated.

(iii) 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.

(iv) The drug is not adulterated or misbranded.

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

(i) The supplies are not adulterated or misbranded.

(ii) The supplies are in their original, unopened, sealed package.

(iii) The donation is accompanied by a cancer drug repository donor form that is provided by the board and states that to the best of the donor's knowledge the donated supply has been properly stored and that the 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's website. The form shall be signed by the person making the donation or that person's authorized representative.

(4) Controlled substances are not eligible for donation or acceptance under the cancer drug repository program. Cancer drugs and supplies that do not meet the criteria described under subsection (3) are not eligible for donation or acceptance under the cancer drug repository program. Cancer drugs and supplies may be donated on the premises of a cancer drug repository to a pharmacist designated by the repository. A drop box shall not be used to deliver or accept donations. Cancer drugs and supplies donated under the cancer drug repository program shall 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.

(5) Cancer drugs and supplies that are donated under the cancer drug repository program shall be dispensed by a pharmacist pursuant to a prescription by a prescriber or may be dispensed or administered by a dispensing prescriber. The cancer drugs and supplies shall be visually inspected by the pharmacist or dispensing prescriber before being dispensed or administered for adulteration, misbranding, and date of expiration. Cancer 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.

(6) Before a cancer drug or supply may be dispensed or administered to an individual, the individual must provide verification that he or she has a current diagnosis of cancer, provide proof of his or her insurance, if any, and 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 be made available to the public on the board's website. The form shall include, at a minimum, the following information:

(a) That the drug or supply being dispensed or administered has been donated and may have been previously dispensed.

(b) That a visual inspection has been conducted by the pharmacist or dispensing prescriber to ensure that the drug has not expired, has not been adulterated or misbranded, and is in its original, unopened packaging.

(c) That the pharmacist, the dispensing or administering prescriber, the cancer drug repository, the board, 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 prescriber 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 prescriber before dispensing or administering.

(7) Any resident of this state who is diagnosed with cancer is eligible to receive drugs or supplies under the cancer drug repository program. Cancer drugs and supplies donated under the cancer drug repository program shall not be resold and shall only be dispensed or administered to residents of this state who are diagnosed with cancer. A pharmacist who dispenses those drugs and supplies donated under the cancer drug repository program shall not submit a claim or otherwise seek reimbursement from any public or private third party payer for drugs or supplies dispensed to any eligible individual in accordance with the program, nor shall a public or private third party payer be required to provide reimbursement for donated drugs or supplies dispensed by a pharmacist to an eligible individual in accordance with the program. Cancer drugs and supplies dispensed under the cancer drug repository program shall be dispensed in the following order of priority:

(a) Individuals who are uninsured or do not have insurance coverage for those cancer drugs or supplies.

(b) Individuals who are enrolled in medicaid, medicare, or any other public assistance health care program.

(c) All other individuals who are residents of this state and diagnosed with cancer.

(8) A cancer drug repository may charge the individual receiving a drug or supply a handling fee of not more than 250% of the medicaid dispensing fee or \$5.00, whichever is less, for each cancer drug or supply dispensed or administered. Cancer drug repositories may distribute drugs and supplies donated under the cancer drug repository program to other repositories if requested by a participating repository. 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. If a cancer drug repository distributes drugs or supplies to another participating repository, the repository shall complete a cancer drug repository donor form provided by the board. The completed form and copy of the donor form that was completed by the original donor under subsection (3) shall be provided to the fully participating cancer drug repository at the time of distribution.

(9) Cancer drug repository donor and recipient forms shall be maintained for at least 5 years. A record of destruction of donated drugs and supplies that are not dispensed under subsection (7) shall be maintained by the dispensing repository for at least 5 years. For each drug or supply destroyed, the record shall include the following information:

(a) The date of destruction.

(b) The name, strength, and quantity of the cancer drug destroyed.

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

(d) The source of the drugs or supplies destroyed.

(10) A manufacturer is not subject to criminal liability or liability in tort or other civil action for injury, death, or loss to a person or to property for any of the following causes of action:

(a) The intentional or unintentional adulteration or misbranding of the drug or supply by a party not under the control of the manufacturer.

(b) 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.

(c) Claims for payment to government or private payers.

(11) A health facility or pharmacy participating in the cancer drug repository program, a pharmacist dispensing a drug or supply pursuant to the program, a prescriber dispensing or administering a drug or supply pursuant to the program, or a donor of a cancer drug or supply 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 prescriber as 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.

(12) As used in this section:

(a) "Cancer drug" means a prescription drug that is used to treat either of the following:

(i) Cancer or the side effects of cancer.

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

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

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

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

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

(f) "Health facility" means a facility licensed in accordance with article 17 as a county medical care facility, freestanding surgical outpatient facility, home for the aged, hospital, hospital long-term care unit, nursing home, and hospice.

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

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

(i) "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.

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