Cancer Drug Repository

This Act creates a Cancer Drug Repository Program and requires the state Department of Health and Human Services to establish a cancer drug repository program for the collection and redistribution of unadulterated cancer drugs in their original sealed and tamper-evident unit dose packaging. The law requires the Director of Health and Human Services in consultation with the Board of Pharmacy to adopt rules and regulations governing the Program. The rules and regulations must include standards and procedures for inspecting, accepting, safely storing and dispensing donated cancer drugs, eligibility standards and an identification card based on economic need to receive cancer drugs from the Program, immunity provisions and forms, a maximum dispensing fee, a list of cancer drugs that will be accepted and a list of cancer drugs that will not be accepted, and a form to be signed by the cancer drug donor.

The Program will be permitted to accept cancer drugs from any person, including a cancer drug manufacturer or health care facility, provided that the cancer drugs are donated at a pharmacy, hospital or nonprofit clinic that has elected to participate in the Program and meets the eligibility requirements adopted by the Board. Participation in the Cancer Drug Repository Program is voluntary. Resale of cancer drugs donated to the Program is prohibited.

Submitted as:
Nebraska
LB 756
Status: Enacted into law in 2003.

Suggested State Legislation

(Title, enacting clause, etc.)

Section 1. [Short Title.] This Act may be cited as the "Cancer Drug Repository Program Act."

Section 2. [Definitions.] As used in this Act:
(1) "Cancer Drug" means a prescription drug used to treat
(a) Cancer or its side effects or
(b) The side effects of a prescription drug used to treat cancer or its side effects;
(2) "Department" means the [department of health and human services regulation and licensure];
(3) "Health Care Facility" has the definition found in [insert citation];
(4) "Health Clinic" has the definition found in [insert citation];
(5) "Hospital" has the definition found in [insert citation];
(6) "Pharmacy" has the definition found in [insert citation];
(7) "Physician's Office" means the office of a person licensed to practice medicine and surgery or osteopathic medicine and surgery;
(8) "Prescribing Practitioner" means a health care practitioner licensed under the Uniform Licensing Law who is authorized to prescribe cancer drugs; and
(9) "Prescription Drug" has the definition found in [insert citation].

Section 3. [Establishing the Cancer Drug Repository Program.] The [department] shall establish a Cancer Drug Repository Program for accepting donated cancer drugs and dispensing such drugs to state residents. Participation in the program shall be voluntary.
Section 4. [Donations: Criteria.]

(1) Any person or entity, including, but not limited to, a cancer drug manufacturer or health care facility, may donate cancer drugs to the Cancer Drug Repository Program.

(2) Cancer drugs may be donated at a physician's office, pharmacy, hospital, or health clinic that elects to participate in the program and meets criteria established by the [department] for such participation.

Section 5. [Donations: Limitations.]

(1) A cancer drug shall only be accepted or dispensed under the Cancer Drug Repository Program if such drug is in its original, unopened, sealed, and tamper-evident unit dose packaging, except that a cancer drug packaged in single unit doses may be accepted and dispensed if the outside packaging is opened but the single-unit-dose packaging is unopened.

(2) A cancer drug shall not be accepted or dispensed under the Cancer Drug Repository Program if:

   (a) Such drug bears an expiration date that is earlier than six months after the date the drug was donated; or

   (b) Such drug is adulterated or misbranded as described in [insert citation].

(3) Subject to limitations provided in this section, unused cancer drugs dispensed under the [Medical Assistance Program] established in [insert citation] may be accepted and dispensed under the Cancer Drug Repository Program.

Section 6. [Storage, Distribution and Dispensing of Drugs.]

(1) A physician's office, pharmacy, hospital, or health clinic that accepts donated cancer drugs under the Cancer Drug Repository Program shall comply with all applicable provisions of state and federal law relating to the storage, distribution, and dispensing of such drugs and shall inspect all such drugs prior to dispensing to determine if they are adulterated or misbranded as described in [insert citation]. Such drugs shall only be dispensed pursuant to a prescription issued by a prescribing practitioner. Such drugs may be distributed to another participating physician's office, pharmacy, hospital, or health clinic for dispensing.

(2) A physician's office, pharmacy, hospital, or health clinic may charge a handling fee for distributing or dispensing cancer drugs under the Cancer Drug Repository Program. Such fee shall be established in rules and regulations adopted and promulgated by the [department]. Cancer drugs donated under the Program shall not be resold.

Section 7. [Liability.]

(1) Any person or entity, including a cancer drug manufacturer, which exercises reasonable care in donating, accepting, distributing, or dispensing cancer drugs under this Act or rules and regulations adopted and promulgated under the Act shall be immune from civil or criminal liability or professional disciplinary action of any kind for any injury, death, or loss to person or property relating to such activities.

(2) Notwithstanding subsection (1) of this section, the donation of a cancer drug by a cancer drug manufacturer does not absolve the manufacturer of any criminal or civil liability that would have existed but for the donation, nor shall such donation increase the liability of such cancer drug manufacturer that would have existed but for the donation.

Section 8. [Rules and Regulations.] The [department], upon the recommendation of the state [Board of Pharmacy], shall adopt and promulgate rules and regulations to carry out this Act. Initial rules and regulations under the Act shall be adopted and promulgated no later than ninety
days after the operative date of this Act. Such rules and regulations shall include, but not be
limited to:

(1) Eligibility criteria and other standards and procedures for physician's offices,
pharmacies, hospitals, and health clinics that accept and distribute or dispense donated cancer
drugs;

(2) Necessary forms for administration of the Cancer Drug Repository Program,
including, but not limited to, forms for use by people or entities that donate, accept, distribute, or
dispense cancer drugs under the Program;

(3) The maximum handling fee that may be charged by physician's offices, pharmacies,
hospitals, or health clinics that accept and distribute or dispense donated cancer drugs; and

(4) (a) Categories of cancer drugs that the Cancer Drug Repository Program will
accept for dispensing; and
(b) Categories of cancer drugs that the Program will not accept for dispensing and
the reason that such drugs will not be accepted.

Section 9. [Severability.] [Insert severability clause.]

Section 10. [Repealer.] [Insert repealer clause.]

Section 11. [Effective Date.] [Insert effective date.]