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STATE OF NEBRASKA

**TITLE 181 CHAPTER 6**

**Cancer Drug Repository Program**

**NEBRASKA HEALTH AND HUMAN SERVICES SYSTEM**



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TITLE 181                      SPECIAL HEALTH PROGRAMS

CHAPTER 6                      CANCER DRUG REPOSITORY PROGRAM

6-001 SCOPE AND AUTHORITY: These regulations apply to the Cancer Drug Repository Program Act pursuant to Neb. Rev. Stat. §§ 71-2422 to 71-2430.

6-002 DEFINITIONS

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.

Department means the Department of Health and Human Services Regulation and Licensure.

Health Care Facility means an ambulatory surgical center, an assisted-living facility, a center or group home for the developmentally disabled, a critical access hospital, a general acute hospital, a health clinic, a hospital, an intermediate care facility, an intermediate care facility for the mentally retarded, a long-term care hospital, a mental health center, a nursing facility, a pharmacy, a psychiatric or mental hospital, a public health clinic, a rehabilitation hospital, a skilled nursing facility, or a substance abuse treatment center.

Health Clinic means

- (1) A facility where advice, counseling, diagnosis, treatment, surgery, care, or services relating to the preservation or maintenance of health are provided on an outpatient basis for a period of less than 24 consecutive hours to persons not residing or confined at such facility. Health clinic includes, but is not limited to, an ambulatory surgical center or a public health clinic.
- (2) Health clinic does not include (a) a health care practitioner facility (i) unless such facility is an ambulatory surgical center, (ii) unless ten or more abortions, as defined in subdivision (1) of Neb. Rev. Stat. § 28-326, are performed during any one calendar week at such facility, or (iii) unless hemodialysis or labor and delivery services are provided at such facility, or (b) a facility which provides only routine health screenings, health education, or immunizations.

- (3) For purposes of this section:
- (a) Public health clinic means the department, any county, city-county, or multicounty health department, or any private not-for-profit family planning clinic licensed as a health clinic;
  - (b) Routine health screenings means the collection of health data through the administration of a screening tool designed for a specific health problem, evaluation and comparison of results to referral criteria, and referral to appropriate sources of care, if indicated; and
  - (c) Screening tool means a simple interview or testing procedure to collect basic information on health status.

Hospital means

- (1) A facility where diagnosis, treatment, medical care, obstetrical care, nursing care, or related services are provided on an outpatient basis or on an inpatient basis for a period of more than twenty-four consecutive hours to persons who have an illness, injury, or deformity or to aged or infirm persons requiring or receiving convalescent care.
- (2) Hospital includes a facility or part of a facility which provides space for a general acute hospital, a rehabilitation hospital, a long-term care hospital, a critical access hospital, or a psychiatric or mental hospital.
- (3) Hospital does not include a health care practitioner facility in which persons do not receive care or treatment for a period of more than twenty-four consecutive hours.

Participant means a physician's office, pharmacy, hospital, or health clinic that has elected to voluntarily participate in the program and that accepts donated cancer drugs under the rules and regulations adopted and promulgated by the department for the program.

Participant registry means a registry of participants established and maintained by the department that includes the participant's name, address, and telephone number and identifies whether the participant is a physician's office, a pharmacy, a hospital, or a health clinic.

Pharmacy means a facility advertised as a pharmacy, drug store, hospital pharmacy, dispensary, or any combination of such titles where drugs or devices are dispensed as defined in Neb. Rev. Stat. § 71-1,142.

Physician's office means the office of a person licensed to practice medicine and surgery or osteopathic medicine and surgery.

Prescribing practitioner means a health care practitioner licensed under the Uniform Licensing Law who is authorized to prescribe cancer drugs.

Prescription drug means (a) a drug or device which is required under federal law to be labeled with one of the following statements prior to being dispensed or delivered: (i) Caution: Federal law prohibits dispensing without prescription; (ii) Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian; or (iii) "Rx Only" or (b) a drug or device which is required by any applicable federal or state law to be dispensed pursuant only to a prescription or chart order or which is restricted to use by practitioners only;

Program means the cancer drug repository program established pursuant to Neb. Rev. Stat. § 71-2424.

### 6-003 DONATING CANCER DRUGS

6-003.01 Any person or entity, including but not limited to a cancer drug manufacturer or health care facility, may donate cancer drugs to the program.

6-003.02 Any person or entity who wishes to donate cancer drugs to the program must contact a participant to obtain a form on which they must specify the cancer drug to be donated. The form must include:

1. Name of the cancer drug;
2. Quantity of the cancer drug;
3. The name of the person to whom the cancer drug was originally prescribed;
4. The relationship between the person or entity donating the cancer drugs and the person to whom the cancer drug was prescribed;
5. Signature of the person donating the cancer drug; and
6. Date the form was signed.

6-003.03 Cancer drugs may be donated to a participant. Participation in the program is voluntary.

6-003.04 There is no limitation on the number of doses that can be donated to the program as long as the donated drugs meet the requirements of these regulations.

6-003.05 Acceptable Cancer Drugs: The following categories of drugs are acceptable for dispensing or distribution under the program:

1. A cancer drug that is in its original, unopened, sealed, and tamper-evident packaging;
2. A cancer drug packaged in single unit doses if the outside packaging is opened but the single-unit-dose packaging is unopened;

3. A cancer drug that was dispensed under the medical assistance program established in Neb. Rev. Stat. § 68-1018 that meets the requirements of 1 or 2 above;
4. A cancer drug that does not require refrigeration, freezing, or other special temperature requirements beyond controlled room temperature; and
5. An injectable cancer drug if it does not have temperature requirements other than controlled room temperature.

6-003.06 Non-Acceptable Cancer Drugs: The following categories of drugs are not acceptable for dispensing or distribution under the program:

1. A cancer drug that bears an expiration date prior to the date of donation because the effectiveness of the cancer drug cannot be ensured;
2. A cancer drug that is adulterated or misbranded pursuant to Neb. Rev. Stat. § 71-2401 or § 71-2402 because the effectiveness and safety of the cancer drug cannot be ensured;
3. A cancer drug that has expired while in the repository program;
4. A cancer drug in packaging that has been opened, unsealed, or tampered with or that is no longer in its original container because the safety of the cancer drug can no longer be ensured;
5. A cancer drug packaged in single unit doses if the outside packaging is opened and the single-unit-dose packaging is also opened because the safety of the cancer drug can no longer be ensured;
6. A cancer drug that requires refrigeration, freezing, or other special temperature requirements beyond controlled room temperature because the effectiveness and safety of the cancer drug cannot be ensured; or
7. Controlled substances because Federal Law prohibits their return.

## 6-004 DISPENSING AND DISTRIBUTION OF CANCER DRUGS

### 6-004.01 Dispensing and Distribution Requirements

6-004.01A A participant must comply with all applicable provisions of state and federal law relating to the storage, distribution, and dispensing of donated cancer drugs. (Nebraska Pharmacy Statutes Pertaining to Practice of Pharmacy Neb. Rev. Stat. §§ 71-1,142 to 71-1,151; 172 NAC 128 Regulations Governing the Practice of Pharmacy; and 175 NAC 8 Regulations Governing Licensure of Pharmacies.)

6-004.01B A participant must inspect all such drugs prior to dispensing or distributing to determine if they are adulterated or misbranded pursuant to Neb. Rev. Stat. § 71-2401 or § 71-2402.

6-004.01C The following persons are authorized pursuant to Neb. Rev. Stat. § 71-1,143 to dispense drugs:

1. Licensed physicians who do not charge a handling fee for the cancer drugs;
2. Licensed physicians who charge a handling fee for the cancer drugs and who hold a valid dispensing practitioner pharmacy license; and
3. Licensed pharmacists.

6-004.01D Cancer drugs may only be dispensed pursuant to a prescription issued by a prescribing practitioner.

6-004.01E Cancer drugs accepted by a participant from the donor may be:

1. Dispensed to an ultimate user of the cancer drug; or
2. Distributed to another participant for dispensing.

6-004.01F Cancer drugs donated under the program must not be resold.

6-004.01G Patients for whom cancer drugs are dispensed under the program must be notified by the prescribing practitioner that the cancer drugs they receive were originally dispensed to another patient and were returned for re-dispensing through the program.

#### 6-004.02 Storage Requirements

6-004.02A The participant that receives donated cancer drugs for dispensing or distribution must:

1. Provide equipment for the storage of cancer drugs donated to the program at controlled room temperature that must be stored between 59 and 86 degrees Fahrenheit;
2. Maintain the inventory of donated cancer drugs separate from all other drug inventory of the participant; and
3. Establish a secure location for the storage of the donated cancer drugs.

#### 6-004.03 Record Keeping Requirements

6-004.03A A perpetual inventory log book of all cancer drugs received, dispensed and distributed by a participant under the program must be maintained.

6-004.03B The perpetual inventory log book must contain the following information regarding all cancer drugs received, dispensed and distributed by a participant under the program:

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

6-004.03C Hard copies of all prescriptions dispensed must be maintained by the participant to document the receipt of a prescription for the cancer drug to be dispensed and must be kept for five years pursuant to Neb. Rev. Stat. § 71-1,146.02.

#### 6-004.04 Handling Fee

6-004.04A A participant that receives donated cancer drugs may charge a handling fee to the ultimate user for dispensing or distribution of cancer drugs under the program, except that a physician must hold a valid dispensing practitioner pharmacy license in order to charge the handling fee.

6-004.04B If a handling fee is charged to the ultimate user to whom the cancer drug is dispensed or to the entity to which the cancer drug was distributed, the handling fee must not exceed the Medicaid provider

dispensing fee that is applicable at the time the dispensing or distribution occurs.

6-005 PARTICIPANT REGISTRY: The department will establish and maintain a participant registry for the program.

6-005.01 Initial Establishment of the Participant Registry

6-005.01A The participant registry must include:

1. Participant's name;
2. Participant's address;
3. Participant's telephone number; and
4. Whether the participant is a physician's office, a pharmacy, a hospital, or a health clinic.

6-005.01B It is the responsibility of the participant to:

1. Notify the department of the desire to participate in the program; and
2. Provide the required registry information to the department.

6-005.01C Any participant in the program will be entered on the participant registry by the department.

6-005.02 Updates to the Participant Registry

6-005.02A It is the responsibility of the participant to notify the department:

1. Of any change of name, address, telephone number, or participant type; and
2. When the participant no longer wishes to participate in the program.

6-005.02B Any updates to the registry will be based on information provided by participants.

6-005.03 Access to the Participant Registry

6-005.03A The department will make the participant registry information available to any person or entity wishing to donate cancer drugs to the program.



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NEBRASKA HEALTH AND HUMAN SERVICES  
REGULATION AND LICENSURE

181 NAC 6

6-005.03B The department will provide public access to the participant registry information on the department's web site, or by contacting the department in person, by telephone, or in writing.

Approved by the Attorney General on March 5, 2007

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