TITLE 181 SPECIAL HEALTH PROGRAMS

CHAPTER 6 CANCER DRUG REPOSITORY PROGRAM

001. SCOPE AND AUTHORITY. These regulations apply to the Cancer Drug Repository Program Act pursuant to Nebraska Revised Statutes (Neb. Rev. Stats.) §§ 71-2422 to 71-2430.

002. DEFINITIONS. Definitions set out in Neb. Rev. Stat. § 71-2423 apply to this chapter.

003. DONATING CANCER DRUGS. 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:

(A) Name of the cancer drug;
(B) Quantity of the cancer drug;
(C) The name of the person to whom the cancer drug was originally prescribed;
(D) The relationship between the person or entity donating the cancer drugs and the person to whom the cancer drug was prescribed;
(E) Signature of the person donating the cancer drug; and
(F) Date the form was signed.

003.01 ACCEPTABLE CANCER DRUGS. Acceptable drugs for dispensing or distribution under the program include those listed by category in Neb. Rev. Stat. § 71-2426 and includes the following: any cancer drug that does not require refrigeration, freezing, or other special temperature requirements beyond controlled room temperature.

003.02 UNACCEPTABLE CANCER DRUGS. Cancer drugs that are not acceptable for dispensing or distribution under the program are those set out in Neb. Rev. Stat. §§ 71-2426, any cancer drug that requires refrigeration, freezing, or other special temperature requirements beyond controlled room temperature because the safety of the cancer drug can no longer be ensured, or any cancer drug that is a controlled substance because federal law prohibits their return.

004. DISPENSING AND DISTRIBUTION REQUIREMENTS. Only those licensees who are authorized to dispense as set out in Neb. Rev. Stat. § 38-2850 may dispense cancer drugs.

004.01 AUTHORIZED TO DISPENSE. The following persons are authorized pursuant to Neb. Rev. Stat. § 38-2850 to dispense drugs:

(A) Licensed physicians who do not charge a handling fee for the cancer drugs;

(B) Licensed physicians who charge a handling fee for the cancer drugs and who hold a valid dispensing practitioner pharmacy license; and
(C) Licensed pharmacists.

004.02 ACCEPTABLE USES OF DONATED DRUGS. Cancer drugs accepted by a participant from the donor may be:
(A) Dispensed to an ultimate user of the cancer drug; or
(B) Distributed to another participant for dispensing.

004.03 PATIENT NOTIFICATION. 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.

004.04 STORAGE REQUIREMENTS. The participant that receives donated cancer drugs for dispensing or distribution must:
(A) 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;
(B) Maintain the inventory of donated cancer drugs separate from all other drug inventory of the participant; and
(C) Establish a secure location for the storage of the donated cancer drugs.

004.05 RECORD KEEPING REQUIREMENTS. A perpetual inventory log of all cancer drugs received, dispensed and distributed by a participant under the program must be maintained.

004.05(A) PERPETUAL LOG BOOK REQUIREMENTS. The perpetual inventory log must contain the following information regarding all cancer drugs received, dispensed and distributed by a participant under the program:
(i) Name of the cancer drug;
(ii) Quantity of the cancer drug;
(iii) Expiration date of the cancer drug;
(iv) Lot number of the cancer drug;
(v) Name of participant;
(vi) Name of person who donated the cancer drug;
(vii) Name of person to whom the cancer drug was originally prescribed;
(viii) Name of person to whom the cancer drug was dispensed;
(ix) Date the cancer drug was dispensed;
(x) Name of the prescribing practitioner who wrote the prescription for the cancer drug to be dispensed under the program;
(xi) Name of the participant to which the cancer drug was distributed;
(xii) Date the cancer drug was distributed to another participant;
(xiii) Date of destruction of the expired cancer drug; and
(xiv) Whether a handling fee was charged and the amount of any such fee.

004.05(B) RECORDS RETENTION. 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 5 years pursuant to Neb. Rev. Stat. § 38-2871.

004.06 HANDLING FEE. A handling fee may be charged for dispensing donated drugs.

004.06(A) DISPENSING PERMIT. 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.

004.06(B) FEE LIMITS. 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.

005. PARTICIPANT REGISTRY. Any licensee listed in 181 Nebraska Administrative Code (NAC) 6-004 that wants to participate in the program must provide the Department with the information set out in Neb. Rev. Stat. §71-2430. It is the responsibility of a participant to notify the Department of any change in the required information or when the participant no longer wishes to participate in the program.