TITLE 181 SPECIAL HEALTH PROGRAMS

CHAPTER 7 IMMUNOSUPPRESSANT DRUG REPOSITORY PROGRAM

001. SCOPE AND AUTHORITY. These regulations implement the Immunosuppressant Drug Repository Program under Nebraska Revised Statutes (Neb. Rev. Stat.) §§ 71-2436 to 71-2443 of the Immunosuppressant Drug Repository Program Act, and the Uniform Credentialing Act.

002. DEFINITIONS. Definitions set out in the Immunosuppressant Drug Repository Program Act apply to this chapter.

003. DONATING IMMUNOSUPPRESSANT DRUGS. Any person or entity who wishes to donate immunosuppressant drugs to the program must contact a participant to obtain a form on which they must specify the immunosuppressant drug to be donated. The form must include:

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

003.01 ACCEPTABLE IMMUNOSUPPRESSANT DRUGS. Acceptable drugs for dispensing or distribution under the program include those listed by category in Neb. Rev. Stat. § 71-2440 and includes any immunosuppressant drug that does not require refrigeration, freezing, or other special temperature requirements beyond controlled room temperature.

003.02 UNACCEPTABLE IMMUNOSUPPRESSANT DRUGS. Unacceptable drugs for dispensing or distribution under the program include those listed by category in Neb. Rev. Stat. § 71-2440 and the following:

(A) An immunosuppressant drug that requires refrigeration, freezing, or other special temperature requirements beyond controlled room temperature because the effectiveness and safety of the immunosuppressant drug cannot be ensured; or
(B) Controlled substances because Federal Law prohibits their return.

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

004.01 DISPENSING AND DISTRIBUTION REQUIREMENTS. Participants must meet the requirements set out in Neb. Rev. Stat. § 71-2441 and these regulations.

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

(i) Licensed physicians who do not charge for the drugs;
(ii) Licensed physicians who hold a valid dispensing practitioner pharmacy license; and
(iii) Licensed pharmacists.

004.01(B) ACCEPTABLE USES OF DONATED DRUGS. Immunosuppressant drugs accepted by a participant from the donor may be:

(i) Dispensed to an ultimate user of the immunosuppressant drug; or
(ii) Distributed to another participant for dispensing.

004.01(C) PATIENT NOTIFICATION. Patients for whom immunosuppressant drugs are dispensed under the program must be notified by the prescribing practitioner that the immunosuppressant drugs they receive were originally dispensed to another patient and were returned for re-dispensing through the program.

004.02 STORAGE REQUIREMENTS. The participant that receives donated immunosuppressant drugs for dispensing or distribution must:

(A) Provide equipment for the storage of immunosuppressant 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 immunosuppressant drugs separate from all other drug inventory of the participant; and
(C) Establish a secure location for the storage of the donated immunosuppressant drugs.

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

004.03(A) PERPETUAL INVENTORY LOG BOOK REQUIREMENTS. The perpetual inventory log must contain the following information regarding all immunosuppressant drugs received, dispensed and distributed by a participant under the program:

(i) Name of the immunosuppressant drug;
(ii) Quantity of the immunosuppressant drug;
(iii) Expiration date of the immunosuppressant drug;
(iv) Lot number of the immunosuppressant drug;
(v) Name of participant;
(vi) Name of person who donated the immunosuppressant drug;
(vii) Name of person to whom the immunosuppressant drug was originally prescribed;
(viii) Name of person to whom the immunosuppressant drug was dispensed;
(ix) Date the immunosuppressant drug was dispensed;

(x) Name of the prescribing practitioner who wrote the prescription for the immunosuppressant drug to be dispensed under the program;
(xi) Name of the participant to which the immunosuppressant drug was distributed;
(xii) Date the immunosuppressant drug was distributed to another participant; and
(xiii) Date of destruction of the expired immunosuppressant drug.

004.03(B) RECORDS RETENTION. Copies of all prescriptions dispensed must be maintained by the participant to document the receipt of a prescription for the immunosuppressant drug to be dispensed and must be kept for five years pursuant to Neb. Rev. Stat. § 38-2871.

005. COMPLIANCE INSPECTIONS. Each participant has the responsibility to be in compliance, and to remain in compliance, with the regulations set out in this chapter. For the purpose of assuring initial and continued compliance, the Department will conduct inspections of participants. Participants must allow such inspections which includes allowing access to and the copying of records.

005.01 RESULTS OF INSPECTIONS. Notifications will be made in writing to the participant.

005.01(A) NOTIFICATION OF IMMINENT DANGER. If notified that the violations would create an imminent danger of death or serious physical harm or immediate adverse effect to the safety or security of the immunosuppressant drugs, the participant must cease participation in the program immediately.

005.01(B) NOTIFICATION OF NON-IMMINENT DANGER. If notified that the violations do not create an imminent danger of death or serious physical harm to the patients of the participant and no direct or immediate adverse effect to the safety or security of the immunosuppressant drugs, the participant must correct any deficiencies noted in the inspection within 30 days after receiving the inspection results.

005.01(C) CORRECTIVE ACTION. Participants that are not fully in compliance with these regulations within 30 days after receiving the inspection results will no longer be allowed to participate in the program.