TITLE 181 SPECIAL HEALTH PROGRAMS

CHAPTER 7 IMMUNOSUPPRESSANT DRUG REPOSITORY PROGRAM

7-001 SCOPE AND AUTHORITY: These regulations apply to the Immunosuppressant Drug Repository Program Act pursuant to Neb. Rev. Stat. §§ 71-2436 to 71-2443.

7-002 DEFINITIONS

Department means the Department of Health and Human Services.

Immunosuppressant Drug means anti-rejection drugs that are used to reduce the body's immune system response to foreign material and inhibit a transplant recipient's immune system from rejecting a transplanted organ. Immunosuppressant drugs are available only as prescription drugs and come in tablet, capsule, and liquid forms. The recommended dosage depends on the type and form of immunosuppressant drug and the purpose for which it is being used. Immunosuppressant drug does not include drugs prescribed for inpatient use.

Participant means a transplant center that has elected to voluntarily participate in the program, that has submitted written notification to the department of its intent to participate in the program, and that accepts donated immunosuppressant drugs under the rules and regulations adopted and promulgated by the department for the program.

Prescribing practitioner means a health care practitioner licensed under the Uniform Licensing Law who is authorized to prescribe immunosuppressant 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 immunosuppressant drug repository program established pursuant to Neb. Rev. Stat. § 71-2438.

Transplant center means a hospital that operates an organ transplant program, including qualifying patients for transplant, registering patients on the national waiting list, performing transplant surgery, and providing care before and after transplant.

Transplant program means the organ-specific facility within a transplant center. A transplant center may have transplant programs for the transplantation of hearts, lungs, livers, kidneys, pancreata, or intestines.

7-003 DONATING IMMUNOSUPPRESSANT DRUGS

7-003.01 Any person or entity, including but not limited to an immunosuppressant drug manufacturer or transplant center, may donate immunosuppressant drugs to a participant or return previously prescribed immunosuppressant drugs to the transplant center where they were originally prescribed.

7-003.02 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:

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

7-003.03 Participation in the program is voluntary.

7-003.04 There is no limitation on the number of doses than can be donated to the program as long as the donated drugs meet the requirements of these regulations.

7-003.05 Acceptable Immunosuppressant Drugs: The following categories of drugs are acceptable for dispensing or distribution under the program:

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

3. An immunosuppressant 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; and
4. An immunosuppressant drug that does not require refrigeration, freezing, or other special temperature requirements beyond controlled room temperature.

7-003.06 Non-Acceptable Immunosuppressant Drugs: The following categories of drugs are not acceptable for dispensing or distribution under the program:

1. An immunosuppressant drug that bears an expiration date prior to the date of donation because the effectiveness of the immunosuppressant drug cannot be ensured;
2. An immunosuppressant drug that is adulterated or misbranded pursuant to Neb. Rev. Stat. § 71-2401 or § 71-2402 because the effectiveness and safety of the immunosuppressant drug cannot be ensured;
3. An immunosuppressant 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 immunosuppressant drug can no longer be ensured;
4. An immunosuppressant 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 immunosuppressant drug can no longer be ensured;
5. 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
6. Controlled substances because Federal Law prohibits their return.

7-004 DISPENSING AND DISTRIBUTION OF IMMUNOSUPPRESSANT DRUGS

7-004.01 Dispensing and Distribution Requirements

7-004.01A A participant must comply with all applicable provisions of state and federal law relating to the storage, distribution, and dispensing of donated immunosuppressant 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.)

7-004.01B 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 or if the drugs bear an expiration date prior to the date of dispensing.

7-004.01C The following persons are authorized pursuant to Neb. Rev. Stat. § 71-1,143 to dispense drugs:

1. Licensed physicians;
2. Licensed physician assistants; and
3. Licensed pharmacists.

7-004.01D Immunosuppressant drugs may only be dispensed pursuant to a prescription issued by a prescribing practitioner.

7-004.01E Immunosuppressant drugs accepted by a participant from the donor may be:

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

7-004.01F Immunosuppressant drugs donated under the program must not be resold.

7-004.01G 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.

7-004.02 Storage Requirements

7-004.02A The participant that receives donated immunosuppressant drugs for dispensing or distribution must:

1. 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;
2. Maintain the inventory of donated immunosuppressant drugs separate from all other drug inventory of the participant; and
3. Establish a secure location for the storage of the donated immunosuppressant drugs.

7-004.03 Record Keeping Requirements

7-004.03A A perpetual inventory log book of all immunosuppressant drugs received, dispensed and distributed by a participant under the program must be maintained.

7-004.03B The perpetual inventory log book must contain the following information regarding all immunosuppressant drugs received, dispensed and distributed by a participant under the program:

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

7-004.03C Hard 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. § 71-1,146.02.

7-005 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 as set out below:

7-005.01 Initial Onsite Inspection: The Department will conduct an initial onsite inspection within 60 days after the Department has received written notification from a transplant center of their intent to participate in the program. The inspection must determine whether the participant is in compliance with these regulations.

7-005.01A Department Determination: Such determination must be made when the pharmacy inspector verifies that the participant:

1. Requires persons or entities wishing to donate immunosuppressant drugs to the program to provide information about the donated drugs pursuant to 181 NAC 7-003.02;
2. Is accepting only donations of immunosuppressant drugs that meet the requirements of 181 NAC 7-003.05;
3. Is not accepting donations of non-acceptable immunosuppressant drugs as specified in 181 NAC 7-003.06;
4. Is storing donated immunosuppressant drugs pursuant to 181 NAC 7-004.02; and
5. Is maintaining records of all immunosuppressant drugs received, dispensed and distributed by the participant under the program pursuant to 181 NAC 7-004.03.

7-005.02 Biennial Onsite Inspection: All participants are subject to an onsite inspection at least once every two years to determine whether a participant is in compliance with these regulations. Biennial onsite inspections will be conducted by the Department in the same manner as an initial onsite inspection pursuant to 181 NAC 7-005.01.

7-005.03 Inspection for Cause: The Department may inspect a participant to determine violations when any one or more of the following conditions or circumstances occur:

1. An accident or natural disaster resulting in damage to the physical plant; or interruption of utility services which could result in adverse effects to the potency, efficacy, safety or security of the immunosuppressant drugs;
2. A complaint alleging violation of the Immunosuppressant Drug Repository Program Act or these regulations;
3. A complaint that raises concern about the maintenance, operation, or management of the participant; and
4. Any other event that raises concerns about the maintenance, operation, or management of the participant.

7-005.04 Results of Inspections

7-005.04A The Department will notify the participant of the results of an inspection within 10 days after conducting the inspection.

7-005.04B When the Department finds that the participant is not in compliance with these regulations, and the nature of 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.

7-005.04C When the Department finds that the participant is not in compliance with these regulations, but the nature of 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.

7-005.04D 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.

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