NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
NOTICE OF PUBLIC HEARING

October 10, 2019
10:00 a.m. Central Time
Gold's Building, Room 534
1033 O Street, Lincoln, Nebraska

The purpose of this hearing is to receive comments on proposed changes to Title 181, Chapters 6 & 7 of the Nebraska Administrative Code (NAC) – *Cancer Drug Repository Program and Immunosuppressant Drug Repository Program.* The regulations provide directions to the public and licensed participants regarding the donation and dispensing of cancer and immunosuppressant drugs. The proposed changes remove duplicative statutory language from the regulations and update formatting.

Authority for these regulations is found in Neb. Rev. Stat. § 81-3117(7).

Interested persons may attend the hearing and provide verbal or written comments or mail, fax or email written comments, no later than the day of the hearing to: DHHS Legal Services, PO Box 95026, Lincoln, NE 68509-5026, (402) 742-2382 or dhhs.regulations@nebraska.gov, respectively.

A copy of the proposed changes is available online at http://www.sos.ne.gov, or by contacting DHHS at the mailing address or email above, or by phone at (402) 471-8417. The fiscal impact statement for these proposed changes may be obtained at the office of the Secretary of State, Regulations Division, 1201 N Street, Suite 120, Lincoln, NE 68508, or by calling (402) 471-2385.

Auxiliary aids or reasonable accommodations needed to participate in a hearing can be requested by calling (402) 471-8417. Individuals with hearing impairments may call DHHS at (402) 471-9570 (voice and TDD) or the Nebraska Relay System at 711 or (800) 833-7352 TDD at least 2 weeks prior to the hearing.

FISCAL IMPACT STATEMENT

Agency: **Department of Health and Human Services**	
Title:181	Prepared by:Jesse Cushman
Chapter: 6	Date prepared: 7-1-19
Subject: Cancer Drug Repository Program	Telephone: (402)471-4915

Type of Fiscal Impact:

	State Agency	Political Sub.	Regulated Public
No Fiscal Impact	(☒)	(☒)	(☒)
Increased Costs	(☐)	(☐)	(☐)
Decreased Costs	(☐)	(☐)	(☐)
Increased Revenue	(☐)	(☐)	(☐)
Decreased Revenue	(☐)	(☐)	(☐)
Indeterminable	(☐)	(☐)	(☐)

Provide an Estimated Cost & Description of Impact:

State Agency: No Change

Political Subdivision: No Change

Regulated Public: There is no change in fees to the regulated public.

If indeterminable, explain why:

FISCAL IMPACT STATEMENT

Agency: **Department of Health and Human Services**	
Title:181	Prepared by:Jesse Cushman
Chapter: 7	Date prepared: 7-1-19
Subject: Immunosuppressant Drug Repository Program	Telephone: (402)471-4915

Type of Fiscal Impact:

	State Agency	Political Sub.	Regulated Public
No Fiscal Impact	(☒)	(☒)	(☒)
Increased Costs	(☐)	(☐)	(☐)
Decreased Costs	(☐)	(☐)	(☐)
Increased Revenue	(☐)	(☐)	(☐)
Decreased Revenue	(☐)	(☐)	(☐)
Indeterminable	(☐)	(☐)	(☐)

Provide an Estimated Cost & Description of Impact:

State Agency: No Change

Political Subdivision: No Change

Regulated Public: There is no change in fees to the regulated public.

If indeterminable, explain why:

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. Stats. §§ 71-404 to 71-431, Neb. Rev. Stat. § 38-2841, and 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 book 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 book 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. 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 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.

2007

STATE OF NEBRASKA

TITLE 181 CHAPTER 6

Cancer Drug Repository Program

NEBRASKA HEALTH AND HUMAN SERVICES SYSTEM

Department of Health and Human Services Regulation and Licensure
Credentialing Division
Nebraska State Office Building
301 Centennial Mall South-Third Floor
P.O. Box 94986
Lincoln, NE 68509-4986

(402) 471-2118

Effective Date: March 25, 2007

EFFECTIVE DATE NEBRASKA HEALTH AND HUMAN SERVICES
March 25, 2007 REGULATION AND LICENSURE 181 NAC 6

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.

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
Approved by the Governor on March 20, 2007
Filed by the Secretary of State on March 20, 2007
Effective Date: March 25, 2007

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 book 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 book 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. 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. § 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.

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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