

ELIGIBILITY REQUIREMENTS TO RECEIVE DRUGS

Rule 4729-35-05 [Effective 01/01/2004]

A pharmacy, hospital, or nonprofit clinic that elects to participate in the drug repository program must determine if a person is eligible to receive drugs. A person must meet the following requirements to become an eligible recipient of drugs from the drug repository program:

- (A) Is a resident of Ohio, and
- (B) (1) Has no active third party prescription drug reimbursement coverage for the drug prescribed; or,
(2) Is a patient of a nonprofit clinic.

=\=\==/\=/=

DONOR FORM

Rule 4729-35-06 [Effective 01/01/2004]

(A) Each donor must sign a form stating that the donor is the owner of the drug and intends to voluntarily donate the drug to the drug repository program. The donor form must be completed prior to any donation and include at least the following:

- (1) The name of the person that was originally dispensed the drugs, or the name of the terminal distributor of dangerous drugs or wholesale distributor of dangerous drugs that owns the drugs.
- (2) The signature of the donor, which may include the person designated by durable power of attorney, a guardian, an individual responsible for the care and well-being of a patient, or the signature of the responsible person or his/her designee from a terminal distributor of dangerous drugs or a wholesale distributor of dangerous drugs.
- (3) The date the form was signed.

(B) The following donor information must also be documented. This information may be documented on the original signed donor form or on an alternate record. If an alternate record is used, the record must include the name of the donor in addition to the required information in this paragraph.

- (1) The brand name of the drug donated, or the generic name and list either the name of the manufacturer or the national drug code number (NDC#).
- (2) The strength of the drug donated.
- (3) The quantity of the drug donated.
- (4) The date the drug was donated.

=\=\==/=/=

RECIPIENT FORM

Rule 4729-35-07 [Effective 01/01/2004]

Each recipient of a donated drug from the drug repository program must sign a form stating they understand the immunity provisions of the program pursuant to division (B) of section 3715.872 of the Revised Code. The recipient form must also include at least the following:

- (A) The signature of the recipient of the donated drug.
- (B) The date the form was signed by the recipient.
- (C) The brand name of the drug received, or the generic name and list either the name of the manufacturer or the national drug code number (NDC#).
- (D) The strength of the drug received by the recipient.
- (E) The quantity of the drug received by the recipient.

=\=\=\/=\

RECORD KEEPING

Rule 4729-35-08 [Update effective 02/01/2005]

- (A) Donor forms must be maintained for a minimum of three years by a terminal distributor of dangerous drugs, a wholesale distributor of dangerous drugs, or an institutional facility.
- (B) Recipient forms must be maintained for a minimum of three years by a pharmacy, hospital, or nonprofit clinic.
- (C) An invoice must be created by the donor location, which includes a terminal distributor of dangerous drugs, a wholesale distributor of dangerous drugs, or an institutional facility where the donor resides. The invoice must include at least the following information:
 - (1) The name and address of the donor location.
 - (2) The brand name of the drug donated, or the generic name and list either the name of the manufacturer or the national drug code number (NDC#).
 - (3) The strength of the drug.
 - (4) The quantity of the drug.
 - (5) The date the drug was sent to a pharmacy, hospital, or nonprofit clinic.
 - (6) The name and address of the recipient pharmacy, hospital, or nonprofit clinic.
- (D) A copy of the invoice must be maintained for a minimum of three years by both the donor location, which includes a terminal distributor of dangerous drugs, a wholesale distributor of dangerous drugs, or an institutional facility, and the recipient location, which includes a pharmacy, hospital, or nonprofit clinic.

=\=\=\/\=\

HANDLING FEE

Rule 4729-35-09 [Effective 01/01/2004]

A pharmacy, a hospital, or a nonprofit clinic may charge the recipient of a donated drug a maximum of two hundred per cent of the medicaid professional dispensing fee to cover restocking and dispensing costs.

=\=\=/=/=

JK

[Skip Navigation](#)

Cancer Drug Repository Program Participant Registry

NEBRASKA

The Cancer Drug Repository Program is a voluntary program established in 2003 for accepting donated cancer drugs and dispensing them to Nebraska residents.

The Department of Health and Human Services Regulation and Licensure is responsible for establishing and maintaining the program and will provide information to any person or entity wishing to donate or receive cancer drugs through the program.

In 2005, LB 331 created a  [Participant Registry](#) that identifies those who accept donated cancer drugs.

The registry is updated weekly and copies can be requested by contacting annette.scheinost@dhhs.ne.gov .

 [Statutes](#)

 [Rules - 181 NAC 6](#)

Documents in  PDF format require the use of Adobe Acrobat Reader which can be downloaded for free from [Adobe Systems, Inc.](#)

[Licensing & Regulatory Affairs Page](#)

56

• **STATUTES PERTAINING TO CANCER DRUG REPOSITORY PROGRAM ACT**

71-2422. Act, how cited. Sections 71-2422 to 71-2430 shall be known and may be cited as the Cancer Drug Repository Program Act.

Source: Laws 2003, LB 756, §1; Laws 2005, LB 331, §1. Effective date September 4, 2005.

71-2423. Terms, defined. For purposes of the Cancer Drug Repository Program Act:

- (1) 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;
- (2) Department means the Department of Health and Human Services Regulation and Licensure;
- (3) Health care facility has the definition found in section 71-413;
- (4) Health clinic has the definition found in section 71-416;
- (5) Hospital has the definition found in section 71-419;
- (6) 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;
- (7) Pharmacy has the definition found in section 71-425;
- (8) Physician's office means the office of a person licensed to practice medicine and surgery or osteopathic medicine and surgery;
- (9) Prescribing practitioner means a health care practitioner licensed under the Uniform Licensing Law who is authorized to prescribe cancer drugs;
- (10) Prescription drug has the definition found in section 71-1,142; and
- (11) Program means the cancer drug repository program established pursuant to section 71-2424.

Source: Laws 2003, LB 756, §2; Laws 2005, LB 331, §2. Effective date September 4, 2005.

71-2424. Cancer drug repository program; established. The department shall establish a cancer drug repository program for accepting donated cancer drugs and dispensing such drugs to Nebraska residents. Participation in the program shall be voluntary.

Source: Laws 2003, LB 756, § 3. Operative date September 15, 2003.

71-2425. Cancer drug donation. Any person or entity, including, but not limited to, a cancer drug manufacturer or health care facility, may donate cancer drugs to the program. Cancer drugs may be donated to a participant.

Source: Laws 2003, LB 756, §4; Laws 2005, LB 331, §3. Effective date September 4, 2005.

71-2426. Cancer drug; accepted or dispensed; conditions. (1) A cancer drug shall only be accepted or dispensed under the program if such drug is in its original, unopened, sealed, and tamper-evident unit dose packaging, except that a cancer drug packaged in single unit doses may be accepted and dispensed if the outside packaging is opened but the single-unit-dose packaging is unopened.

(2) A cancer drug shall not be accepted or dispensed under the program if (a) such drug bears an expiration date that is earlier than six months after the date the drug was donated or (b) such drug is adulterated or misbranded as described in section 71-2401 or 71-2402.

(3) Subject to limitations provided in this section, unused cancer drugs dispensed under the medical assistance program established in section 68-1018 may be accepted and dispensed under the program.

Source: Laws 2003, LB 756, §5; Laws 2005, LB 331, §4. Effective date September 4, 2005.

71-2427. Participant; duties; fee authorized. (1) A participant shall comply with all applicable provisions of state and federal law relating to the storage, distribution, and dispensing of donated cancer drugs and shall inspect all such drugs prior to dispensing to determine if they are adulterated or misbranded as described in section 71-2401 or 71-2402. Such drugs shall only be dispensed pursuant to a prescription issued by a prescribing practitioner. Such drugs may be distributed to another participant for dispensing.

(2) A participant may charge a handling fee for distributing or dispensing cancer drugs under the program. Such fee shall be established in rules and regulations adopted and promulgated by the department. Cancer drugs donated under the program shall not be resold.

Source: Laws 2003, LB 756, §6; Laws 2005, LB 331, §5. Effective date September 4, 2005.

71-2428. Immunity. (1) Any person or entity, including a cancer drug manufacturer, which exercises reasonable care in

donating, accepting, distributing, or dispensing cancer drugs under the Cancer Drug Repository Program Act or rules and regulations adopted and promulgated under the act shall be immune from civil or criminal liability or professional disciplinary action of any kind for any injury, death, or loss to person or property relating to such activities.

(2) Notwithstanding subsection (1) of this section, the donation of a cancer drug by a cancer drug manufacturer does not absolve the manufacturer of any criminal or civil liability that would have existed but for the donation, nor shall such donation increase the liability of such cancer drug manufacturer that would have existed but for the donation.

Source: Laws 2003, LB 756, § 7. Operative date September 15, 2003.

71-2429. Rules and regulations. The department, upon the recommendation of the Board of Pharmacy, shall adopt and promulgate rules and regulations to carry out the Cancer Drug Repository Program Act. Such rules and regulations shall include, but not be limited to:

(1) Eligibility criteria and other standards and procedures for participants that accept and distribute or dispense donated cancer drugs;

(2) Necessary forms for administration of the program, including, but not limited to, forms for use by persons or entities that donate, accept, distribute, or dispense cancer drugs under the program;

(3) The maximum handling fee that may be charged by participants that accept and distribute or dispense donated cancer drugs;

(4)(a) Categories of cancer drugs that the program will accept for dispensing and (b) categories of cancer drugs that the program will not accept for dispensing and the reason that such drugs will not be accepted; and

(5) Maintenance and distribution of the participant registry established in section 71-2430.

Source: Laws 2003, LB 756, §8; Laws 2005, LB 331, §6. Effective date September 4, 2005.

71-2430. Participant registry. The department shall establish and maintain a participant registry for the program. The participant registry shall include the participant's name, address, and telephone number and shall identify whether the participant is a physician's office, a pharmacy, a hospital, or a health clinic. The department shall make the participant registry available to any person or entity wishing to donate cancer drugs to the program.

Source: Laws 2005, LB 331, §7. Effective date September 4, 2005.

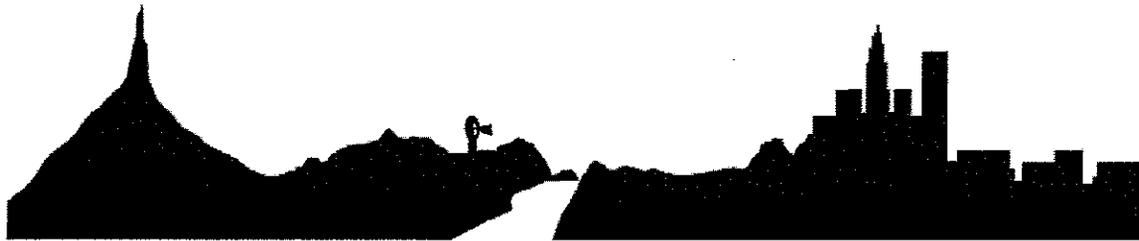
2007

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

59

EFFECTIVE DATE
March 25, 2007

NEBRASKA HEALTH AND HUMAN SERVICES
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;

62

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

64

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.

EFFECTIVE DATE
March 25, 2007

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

67

North Dakota Prescription Drug Repository Program Description

In the summer of 2006, the American Cancer Society approached the board of pharmacy with the possibility of creating a drug donation and repository program in North Dakota. The program discussed and envisioned was one where the board of pharmacy would develop criteria for the establishment of the program and register voluntary participants for the intake of donated items as well as for the dispensing of items.

As a result, on April 17, 2007 Governor John Hoeven signed House Bill 1256, which took effect July 1, 2007, authorizing a state Prescription Drug Repository Program to collect and distribute unused medications so that pharmacies and physicians can dispense them to those who need them.

A drug donated, or dispensed under the program must be in the original, unopened package, except drugs packaged in single-unit doses, or punch cards, may be accepted and dispensed if the outside packaging has been opened and the single-unit dose package is unopened. A few cases where the shipped package has not been opened may also be allowed.

Those who choose to volunteer to participate in the dispensing of the donated drugs, are defined as either a practitioner or pharmacy that has elected to participate in the program and accept legend drugs, devices, and supplies from donors for the program. Those who receive the donations will be able to post the availability of the medications on a website, where both patients and practitioners can access the information. Pharmacies and practitioners must register with the Board of Pharmacy, as participants.

Before being dispensed to an eligible individual, the legend drugs, devices, and supplies donated under the program must be inspected by a pharmacist to determine that they are not adulterated or misbranded. The participating pharmacist or practitioner must keep a record of the source of the donation for 2 years.

Because this is a volunteer program, the dispenser of donated legend drugs, devices, or supplies may not submit a claim or otherwise seek reimbursement from any public or private third-party payer for the cost of donated legend drugs, devices, or supplies dispensed to any eligible individual under the program. You may charge a small fee of up to 2.5 times the Medicaid fee of \$4.60 to cover your costs.

68

CHAPTER 43-15.2
Legend Drug Donation and Repository Program

43-15.2-01. Definitions. In addition to the definitions under section 43-15-01, in this chapter unless the context otherwise requires:

1. "Donor" means a person that donates to the program legend drugs, devices, or supplies needed to administer such drugs.
2. "Participant" means a practitioner or pharmacy that has elected to participate in the program and accepts legend drugs, devices, and supplies from donors for the program.
3. "Program" means the legend drug donation and repository program established under this chapter.
4. "Supplies" means any supplies used in the administration of a legend drug.

43-15.2-02. Administration.

1. The state board of pharmacy shall establish and contract with a third party to administer a legend drug donation and repository program.
2. The board may develop and maintain a participant registry for the program. A participant registry created under this subsection must include the name, address, and telephone number of the participants. A participant registry created under this subsection must be available through the board or on the board's web site.
3. The board may cooperate with nongovernmental organizations to maintain a web-based list of legend drugs, devices, or supplies that have been donated and are available through the program and the participants from which the donated items may be available.

43-15.2-03. Conditions for participation.

1. A donor may donate legend drugs, devices, or supplies to the program through a practitioner or pharmacy that meets the criteria established for such participation. Legend drugs, devices, or supplies may not be donated directly to a specific patient and donated items may not be resold.
2. The items donated to the program may be prescribed for use by an individual by a practitioner who is authorized by law to prescribe and only a participant may dispense donated items.

43-15.2-04. Conditions for acceptance of a donation.

1. A drug donated, prescribed, or dispensed under the program must be in the original, unopened, sealed, and tamper-evident unit dose packaging, except a drug packaged in single-unit doses may be accepted and dispensed if the outside packaging has been opened and the single-unit-dose package is unopened.
2. A drug may not be accepted or dispensed under the program if the drug has reached its expiration date or if the drug is adulterated or misbranded as determined under subsection 3.
3. Before being dispensed to an eligible individual, the legend drugs, devices, and supplies donated under the program must be inspected by a pharmacist to determine that the legend drugs, devices, and supplies are not adulterated or misbranded.

43-15.2-05. Storage, distribution, and dispensing.

1. A participant that accepts donated legend drugs, devices, or supplies under the program shall comply with all applicable provisions of state and federal law relating to the storage, distribution, and dispensing of the donated legend drugs, devices, or supplies.
2. A participant may charge an individual a handling fee that does not exceed two hundred fifty percent of the medicaid prescription dispensing fee for dispensing donated legend drugs, devices, or supplies under the program.

3. A dispenser of donated legend drugs, devices, or supplies may not submit a claim or otherwise seek reimbursement from any public or private third-party payer for the cost of donated legend drugs, devices, or supplies dispensed to any eligible individual under the program. A public or private third-party payer is not required to provide reimbursement to a dispenser for the cost of donated legend drugs, devices, or supplies dispensed to any eligible individual under the program.

43-15.2-06. Liability.

1. A donor of legend drugs, devices, or supplies, or any participant in the program, that exercises reasonable care in donating, accepting, distributing, prescribing, and dispensing legend drugs, devices, or supplies under the program and the rules adopted to implement this chapter is immune from civil or criminal liability and from professional disciplinary action of any kind for any injury, death, or loss to personal property relating to such activities.
2. In the absence of intentional misconduct, a pharmaceutical manufacturer is immune from civil or criminal liability for any claim, injury, death, or loss to person or property arising from transfer, donation, dispensing, or acceptance of any legend drugs, devices, or supplies under this chapter, including liability for failure to transfer or communicate product or consumer information regarding the transferred legend drugs, devices, or supplies as well as the expiration date of the legend drugs, devices, or supplies under the program.

43-15.2-07. Recordkeeping.

1. A participant shall retain separate records detailing the receipt, distribution, and dispensing of legend drugs, devices, and supplies under this program.
2. The records of receipt must include:
 - a. The name and address of the donor;
 - b. The drug name and strength;
 - c. The manufacturer of the legend drugs, devices, or supplies;
 - d. The manufacturer lot number;
 - e. The drug expiration date;
 - f. The date received; and
 - g. The quantity received.
3. Records of distribution and dispensing must include:
 - a. The name and address of the participant;
 - b. The drug or device name;
 - c. The drug strength;
 - d. The quantity distributed;
 - e. The identity of the manufacturer of the legend drugs, devices, or supplies;
 - f. The manufacturer lot number;
 - g. The expiration date;
 - h. The date of distribution or dispensing; and
 - i. The name and address of the individual to whom the donated item was distributed.
4. Records of dispensing must include:
 - a. The requirements for a prescription label; and
 - b. The manufacturer's lot number.

Prescription Drug Repository Program



Participants

This page offers information about participating pharmacies and prescribers.

Disclaimer

The North Dakota State Board of Pharmacy presents the information on this website as a service to the public. The Board shall not be liable for errors contained herein or for any damages resulting from the use of the information contained herein.

Participant	Location	Phone
<u>25/40 Health Station</u>	Bismarck, ND	7012240499
<u>Almklov's Pharmacy</u>	Cooperstown, ND	7017972414
<u>B & B Northwest Pharmacy</u>	Minot, ND	7018382213
<u>Bowman Drug Company [The]</u>	Bowman, ND	7015233233
<u>Dakota Drug of Stanley</u>	Stanley, ND	7016282255
<u>Forman Drug</u>	Forman, ND	7017246222
<u>Greene Drug & Gift Co.</u>	Dickinson, ND	7012255171
<u>Hospice of the Red River Valley</u>	Fargo, ND	7013561509
<u>Medicine Shoppe [The]</u>	Jamestown, ND	7012523002
<u>Medicine Shoppe [The]</u>	Jamestown, ND	7012523002
<u>Mott Drug Store, Inc</u>	Mott, ND	7018242897
<u>ND Pharmacy Inc</u>	Dickinson, ND	7012254434
<u>Prairie St John's</u>	Fargo, ND	7014787550
<u>Service Drug and Gift Inc.</u>	Harvey, ND	7013242227
<u>Skip's Budget Drug</u>	Grand Forks, ND	7017724805
<u>Southtown Econodrug</u>	Wahpeton, ND	7016422336
<u>St Alexius Med Ct Pharmacy</u>	Bismarck, ND	7015306926
<u>Thrifty*White Drug #43</u>	Mandan, ND	7016635188
<u>Turtle Lake Rexall Drug, Inc.</u>	Turtle Lake, ND	7014482542
<u>Velva Drug Co</u>	Velva, ND	7013382911
<u>Walhalla Prescription Shop</u>	Walhalla, ND	7015492662
<u>Walz Pharmacy, Inc.</u>	Jamestown, ND	7012523181
<u>White Drug #05</u>	Bismarck, ND	7012230945
<u>White Drug #05</u>	Bismarck, ND	7012230945
<u>White Drug #17</u>	Minot, ND	7018524181
<u>White Drug #30</u>	Grand Forks, ND	7017464455
<u>White Drug #34</u>	Dickinson, ND	7012252121
<u>White Drug #39</u>	Fargo, ND	7012355511
<u>White Drug #40</u>	Minot, ND	7018520388
<u>White Drug #45</u>	Jamestown, ND	7012511432
<u>White Drug #46</u>	West Fargo, ND	7012815695
<u>White Drug #47 dba Bell Drug</u>	Devils Lake, ND	7016623022
<u>White Drug #50</u>	Rugby, ND	7017765741
<u>White Drug #53</u>	Cavalier, ND	7012654744
<u>White Drug #55</u>	Hettinger, ND	7015672533
<u>White Drug #59 dba Valley Drug</u>	Valley City, ND	7018451763
<u>White Drug #60</u>	Valley City, ND	7018451421
<u>White Drug #63</u>	Devils Lake, ND	7016626270

71

<u>White Drug #65</u>	Grafton, ND	7013521760
<u>White Drug #65</u>	Grafton, ND	7013521760
<u>White Drug #67</u>	Williston, ND	7017743923
<u>White Drug #68</u>	Fargo, ND	7012393543
<u>White Drug #9</u>	Grand Forks, ND	7017754209
<u>White Plaza Drug #15</u>	Jamestown, ND	7012525980

To minimize the drug listing select either a participant or a drug from either list or both then hit the "Enter" button. To see the entire list of drugs and participants click the enter button without making a selection.

72

Prescription Drug Repository Program

**CONSUMERS
STALCH FOR
NEED TO DRUG**



Inventory

This page offers information about drugs that are currently in the repository. If you are searching for a drug that does not appear in this repository, it is not currently available.

Disclaimer

The North Dakota State Board of Pharmacy presents the information on this website as a service to the public. The Board shall not be liable for errors contained herein or for any damages resulting from the use of the information contained herein.

How to Search

To search, type in your criteria and click the "Enter" button. You may search by any individual field or any combination of fields.

Participant:

Drug:

To minimize the drug listing select either a participant or a drug from either list or both then hit the "Enter" button. To see the entire list of drugs and participants click the enter button without making a selection.

73

North Dakota Prescription Drug and Device Donation Program

Recipient [Patient] Information

(copy of dispensing label with adequate information will suffice for these requirements)

Name of Pharmacy or Practitioner dispensing donated medication:

Name of recipient:

Address of recipient:

CITY

STATE

ZIP

Name, quantity, and expiration date of drugs received:

Prescription #s _____

I understand that the above named drug or device I am receiving has been donated, may have been previously dispensed, and has potentially been stored in a non-controlled environment.

Signature of recipient:

Date Signed

* Please ask your pharmacist or physician if you have any other questions.

This form should be kept on file by the pharmacy or physician dispensing the medication. Inclusion in the patient chart meets this requirement.

This program is authorized by ND Century Code Chapter 43-15.2.

74

Prescription Drug Repository Program



Items in bold are required.

Donate

Login

**DATABASE
UPDATED ?**

Please log in to donate drugs to the Prescription Drug Repository.

License or Permit Number:

License Type:

75

Prescription Drug Repository Program



These files are **large** in size and take time to download.
Please be patient.

- **Program Description**  -15KB
- **Law**  -20KB
- **Participant Registration**
- **Donor Registration Form**  -10KB
- **Update Inventory**
- **Searches:**
 - **Search for a Participating Pharmacy or Prescriber**
 - **Search for a Donated Drug**
- **Recipient Information**  -11KB

-  Indicates an Adobe PDF document, which requires the free Adobe Reader to view.
-  Indicates a Microsoft Word document.
-  Indicates a Microsoft Excel document.

If you encounter any problems with this site email the **webmaster**
© 2000 APT, Inc. Designed, Maintained and Hosted by **APT, Inc.**

76

**Unprofessional Conduct
Regulations from Other
Professions at DHP and from
2 Neighboring States**

77

28

MEDICINE

Part II. Standards of Professional Conduct.

18VAC85-20-25. Treating and prescribing for self or family.

- A. Treating or prescribing shall be based on a bona fide practitioner-patient relationship, and prescribing shall meet the criteria set forth in § 54.1-3303 of the Code of Virginia.
- B. A practitioner shall not prescribe a controlled substance to himself or a family member, other than Schedule VI as defined in § 54.1-3455 of the Code of Virginia, unless the prescribing occurs in an emergency situation or in isolated settings where there is no other qualified practitioner available to the patient, or it is for a single episode of an acute illness through one prescribed course of medication.
- C. When treating or prescribing for self or family, the practitioner shall maintain a patient record documenting compliance with statutory criteria for a bona fide practitioner-patient relationship.

18VAC85-20-26. Patient records.

- A. Practitioners shall comply with provisions of § 32.1-127.1:03 of the Code of Virginia related to the confidentiality and disclosure of patient records.
- B. Practitioners shall provide patient records to another practitioner or to the patient or his personal representative in a timely manner in accordance with provisions of § 32.1-127.1:03 of the Code of Virginia.
- C. Practitioners shall properly manage patient records and shall maintain timely, accurate, legible and complete patient records.
- D. Practitioners shall maintain a patient record for a minimum of six years following the last patient encounter with the following exceptions:
1. Records of a minor child, including immunizations, shall be maintained until the child reaches the age of 18 or becomes emancipated, with a minimum time for record retention of six years from the last patient encounter regardless of the age of the child; or
 2. Records that have previously been transferred to another practitioner or health care provider or provided to the patient or his personal representative; or
 3. Records that are required by contractual obligation or federal law [may need] to be maintained for a longer period of time.
- E. From October 19, 2005, practitioners shall post information or in some manner inform all patients concerning the time frame for record retention and destruction. Patient records shall

78 1

only be destroyed in a manner that protects patient confidentiality, such as by incineration or shredding.

F. When a practitioner is closing, selling or relocating his practice, he shall meet the requirements of § 54.1-2405 of the Code of Virginia for giving notice that copies of records can be sent to any like-regulated provider of the patient's choice or provided to the patient.

18VAC85-20-27. Confidentiality.

A practitioner shall not willfully or negligently breach the confidentiality between a practitioner and a patient. A breach of confidentiality that is required or permitted by applicable law or beyond the control of the practitioner shall not be considered negligent or willful.

18VAC85-20-28. Practitioner-patient communication; termination of relationship.

A. Communication with patients.

1. Except as provided in § 32.1-127.1:03 F of the Code of Virginia, a practitioner shall accurately inform a patient or his legally authorized representative of his medical diagnoses, prognosis and prescribed treatment or plan of care. A practitioner shall not deliberately make a false or misleading statement regarding the practitioner's skill or the efficacy or value of a medication, treatment, or procedure prescribed or directed by the practitioner in the treatment of any disease or condition.

2. A practitioner shall present information relating to the patient's care to a patient or his legally authorized representative in understandable terms and encourage participation in the decisions regarding the patient's care.

3. Before surgery or any invasive procedure is performed, informed consent shall be obtained from the patient in accordance with the policies of the health care entity. Practitioners shall inform patients of the risks, benefits, and alternatives of the recommended surgery or invasive procedure that a reasonably prudent practitioner in similar practice in Virginia would tell a patient.

a. In the instance of a minor or a patient who is incapable of making an informed decision on his own behalf or is incapable of communicating such a decision due to a physical or mental disorder, the legally authorized person available to give consent shall be informed and the consent documented.

b. An exception to the requirement for consent prior to performance of surgery or an invasive procedure may be made in an emergency situation when a delay in obtaining consent would likely result in imminent harm to the patient.

c. For the purposes of this provision, "invasive procedure" shall mean any diagnostic or therapeutic procedure performed on a patient that is not part of routine, general care and for

79 30
2

which the usual practice within the health care entity is to document specific informed consent from the patient or surrogate decision-maker prior to proceeding.

4. Practitioners shall adhere to requirements of § 32.1-162.18 of the Code of Virginia for obtaining informed consent from patients prior to involving them as subjects in human research, with the exception of retrospective chart reviews.

B. Termination of the practitioner/patient relationship.

1. The practitioner or the patient may terminate the relationship. In either case, the practitioner shall make a copy of the patient record available, except in situations where denial of access is allowed by law.

2. Except as provided in § 54.1-2962.2 of the Code of Virginia, a practitioner shall not terminate the relationship or make his services unavailable without documented notice to the patient that allows for a reasonable time to obtain the services of another practitioner.

18VAC85-20-29. Practitioner responsibility.

A. A practitioner shall not:

1. Knowingly allow subordinates to jeopardize patient safety or provide patient care outside of the subordinate's scope of practice or area of responsibility. Practitioners shall delegate patient care only to subordinates who are properly trained and supervised;

2. Engage in an egregious pattern of disruptive behavior or interaction in a health care setting that interferes with patient care or could reasonably be expected to adversely impact the quality of care rendered to a patient;

3. Exploit the practitioner/patient relationship for personal gain.

B. Advocating for patient safety or improvement in patient care within a health care entity shall not constitute disruptive behavior provided the practitioner does not engage in behavior prohibited in A 2 of this section.

18VAC85-20-30. Advertising ethics.

A. Any statement specifying a fee, whether standard, discounted or free, for professional services which does not include the cost of all related procedures, services and products which, to a substantial likelihood, will be necessary for the completion of the advertised service as it would be understood by an ordinarily prudent person shall be deemed to be deceptive or misleading, or both. Where reasonable disclosure of all relevant variables and considerations is made, a statement of a range of prices for specifically described services shall not be deemed to be deceptive or misleading.

B. Advertising a discounted or free service, examination, or treatment and charging for any additional service, examination, or treatment which is performed as a result of and within 72

80 → 3

hours of the initial office visit in response to such advertisement is unprofessional conduct unless such professional services rendered are as a result of a bona fide emergency. This provision may not be waived by agreement of the patient and the practitioner.

C. Advertisements of discounts shall disclose the full fee that has been discounted. The practitioner shall maintain documented evidence to substantiate the discounted fees and shall make such information available to a consumer upon request.

D. A licensee shall disclose the complete name of the specialty board which conferred the certification when using or authorizing the use of the term "board certified" or any similar words or phrase calculated to convey the same meaning in any advertising for his practice.

E. A licensee of the board shall not advertise information which is false, misleading, or deceptive. For an advertisement for a single practitioner, it shall be presumed that the practitioner is responsible and accountable for the validity and truthfulness of its content. For an advertisement for a practice in which there is more than one practitioner, the name of the practitioner or practitioners responsible and accountable for the content of the advertisement shall be documented and maintained by the practice for at least two years.

F. Documentation, scientific and otherwise, supporting claims made in an advertisement shall be maintained and available for the board's review for at least two years.

18VAC85-20-40. Vitamins, minerals and food supplements.

A. The recommendation or direction for the use of vitamins, minerals or food supplements and the rationale for that recommendation shall be documented by the practitioner. The recommendation or direction shall be based upon a reasonable expectation that such use will result in a favorable patient outcome, including preventive practices, and that a greater benefit will be achieved than that which can be expected without such use.

B. Vitamins, minerals, or food supplements, or a combination of the three, shall not be sold, dispensed, recommended, prescribed, or suggested in doses that would be contraindicated based on the individual patient's overall medical condition and medications.

C. The practitioner shall conform to the standards of his particular branch of the healing arts in the therapeutic application of vitamins, minerals or food supplement therapy.

18VAC85-20-50. Anabolic steroids.

A practitioner shall not sell, prescribe, or administer anabolic steroids to any patient for other than accepted therapeutic purposes.

18VAC85-20-60 to 18VAC85-20-70. [Repealed]

18VAC85-20-80. Solicitation or remuneration in exchange for referral.

A practitioner shall not knowingly and willfully solicit or receive any remuneration, directly or indirectly, in return for referring an individual to a facility or institution as defined in §37.2-100 of the Code of Virginia, or hospital as defined in §32.1-123 of the Code of Virginia. Remuneration shall be defined as compensation, received in cash or in kind, but shall not include any payments, business arrangements, or payment practices allowed by Title 42, §1320a-7b(b) of the United States Code, as amended, or any regulations promulgated thereto.

18VAC85-20-90. Pharmacotherapy for weight loss.

A. A practitioner shall not prescribe amphetamine, Schedule II, for the purpose of weight reduction or control.

B. A practitioner shall not prescribe controlled substances, Schedules III through VI, for the purpose of weight reduction or control in the treatment of obesity, unless the following conditions are met:

1. An appropriate history and physical examination are performed and recorded at the time of initiation of pharmacotherapy for obesity by the prescribing physician, and the physician reviews the results of laboratory work, as indicated, including testing for thyroid function;

2. If the drug to be prescribed could adversely affect cardiac function, the physician shall review the results of an electrocardiogram performed and interpreted within 90 days of initial prescribing for treatment of obesity;

3. A diet and exercise program for weight loss is prescribed and recorded;

4. The patient is seen within the first 30 days following initiation of pharmacotherapy for weight loss, by the prescribing physician or a licensed practitioner with prescriptive authority working under the supervision of the prescribing physician, at which time a recording shall be made of blood pressure, pulse, and any other tests as may be necessary for monitoring potential adverse effects of drug therapy;

5. The treating physician shall direct the follow-up care, including the intervals for patient visits and the continuation of or any subsequent changes in pharmacotherapy. Continuation of prescribing for treatment of obesity shall occur only if the patient has continued progress toward achieving or maintaining a target weight and has no significant adverse effects from the prescribed program.

18VAC85-20-100. Sexual contact.

A. For purposes of § 54.1-2915 A 12 and A 19 of the Code of Virginia and this section, sexual contact includes, but is not limited to, sexual behavior or verbal or physical behavior which:

1. May reasonably be interpreted as intended for the sexual arousal or gratification of the practitioner, the patient, or both; or

2. May reasonably be interpreted as romantic involvement with a patient regardless of whether such involvement occurs in the professional setting or outside of it.

B. Sexual contact with a patient.

1. The determination of when a person is a patient for purposes of § 54.1-2915 A 19 of the Code of Virginia is made on a case-by-case basis with consideration given to the nature, extent, and context of the professional relationship between the practitioner and the person. The fact that a person is not actively receiving treatment or professional services from a practitioner is not determinative of this issue. A person is presumed to remain a patient until the patient-practitioner relationship is terminated.

2. The consent to, initiation of, or participation in sexual behavior or involvement with a practitioner by a patient does not change the nature of the conduct nor negate the statutory prohibition.

C. Sexual contact between a practitioner and a former patient.

Sexual contact between a practitioner and a former patient after termination of the practitioner-patient relationship may still constitute unprofessional conduct if the sexual contact is a result of the exploitation of trust, knowledge, or influence of emotions derived from the professional relationship.

D. Sexual contact between a practitioner and a key third party shall constitute unprofessional conduct if the sexual contact is a result of the exploitation of trust, knowledge or influence derived from the professional relationship or if the contact has had or is likely to have an adverse effect on patient care. For purposes of this section, key third party of a patient shall mean: spouse or partner, parent or child, guardian, or legal representative of the patient.

E. Sexual contact between a medical supervisor and a medical trainee shall constitute unprofessional conduct if the sexual contact is a result of the exploitation of trust, knowledge or influence derived from the professional relationship or if the contact has had or is likely to have an adverse effect on patient care.

18VAC85-20-105. Refusal to provide information.

A practitioner shall not willfully refuse to provide information or records as requested or required by the board or its representative pursuant to an investigation or to the enforcement of a statute or regulation.

DENTISTRY

Part V. Unprofessional Conduct.

18VAC60-20-150 to 18VAC60-20-160. [Repealed]



18VAC60-20-170. Acts constituting unprofessional conduct.

The following practices shall constitute unprofessional conduct within the meaning of §54.1-2706 of the Code of Virginia:

1. Fraudulently obtaining, attempting to obtain or cooperating with others in obtaining payment for services;
2. Performing services for a patient under terms or conditions which are unconscionable. The board shall not consider terms unconscionable where there has been a full and fair disclosure of all terms and where the patient entered the agreement without fraud or duress;
3. Misrepresenting to a patient and the public the materials or methods and techniques the licensee uses or intends to use;
4. Committing any act in violation of the Code of Virginia reasonably related to the practice of dentistry and dental hygiene;
5. Delegating any service or operation which requires the professional competence of a dentist or dental hygienist to any person who is not a dentist or dental hygienist as authorized by this chapter;
6. Certifying completion of a dental procedure that has not actually been completed;
7. Knowingly or negligently violating any applicable statute or regulation governing ionizing radiation in the Commonwealth of Virginia, including, but not limited to, current regulations promulgated by the Virginia Department of Health; and
8. Permitting or condoning the placement or exposure of dental x-ray film by an unlicensed person, except where the unlicensed person has complied with 18VAC60-20-195.

NURSING

Part V. Disciplinary Provisions.

18VAC90-20-300. Disciplinary provisions.

A. The board has the authority to deny, revoke or suspend a license or multistate licensure privilege issued, or to otherwise discipline a licensee or holder of a multistate licensure privilege upon proof that the licensee or holder of a multistate licensure privilege has violated any of the provisions of § 54.1-3007 of the Code of Virginia. For the purpose of establishing allegations to be included in the notice of hearing, the board has adopted the following definitions:

1. Fraud or deceit in procuring or maintaining a license means, but shall not be limited to:
 - a. Filing false credentials;

84
7

- b. Falsely representing facts on an application for initial license, reinstatement or renewal of a license; or
 - c. Giving or receiving assistance in the taking of the licensing examination.
2. Unprofessional conduct means, but shall not be limited to:
- a. Performing acts beyond the limits of the practice of professional or practical nursing as defined in Chapter 30 (§54.1-3000 et seq.) of Title 54.1 of the Code of Virginia, or as provided by §§54.1-2901 and 54.1-2957 of the Code of Virginia;
 - b. Assuming duties and responsibilities within the practice of nursing without adequate training or when competency has not been maintained;
 - c. Obtaining supplies, equipment or drugs for personal or other unauthorized use;
 - d. Employing or assigning unqualified persons to perform functions that require a licensed practitioner of nursing;
 - e. Falsifying or otherwise altering patient, employer, student, or educational program records, including falsely representing facts on a job application or other employment-related documents;
 - f. Abusing, neglecting or abandoning patients or clients;
 - g. Practice of a clinical nurse specialist beyond that defined in 18VAC90-20-290;
 - h. Representing oneself as or performing acts constituting the practice of a clinical nurse specialist unless so registered by the board;
 - i. Delegating nursing tasks to an unlicensed person in violation of the provisions of Part VIII (18VAC90-20-420 et seq.) of this chapter;
 - j. Giving to or accepting from a patient or client property or money for any reason other than fee for service or a nominal token of appreciation;
 - k. Obtaining money or property of a patient or client by fraud, misrepresentation or duress;
 - l. Entering into a relationship with a patient or client that constitutes a professional boundary violation in which the nurse uses his professional position to take advantage of a patient or client's vulnerability, to include but not limited to actions that result in personal gain at the expense of the patient or client, a nontherapeutic personal involvement or sexual conduct with a patient or client; or
 - m. Violating state laws relating to the privacy of patient information, including but not limited to §32.1-127.1:03 of the Code of Virginia.
 - n. Violating any provision of this chapter.
- B. Any sanction imposed on the registered nurse license of a clinical nurse specialist shall have the same effect on the clinical nurse specialist registration.

A handwritten signature or set of initials in black ink, located in the bottom right corner of the page. The signature is stylized and appears to consist of a large, bold letter 'B' followed by a smaller, more complex mark.

Kentucky

- (2) Unprofessional or unethical conduct includes but is not limited to the following acts of a pharmacist or pharmacist intern:
- (a) Publication or circulation of false, misleading, or deceptive statements concerning the practice of pharmacy;
 - (b) Divulging or revealing to unauthorized persons patient information or the nature of professional services rendered without the patient's express consent or without order or direction of a court. In addition to members, inspectors, or agents of the board, the following are considered authorized persons:
 - 1. The patient, patient's agent, or another pharmacist acting on behalf of the patient;
 - 2. Certified or licensed health-care personnel who are responsible for care of the patient;
 - 3. Designated agents of the Cabinet for Health and Family Services for the purposes of enforcing the provisions of KRS Chapter 218A;
 - 4. Any federal, state, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person; or
 - 5. An agency of government charged with the responsibility of providing medical care for the patient, upon written request by an authorized representative of the agency requesting such information;
 - (c) Selling, transferring, or otherwise disposing of accessories, chemicals, drugs, or devices found in illegal traffic when the pharmacist or pharmacy intern knows or should have known of their intended use in illegal activities;
 - (d) Engaging in conduct likely to deceive, defraud, or harm the public, demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, or engaging in conduct which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist or pharmacy intern, with or without established proof of actual injury;
 - (e) Engaging in grossly negligent professional conduct, with or without established proof of actual injury;
 - (f) Selling, transferring, dispensing, ingesting, or administering a drug for which a prescription drug order is required, without having first received a prescription drug order for the drug;
 - (g) Willfully or knowingly failing to maintain complete and accurate records of all drugs received, dispensed, or disposed of in compliance with federal and state laws, rules, or administrative regulations;
 - (h) Obtaining any remuneration by fraud, misrepresentation, or deception;
 - (i) Accessing or attempting to access confidential patient information for persons other than those with whom a pharmacist has a current pharmacist-patient relationship and where such information is necessary to the pharmacist to provide pharmacy care; or



- (j) Failing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful.
- (3) Any licensee, permit holder, or certificate holder entering an "Alford" plea, pleading nolo contendere, or who is found guilty of a violation prescribed in subsection (1)(c) of this section shall within thirty (30) days notify the board of that plea or conviction. Failure to do so shall be grounds for suspension or revocation of the license, certificate, or permit.
- (4) Any person whose license, permit, or certificate has been revoked in accordance with the provisions of this section, may petition the board for reinstatement. The petition shall be made in writing and in a form prescribed by the board. The board shall investigate all reinstatement petitions, and the board may reinstate a license, permit, or certificate upon showing that the former holder has been rehabilitated and is again able to engage in the practice of pharmacy with reasonable skill, competency, and safety to the public. Reinstatement may be on the terms and conditions that the board, based on competent evidence, reasonably believes necessary to protect the health and welfare of the citizens of the Commonwealth.
- (5) Upon exercising the power of revocation provided for in subsection (1) of this section, the board may reasonably prohibit any petition for reinstatement for a period up to and including five (5) years.
- (6) Any licensee, permit holder, or certificate holder who is disciplined under this section for a minor violation may request in writing that the board expunge the minor violation from the licensee's, permit holder's, or certificate holder's permanent record.
 - (a) The request for expungement may be filed no sooner than three (3) years after the date on which the licensee, permit holder, or certificate holder has completed disciplinary sanctions imposed and if the licensee, permit holder, or certificate holder has not been disciplined for any subsequent violation of the same nature within this period of time.
 - (b) No person may have his or her record expunged under this section more than once.

The board shall promulgate administrative regulations under KRS Chapter 13A to establish violations which are minor violations under this subsection. A violation shall be deemed a minor violation if it does not demonstrate a serious inability to practice the profession; adversely affect the public health, safety, or welfare; or result in economic or physical harm to a person, or create a significant threat of such harm.

Effective: June 20, 2005

History: Amended 2005 Ky. Acts ch. 99, sec. 598, effective June 20, 2005. -- Amended 2003 Ky. Acts ch. 51, sec. 4, effective June 24, 2003. -- Amended 2002 Ky. Acts ch. 335, sec. 1, effective July 15, 2002. -- Amended 1998 Ky. Acts ch. 426, sec. 549, effective July 15, 1998. -- Amended 1996 Ky. Acts ch. 257, sec. 14, effective July 15, 1996. --Created 1982 Ky. Acts ch. 191, sec. 11, effective July 15, 1982.

87 0

(Rule 1140-2-.01, continued)

- (b) without discriminating in any manner between patients or groups of patients; and
 - (c) without compromising the kind or extent of services or facilities made available.
- (12) A pharmacist shall recognize the Tennessee Board of Pharmacy as the governing body of the practice of pharmacy in the State of Tennessee, and report to the board any violations of pharmacy laws or rules which may come to the pharmacist's attention. The pharmacist at all times shall refrain from discussing these matters with nonmembers of the profession.
- (13) The following functions must be performed personally by a pharmacist or by a pharmacy intern under the personal supervision and in the presence of a pharmacist:
- (a) Certification of medical and prescription orders;
 - (b) Performance of final verification of the product prior to dispensing;
 - (c) Initialing of medical and prescription orders noting appropriate comments;
 - (d) Providing patient counseling;
 - (e) Providing direct patient care services;
 - (f) Providing drug information to patients, care givers, and health care providers;
 - (g) Supervision of compounding;
 - (h) Evaluation and establishment of criteria for selection of drug product(s) and supplier(s); and
 - (i) Daily opening and closing of a pharmacy practice site.
- (14) A pharmacist and pharmacy intern shall wear appropriate identification showing name and appropriate title.
- (15) A pharmacist shall immediately notify the board office in writing of a change in location of primary practice site and permanent residence.
- (16) A pharmacist shall conspicuously display the pharmacist's license and certificate of registration at the primary pharmacy practice site. Pharmacists shall possess at all times, while engaged in the practice of pharmacy, proof of a license.
- (17) A pharmacist convicted of any crime, including driving under the influence of alcohol or controlled substances, shall report such conviction to the board within ten (10) days of the conviction becoming final. For purposes of this reporting requirement, a conviction includes pretrial or judicial diversion.
- (18) A pharmacist shall comply with lawful order(s) of the board.

Authority: T.C.A. §§63-10-404(26),(27), and (29), 63-10-504(b)(1), and 63-10-504(b)(1)(C). **Administrative History:** Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-2-.02 PHARMACY TECHNICIANS.

- (1) Any person acting as a pharmacy technician shall register with the board by submitting an application on a form prescribed by the board. The applicant shall also:
 - (a) Provide a statement of good moral character;
 - (b) Submit an affidavit from his employer attesting that the applicant has read and understands the statutes and regulations pertaining to the practice of pharmacy in Tennessee. (A copy of this affidavit shall be retained at the place of employment.)
 - (c) Submit the appropriate application fee as set in Rule 1140-1-.10 of the Rules of the Board of Pharmacy.
- (2) The pharmacist in charge at each pharmacy practice site is responsible for compliance with the provisions of this chapter by pharmacy technicians at that pharmacy practice site.
- (3) A pharmacy technician may perform the following functions, but only in the presence of and under the supervision of a pharmacist:
 - (a) Accept a request from a patient to refill a medical or prescription order;
 - (b) Accept or request authorization for a refill of a medical or prescription order from a practitioner or a practitioner's agent;
 - (c) Prepare a label to be placed on the dispensing container;
 - (d) Obtain and enter patient or medical or prescription order data into the patient information system;
 - (e) Retrieve prescription drugs and devices and related materials from stock, count or measure prescription drugs and devices and related materials, and place the prescription drugs and devices and related materials in the dispensing container;
 - (f) Affix a label to a dispensing container;
 - (g) Assist in reconstituting of prescription drugs;
 - (h) Assist in compounding;
 - (i) Transmit pharmacist approved orders to suppliers;
 - (j) Place ancillary information on the dispensing container;
 - (k) Prepackage and label drugs and devices and related materials for future dispensing;
 - (l) Deliver drugs and devices and related materials provided an established procedure is followed to ensure proper and safe delivery;
 - (m) Issue drugs and devices and related materials to authorized persons when such are to be used for administration to an inpatient;
 - (n) Prepare unit dose carts for final review by a pharmacist;
 - (o) Order drugs and devices and related materials from suppliers according to established criteria; and

(Rule 1140-2-.02, continued)

- (p) Retrieve and transport drugs and devices and related materials to and from approved areas.
- (4) In addition to the functions contained in paragraph (2) above, certified pharmacy technicians may receive new, or transferred oral medical and prescription orders.
 - (5) No prescription drugs and devices and related materials may be released to a patient without verification by a pharmacist of the functions performed by the pharmacy technician.
 - (6) The actual working ratio of pharmacy technicians to pharmacists shall not be more than 2:1 in any pharmacy practice site; provided, however, that the ratio may be increased to a maximum of 3:1 if at least one (1) of the pharmacy technicians is a certified pharmacy technician. For purposes of this rule, a pharmacy intern is not considered to be a pharmacy technician.
 - (7) Pharmacy technicians must wear appropriate identification showing name and appropriate title (e.g., pharmacy technician, certified pharmacy technician).
 - (8) All pharmacy technician functions shall be performed under the supervision of a pharmacist, who shall direct and verify the accuracy of all pharmacy technician functions. Supervision requires the physical presence of the pharmacist making appropriate in-process and end-process verifications of the pharmacy technician's activities.
 - (9) All registered technicians shall conspicuously display the technician's registration certificate at the primary practice site; additionally, all certified technicians shall display in like manner evidence of certification. Pharmacy technicians shall possess at all times, while on duty, proof of registration and proof of certification, if applicable.
 - (10) All registered technicians shall immediately notify the board in writing of any change of address or employer.

Authority: T.C.A. §§63-10-404(30), 63-10504(b)(1), 63-10-504(b)(1)(C), 63-10-506, and 63-10-508.
Administrative History: Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002

91
43