TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 8 PHARMACIES

001. SCOPE AND AUTHORITY. These regulations govern licensure of Pharmacies. The regulations are authorized under the Health Care Facility Licensure Act, Nebraska Revised Statutes (Neb. Rev. Stat.) §§ 71-401 to 71-475; the Pharmacy Practice Act, Neb. Rev. Stat. §§ 38-2801 to 38-28,116; the Uniform Controlled Substances Act, Neb. Rev. Stat. §§ 28-401 to 28-456.01 and 28-458 to 28-475; and the Prescription Drug Safety Act, Neb. Rev. Stat. §§ 71-2457 to 71-2483.

002. DEFINITIONS. Definitions set out in the Health Care Facility Licensure Act, Neb. Rev. Stat. §§ 71-401 to 71-475; the Pharmacy Practice Act, Neb. Rev. Stat. §§ 38-2801 to 38-28,116; the Uniform Controlled Substances Act, Neb. Rev. Stat. §§ 28-401 to 28-456.01 and 28-458 to 28-475 and the following apply to this chapter:

002.01 COMPLETE APPLICATION. An application that contains all of the information requested on the application, with attestation to its truth and completeness, and submitted with all required fees and documentation.

002.02 COMPLETE PETITION. A complete petition contains all of the requested information on a form provided by the Department, with attestation to it truth and completeness, signatures of the applicant(s), submitted with all required fees and documentation.

003. LICENSING REQUIREMENTS. An applicant for an initial license must submit a completed application provided by the Department and documentation that the applicant meets the requirements set in statute and this chapter.

003.01 PROVISIONAL PHARMACY LICENSE. To obtain a provisional pharmacy license, an applicant must substantially meet the requirements in the Health Care Facility Licensure Act and sections 175 NAC 8-006 through 175 NAC 8-008 of this chapter. A pharmacy license will be issued after a satisfactory initial inspection is completed.

003.02 RENEWAL. All pharmacy licenses expire annually on July 1. To renew a license an applicant for a renewal license must submit a complete application provided by the Department and documentation that the applicant meets the requirements in statute and in this chapter.

003.03 PERMANENTLY CLOSING A PHARMACY. When a licensee discontinues providing pharmacy services, the Department must be notified in writing within 15 days of the services being discontinued. The notice must include the following information:

(1) The sale or other disposition of legend drug, device, or biological inventory,
(2) The sale or other disposition of controlled substances and controlled substances invoices and inventory records, and
(3) The location of all patient records including prescription files.

003.03(A) RETURN OF DOCUMENTS AND FORMS. Upon permanent closure of the pharmacy, the licensee must return the pharmacy license to the Department and may return the following to the Department to be forwarded to the Drug Enforcement Administration (DEA):

(i) The pharmacy's Drug Enforcement Administration (DEA) Registration, if any; and
(ii) All unused Drug Enforcement Administration (DEA) Forms for the pharmacy, if any.

003.03(B) PATIENT NOTIFICATION. When the permanent closing of a pharmacy is anticipated, the licensee is responsible for notifying patients of that pharmacy within 15 days of the permanent closing that they will need to seek service elsewhere. The notification can be accomplished through:

(i) Advertisement in a newspaper appropriate to the location of the pharmacy;
(ii) Written notice to patients of the pharmacy; or
(iii) Other such notice as is appropriate.

003.04 REINSTATEMENT. Unless otherwise stated, a request for reinstatement must submit complete application provided by the Department and meet the requirements of Neb. Rev. Stat. § 71-433, 71-456, and 175 NAC 8.

003.04(A) REINSTATEMENT PRIOR TO THE COMPLETION OF PROBATION. A licensee may petition for reinstatement prior to the completion of probation or suspension and must submit a complete petition form provided by the Department.

004. INSPECTIONS. For the purpose of assuring compliance, each licensee must prepare an annual Pharmacy Quality Assurance Report (PQAR).

004.01 PHARMACY QUALITY ASSURANCE REPORT (PQAR). The Pharmacy Quality Assurance Report (PQAR) is due 1 year from the date of the initial on-site inspection and annually thereafter. All licensees must ensure that the pharmacist in charge or the practitioner on behalf of the licensee, annually submits a completed Pharmacy Quality Assurance Report (PQAR) on a form provided by the Department, electronically, or upon request. A Pharmacy Quality Assurance Report (PQAR) self-inspection may be completed no more than 30 days before the due date of the report.

004.01(A) REPORTED INFORMATION. At a minimum, the Pharmacy Quality Assurance Report (PQAR) must provide information on the following:

(i) Standards for the Operations of a Pharmacy
(1) Staffing requirements;

(2) Storage requirements;
(3) Record keeping requirements;
(4) Dispensing requirements;
(5) Controlled substance dispensing requirement for emergency situations; and
(6) Disaster preparedness management;

(ii) Physical Plant Standards
(1) Equipment, facilities, and utilities;
(2) Shelving, counters, floor, inventory, fixtures, equipment, and utensils; and
(3) Reference material;

(iii) Sterile Compounding Requirements, if applicable for the facility

(iv) Non-sterile compounding requirements, if applicable for the facility.

004.01(B) VERIFICATION OF THE REPORT. The Pharmacy Quality Assurance Report (PQAR) must include a signed statement from the pharmacist in charge or the practitioner verifying that all information in the Pharmacy Quality Assurance Report (PQAR) is accurate, complete, and correct.

004.02 ANNUAL INSPECTION. All licensees are required to complete and submit the Department Pharmacy Quality Assurance Report (PQAR) form for an annual self-inspection, and may be subject to an on-site inspection to verify the pharmacy fully complies with all requirements.

004.02(A) SELF-INSPECTION. The Pharmacy Quality Assurance Report (PQAR) will fulfill the annual inspection requirement when the Department determines that the report indicates that the licensee is in full compliance with the Health Care Facility Licensure Act, the Controlled Substances Act, the Prescription Drug Safety Act, and this chapter. However, the report will not fulfill the annual inspection requirement when:

(i) The Department has determined, based on the review of the Pharmacy Quality Assurance Report (PQAR), that the pharmacy is not in compliance with the Health Care Facility Licensure Act, or this chapter;

(ii) The pharmacy failed to be in full compliance with the Health Care Facility Licensure Act, or this chapter at the time of its last inspection;

(iii) The licensee failed to submit a Pharmacy Quality Assurance Report (PQAR);

(iv) The pharmacy is randomly selected as part of the 25% of licensed pharmacies chosen annually for inspection; and

(v) Any other event that raises concerns about the maintenance, operation, or management of the pharmacy.

004.02(B) COMPLIANCE INSPECTION. An unannounced inspection may be conducted of the facility or service anytime the Department deems necessary, including, the passage of five years without an inspection.

005. GENERAL REQUIREMENTS. The following requirements are applicable to all pharmacy licenses.

005.01 LICENSE NOT TRANSFERABLE. Change of ownership or change of premises terminates the license. The new owner or owners must apply for a new pharmacy license.

005.02 NOTIFICATION. An applicant or licensee must notify the Department of any change as set forth in 175 NAC 8-005.03 through 8-005.08. The following information is required for all notifications:

(A) Current name and license number of the pharmacy or practitioner;
(B) Street address of pharmacy or practitioner;
(C) Name of owner(s), partners, or corporation;
(D) If a corporation the name of corporate officers;
(E) Mailing address(es) of owner(s), partners, or corporation;
(F) Reason for notifying the Department about a change in the existing license;
(G) A signed statement from the applicant or licensee verifying that all information is correct; and
(H) The required fee as specified in this chapter, if any.

005.03 CHANGE OF PHARMACIST IN CHARGE. The licensee must notify the Department within 1 business day when there is a change in the pharmacist-in-charge.

005.04 CHANGE OF OWNERSHIP OR PREMISES. The licensee must notify the Department in writing 15 days of when the pharmacy is sold, leased, discontinued, or moved to a new premises.

005.05 CHANGE OF NAME OF THE PHARMACY. The licensee must notify the Department in writing within 5 working days when there is a change in the name of the pharmacy.

005.06 DEATH OF A LICENSEE. The heirs or executor of the estate must notify the Department within 30 days of the death of a licensee.

005.07 AN ACCIDENT, NATURAL DISASTER, OR INTERUPTION IN UTILITY SERVICES. The licensee must notify the Department in writing by electronic mail, facsimile, or postal service within 24 hours of any change in environment which will adversely affect the potency, efficacy, safety or security of the drugs, devices, or biologicals in the pharmacy. The notification may be made by telephone if the event has affected the licensee's capacity to communicate in writing.

005.08 FEES. The Following fees apply to this chapter:

(A) Initial pharmacy license fee is $625.
(B) Annual pharmacy license renewal fee is $625.
(C) Duplicate license fee is $10.

006. STANDARDS FOR THE OPERATION OF A PHARMACY. The licensee must comply with the Prescription Drug Safety Act, the Pharmacy Practice Act, the Controlled Substances Act, and the following:

006.01 STAFFING. Each licensee must have a pharmacist in charge or be a practitioner with the qualifications, training, and skills necessary to meet the requirements according to this chapter.

006.01(A) LICENSED PHARMACIST. Each licensee must employ a sufficient number of licensed pharmacists to safely meet the needs of the individuals seeking services at the pharmacy.

006.02 STORAGE REQUIREMENTS. All drugs, medical devices, and biologicals must be stored in a manner that meets the manufacturer's labeled requirements or in the absence of manufacturer's requirements in accordance with those listed in this chapter.

006.02(A) TEMPERATURE AND LABEL REQUIREMENTS. The licensee must provide equipment for the storage of drugs, devices, and biologicals at the proper temperature:

(i) Drugs, devices, or biologicals requiring refrigeration must be stored between 36 and 46 degrees Fahrenheit;

(ii) Drugs, devices, or biologicals requiring a freezer must be stored between -13 and 14 degrees Fahrenheit;

(1) For drugs, devices, or biologicals requiring a storage temp under -4 degrees Fahrenheit the temperature of the storage location must be within plus or minus 10 degrees;

(iii) Drugs, devices, or biologicals requiring storage in a cool place must be stored between 46 and 59 degrees Fahrenheit, or under refrigeration, between 36 and 46 degrees Fahrenheit, unless otherwise specified;

(iv) Drugs, devices, or biologicals requiring storage at controlled room temperature must be stored between 68 and 77 degrees Fahrenheit; and

(v) Other labeled storage instruction for drugs, devices, or biologicals must be followed.

006.02(B) SEPARATE STORAGE. Drugs, devices, biologicals, dietary supplements or substances used in compounding that require refrigeration cannot be stored in the same compartment as staff food or beverages.

006.02(C) MISBRANDED OR ADULTERATED DRUG STORAGE. All drugs which are misbranded or adulterated shall not be stored with saleable inventory.

007. RECORD KEEPING REQUIREMENTS. Complete and accurate records must be maintained as set out in this chapter.

007.01 SECURE RECORDS. The prescription inventory and prescription records of the pharmacy must be maintained in a secure location.

007.02 DISASTER PREPAREDNESS AND MANAGEMENT. The licensee must have and implement disaster preparedness plans and procedures to protect the potency, efficacy, safety, and security of the drugs, devices, or biologicals in the pharmacy in instances of natural or other disasters, disease outbreaks, interruption of utility services, or other similar situations. Such plans and procedures must address how the licensee will:

(A) Provide for the storage of drugs, devices, and biologicals at the proper temperature;

(B) Provide for the disposal of drugs, devices, and biologicals if the pharmacy determines their potency, efficacy, or safety has been adversely affected;

(C) Secure the drugs, devices, and biologicals from the public; and

(D) Maintain patient records and inventory records.

008. PHYSICAL PLANT STANDARDS. A licensee must meet the requirements set out in this chapter.

008.01 ACCESS BY PHARMACIST. The licensee must provide the appropriate staff access to all equipment, facilities, and utilities appropriate for the accurate, efficient, and safe provision of the clinical services available in that pharmacy.

008.02 CONDITIONS. The licensee must assure the prescription department, including shelving, counters, floor, inventory, fixtures, equipment, and utensils are maintained in a clean, orderly, and sanitary manner that supports the scope of pharmacy services provided at the site.

008.03 REFERENCE MATERIAL. The licensee must provide the appropriate staff access to all reference material appropriate for the accurate, efficient, and safe practice of pharmacy. These references materials must be up to date, in either printed or electronic form, and available at all times while the practice of pharmacy is occurring.