

TITLE 172 PROFESSIONAL AND OCCUPATIONAL LICENSURE

CHAPTER 134 DELEGATED DISPENSING PERMITS

001. SCOPE OF AUTHORITY. These regulations govern the issuance of delegated dispensing permits under the Pharmacy Practice Act, Nebraska Revised Statutes (Neb. Rev. Stat.) §§ 38-2801 to 38-28,116, and the Uniform Credentialing Act (UCA).

002. DEFINITIONS. Definitions set out in the Pharmacy Practice Act, the Prescription Drug Safety Act, the Uniform Credentialing Act, and 172 Nebraska Administrative Code (NAC) 10.

002.01 APPROVED FORMULARY. A formulary as recommended by the Board and approved by the Director as set out in Neb. Rev. Stat. §38-2881.

003. PERMIT REQUIREMENTS. To obtain a delegated dispensing permit, an applicant must submit a completed application provided by the Department and provide documentation demonstrating that the applicant meets the requirements of Neb. Rev. Stat. § 38-2873 and this chapter. An applicant must pass an initial inspection before a permit may be issued.

004. INSPECTIONS. An applicant for a delegated dispensing permit must meet the requirements of Neb. Rev. Stat. § 38-2874 and this chapter and may be inspected as determined by the Department. A follow-up inspection may be conducted by the Department under Neb. Rev. Stat. § 38-2875.

004.01 CLOSING. When a delegated dispensing permit holder anticipates closing for business, the Department must be notified in writing within 15 days of the closing date. Documentation must be provided to the Department which verifies that the delegated dispensing permit holder has completed a closing inventory and has distributed properly disposed of all legend drugs and devices to an authorized recipient and disposed of all expired legend drugs and devices.

005. STAFFING REQUIREMENTS FOR A DELEGATED DISPENSING PERMIT. An individual working as a public health clinic worker in a delegated dispensing site must meet the requirements of Neb. Rev. Stat. §§ 38-2884 to 38-2889, and this chapter.

005.01 TRAINING. Training required for licensed health care workers and public health clinic workers prior to staff dispensing drugs and devices under a delegated dispensing permit. The training is required to include the following:

- (A) Procedures for dispensing initial prescriptions and authorized refills of ~~oral~~ contraceptives;
- (B) Procedures for dispensing approved drugs and devices;
- (C) Federal and State laws regarding drug dispensing;
- (D) Proper labeling of ~~oral~~ contraceptives and approved drugs and devices;
- (E) Proper record keeping of initial and refilled prescriptions;
- (F) Proper pharmacist referral;
- (G) Procedures for reaching the consultant or the on-call pharmacist;
- (H) Storage and security of approved formulary drugs and devices; and

(l) Patient information.

005.02 TRAINING HOURS. The following training hours are required:

- (A) Licensed physicians, osteopathic physicians, physician assistants, nurse practitioners, or nurse midwives must have ~~at least one hour on the requirements of delegated dispensing~~2 hours of training;
- (B) Licensed practical nurses, or Registered nurses who are not also nurse practitioners or nurse midwives, ~~or licensed practical nurses~~ must have ~~at least one hour of training on the requirements of delegated dispensing and two hours on the pharmacology of drugs on the approved formulary~~8 hours of training; and
- (C) Public health clinic workers must have ~~one hour of 6 hours of classroom~~ training on the requirements of delegated dispensing, and two hours on the dispensing and pharmacology of authorized contraceptives.
 - (i) After the initial training has been completed, public health clinic workers must have an annual ~~review of at least 1 hour on~~2-hour in-service regarding oral contraceptive s pharmacology.

005.03 DOCUMENTATION OF TRAINING. Documentation of successful completion of all training must be maintained in the employee's personnel file and in the delegated dispensing permit holder's policy and procedure manual. The permit holder and the consultant pharmacist must provide the training before staff dispense any drugs and devices and that documentation of training has been completed.

005.04 PROFICIENCY DEMONSTRATION. Following training, public health clinic workers must be supervised by ~~4 of the a~~ licensed health care professionals trained to dispense drugs for the first month the public health clinic worker dispenses authorized refills of ~~oral~~ contraceptives, and that the worker demonstrate proficiency to the consultant pharmacist at least annually or as requested by the consultant pharmacist.

005.04(A) PROFICIENCY STANDARDS. Demonstrate to the contract pharmacist the ability to follow the procedures outlined in 172 NAC 134-005.01.

005.04(AB) PROFICIENCY DOCUMENTATION. Completed proficiency demonstrations must be documented in the employee's personnel file and in the delegated dispensing permit holder's policy and procedure manual.

006. STANDARDS FOR DISPENSING LEGEND DRUGS AND DEVICES. The requirements for dispensing drugs are set out in the Pharmacy Practice Act, and this chapter.

006.01 CONSULTANT PHARMACIST. The consulting pharmacist must meet the requirements of Neb. Rev. Stat. § 38-2882 and must report any ~~significant~~ discrepancies in the inventory of the delegated dispensing site to the Board and the administrator of the delegated dispensing site.

006.02 PRESCRIPTION REFILL. Refills ~~under Neb. Rev. Stat 38-2884(3) for contraceptives~~ cannot be authorized for greater than 1 year from the date of issuance of the original prescription.

006.03 DISPENSING. Drugs must be dispensed in accordance with Neb. Rev. Stat. § 38-2884.

006.04 PACKAGING. All drugs or devices dispensed under a delegated dispensing permit are to be prepackaged by the manufacturer or a pharmacist on-site into the quantity to be prescribed and dispensed at the delegated dispensing site.

006.05 CONTAINERS. All new and refilled prescriptions must be packaged in new sanitary containers before they are dispensed; original unopened containers as received from the manufacturer, distributor or packer may be utilized provided the pharmacist ensures all labeling requirements of this chapter are met.

006.06 PRESCRIPTION AND PRESCRIBED MEDICAL ARTICLES RETURNS. A delegated dispensing permit holder is prohibited from accepting for any purpose ~~any dispensed prescriptions.~~ the following items:

- ~~(A) Unused portions of dispensed prescriptions; or~~
- ~~(B) Prescribed devices or products used upon or applied to the human body, except those defective prescribed drugs, prescribed devices or products sold under warranty or guaranteed by the manufacturer, supplier, or wholesaler which must be returned by the retailer before a refund will be issued to the consumer or user; or~~
- ~~(C) Those prescribed drugs which are voluntarily recalled by manufacturers or that are recalled by order of the Federal Food and Drug Administration.~~

006.07 INVENTORY. A pharmacist must ensure that the inventory of all drugs and devices in the delegated dispensing site have affixed to them the original label of the manufacturer, distributor or packer. Information contained on all labels and packages must be complete and accurate. A pharmacist must ensure that the inventory of all drugs in the drug dispensing area have affixed to them a label with the information set out in Neb. Rev. Stat. § 38-2884. Drugs stored in the drug dispensing area or dispensed to patients are deemed misbranded if they are not labeled as specified in Neb. Rev. Stat. § 38-2884 or as set out in Neb. Rev. Stat. § 71-2470.

006.08 STORAGE AND ENVIRONMENT. ~~The site, furnishings, and equipment must be maintained in a clean, orderly, and sanitary manner at all times. All drugs and devices must be stored in a manner that meets the recommended storage requirements of the manufacturer or those listed in 175 NAC 8-006.02. There must be adequate lighting in the drug dispensing area to allow staff to properly observe the identities of all drugs and devices and to dispense such. The site, furnishings, and equipment must be maintained in a clean, orderly, and sanitary manner at all times. When drugs that require refrigeration are stored or dispensed there must be adequate refrigeration. All drugs and devices must be stored in a manner that meets the recommended storage requirements of the manufacturer.~~

006.09 RECORDKEEPING. The delegated pharmacists are responsible for recordkeeping as set out in Neb. Rev. Stat. § 38-2882 and the following:

- (A) A delegated dispensing permit holder must maintain a single file of the prescription information;
- (B) The delegated dispensing permit holder must maintain records of all drugs and devices dispensed for 5 years;

- (C) When an electronic recordkeeping system is used and it becomes inoperable, dispensing transactions occurring during this period of inoperability must be entered into the system when the system becomes operable;
- (D) Dispensing records must be readily retrievable;
- (E) Appropriate reference material for the practice of pharmacy must be kept; and
- (F) A manual of current policies and procedures must be kept and includes the following:
 - (i) Labeling requirements;
 - (ii) Storage and security of drugs and devices;
 - (iii) Proper patient instruction;
 - (iv) Formulary;
 - (v) Library resources;
 - (vi) Record keeping, to include the medical chart;
 - (vii) Drug recall procedures;
 - (viii) Policies for licensed or certified health care staff; and
 - (ix) Policies for public health clinic workers.

006.10 REQUIRED SIGNAGE. Each site must display a Poison Control Center phone number in a conspicuous location. Each permit holder must display the permit in a conspicuous manner in the drug dispensing area.

007. RENEWAL, WAIVER OF CONTINUING EDUCATION, AND INACTIVE STATUS. All [delegated dispensing permist expire on July 1](#). The applicant must meet the requirements set out in 172 NAC 10 and this chapter.

008. REINSTATEMENT. The applicant must meet the requirements set out in 172 NAC 10.

009. UNPROFESSIONAL CONDUCT. Unprofessional conduct is set out in Neb. Rev. Stat. § 38-179, and this chapter.

- (A) Misrepresentation or fraud in the conduct of a delegated dispensing site;
- (B) Dispensing without a prescription of a drug or device which under state or federal law or regulation is prohibited from being dispensed without a prescription or the renewal of such a prescription without the authorization of the prescriber; and
- (C) Dispensing a different drug or device in place of the drug or device ordered or prescribed without the express permission of the person ordering or prescribing the same.