NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
NOTICE OF PUBLIC HEARING

January 10, 2023
10:00 a.m. Central Time
Nebraska State Office Building – Lower Level A
301 Centennial Mall South, Lincoln, Nebraska
Phone call information: 888-820-1398; Participant code: 3213662#

The purpose of this hearing is to receive additional comments on the adoption of amendments to the following regulations:

172 NAC 131 – *Wholesale Drug Distributors*

The proposed changes remove all duplicative statutory language from the regulations and remove any repetitive regulatory language found in 172 NAC 10. Proposed changes also include updating definitions; incorporating federal requirements regarding license applications and standards for engaging in wholesale drug distribution; and removing language prescribing procedures and other requirements for the Department. Additionally, clarification language was added.

172 NAC 134 – *Delegated Dispensing Permits*

The proposed changes remove all duplicative statutory language from the regulations and remove any repetitive regulatory language found in 172 NAC 10. Other proposed changes include updating definitions; consolidating language; removing procedural language; revising the staffing requirements for delegated dispensing permits; updating all citations referring to statutes or other regulations; and restructuring the regulatory chapter. Additionally, contract pharmacist was changed to delegating pharmacist; added new definition of approved formulary as provided in Neb. Rev. Stat. § 38-2881; removed required training hours; and modified language to allow for distribution to be made to an authorized recipient to facilitate the return.

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

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

In order to encourage participation in this public hearing, a phone conference line will be set up for any member of the public to call in and provide oral comments. Interested persons may provide verbal comments by participating via phone conference line by calling 888-820-1398; Participant code: 3213662#.

A copy of the proposed changes is available online at http://www.sos.ne.gov, or by contacting DHHS at the mailing address or email above, or by phone at (402) 471-8417.

The fiscal impact statement for these proposed changes may be obtained at the office of the Secretary of State, Regulations Division, 1201 N Street, Suite 120, Lincoln, NE 68508, or by calling (402) 471-2385.

Auxiliary aids or reasonable accommodations needed to participate in a hearing can be requested by calling (402) 471-8417. Individuals who are deaf or hard of hearing may call DHHS via the Nebraska Relay System at 711 or (800) 833-7352 TDD at least 2 weeks prior to the hearing.

FISCAL IMPACT STATEMENT

Agency: Department of Health and Human Services	
Title: 172	Prepared by: Jesse Cushman
Chapter: 131	Date prepared: 10/04/2022
Subject: Wholesale Drug Distributors	Telephone: (402) 471-4915

Type of Fiscal Impact:

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

Provide an Estimated Cost & Description of Impact:

State Agency: No Change.

Political Subdivision: No Change.

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

If indeterminable, explain why:

FISCAL IMPACT STATEMENT

Agency: Department of Health and Human Services	
Title: 172	Prepared by: Jesse Cushman
Chapter: 134	Date prepared: 10/04/2022
Subject: Delegated Dispensing Permit	Telephone: (402) 471-4915

Type of Fiscal Impact:

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

Provide an Estimated Cost & Description of Impact:

State Agency: No Change.

Political Subdivision: No Change.

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

If indeterminable, explain why:

TITLE 172 PROFESSIONAL AND OCCUPATIONAL LICENSURE

CHAPTER 131 WHOLESALE DRUG DISTRIBUTORS

001. SCOPE AND AUTHORITY. These regulations govern the licensure of wholesale drug distributors under Nebraska Revised Statutes (Neb. Rev. Stat.) §§ 71-7427 to 71-7463 of the Wholesale Drug Distributor Licensing Act.

002. DEFINITIONS. Definitions set out in the Wholesale Drug Distributor Licensing Act, 21 Code of Federal Regulations (CFR) Part 205, and the following apply to this chapter.

002.01 ATTEST OR ATTESTATION. An affirmation that the individual declares that all statements on the application are true and complete.

002.02 AUTHENTICATE. To affirmatively verify that each transaction listed on the pedigree and any other accompanying documentation has occurred.

002.03 CO-LICENSEE. A pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a prescription drug.

002.04 COMMON CARRIER. An entity that provides transportation or delivery of prescription drugs without storing, warehousing, or taking legal ownership of such drugs.

002.05 DESIGNATED REPRESENTATIVE. An individual designated by the wholesale drug distributor who will serve as the responsible individual of the daily operations of the wholesale drug distributor.

002.06 DROP SHIPMENT. The sale, by a manufacturer, that manufacturer's co-licensee, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor of the manufacturer's prescription drug, to a wholesale drug distributor whereby the wholesale drug distributor takes title to but not possession of such prescription drug and the wholesale drug distributor invoices the pharmacy, the chain pharmacy warehouse, or other designated persons authorized by law to dispense, administer or distribute such drug and the pharmacy, chain pharmacy warehouse, or other designated persons authorized by law to dispense, administer or distribute such drug, receives delivery of the prescription drug directly from the manufacturer, that manufacturer's co-licensee, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor, of such prescription drug. Drop shipments must be part of the "normal distribution chain".

002.07 EXCLUSIVE DISTRIBUTOR. An entity that:

(A) Contracts with a manufacturer to provide or coordinate warehousing, wholesale drug distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug; and

(B) Is licensed as a wholesale drug distributor under this chapter.

002.08 NATIONALLY RECOGNIZED ACCREDITATION PROGRAM. An accreditation program that conforms to the standards required for accreditation by the Verified-Accredited Wholesale Distributors (VAWD) program, established and operated by the National Association of Boards of Pharmacy (NABP), and is approved by the Board.

002.09 NORMAL DISTRIBUTION CHAIN. Defined by Neb. Rev. Stat. § 71-7439 and this chapter.

(A) From a manufacturer or co-licensee to a wholesale drug distributor, to a pharmacy buying cooperative warehouse, to a pharmacy that is a member or member owner of such pharmacy buying cooperative warehouse, and then to a patient or a patient's agent;

(B) From a manufacturer or co-licensee to a pharmacy buying cooperative warehouse, to a pharmacy that is a member or member owner of such pharmacy buying cooperative warehouse, and then to a patient or a patient's agent;

(C) From a manufacturer or co-licensee, to a third party logistics provider or an exclusive distributor, to a wholesale drug distributor, to a pharmacy, and then to a patient or a patient's agent;

(D) From a manufacturer or co-licensee to a third party logistics provider or an exclusive distributor, to a wholesale drug distributor, to a pharmacy, to a health care practitioner, health care practitioner facility, or hospital, and then to a patient or a patient's agent;

(E) From a manufacturer or co-licensee to a third party logistics provider or an exclusive distributor, to a pharmacy, to a health care practitioner, health care practitioner facility, or hospital, and then to a patient or a patient's agent;

(F) From a manufacturer or co-licensee to a third party logistics provider or an exclusive distributor, to a wholesale drug distributor, to a chain pharmacy warehouse, to a pharmacy affiliated with the chain pharmacy warehouse, and then to a patient or a patient's agent;

(G) From a manufacturer or co-licensee to a third party logistics provider or an exclusive distributor, to a chain pharmacy warehouse, to a pharmacy affiliated with the chain pharmacy warehouse, and then to a patient or a patient's agent; or

(H) From a manufacturer or co-licensee either through drop shipment or directly to a pharmacy, health care practitioner, health care practitioner facility, hospital, chain pharmacy warehouse, or other designated persons authorized by law to dispense, administer or distribute such drug, and then to a patient or a patient's agent.

002.10 PHARMACY BUYING COOPERATIVE WAREHOUSE. A permanent physical location that acts as a central warehouse for prescription drugs and from which sales of such drugs are made to an exclusive group of pharmacies that are members or member owners of the buying cooperative operating the warehouse and must be licensed as a wholesaler.

002.11 REVERSE DISTRIBUTOR. A person whose primary function is to act as an agent for a pharmacy, wholesaler, manufacturer, or other entity by receiving, inventorying, and managing the disposition of outdated, expired, or otherwise non-saleable medications.

002.12 THIRD PARTY LOGISTICS PROVIDER. An entity that~~:~~

(A) P~~p~~rovides or coordinates warehousing, drug distribution, or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition~~; and~~

~~(B) Is licensed as a wholesale drug distributor under this chapter~~.

002.13 WHOLESALE DRUG DISTRIBUTION. Wholesale drug distribution is defined in Neb. Rev. Stat. § 71-7444 and also to exclude the sale, transfer, merger, or consolidation of all or part of the business of a retail pharmacy or pharmacies from or with another retail pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with this chapter.

003. LICENSE REQUIREMENTS. To obtain a license, an applicant must submit a complete application provided by the Department and provide documentation demonstrating that the applicant meets the licensing requirements of Neb. Rev. Stat. §§ 71-7448, 71-7452, and this chapter.

003.01 APPLICATION. All applications submitted to the Department must contain the information required by 21 CFR § 205.5, Neb. Rev. Stat. § 71-7448, and the following:

(A) Drug Enforcement Administration (DEA) Controlled Substances Registration number, if applicable; and

(B) Business hours.

003.02 INSPECTION REPORT. An inspection report of an inspection conducted of the applicant within the 6 months prior to the date of application which meets the requirements of 172 Nebraska Administrative Code (NAC) 131-004.

003.03 CRIMINAL BACKGROUND CHECK. Submit to the Nebraska State Patrol complete fingerprint cards under Neb. Rev. Stat. § 71-7448 and this chapter:

(A) In the section of the fingerprint cards marked "Reason Fingerprinted", print "Wholesale Drug § 71-7448" or an acceptable equivalent; and

(B) Submit the completed fingerprint cards and payment for the criminal background check to the Nebraska State Patrol, CID Division, P.O. Box 94907, Lincoln, NE 68509.

004. INSPECTIONS. Inspections must meet the requirements set out in Neb. Rev. Stat. §§ 71-7453 to 71-7456, and this chapter.

004.01 TRIENNIAL INSPECTION. On a triennial basis after initial licensure, all wholesale drug distributor facilities must be inspected. The licensee must ensure that:

(1) The designated representative is present at the facility at the time of inspection;

(2) All records which describe the wholesale drug distribution activities for the triennium are accessible during the inspection, including drug analysis; and

(3) Any required fees for conducting the inspection are paid.

004.01(A) INSPECTION BY OTHER ENTITY. If the inspection is performed by a nationally recognized accreditation program approved by the Board or by another state or federal regulatory agency approved by the Board, the inspection must meet the requirements in this chapter, including standards for:

(i) Personnel;
(ii) Facility;
(iii) Pedigrees;
(iv) Policies and procedures; and
(v) Records.

004.02 INSPECTION FOR CAUSE. The Department may inspect a wholesale drug distributor to determine violations when any 1 or more of the following conditions or circumstances occur:

(A) An accident or natural disaster resulting in damage to the facility or interruption of utility services which could result in adverse effects to the potency, efficacy, safety or security of the prescription drugs;
(B) A complaint alleging violation of the Wholesale Drug Distributor Licensing Act or these regulations;
(C) A complaint that raises concern about the maintenance, operation, or management of the facility;
(D) Change of scope or type of services offered, management or location;
(E) Change in the designated representative; and
(F) Any other event that raises concerns about the maintenance, operation, or management of the facility.

004.03 SUCCESSFUL COMPLETION OF INSPECTION. Each applicant for a wholesale drug distributor license must successfully complete an inspection to receive a wholesale drug distributor license and to retain such license by demonstrating compliance with the standards found in Section 005 of this chapter.

004.04 FAILED INITIAL INSPECTION. When an applicant of a wholesale drug distributor license does not meet all of the inspection standards and receives a rating of "Fail" on the initial inspection, the applicant:

(A) Must not open the wholesale drug distribution facility;
(B) Must pay the re-inspection fee; and
(C) Must be subject to a re-inspection within 90 days after failing the initial inspection to determine if the applicant meets the requirements.

004.05 FAILED TRIENNIAL INSPECTION. When a licensee does not meet all of the inspection standards and receives a rating of "Fail" on a triennial inspection, the licensee:

(A) Will be granted up to 90 days from the date of the triennial inspection to meet the requirements.
(B) Must pay the re-inspection fee; and
(C) Must be subject to a re-inspection within 90 days after failing the triennial inspection to determine if the licensee meets the requirements.

005. STANDARDS FOR ENGAGING IN WHOLESALE DRUG DISTRIBUTION. All wholesale drug distributors must meet the requirements in 21 CFR Part 205 and the following standards for engaging in wholesale drug distribution.

005.01 PERSONNEL. A wholesale drug distributor must employ staff to operate the wholesale drug distribution facility under this chapter and must designate a representative to be in charge of wholesale drug distribution and the storage and handling of all drugs. Such designated representative must:

(A) Have knowledge of federal and state statutes applicable to wholesale drug distribution;

(B) Have had no convictions under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

(C) Have a minimum of 2 years of verifiable full-time managerial or supervisory experience in a pharmacy or wholesale drug distributor licensed in this state or another state, where the designated representative's responsibilities included but were not limited to recordkeeping, storage, and shipment of prescription drugs; and

(D) Be actively involved in and aware of the actual daily operations of the wholesale drug distributor, including the following:

(i) Employed full-time in a managerial position by the wholesale drug distributor;

(ii) Physically present at the wholesale drug distributor during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation, or other authorized absence; and

(iii) Aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale drug distributor.

005.02 FACILITY. All Wholesale Drug Distributor facilities at which prescription drugs are received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from must meet the requirements of 21 CFR § 205.50 and the following:

(A) Be a commercial location and not a personal dwelling or residence;

(B) Provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of the information;

(C) Provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting, or diversion of prescription drugs; and

(D) Provide to another wholesale drug distributor or pharmacy pedigrees for prescription drugs that leave the normal distribution chain before wholesale drug distribution to such other wholesale drug distributor or pharmacy in accordance with this chapter.

005.03 PEDIGREES. Each licensee must meet the requirements of Neb. Rev. Stat. § 71-7456 and 21 CFR § 205.50.

005.04 RECORDS. Each licensee must meet the requirements of Neb. Rev. Stat. §§ 71-7455 to 71-7456, 21 CFR § 205.50, and the following:

(A) Wholesale drug distributors and manufacturers must maintain an ongoing list of persons with whom they do business to sell or purchase prescription drugs;

(B) All facilities must establish and maintain procedures for reporting counterfeit and contraband, or suspected counterfeit and contraband drugs or counterfeiting and contraband or suspected counterfeiting and contraband activities to the Department and Food and Drug Administration (FDA);

(C) Wholesale drug distributors must maintain a system for the mandatory reporting of significant shortages or losses of prescription drugs where it is known or suspected that diversion is occurring to the Department and the Food and Drug Administration

(FDA), and, where applicable, to the Drug Enforcement Administration (DEA);

(D) Records must be maintained by the wholesale drug distributor to document all purchases, sales, destruction, transfer, loss, and return of drugs; and

(E) Records may be kept manually or by electronic or automated means. When an automated recordkeeping system is used, there must be a complete back-up system every 7 days that is verifiable to prevent loss of records.

006. AMENDING A WHOLESALE DRUG DISTRIBUTOR APPLICATION OR LICENSE. A license is issued only for the premises and persons named in the application and is not transferable or assignable. Change of ownership or change of premises terminates the license. The owner or owners must apply for a new wholesale drug distributor license.

006.01 AMENDMENT. An applicant or licensee must notify the Department when there is a change in the designated representative or the information required by 21 CFR § 205.5(a). The applicant or licensee is responsible for meeting the requirements of this chapter and may amend the wholesale drug distributor application or license by submitting the required information to the Department.

007. RENEWAL. To renew a license, applicants must meet the requirements of Neb. Rev. Stat. § 71-7448, §§ 71-7451 to 71-7453, and this chapter, including the following:

(A) Respond whether, since initial license or renewal, has any license of the facility in another state been revoked, suspended, limited or disciplined in any manner;

(B) Pass any inspection that has been conducted prior to the renewal of the license;

(C) If any misdemeanor or felony convictions of the designated representative, the supervisor of the designated representative and each owner of the licensee or any disciplinary action was taken against the licensee by another state, submit to the Department an official copy of the disciplinary action or court records, including charges and disposition; and

(D) Attest that the information provided is true and correct to the best of their knowledge.

008. REINSTATEMENT. To reinstate a license, applicants must submit an application provided by the Department that contains the information in 172 NAC 131-003 and the following:

(A) The license number;

(B) The expiration date;

(C) The renewal fee and the reinstatement fee as set out in 172 NAC 131-010; and

(D) The licensee's last known address of record.

008.01 REINSTATEMENT AFTER EXPIRATION. If more than 30 days has passed since a license expired an applicant must apply to reinstate the license.

008.01(A) NOTICE OF DISCIPLINE OR ACTION TAKEN IN ANOTHER JURISDICTION. All applicants for reinstatement after expiration must include the following related to the time period since the last renewal or since the initial issuance of the license if the applicant has not previously renewed:

(i) Submit to the Department an official copy of the disciplinary action or court records if the designated representative of the licensee been convicted of a misdemeanor or felony; and

(ii) Submit to the Department an official copy of the disciplinary action if any license

of the designated representative of the licensee or any other license held by the licensee in any profession in another state has been revoked, suspended, limited or disciplined in any manner.

008.02 REINSTATEMENT AFTER DISCIPLINARY ACTION. A wholesale drug distributor license that has been suspended or revoked as set out in Neb. Rev. Stat. § 71-7457 may be reinstated by the Department upon the recommendation of the Board of Pharmacy. Applicants must reapply on an application provided by the Department that contains the information in 172 NAC 131-003.

009. GROUNDS ON WHICH THE DEPARTMENT MAY DENY, REFUSE RENEWAL OF, OR DISCIPLINE A WHOLESALE DRUG DISTRIBUTOR LICENSE. Grounds are set out in Neb. Rev. Stat. § 38-178, § 38-179, § 71-7461 and this chapter.

(A) Unprofessional conduct which includes:
  (i) Misrepresentation or fraud in the conduct of a wholesale drug distribution facility; or
  (ii) Knowingly purchasing or receiving prescription drugs from any source other than a person or entity licensed or exempt from licensure pursuant to the Wholesale Drug Distributor Licensing Act, except transfers for emergency medical reasons. This will not apply to returns or recalls, misshipments, misorders, or damaged goods;
(B) Failure of the licensee to maintain and make available to the Department or to Federal, State, or local law enforcement officials, records required by this chapter;
(C) Falsification of a pedigree;
(D) The purchase or receipt of a prescription drug from a person that is not licensed to wholesale distribute prescription drugs to that purchaser or recipient;
(E) The sale or transfer of a prescription drug to a person who is not legally authorized to receive a prescription drug;
(F) The failure to obtain, authenticate, or pass on a pedigree when required under these rules;
(G) The receipt of a prescription drug pursuant to a wholesale drug distribution without first receiving a pedigree, when required, that was attested to as accurate and complete by the wholesale drug distributor; or
(H) The distributing or wholesale drug distributing of a prescription drug that was previously dispensed by a pharmacy or distributed by a practitioner.

010. SCHEDULE OF FEES. The following fees have been set by the Department as set out in Neb. Rev. Stat. § 71-7450 and this chapter.

010.01 INITIAL LICENSE FEE. The fee for initial licensure as a wholesale drug distributor is set at $550.

010.02 INSPECTION FEE. The fee for issuance or renewal of a wholesale drug distributor license who requests an inspection to be conducted by a pharmacy inspector of the Department, is set at $3,000 in addition to actual costs for transportation, lodging and meals of the pharmacy inspector who conducts the inspection.

010.03 RE-INSPECTION FEE. The fee for issuance or renewal of a wholesale drug distributor license who requests a re-inspection to be conducted by a pharmacy inspector of the Department is set at $750 in addition to actual costs for transportation, lodging and meals of

the pharmacy inspector who conducts the re-inspection.

010.04 RENEWAL FEE. The fee for renewal on an annual basis of a credential is set at $550.

010.05 RENEWAL LATE FEE. The fee for renewal on an annual basis of a credential, who fails to pay the renewal fee on or before the expiration date of the credential is set at $100.

010.06 REINSTATEMENT FROM EXPIRED OR LAPSED STATUS. The fee for reinstatement of a lapsed or expired credential is set at $50 in addition to renewal fee.

010.07 REINSTATEMENT FEE AFTER DISCIPLINE. For reinstatement of a wholesale drug distributor credential following suspension, limitation, or revocation for disciplinary reasons, the fee of $100.

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~~ delegating or the on-call pharmacist;
(H) Storage and security of approved formulary drugs and devices; and
(I) 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 contraceptives pharmacology.~~

005.0~~3~~2 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~~ delegating pharmacist must provide the training before staff dispense any drugs and devices and the permit holder must ensure that documentation of training has been completed.

005.0~~4~~3 PROFICIENCY DEMONSTRATION. Following training, public health clinic workers must be supervised by ~~1 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 delegating ~~consultant~~ pharmacist at least annually or as requested by the delegating ~~consultant~~ pharmacist.

005.0~~4~~3(A) PROFICIENCY STANDARDS. Demonstrate to the delegating pharmacist the ability to follow the procedures outlined in 172 NAC 134-005.01.

005.0~~4~~3(~~A~~B) 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 DELEGATING ~~CONSULTANT~~ PHARMACIST. The delegating ~~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~~ delegating pharmacist~~s~~ ~~are~~ is 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 permits 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.