NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
NOTICE OF PUBLIC HEARING

September 7, 2022
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; 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: 8/24/2021
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: 8/24/2021
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) Provides 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 131 WHOLESALE DRUG DISTRIBUTORS

131-001 SCOPE AND AUTHORITY: These regulations apply to licensure of wholesale drug distributors pursuant to Neb. Rev. Stat. §§ 71-7427 to 71-7463 which is cited as the Wholesale Drug Distributor Licensing Act.

131-002 DEFINITIONS

Act means the Wholesale Drug Distributor Licensing Act.

Attest/Attestation means that the individual declares that all statements on the application/petition are true and complete. Section kept in section 002 as modified

Authenticate means to affirmatively verify that each transaction listed on the pedigree and any other accompanying documentation has occurred, in accordance with 172 NAC 131. Section kept in section 002 as modified

Blood means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

Blood component means that part of blood separated by physical or mechanical means.

Board means the Board of Pharmacy.

Bond means a "surety" bond of not less than $100,000, or other equivalent means of security acceptable to the Department, including insurance, an irrevocable letter of credit, or funds deposited in a trust account or financial institution, to secure payment of any administrative penalties imposed by the Department and any fees or costs incurred by the Department regarding that licensee when those penalties, fees, or costs are authorized under state law and the licensee fails to pay 30 days after the penalty, fee, or costs becomes final. A separate surety bond or other equivalent means of security is not required for each company's separate locations or for affiliated companies/groups when such separate locations or affiliated companies/groups are required to apply for or renew their wholesale drug distributor license with the Department. The Department may make a claim against such bond or other equivalent means of security until one year after the expiration of the wholesale drug distributor's license.

Chain pharmacy warehouse means a facility utilized as a central warehouse for intracompany sales or transfers of prescription drugs or devices by two or more pharmacies operating under common ownership or common control.

Co-licensed products means prescription drugs that have been approved by the federal Food and Drug Administration (FDA) and are the subject of an arrangement by which two or more parties have the right to engage in a business activity or occupation concerning such drugs.

Co-licensee means 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. Section kept in section 002 as modified

Common carrier means an entity that provides transportation or delivery of prescription drugs without storing, warehousing, or taking legal ownership of such drugs. Section kept in section 002 as modified

Common control means that the power to direct or cause the direction of the management and policies of a person or an organization by ownership of stock or voting rights, by contract, or otherwise is held by the same person or persons.

Department means the Division of Public Health of the Department of Health and Human Services.

Designated representative means an individual designated by the wholesale drug distributor who will serve as the responsible individual of the wholesale drug distributor who is actively involved in and aware of the actual daily operation of the wholesale drug distributor. Section kept in section 002 as modified

Director means the Director of Public Health of the Division of Public Health or the Chief Medical Officer if one has been appointed.

Drop shipment means 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". Section kept in section 002 as modified

Drug Sample means a unit of a prescription drug intended to promote the sale of the drug and not intended to be sold.

Emergency Medical Reasons means the alleviation of a temporary shortage by transfers of prescription drugs between any of the following: (1) Holders of pharmacy licenses, (2) health care practitioner facilities as defined in section 71-414, (3) hospitals as defined in section 71-419, and (4) practitioners as defined in section 71-1,142. Emergency medical reasons also means a natural disaster or other situations of local, state or national emergency. Section kept in section 002 as modified

Exclusive distributor means an entity that:

1. 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
2. Is licensed as a wholesale drug distributor under 172 NAC 131. Section kept in section 002 as modified

Facility means a physical structure utilized by a wholesale drug distributor for the storage, handling, or repackaging of prescription drugs or the offering of prescription drugs for sale.

FDA means the federal Food and Drug Administration.

Licensee means wholesale drug distributor as defined in 172 NAC 131-002.

Manufacturer means any entity engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repacking, or labeling a prescription drug.

NAC means the Nebraska Administrative Code, the system for classifying State agency rules and regulations. These regulations are 172 NAC 131.

Nationally recognized accreditation program means 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. Section kept in section 002 as modified

Normal distribution chain means the transfer of a prescription drug or the co-licensed product of the original manufacturer of the finished form of a prescription drug along a chain of custody directly from the manufacturer or co-licensee of such drug to a patient or ultimate consumer of such drug. Normal distribution chain includes reverse distribution and transfers of a prescription drug or co-licensed product: Section kept in section 002 as modified

1. From a manufacturer or co-licensee to a wholesale drug distributor, to a pharmacy, and then to a patient or a patient's agent;

2. From a manufacturer or co-licensee 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;

3. From a manufacturer or co-licensee 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;

4. From a manufacturer or co-licensee to a chain pharmacy warehouse, to a pharmacy affiliated with the chain pharmacy warehouse, and then to a patient or a patient's agent;

5. 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; Section kept in section 002 as modified

6. 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; Section kept in section 002 as modified

7. 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; Section kept in section 002 as modified

8. 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; Section kept in section 002 as modified

9. 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; Section kept in section 002 as modified

10. 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; Section kept in section 002 as modified

11. 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 Section kept in section 002 as modified

12. 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. Section kept in section 002 as modified

Owner or ownership means a person who has control over the operations of an entity pursuant to 172 NAC 131-002.

Pedigree means a written or electronic documentation of every transfer of a prescription drug as provided in Neb. Rev. Stat. §§71-7455 and 71-7456.

Pharmacy Buying Cooperative Warehouse means 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 shall be licensed as a wholesaler. Section kept in section 002 as

modified

Prescription drug means any human drug required by federal law or regulation to be dispensed only by prescription, including finished dosage forms and active ingredients subject to section 503 (b) of the Federal Food, Drug, and Cosmetic Act, as such section existed on August 1, 2006.

Repackage means repackaging or otherwise changing the container, wrapper, or labeling of a prescription drug to facilitate the wholesale distribution of such drug.

Repackager means a person who repackages.

Reverse distributor means 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. Section kept in section 002 as modified

Third party logistics provider means an entity that:

1. Provides 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

2. Is licensed as a wholesale drug distributor under 172 NAC 131. Section kept in section 002 as modified

Wholesale drug distribution means distribution of prescription drugs to a person other than a consumer or patient. Wholesale drug distribution does not include: Section kept in section 002 as modified

1. Intracompany sales of prescription drugs, including any transaction or transfer between any division, subsidiary, or parent company and an affiliated or related company under common ownership or common control;

2. The sale, purchase, or trade of or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code, a state, a political subdivision, or any other governmental agency to a nonprofit affiliate of the organization, to the extent otherwise permitted by law;

3. The sale, purchase, or trade of or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities operating under common ownership or common control;

4. The sale, purchase, or trade of or an offer to sell, purchase, or trade a prescription drug for emergency medical reasons;

5. The sale, purchase, or trade of, an offer to sell, purchase, or trade, or the dispensing of a prescription drug pursuant to a prescription;

6. The distribution of drug samples by representatives of a manufacturer or of a wholesale drug distributor;

7. The sale, purchase, or trade of blood and blood components intended for transfusion;

8. The delivery of or the offer to deliver a prescription drug by a common carrier solely in the usual course of business of transporting such drugs as a common carrier if the common carrier does not store, warehouse, or take legal ownership of such drugs; or

9. 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 these regulations.~~

Wholesale drug distributor means any person or entity engaged in wholesale drug distribution in this state, including manufacturers, repackagers, own-label distributors, jobbers, private-label distributors, brokers, warehouses including manufacturer and distributor warehouses, chain pharmacy warehouses, and wholesale drug warehouses, wholesale medical gas distributors, independent wholesale drug traders, and retail pharmacies that engage in wholesale drug distribution in this state. Wholesale drug distributor also includes reverse distributors. Wholesale drug distributor does not include a common carrier or other person or entity hired solely to transport prescription drugs if the common carrier, person, or entity does not store, warehouse, or take legal ownership of such drugs.

Wholesale medical gas distributor means any person engaged in the wholesale drug distribution of medical gases provided to suppliers or other entities licensed or otherwise authorized to use, administer, or distribute such gases.

131-003 REQUIREMENTS FOR ISSUANCE OF LICENSE: Any person, partnership, corporation, or business firm, or other entity that engages in wholesale drug distribution pursuant to Neb. Rev. Stat. § 71-7447 of the Act and 172 NAC 131-002 must obtain a wholesale drug distributor license from the Department. A separate license must be obtained for each facility engaged in wholesale drug distribution. The criteria for issuance of a license and the documentation required by the Department are set forth below. Section kept in section 003 as modified

131-003.01 Requirements for Issuance of a Wholesale Drug Distributor License

131-003.01A The Department, upon the recommendation of the Board, will issue a wholesale drug distributor license to an applicant who:

1. Makes application to the Department for a wholesale drug distributor license; and
2. Passes an inspection conducted pursuant to 172 NAC 131-005. Inspections will be accepted by the Department if they have been conducted within the six months preceding the date of application or if accreditation status by either a nationally recognized accreditation program or another state or federal regulatory agency inspection approved by the Board remains current.

131-003.02 Procedures for Issuance of a Wholesale Drug Distributor License

131-003.02A An applicant for a wholesale drug distributor license must:

1. Submit an application for a wholesale drug distributor license on a form provided by the Department Section kept in section 003 as modified or on an alternate format. Only applications that are complete will be considered. The application must be completed by the designated representative and must include the following information, except that for wholesale medical gas distributors, 172 NAC 131-003.02A items 1.a. through 1.h. are required; and for manufacturers of FDA-approved drugs, the application may be completed by a corporate officer or other designated managerial employee, only 172 NAC 131-003.02A items 1.a. through 1.h. and

6 are required, and inspection, bonding and

appointment of a designated representative are not a condition of licensure:

a. Applicant's name;
b. Business address;
c. Telephone number;
d. Type of business entity:
(1) If the applicant is a partnership:
(a) the name of each partner; and
(b) the name of the partnership;
(2) If the applicant is a corporation:
(a) the name of each corporate officer and director;
(b) the title of each corporate officer and director;
(c) all corporate names of the applicant; and
(d) the applicant's state of incorporation;
(3) If the applicant is a sole proprietorship:
(a) the name of the sole proprietor;
(b) the name of the proprietorship; and
(c) Social Security Number of the sole proprietor;
e. All trade or business names used by the applicant;
f. Addresses of all facilities used by the applicant for the storage, handling, and wholesale distribution of prescription drugs;
g. Telephone numbers of all facilities used by the applicant for the storage, handling, and wholesale distribution of prescription drugs;
h. Name(s) of the person(s) in charge of such facilities;
i. List of all licenses, permits, or other similar documentation issued to the applicant in any other state authorizing the applicant to purchase or possess prescription drugs;
j. Name(s) and address(es) of the following:
(1) Owner(s);
(2) Manager(s);
(3) Designated representative;
k. Name(s) of all managerial employees for the facility;
l. Entity conducting the initial inspection:
(1) Department;
(2) Nationally recognized accreditation program;
(3) Another state regulatory agency; or
(4) A federal regulatory agency;
m. Signature of the designated representative, attesting that s/he has completed the application; and
n. Required signature(s)
(1) If applicant is an individual or partnership, signature of owner;
(2) If applicant is a limited liability company with two members or less, signature of one member;

(3) If applicant is a limited liability company with more than two members, signature of two or more members;

(4) If the applicant is a corporation, signature of two officers.

2. Obtain a criminal background check pursuant to 172 NAC 131-004 for the following personnel:
   a. The designated representative;
   b. The supervisor of the designated representative; and
   c. If the company is non-publicly held, each owner with greater than ten percent interest in the wholesale drug distributor;
3. Provide the following information regarding the designated representative:
   a. Place of residence for the immediately preceding seven years;
   b. Date of birth;
   c. Place of birth;
   d. List of all occupations, positions of employment, and offices held during the immediately preceding seven years;
   e. The principal businesses, including addresses of any business, corporation, or other organization in which such occupations, positions, or offices were held;
   f. Whether s/he has been, at any time during the immediately preceding seven years, the subject of any proceeding for the revocation of any license, and if so, the nature of the proceeding and its disposition;
   g. Whether s/he has been, at any time during the immediately preceding seven years, either temporarily or permanently enjoined by a court of competent jurisdiction from violations of any federal or state law regulating the possession, control, or distribution of prescription drugs, and, if so, the details of such order;
   h. A description of any involvement by the designated representative during the immediately preceding seven years, other than the ownership of stock in a publicly traded company or mutual fund, with any business which manufactured, administered, distributed, or stored prescription drugs and any lawsuits in which such businesses were named as a party;
   i. Whether s/he has ever been convicted of any felony and details relating to such conviction; and
   j. A photograph of the designated representative taken within the immediately preceding 30 days.
4. Provide proof of a bond;
5. Submit documentation of passing an initial inspection pursuant to 172 NAC 131-005.01; and
6. Submit the required fee pursuant to 172 NAC 131-012.

131-003.02B The Department will act within 150 days of receipt of a completed application.

131-004 CRIMINAL BACKGROUND CHECKS: The following individuals are subject to a criminal background check:

1. The designated representative of a wholesale drug distributor;
2. The supervisor of the designated representative of a wholesale drug distributor; and
3. Each owner with greater than a ten percent interest in the wholesale drug distributor, if the wholesale drug distributor is a non-publicly held company.

131-004.01 Procedures for Providing Background Checks: The individuals specified above must:

1. Obtain two fingerprint cards from the Department or from any State Patrol office or law enforcement agency;
2. Print the following information on the fingerprint cards:
   a. Name;
   b. Address;
   c. Social Security Number;
   d. Date of birth;
   e. Place of birth;
   f. Any physical identifiers; and
   g. In the space on the fingerprint cards marked "Reason Fingerprinted", print "Credential"; Section moved to section 003 as modified
3. Report to any State Patrol office, law enforcement agency, or other entity that offers the service of fingerprinting to provide their fingerprints on the fingerprint cards;
4. Forward the completed fingerprint cards and payment for the criminal background check as specified in 172 NAC 131-004.02 to the Nebraska State Patrol, CID Division, P.O. Box 94907, Lincoln, NE 68509. Section moved to section 003 as modified

131-004.02 Payment for criminal background checks is the responsibility of the individual and can be made by personal check, money order or cashier's check, payable to the Nebraska State Patrol. The fee for criminal background checks is established by the Nebraska State Patrol and can be found on the web site of the Department at www.hhss.ne.gov/crl/crlindex.htm.

131-004.03 Submission by the individual of completed fingerprint cards and the appropriate payment to the Nebraska State Patrol authorizes the release of the results of the criminal background check to the Department. The results will be forwarded by the Nebraska State Patrol directly to the Department for consideration with the application for licensure.

131-005 INSPECTION REQUIREMENTS: Each wholesale drug distributor doing business in Nebraska must be inspected onsite by the Department, by a nationally recognized accreditation program approved by the Board, or by another state or federal regulatory agency approved by

~~the Board. Such inspections will occur as a condition of receiving and retaining a wholesale drug distributor license.~~ Section moved to section 004 as modified

131-005.01 Procedures for Initial Inspection: Prior to the issuance of a wholesale drug distributor license, the Department, a nationally recognized accreditation program approved by the Board, or another state or federal regulatory agency approved by the Board will conduct an inspection of the applicant's facility within which wholesale drug distribution is to occur.

131-005.01A Applicant Responsibilities:

1. If inspected by the Department, the applicant must:

   a. Contact the Department to schedule an inspection; and
   b. Pay to the Department all fees for conducting the inspection, including but not limited to transportation costs, lodging, meals, and an inspection fee pursuant to 172 NAC 131-012.

2. If inspected by a nationally recognized accreditation program approved by the Board, the applicant must:

   a. Submit documentation of current accreditation; or
   b. Contact the nationally recognized accreditation program to schedule an inspection; and
   c. Pay to the nationally recognized accreditation program all fees necessary for conducting the inspection.

3. If inspected by another state or federal regulatory agency approved by the Board, the applicant must:

   a. Submit documentation of current state or federal inspection; or
   b. Make arrangements with a state or federal regulatory agency to schedule an inspection; and
   c. Pay any fees required by the state or federal regulatory agency for conducting the inspection.

131-005.01B Department Responsibilities: The Department will:

1. Respond to requests for inspections to be conducted by the Department;
2. Conduct an inspection within 90 days after the request for inspection; or
3. Determine, upon the recommendation of the Board, whether an inspection conducted by a nationally recognized accreditation program or another state or federal regulatory agency meets the inspection criteria pursuant to 172 NAC 131-005.04; and
4. Review the application for completeness and inform the applicant in writing if the application is incomplete and warrants the submission of additional information; or
5. Issue a wholesale drug distributor license to each applicant who meets the criteria pursuant to 172 NAC 131-003.

131-005.02 Procedures for Triennial Inspection: A pharmacy inspector of the Department, a nationally recognized accreditation program approved by the Board, or another state or federal regulatory agency approved by the Board must conduct a triennial inspection of each facility engaging in wholesale drug distribution to determine if the licensee remains in compliance with the standards pursuant to 172 NAC 131-006. A wholesale drug distributor must be inspected every three years. Inspections may occur more frequently if the Department considers it necessary. Section moved to section 004 as modified

131-005.02A Licensee Responsibilities:

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 pursuant to 172 NAC 131-006, during the inspection; and
3. Pay any required fees for conducting the inspection. Section moved to section 004 as modified

131-005.02B Department Responsibilities:

1. If the inspection is performed by the Department, the inspection will be:

   a. Conducted by a pharmacy inspector of the Department, using a Wholesale Drug Distributor Inspection Report pursuant to 172 NAC 131-005.04; and
   b. Conducted during normal business hours in which wholesale drug distribution occurs.

2. If the inspection is performed by a nationally recognized accreditation program approved by the Board or another state or federal regulatory agency approved by the Board, the inspection must meet the inspection criteria pursuant to 172 NAC 131-005.04, as determined by the Department, upon the recommendation of the Board.

131-005.03 Inspection for Cause: The Department may inspect a wholesale drug distributor to determine violations when any one or more of the following conditions or circumstances occur: Section moved to section 004 as modified

1. 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;
2. A complaint alleging violation of the Wholesale Drug Distributor Licensing Act or these regulations;
3. A complaint that raises concern about the maintenance, operation, or management of the facility;
4. Change of scope or type of services offered, management or location;
5. Change in the designated representative;
6. Any other event that raises concerns about the maintenance, operation, or

~~management of the facility.~~ Section moved to section 004 as modified

131-005.04 Wholesale Drug Distributor Inspection Report: A pharmacy inspector will conduct a Department inspection using the Wholesale Drug Distributor Inspection Report. The report will include the following: Section moved to section 004 as modified

1. Business name;
2. Street address;
3. City, state, Zip Code;
4. Name of designated representative of the facility;
5. Telephone number;
6. Wholesale drug distributor license number;
7. DEA Controlled Substances Registration number (if applicable);
8. Business hours;
9. Type of business entity:
   a. Partnership;
   b. Corporation; or
   c. Sole proprietor; and
10. Standards for:
    a. Personnel;
    b. Facility;
    c. Pedigrees;
    d. Policies and procedures; and
    e. Records. Section moved to section 004 as modified

131-005.04A Upon completion of an inspection using the Wholesale Drug Distributor Inspection Report, the pharmacy inspector will assess the compliance of the wholesale drug distributor with the standards for engaging in wholesale drug distribution pursuant to 172 NAC 131-006.

131-005.05 CRITERIA FOR SUCCESSFUL COMPLETION OF WHOLESALE DRUG DISTRIBUTOR INSPECTION: Each applicant for a wholesale drug distributor license pursuant to 172 NAC 131-003.01 must successfully complete an inspection to receive a wholesale drug distributor license and to retain such license. Section moved to section 004 as modified The criteria for successful completion of inspections conducted by the Department are set forth below.

131-005.05A Criteria for Successful Completion of Initial Inspection

1. The Department will issue a rating of "Pass/Fail" on an initial inspection.

2. The Department will issue a rating of "Fail," on the initial inspection when an applicant of a wholesale drug distributor license does not meet all the applicable requirements.

   a. When an applicant receives a rating of "Fail" the applicant must not open the wholesale drug distribution facility; Section moved to section 004 as modified

   b. The applicant must pay the re-inspection fee Section

moved to section 004 as modified pursuant to 172 NAC 131-012.

c. The Department will conduct a re-inspection within 90 days

after the applicant has failed the initial inspection to determine if the applicant meets the requirements. Section moved to section 004 as modified

d. When the applicant receives a "Fail" rating, at the time of the re-inspection, the Department will deny the issuance of a license to engage in wholesale drug distribution.

3. The Department will issue a rating of "Pass" when the applicant meets all the applicable requirements.

131-005.05B Criteria for Successful Completion of a Triennial Inspection

1. The Department will issue a rating of "Pass" on a triennial inspection when the licensee meets all the standards for engaging in wholesale drug distribution pursuant to 172 NAC 131-006.

2. The Department will issue a rating of "Fail" on the triennial inspection when the licensee does not meet all the standards for engaging in wholesale drug distribution pursuant to 172 NAC 131-006.

a. When a licensee receives a rating of "Fail," it will be granted up to 90 days from the date of the triennial inspection to meet the requirements. Section moved to section 004 as modified

b. The licensee must pay the re-inspection fee pursuant to 172 NAC 131-012. Section moved to section 004 as modified

c. The Department will conduct a re-inspection within 90 days after the wholesale drug distributor has failed the inspection to determine if the wholesale drug distributor meets the requirements necessary to pass the inspection. Section moved to section 004 as modified

(1) If the wholesale drug distributor meets the requirements at the time of re-inspection, the Department will change the "Fail" rating and enter a "Pass" rating.

(2) If the wholesale drug distributor fails to meet the requirements at the time of re-inspection, the Department will, within ten days of the completion of the re-inspection, give notice to the wholesale drug distributor that the wholesale drug distributor license is revoked. Such notice will be in written form and will:

(a) State that the wholesale drug distributor license is revoked;

(b) State the reasons for the license revocation;

(c) State that the license revocation will become

final 30 days after the mailing of the notice of revocation unless the licensee submits a written request for a hearing within such 30 day period; and

(d) Be sent to the licensee by certified mail.

(3) Upon receipt of a written request for a hearing the licensee must be given a hearing before the Department.

(4) The Department's decision regarding the revocation of the wholesale drug distributor license will become final 30 days after a copy of the decision is mailed to the licensee unless the licensee appeals the decision pursuant to the Administrative Procedure Act and regulations adopted thereto as 184 NAC 1.

d. When a wholesale drug distributor license is revoked for failure of a triennial inspection the wholesale drug distributor must reapply to the Department for a license to engage in wholesale drug distribution pursuant to 172 NAC 131-003.02.

131-006 STANDARDS FOR ENGAGING IN WHOLESALE DRUG DISTRIBUTION Section moved to section 005 as modified

131-006.01 Personnel: A wholesale drug distributor must employ staff to operate the wholesale drug distribution facility pursuant to 172 NAC 131. To this end, the wholesale drug distributor must designate a representative to be in charge of wholesale drug distribution and the storage and handling of all drugs. Such designated representative must: Section moved to section 005 as modified

1. Have knowledge of federal and state statutes applicable to wholesale drug distribution; Section moved to section 005 as modified

2. 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; Section moved to section 005 as modified

3. Have a minimum of two 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; Section moved to section 005 as modified

4. Be actively involved in and aware of the actual daily operations of the wholesale drug distributor:

a. Employed full-time in a managerial position by the wholesale drug

distributor;

b. 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

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

Section moved to section 005 as modified

131-006.02 Facility: All facilities at which prescription drugs are received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from must:

Section moved to section 005 as modified

1. Be of suitable construction to ensure that all prescription drugs in the facilities are maintained in accordance with the product labeling of such prescription drugs, or in compliance with official compendium standards such as the United States Pharmacopeia–USP/NF;

2. Be of suitable size and construction to facilitate cleaning, maintenance, and proper wholesale drug distribution operations;

3. Have adequate storage areas to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

4. Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, counterfeit, or suspected of being counterfeit, otherwise unfit for distribution or wholesale drug distribution, or that are in immediate or sealed secondary containers that have been opened;

5. Be maintained in a clean and orderly condition;

6. Be free from infestation of any kind;

7. Be a commercial location and not a personal dwelling or residence;

Section moved to section 005 as modified

8. 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; Section moved to section 005 as modified

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

Section moved to section 005 as modified

10. 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 172 NAC 131-006.03;~~ Section moved to section 005 as modified

~~11. Maintain records of pedigrees for three years; and~~

~~12. Be duly registered with Drug Enforcement Administration (DEA) and appropriate state controlled substance agency and in compliance with all applicable laws and rules for the storage, handling, transport, shipment, and~~

wholesale drug distribution of controlled substances, if the wholesale drug distributor is involved in the distribution of controlled substances.

131-006.03 Pedigrees Section moved to section 005 as modified

131-006.03A Pedigree Requirements: All prescription drugs that leave the normal distribution chain must be accompanied by a paper or electronic pedigree. A pedigree must include all necessary identifying information concerning each sale or other transfer in the chain of distribution of the prescription drug from the manufacturer, through acquisition and sale by any wholesale drug distributor, until final sale to a pharmacy or other person dispensing or administering such drug, including:

1. Name of the prescription drug;
2. Dosage form and strength of the prescription drug;
3. Size of the container;
4. Number of containers;
5. Lot number of the prescription drug;
6. Name of the original manufacturer of the finished dosage form of the prescription drug;
7. Name, address, telephone number, and if available, the e-mail address of each owner of the prescription drug and each wholesale drug distributor who does not take title to the prescription drug;
8. Name and address of each location from which the prescription drug was shipped if different from the owner's;
9. Transaction dates;
10. Certification that each recipient has authenticated the pedigree;
11. Name of any repackager, if applicable; and
    a. Name and address of person certifying the delivery.
    b. Each paper or electronic pedigree must be maintained by the purchaser and the wholesale drug distributor for three years from the date of sale or transfer and available for inspection or use upon request of law enforcement or an authorized agent of the Department.

131-006.03B Authentication of Pedigrees

1. Wholesale drug distributors and manufacturers from whom wholesale drug distributors have acquired prescription drugs must cooperate with pedigree authentication efforts and provide the requested information within 48 hours.

2. If the wholesale drug distributor attempting to authenticate the pedigree of the prescription drug is unable to authenticate the pedigree, the wholesale drug distributor must quarantine the prescription drug and file a report with the Department within five business days after completing the attempted authentication; and

3. If the wholesale drug distributor attempting to authenticate the pedigree of the prescription drug is able to authenticate the pedigree, the wholesale drug distributor must maintain records of the authentication for three years, and must produce them to the Department upon request.

131-006.04 Policies and Procedures: Wholesale drug distributors must include in their written policies and procedures the following:

1. A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure must be adequate to deal with recalls and withdrawals due to:

a. Any action initiated at the request of FDA or any other federal, state, or local law enforcement or other government agency, including the Board; or

b. Any volunteer action by the manufacturer to remove defective or potentially defective prescription drugs from the market.

2. A procedure for guarding against losses and/or employee theft.

3. A procedure for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories.

4. A procedure for reporting criminal or suspected criminal activities involving the inventory of prescription drug(s) to the Department within the five business days.

5. A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

6. A procedure that provides for inspection of all incoming and outgoing prescription drug shipments.

7. A procedure to ensure that any outdated prescription drugs must be segregated from other prescription drugs and are then either returned to the manufacturer or a reverse distributor or destroyed in accordance with federal and state laws, including all necessary documentation and the appropriate witnessing. This procedure must provide for written documentation of the

disposition of outdated prescription drugs. This documentation must be maintained for two years after disposition of the outdated prescription drugs.

8. A procedure for the destruction of outdated prescription drugs in accordance with federal and state laws, including all necessary documentation, maintained for a minimum of three years, and the appropriate witnessing of the destruction of outdated prescription drugs in accordance with all applicable federal and state requirements.

9. A procedure for the disposing and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging cannot be used in counterfeiting activities, including all necessary documentation, maintained for a minimum of three years, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers, or containers in accordance with all applicable federal and state requirements.

10. A procedure for identifying, investigating and reporting significant prescription drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory and reporting of such discrepancies within five business days to the Department and/or appropriate federal or state agency upon discovery of such discrepancies.

11. A procedure for conducting authentication of pedigrees pursuant to 172 NAC 131-006.03B.

131-006.05 Records: A wholesale drug distributor must have records to document all drug purchases and sales.

131-006.05A Wholesale drug distributors must establish and maintain inventories and records of all transactions regarding the receipt and wholesale drug distribution or other disposition of prescription drugs. These records must include:

1. Dates of receipt and wholesale drug distribution or other disposition of the prescription drugs; and

2. Pedigrees for all prescription drugs that are wholesale distributed outside the normal distribution chain.

131-006.05B Such records must include the inventories and records must be made available for inspection and photocopying by any authorized official of any state, federal, or local governmental agency for a period of three years following their creation date.

131-006.05C Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically

~~retrievable must be made available for inspection within two working days of a request by an~~

authorized official of any state or federal governmental agency charged with enforcement of these rules.

131-006.05D Wholesale drug distributors and manufacturers must maintain an ongoing list of persons with whom they do business to sell or purchase prescription drugs. Section moved to section 005 as modified

131-006.05E 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 FDA. Section moved to section 005 as modified

131-006.05F 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 FDA, and, where applicable, to DEA. Section moved to section 005 as modified

131-006.05G Records must be maintained by the wholesale drug distributor to document all purchases, sales, destruction, transfer, loss, and return of drugs. Section moved to section 005 as modified

131-006.05H 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 seven days that is verifiable to prevent loss of records. Section moved to section 005 as modified

131-007 AMENDING A WHOLESALE DRUG DISTRIBUTOR APPLICATION OR LICENSE: A license is issued only for the premises and person(s) named in the application and is not transferable or assignable. Change of ownership or change of premises terminates the license. The owner(s) must apply for a new wholesale drug distributor license. Section moved to section 006 as modified

131-007.01 Amendment: An applicant or licensee must notify the Department when there is a change in the designated representative. The applicant or licensee is responsible for meeting the requirements pursuant to 172 NAC 131-003.02A item 3 and may amend the wholesale drug distributor application or license by submitting the required information regarding the new designated representative to the Department. Section moved to section 006 as modified

131-008 PROCEDURES FOR RENEWAL OF A LICENSE: All licenses issued by the Department pursuant to the Act and 172 NAC 131 expire on July 1 of each year. Section moved to section 007 as modified

131-008.01 Renewal process: Any licensee who wishes to renew his/her license must:

1. Pay the renewal fee pursuant to 172 NAC 131-012;
2. Provide proof of a bond;
3. Respond to the following questions:

a. Has any license of the facility in another state been revoked, suspended, limited or disciplined in any manner? Section moved to section 007 as modified

This question relates to the time period since the last renewal of the license

or during the time period since initial licensure in Nebraska if such license was issued within the last year.

b. Since the last renewal of the license or since initial licensure in Nebraska if such license was issued within the last year, has the designated representative of the facility been:

(1) The subject of any proceeding for the revocation of any license, and if so, the nature of the proceeding and its disposition;

(2) Either temporarily or permanently enjoined by a court of competent jurisdiction from violations of any federal or state law regulating the possession, control, or distribution of prescription drugs, and if so, the details of such order;

(3) Involved in any lawsuits regarding the manufacture, administration, distribution or storage of prescription drugs; or

(4) Convicted of any felony, and if so, the details relating to such conviction. Section moved to section 007 as modified

5. Attest that the information provided is true and correct to the best of their knowledge; Section moved to section 007 as modified

6. Be inspected pursuant to 172 NAC 131-005.02 prior to the renewal of the license; and Section moved to section 007 as modified

7. Submit to the Department:

a. The completed renewal notice;

b. Proof of a bond;

c. Proof of an acceptable inspection completed with the previous three years;

d. If any misdemeanor or felony conviction(s) of the designated representative of the licensee or any disciplinary action was taken against the licensee by another state, an official copy of the disciplinary action or court records, including charges and disposition;

e. Attestation that the completed renewal notice is true and correct to the best of their knowledge; and

f. The renewal fee;

131-008.02 First Notice: At least 30 days before July 1 of each year, the Department will send a renewal notice by means of regular mail to each licensee at the licensee's current mailing address as noted in the records of the Department. It is the responsibility of the licensee prior to the renewal period to notify the Department of any name and/or address changes.

131-008.02A The renewal notice must specify:

1. The name of the licensee;

2. The licensee's last known address of record;

3. The license number;

4. The expiration date of the license;

5. The renewal fee pursuant to 172 NAC 131-012;

131-008.02B The licensee must apply for renewal by submitting to the Department:

1. The completed renewal notice;
2. Proof of a bond;
3. Proof of an acceptable inspection completed within the previous three years;
4. Documentation relating to misdemeanor or felony conviction(s) of the designated representative of the licensee or licensure revocation, suspension, limitation or disciplinary action of the licensee since the last renewal (if applicable); and
5. The renewal fee.

131-008.03 Second Notice: The Department will send to each licensee who fails to renew his/her license in response to the first notice, a second notice of renewal pursuant to 172 NAC 131-005.01 that specifies:

1. The licensee failed to pay the renewal fee;
2. The license has expired;
3. Upon receipt of the renewal fee, together with an additional late fee of $100, no order of revocation will be entered; and
4. Upon failure to receive $100 in addition to the regular renewal fee, the license will be revoked pursuant to 172 NAC 131-009.

131-008.03A The licensee must apply for renewal by submitting to the Department:

1. The renewal notice; and
2. The renewal fee and the additional late fee of $100;

131-008.04 When any licensee fails, within 30 days of expiration of a license, to pay the renewal fee and/or to pay an additional late fee of $100, the Department will automatically revoke the license without further notice or hearing and make proper record of the revocation.

131-008.05 The Department may refuse to renew a license for falsification of any information submitted for renewal of a license. The refusal must be made pursuant to Neb. Rev. Stat. §§ 71-149 to 71-155 and 184 NAC 1, Rules of Practice and Procedure of the Department.

131-009 CREDENTIAL REVOCATION FOR FAILURE TO MEET RENEWAL REQUIREMENTS: The Department will revoke a wholesale drug distributor license when the licensee fails to meet the renewal requirements.

131-009.01 Revocation for Non-Renewal within 30 Days of Expiration of the License.

131-009.01A When a licensee fails to meet the renewal requirements, pay the required renewal fee, and/or to pay a late fee of $100 within 30 days of its expiration,

the Department automatically revokes the credential without further notice or hearing.

131-009.01A1 A revocation notice will be sent which will specify that:

1. The licensee was given a first and final notice of renewal requirements and the respective dates for these notices;
2. Department has revoked the license; and
3. The licensee has a right to request reinstatement of the license.

131-010 PROCEDURES FOR REINSTATEMENT OF WHOLESALE DRUG DISTRIBUTOR LICENSE Section moved to section 008 as modified

131-010.01 Reinstatement After Revocation for Non-Renewal: A wholesale drug distributor whose license has been revoked for not meeting the renewal requirements may have such license reinstated by the Department, upon recommendation of the Board, and meeting the renewal requirements, payment of renewal fee and penalty fee when the application for reinstatement is made within one year of revocation.

131-010.01A The licensee must submit:

1. A verified completed application for reinstatement on a form provided by the Department, which includes the following information:
   a. The name of the licensee;
   b. The licensee's last known address of record;
   c. The license number;
   d. The expiration date of the license; Section moved to section 008 as modified
   e. Provide proof of a bond;
   f. Respond to the following questions:

      (1) Has designated representative of the licensee been convicted of a misdemeanor or felony?
      (2) Has any license of the entity in any profession in another state been revoked, suspended, limited or disciplined in any manner?

      These questions relate to the time period since the last renewal of the license or during the time period since initial licensure in Nebraska if such occurred within the two years prior to the license expiration date.

   g. Be inspected pursuant to 172 NAC 131-005.02 prior to the renewal of the license: and

2. Cause to be submitted to the Department:

   a. The renewal notice;
   b. Proof of a bond;

c. Proof of an acceptable inspection completed with the previous three years;

d. If any misdemeanor or felony conviction(s) of the designated representative of the licensee or any disciplinary action was taken against the licensee by another state, an official copy of the disciplinary action or court records, including charges and disposition; and Section moved to section 008 as modified

e. The renewal fee and the reinstatement fee pursuant to 172 NAC 131-012. Section moved to section 008 as modified

131-010.02 Reapplication After One Year of Revocation for Non-Payment of Renewal Fee: A wholesale drug distributor whose license has been revoked for more than one year for not meeting renewal requirements, may reapply to the Department for a license. Such reapplication must be made in the same manner as an application for an initial license. The procedures for such are pursuant to 172 NAC 131-003.02.

131-010.03 Reinstatement After Disciplinary Action: A wholesale drug distributor license which has been suspended or revoked for disciplinary action, may be reinstated by the Department upon the recommendation of the Board.

131-010.03A A wholesale drug distributor license, when suspended for disciplinary action, will be suspended for a definite period of time to be fixed by the Director and may be reinstated upon the expiration of such period, payment of the current renewal fee and reinstatement fee after discipline pursuant to 172 NAC 131.012, and meeting the requirements of 172 NAC 131-003.02. Section moved to section 008 as modified

131-010.03B A wholesale drug distributor license, when revoked for disciplinary action, will be revoked permanently, except that at any time after the expiration of two years, a petition for reinstatement may be made.

131-010.03B1 The petitioner must submit an application in the same manner as an application for an initial license. The procedures for such are pursuant to 172 NAC 131-003.02.

131-011 GROUNDS ON WHICH THE DEPARTMENT MAY DENY, REFUSE RENEWAL OF, OR DISCIPLINE A WHOLESALE DRUG DISTRIBUTOR LICENSE Section moved to section 009 as modified

131-011.01 The Department will deny an application for a wholesale drug distributor license when an applicant fails to meet the requirements pursuant to 172 NAC 131-003.

131-011.02 The Department will refuse renewal of a wholesale drug distributor license if the licensee fails to meet the renewal requirements pursuant to 172 NAC 131-008, or is found to be in violation of any of the provisions pursuant to 172 NAC 131-011.03.

131-011.03 The Department may deny, suspend, limit, or revoke a wholesale drug distributor license when the Director finds that the licensee has violated any provisions of the Wholesale Drug Distributor Licensing Act or of these regulations; or any of the following acts:

1. Conviction of any crime that has rational connection with the licensee's fitness to hold a license as a wholesale drug distributor;

2. Obtaining a wholesale drug distributor license by false representation and/or fraud;

3. Operating a wholesale drug distribution facility without a currently valid license;

4. Any conviction under Federal, State, or local laws or regulations relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

5. Unprofessional conduct which is hereby defined to include: Section moved to section 009 as modified

a. Misrepresentation or fraud in the conduct of a wholesale drug distribution facility; Section moved to section 009 as modified

b. Aiding or abetting an unlicensed facility to engage in wholesale drug distribution; and

c. 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, etc. Section moved to section 009 as modified

6. Failure of the licensee to maintain and make available to the Department or to Federal, State, or local law enforcement officials records required by these regulations; Section moved to section 009 as modified

7. Falsification of a pedigree; Section moved to section 009 as modified

8. Selling, distributing, transferring, manufacturing, repackaging, handling, or holding a counterfeit prescription drug intended for human use;

9. Commission of any acts pursuant to Neb. Rev. Stat. §§ 71-147 and 71-148 of the Uniform Licensing Law;

10. The adulteration, misbranding, or counterfeiting of any prescription drug;

11. The receipt of any prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, or the delivery or proffered delivery of such prescription drug for pay or otherwise;

12. The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the product labeling of a prescription drug or the commission of any other act with respect to a prescription drug that results in the prescription drug being misbranded;

13. 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; Section moved to section 009 as modified

14. The sale or transfer of a prescription drug to a person who is not legally authorized to receive a prescription drug; Section moved to section 009 as modified

15. Providing the Department or any of its representatives or any state or federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of this Act and rules;

16. The obtaining of or attempting to obtain a prescription drug by fraud, deceit, misrepresentation or engaging in misrepresentation or fraud in the distribution or wholesale distribution of a prescription drug;

17. The failure to obtain, authenticate, or pass on a pedigree when required under these rules;

18. 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; Section moved to section 009 as modified

19. The distributing or wholesale drug distributing of a prescription drug that was previously dispensed by a pharmacy or distributed by a practitioner; and Section moved to section 009 as modified

20. The failure to report any prohibited act as listed in these rules.

131-011.04 If the Department determines to deny, suspend, limit, revoke, or refuse renewal of a wholesale drug distributor license for any of the grounds specified in 172 NAC 131-011, it will give the applicant or licensee an opportunity for a hearing before the Department; and the applicant or licensee must have a right to present evidence on his/her own behalf.

131-011.05 Hearings before the Department will be conducted pursuant to the Administrative Procedure Act and 184 NAC 1, Rules of Practice and Procedure of the Department.

131-011.06 The Department, upon issuance of a final disciplinary action against a person who violates any provision of these regulations, will assess a fine of $1,000 against such person. For each subsequent final disciplinary action for such violation issued by the Department against such person, the Department will assess a fine of $1,000 plus $1,000 for each final disciplinary action for such violation previously issued against such person, not to exceed $10,000.

131-011.07 The Department, upon issuance of a final disciplinary action against a person who fails to provide authorized personnel the right of entry pursuant to 172 NAC 131-005

will assess a fine of $500 against such person. For each subsequent final disciplinary action for such failure issued against such person, the Department will assess a fine equal to $1,000 times the number of such disciplinary actions, not to exceed $10,000.

131-011.08 All fines collected under 172 NAC 131-011 will be remitted to the State Treasurer for credit to the Permanent School Fund.

131-012 SCHEDULE OF FEES: The following fees have been set by the Department: Section moved to section 009 as modified

131-012.01 Initial License Fee: By an applicant for a wholesale drug distributor license, the fee of $550; Section moved to section 009 as modified

131-012.02 License Renewal Fee: By an applicant for a renewal on a wholesale drug distributor license, the fee of $550; Section moved to section 009 as modified

131.012.03 Inspection Fee: By an applicant for issuance or renewal of a wholesale drug distributor license who requests an inspection to be conducted by a pharmacy inspector of the Department, the fee of $3,000 in addition to actual costs for transportation, lodging and meals of the pharmacy inspector who conducts the inspection. Section moved to section 009 as modified

131-012.04 Re-inspection Fee: By an applicant 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, the fee of $750 in addition to actual costs for transportation, lodging and meals of the pharmacy inspector who conducts the re-inspection. Section moved to section 009 as modified

131-012.05 Renewal Late Fee: By an applicant for renewal on a annual basis of a credential, who fails to pay the renewal fee on or before the expiration date of the credential, the fee of $100 as a late fee in addition to the renewal fee. Section moved to section 009 as modified

131-012.06 Reinstatement Fee: For a reinstatement of a credential for failure to meet renewal requirements, the fee of $50. Section moved to section 009 as modified

131-012.07 Reinstatement Fee After Discipline: For reinstatement of a wholesale drug distributor credential following suspension, limitation, or revocation for disciplinary reasons, the fee of $100. Section moved to section 009 as modified

131-012.08 Duplicate License Fee: By an applicant for a duplicate original license or a reissued license, the fee of $10.

131-011.08 Administrative Fee: For a denied credential or a withdrawn application, the administrative fee of $25 will be retained by the Department, except if onsite inspection has been completed prior to such denial, the Department may retain the entire license fee.

Approved by the Attorney General on June 6, 2007

~~Approved by the Governor on June 26, 2007~~
~~Filed by the Secretary of State on June 26, 2007~~
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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

(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~~ 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 ~~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.

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

005.04(~~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 delegating~~ed~~ pharmacist~~s~~ 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 permit 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.

TITLE 172 - NEBRASKA DEPARTMENT OF HEALTH BUREAU OF EXAMINING BOARDS

CHAPTER 134 - REGULATIONS GOVERNING PUBLIC HEALTH CLINICS OPERATING WITH A DRUG DISPENSING PERMIT

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TITLE 172 - NEBRASKA DEPARTMENT OF HEALTH BUREAU OF EXAMINING BOARDS

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BUREAU OF EXAMINING BOARDS

CHAPTER 134 - REGULATIONS GOVERNING PUBLIC HEALTH CLINICS OPERATING WITH A DRUG DISPENSING PERMIT

001 SCOPE OF REGULATIONS. These regulations shall apply to the issuance of drug dispensing permits for public health clinics, and are based upon Neb. Rev. Stat. §§71-1,147.39 to 71-1,147.61 and 71-5401 to 71-5408, 71-2401 to 71-2405, 71-2406 to 71-2409, and the Uniform Licensing Law. Section kept in section 001 as modified

002 DEFINITIONS. Section kept in section 002 as modified

002.01 Approved Formulary or Formulary shall mean a list of drugs and devices and patient instruction requirements recommended by the Formulary Advisory Committee, approved by the Board and adopted by the Department for dispensing by public health clinics.

002.02 Approved Training shall mean training provided by a licensed, actively practicing pharmacist according to the standards set out by the Board upon the recommendation of the Formulary Advisory Committee.

002.03 Available as used in these regulations shall mean the immediate ability to contact the consultant pharmacist or on-call pharmacist of a public health clinic with a drug dispensing permit during dispensing either in person or by telephone by health care professionals as defined in Subsection 002.15 of these regulations and public health clinic workers as defined in Subsection 002.24 of these regulations, to answer questions from clients, staff, public health clinic workers or volunteers.

002.04 Board or Board of Pharmacy shall mean the Board of Examiners in Pharmacy.

002.05 Bureau shall mean the Bureau of Examining Boards of the Nebraska Department of Health.

002.06 Calculated Expiration Date shall mean an expiration date on the prepackaged product which is not greater than twenty-five percent of the time between the date of repackaging and the expiration date of the bulk container nor greater than six months from the date of repackaging.

002.07 Consultant Pharmacist as used in these regulations shall mean an actively practicing Nebraska pharmacist who holds an unrestricted license designated on the drug dispensing permit as the pharmacist who is responsible for all duties set forth in Part 009.01A of these regulations.

002.08 Department shall mean the Nebraska Department of Health.

002.09 Device shall mean an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory, which is prescribed by a medical practitioner and dispensed by a pharmacist or other person authorized by law to do so.

002.10 Director shall mean the Director of the Nebraska Department of Health.

002.11 Dispense or dispensing shall mean the preparation and delivery of a drug or device pursuant to a lawful order of a medical practitioner, in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the drug or device.

002.12 Drug Dispensing Permit shall mean a permit issued by the Department upon the recommendation of the Board to a public health clinic which allows for the dispensing of drugs and devices with the formulary approved by the Director of Health pursuant to Section 006 of these regulations.

002.13 Drugs, Medicines, and Medicinal Substances as used in these regulations shall mean (a) articles recognized in the official United States Pharmacopoeia, the Homeopathic Pharmacopoeia of the United States, the official National Formulary, or any supplement to any of them, (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in humans, (c) articles, except food, intended to affect the structure or any function of the body of a human, (d) articles intended for use as a component of any articles specified in division (a), (b), or (c) or this subdivision, except any device or its components, parts or accessories, and (e) prescription drugs as defined in Subsection 002.22 of these regulations.

002.14 Formulary Advisory Committee shall mean an advisory committee to the Board composed of eight (8) members: two (2) members designated by the Board; two (2) actively practicing licensed pharmacists; two (2) members who are employees of the department with knowledge of and interest in reproductive health and sexually transmitted diseases and who work with such programs; and two (2) members who are employed by public health clinics and are recommended by same.

002.15 Health Care Professional as used in these regulations shall mean any person licensed in Nebraska to practice medicine and surgery or pharmacy or licensed or certified in Nebraska as a registered nurse, licensed practical nurse, or physician assistant.

002.16 Labeling shall mean the process of preparing, and affixing a label to any drug container or device container, exclusive of the labeling by a manufacturer, packer, or distributor of a nonprescription drug or commercially packaged legend drug or device. Any such label shall include all information required by federal and state law or regulation.

002.17 License, licensing or licensure shall mean permission to engage in a health profession which would otherwise be unlawful in this state in the absence of such permission and which is granted to individuals who meet prerequisite qualifications and allows them to perform prescribed health professional tasks and use a particular title.

002.18 Medical Practitioner as used in these regulations shall mean any licensed physician, surgeon, or other person licensed or certified to write prescriptions intended for treatment or prevention of disease or to affect body function in humans.

002.19 On-call pharmacist shall mean an actively practicing pharmacist who holds an unrestricted license to practice pharmacy in Nebraska and who is available in the event the consultant pharmacist is not available as defined in Subsection 002.03 of the these regulations.

002.20 Pharmaceutical Care shall mean the provision of drug therapy for the purpose of achieving therapeutic outcomes that improve a patient's quality of life. Such outcomes shall include (a) the cure of disease, (b) the elimination or reduction of a patient's symptomatology, (c) the arrest or slowing of a disease process, or (d) the prevention of a disease or symptomatology. Pharmaceutical care shall include the process through which the pharmacist works in concert with the patient and his or her caregiver, physician, or other professionals in designing, implementing, and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient.

002.21 Pharmacist shall mean the person who (a) is licensed by the State of Nebraska to practice pharmacy or (b) is primarily responsible for providing pharmaceutical care as defined in Subsection 002.20 of these regulations.

002.22 Prescription drug or legend drug shall mean (a) a drug which under federal law is required, prior to being dispensed or delivered, to be labeled with either of the following statements: (i) Caution: Federal law prohibits dispensing without prescription; or (ii) Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian, or (b) a drug which is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by medical practitioners only.

002.23 Prescription order or prescription shall mean a lawful written or verbal order of a medical practitioner for a drug or device.

002.24 Public Health Clinic Worker shall mean a person in a public health clinic operating with a drug dispensing permit who has completed the approved training and has demonstrated proficiency to perform the task of dispensing authorized refills of oral contraceptives.

002.25 Public Health Clinic shall mean the department, any county, city-county or multi-county health department, or any private not-for-profit family planning or reproductive health care clinic licensed as a health clinic as defined in Neb. Rev. Stat. §71-2017.01.

002.26 State shall mean the State of Nebraska.

002.27 Unrestricted license or certificate as used in these regulations, shall mean any licensee or certificate holder who has been approved by the appropriate Board of Examiners to work in a public health clinic.

003 REQUIREMENTS FOR ISSUANCE OF A DRUG DISPENSING PERMIT. Any public health clinic who does not hold a pharmacy permit and who wishes to dispense and store drugs and devices which are listed on the approved formulary must obtain a drug dispensing permit. The criteria for issuance of a drug dispensing permit and documentation required by the Department and the Board are set forth below. Section kept in section 003 as modified

003.01 Applicant Requirements. An applicant for a drug dispensing permit must:

003.01A Be a public health clinic as defined in Subsection 002.25 of these regulations.

003.01B Have an actively practicing Nebraska-licensed pharmacist listed as a consultant pharmacist who has an unrestricted license as defined in Subsection 002.27 of these regulations;

003.01C Submit to the Department:

003.01C1 A verified complete application on a form provided by the Department, a copy of which is attached hereto as Attachment A, and incorporated in these regulations by this reference. Only applications which are complete will be considered;

003.01C2 A completed application for a drug dispensing permit must be submitted at least thirty (30) days before the anticipated opening date to allow for an initial on-site inspection to be conducted; and

003.01C3 The required initial inspection fee of $125.00.

003.02 Department Responsibility. The Department shall:

003.02A Review the application to determine its completeness;

003.02B Acknowledge receipt of the application with a copy of the acknowledgement letter provided to the appropriate pharmacy inspector;

003.02C Schedule with the applicant and conduct an inspection pursuant to Section 004 of these regulations prior to the issuance of the initial drug dispensing permit. The results of such inspection shall be recorded on a form entitled "The Drug Dispensing Permit Inspection Report," a copy of which is attached hereto as Attachment B, and incorporated in these regulations by this reference;

003.02D Act within 150 days of receipt of a completed application for a drug dispensing permit; and

003.02E Issue a drug dispensing permit to each establishment which meets the requirements as defined in Section 004 of these regulations.

003.03 Separate drug dispensing permits shall be required for public health clinics maintained on separate premises even though operated under the same management.

003.03A A separate drug dispensing permit shall not be required for an ancillary facility which offers intermittent services, which is staffed by personnel from the public health clinic site for which a drug dispensing permit has been issued, and at which no legend drugs or devices are stored.

003.04 Permit Display. Each permittee must conspicuously display the drug dispensing permit in the drug dispensing area. Moved to section 006 as modified

004 PROCEDURES FOR INSPECTIONS In order for a public health clinic to obtain a drug dispensing permit, an initial on-site inspection must be successfully completed. Kept in section 004 as modified

004.01 Initial Inspection A scheduled initial on-site inspection shall be conducted by a pharmacist of the Department using "The Drug Dispensing Permit Inspection Report" provided by the Department, a copy of which is attached hereto as Attachment B, and incorporated in these regulations by this reference, to determine if the public health clinic complies with the following standards:

004.01A At the time of the initial inspection, the inspector must be provided with the following:

004.01A1 Photocopy of current license(s) of pharmacist(s) on file in the drug dispensing area;

004.01A2 A sign which displays in letters not less than 1" in height, "Licensed Pharmacist Not Available For Consultation. No Prescriptions May Be Dispensed At This Time" to be used whenever a licensed pharmacist is not available;

004.01A3 The name of the consultant pharmacist;

004.01A4 Evidence that in the event the drug dispensing area hours are different than the public health clinic hours (i.e., late opening, early closing, both, or any variation of the preceding), the drugs, devices, supplies and acquisition and dispensing records of drugs and devices will be completely enclosed, locked and secured;

004.01A5 Evidence of environmental control of the drug dispensing area which allows products to be stored at the manufacturer's recommended storage requirements;

004.01A6 Adequate lighting of the drug dispensing area to enable the personnel to properly observe the identities of all drugs and devices, and to dispense drugs and devices; Moved to section 006 as modified

004.01A7 Evidence that facilities allow for cleaning of the drug dispensing area and the equipment and utensils used in dispensing of drugs and devices;

004.01A8 Evidence that the drug dispensing area, including shelving, counters, floor, refrigerator, drug inventory, equipment and utensils are maintained in a clean, orderly, and sanitary manner at all times; Moved to section 006 as modified

004.01A8a If approved formulary does not include drugs or devices which require refrigeration, then a refrigerator is not required.

004.01A9 A public health clinic with a drug dispensing permit shall maintain a library which consists of either printed or automated form of the following:

004.01A9a Any United States Pharmacopoeia Drug Information (U.S.P.D.I.) Volumes 1 and 2 which contain all drugs listed in the formulary;

004.01A9b Current copies of the Nebraska Pharmacy Statutes and Regulations applicable to the dispensing of legend drugs and devices in public health clinics; and

004.01A9c A medical dictionary.

004.01A10 Mid-Plains Poison Control Center phone number displayed in a conspicuous place; Moved to section 006 as modified

004.01A11 At least three spatulas and a counting tray;

004.01A12 Adequate refrigeration when required which ensures the preservation and maintenance of the integrity of approved formulary drugs and devices. The consultant pharmacist is responsible for periodically reviewing and evaluating the refrigeration storage conditions to ensure sanitary conditions exist; Moved to section 006 as modified

004.01A13 A current copy of the policy and procedure manual which shall identify and locate at least the following: Moved to section 006 as modified

004.01A13a Consultant pharmacist monthly inspection reports;

004.01A13b Labeling requirements; Moved to section 006 as modified

004.01A13c Storage and security of drugs and devices; Moved to section 006 as modified

004.01A13d Proper patient instruction; Moved to section 006 as modified

004.01A13e Formulary; Moved to section 006 as modified

004.01A13f Library resources; Moved to section 006 as modified

004.01A13g Record keeping, to include the medical chart; Moved to section 006 as modified

004.01A13h Drug recall procedures; Moved to section 006 as modified

004.01A13i Policies for licensed or certified health care staff; and Moved to section 006 as modified

004.01A13j Policies for public health clinic workers. Moved to section 006 as modified

004.02 Annual Inspection. An annual inspection of the drug dispensing area of a public health clinic with a drug dispensing permit shall be conducted by a pharmacist of the Department to ensure compliance with requirements specified in Sections 003 and 005 of these regulations.

004.02A Inspections may occur more frequently if the Department considers it necessary.

004.03 Follow-up Inspection. A follow-up inspection is conducted by a pharmacist of the Department whenever the Department or Board deems necessary based upon a complaint filed against a public health clinic or any staff member, public health clinic worker, volunteer, or any consultant in association with work performed under a drug dispensing permit. Kept in section 004 as modified

~~004.04 Closing Inspection. When a public health clinic with a drug dispensing permit anticipates closing for business, the Department must be notified in writing at least thirty (30) days before closing date. Such notification shall state the anticipated closing date.~~ Kept in section 004 as modified

004.04A The Department shall conduct a closing inspection;

004.04B Documentation shall be provided to the Department which verifies that the permittee has completed a closing inventory and has properly disposed of all legend drugs and devices; and

004.04C Record of such closing shall be on a form entitled "Drug Dispensing Permit Closing Form" a copy of which is attached hereto as Attachment C, and incorporated in these regulations by this reference.

005 CRITERIA FOR SUCCESSFUL COMPLETION OF AN INSPECTION Each applicant for a drug dispensing permit must successfully complete an on-site inspection to receive a permit to operate. The criteria for successful completion of inspections are set forth below.

005.01 Criteria for Successful Completion of an Initial Inspection.

005.01A The Department shall issue a rating of "Pass/Fail" on an initial inspection.

005.01B The Department shall issue a rating of "Fail" on the initial inspection when an applicant does not meet the requirements of inspection.

005.01B1 When an applicant receives a rating of "Fail," the applicant shall not dispense drugs or devices and shall be granted ninety (90) days from the date of the initial inspection to meet the requirements.

005.01B2 The Department shall conduct a re-inspection within ninety (90) days after the applicant has failed the initial inspection to determine if the applicant meets the requirements.

005.01B3 When the applicant for a drug dispensing permit receives a "Fail" rating, after the re-inspection, the Department shall deny the applicant the issuance of a drug dispensing permit to a public health clinic.

005.01C The Department shall issue a rating of "Pass" when the applicant meets 100% of all applicable requirements.

005.02 Criteria for Successful Completion of an Annual Inspection.

005.02A The Department shall issue a rating of "Pass" on an annual inspection when the permittee receives an overall inspection rating of 90% or greater.

005.02B The Department shall issue a rating of "Fail" on the annual inspection when the permittee receives an overall inspection rating of less than 90%.

005.02B1 When a permittee receives a rating of "Fail," it shall be granted up to ninety (90) days from the date of the annual inspection to meet the requirements.

005.02B2 The Department shall conduct a re-inspection within ninety (90) days after the permittee has failed the annual inspection to determine if the public health clinic with a drug dispensing permit meets the requirements.

005.02B2a If the permittee meets the requirements at the time of re-inspection, the Department shall change the "Fair" rating and enter a "Pass" rating.

005.02B2b If the permittee fails to meet the requirements at the time of re-inspection, the Department shall, within ten (10) days of the completion of the re-inspection, give notice to the permittee that the drug dispensing permit is revoked or suspended. Such notice shall be in written form and shall:

005.02B2b(1) State that the drug dispensing permit is revoked or suspended;

005.02B2b(2) State the reasons for the permit revocation or suspension;

005.02B2b(3) State that the permit revocation or suspension will become final thirty (30) days after the mailing of the notice of revocation or suspension unless the permittee submits a written request for a hearing within such thirty (30) day period; and

005.02B2b(4) Be sent to the permittee by certified mail.

005.02B2c Upon receipt of a written request for a hearing the permittee shall be given a hearing before the Department.

005.02B2d The Department's decision regarding the revocation or suspension of the drug dispensing permit shall become final thirty (30) days after a copy of the decision is mailed to the permittee unless the permittee appeals the decision pursuant to Neb. Rev. Stat. §71-1,147.12.

005.02B3 When a drug dispensing permit is revoked or suspended for failure of an annual inspection, the public health clinic must reapply to the Department for a permit to operate as specified in Section 003 of these regulations.

006 ESTABLISHMENT OF THE FORMULARY ADVISORY COMMITTEE. The Formulary Advisory Committee is an advisory committee to the Board.

006.01 Composition of the Committee. The Formulary Advisory Committee shall consist of eight members as follows:

006.01A Two members designated by the Board;

006.01B Two members who are employees of the Department who have knowledge and interest in reproductive health care and sexually transmitted diseases and who work with such programs;

006.01C Two members who are actively practicing pharmacists and who hold unrestricted licenses to practice pharmacy in Nebraska;

006.01C1 The Nebraska Pharmacists Association may submit to the Director a list of five (5) persons of recognized ability in the profession.

006.01C2 The Director shall consider the five (5) names submitted by the Nebraska Pharmacists Association and may appoint one or two of the persons to be committee members.

006.01C3 The Director may appoint any qualified pharmacist even if such persons are not named on the list submitted by the Nebraska Pharmacists Association.

006.01D Two members who are employees of public health clinics which are or will operate with drug dispensing permits.

006.01D1 The Director will select these two members from names recommended by public health clinics which are or will operate with drug dispensing permits.

006.02 Committee appointments. Initial recommendations shall be made to the Director.

006.02A Recommendations to the Director shall be submitted in July prior to the meeting during the third quarter of the calendar year.

006.02B Members shall serve for terms of two years each beginning with the meeting held during the third quarter of the calendar year except that one-half of the initial members appointed to the Committee, as appointed by the Director, shall serve for terms of three years each.

006.02C The Director may approve members to serve consecutive terms.

006.02D The Director may remove a member of the Committee for inefficiency, neglect of duty, or misconduct in office.

006.03 Committee Responsibilities. The Formulary Advisory Committee responsibilities are as follows:

006.03A The Committee shall meet annually but may meet quarterly.

006.03B The Committee shall recommend to the Board:

006.03B1 The formulary of drugs and devices to be dispensed by public health clinics operating with drug dispensing permits;

006.03B2 The addition or deletion of drugs and devices to the formulary;

006.03B3 The patient instruction requirements including directions for use, potential side effects, drug interactions, criteria for contacting the on-call pharmacist, and written information to be given to patients;

006.03B4 The standards for the training of the public health clinic workers; and

006.03B5 The standards for proficiency for public health clinic workers.

006.03C The Board shall recommend the formulary to the Director.

006.03D The Director shall approve the formulary to be used by public health clinics operating with a drug dispensing permit.

007 APPROVED FORMULARY. Only drugs and devices that have been approved by the Director upon the recommendation of the Board which shall be based upon the recommendation of the Formulary Advisory Committee shall be included on the formulary used by public health clinics operating with a drug dispensing permit.

007.01 Types of Drugs and Devices to be Included in Formulary. The formulary shall consist of a list of drugs and devices for contraception, or the treatment of sexually transmitted diseases, and the treatment of vaginal infections.

007.02 Specific Requirements of Drugs or Devices Included on the Formulary. Drugs or devices dispensed and stored at a public health clinic with a drug dispensing permit may be included on the formulary only if they include the following:

007.02A Patient instruction requirements which shall include directions on the use of the drug or device;

007.02B Potential side effects and drug interactions;

007.02C Criteria for contacting the on-call pharmacist; and

007.02D Accompanying written patient information.

007.03 Drugs and Devices Not Permitted on the Formulary. Drugs and devices with the following characteristics shall not be eligible to be included in the formulary:

007.03A Controlled substances;

007.03B Drugs with significant dietary interactions;

007.03C Drugs with significant drug-drug interactions; and

007.03D Drugs or devices with complex counseling profiles.

007.04 Changes to the formulary. Any additions or deletions of drugs or devices to the formulary must be approved by the Director, upon the recommendation of the Board which shall be based upon the recommendation of the Formulary Advisory Committee.

008 STAFFING REQUIREMENTS FOR A PUBLIC HEALTH CLINIC WITH A DRUG DISPENSING PERMIT. Moved to section 005 as modified

008.01 Staff Qualifications. The following requirements must be met for staff working in public health clinics with a drug dispensing permit:

008.01A Consultant Pharmacist. A consultant pharmacist to a public health clinic must be an actively practicing pharmacist who holds an unrestricted license to practice pharmacy issued by the state of Nebraska;

008.01B On-Call Pharmacist. An on-call pharmacist who is available to the public health clinic must be an actively practicing pharmacist who holds an unrestricted license to practice pharmacy issued by the state of Nebraska;

008.01C Physician. A physician must hold an unrestricted license to practice medicine and surgery in the state of Nebraska and has completed approved training as provided in Subpart 008.02A1 of these regulations;

008.01D Nurse Practitioner. A nurse practitioner must be a licensed professional nurse who holds an unrestricted license issued by the state of Nebraska to practice as a Nurse Practitioner in the specialty for which he or she has been educated and has completed approved training as provided in Subpart 008.02A1 of these regulations;

008.01E Nurse Midwife. A nurse midwife must be a licensed professional nurse who holds an unrestricted license to practice midwifery in the state of Nebraska and has completed approved training as provided in Subpart 008.02A1 of these regulations;

008.01F Physician Assistant. A physician assistant must hold an unrestricted certificate to practice as a physician assistant in the state of Nebraska and has completed approved training as provided in Subpart 008.02A1 of these regulations;

008.01G Licensed Professional Nurse. A licensed professional nurse must hold an unrestricted license to practice nursing in the state of Nebraska and has completed approved training as provided in Subpart 008.02A2 of these regulations;

008.01H Licensed Practical Nurse. A licensed practical nurse must hold an unrestricted license to practice as a practical nurse in the state of Nebraska and has completed approved training as provided in Subpart 008.02A2 of these regulations;

008.01I Public Health Clinic Worker. A public health clinic worker must:

008.01I1 Be at least eighteen (18) years of age;

008.01I2 Hold a high school diploma or the equivalent;

008.01I3 Complete approved training as provided in Subpart 008.02A3;

008.01I4 Demonstrate proficiency as provided in Subsection 008.03; and

008.01I5 Be supervised with documentation by a licensed or certified health care professional for the first month that dispensing of authorized refills of oral contraceptives occurs.

008.02 Training Requirements. The training shall be approved according to the standards determined by the Board upon recommendation of the Formulary Advisory Committee. Such training is required prior to dispensing drugs and devices under a drug dispensing permit. All training shall be conducted by an actively practicing pharmacist who holds an unrestricted Nebraska pharmacy license. Moved to section 005 as modified

008.02A Approved training shall include but is not limited to the following:

008.02A1 Persons licensed to practice medicine and surgery and persons certified as a physician assistant, nurse practitioner, or nurse midwife who shall have two hours of training in the following: Moved to section 005 as modified

008.02A1a Procedures for dispensing initial prescriptions and authorized refills of oral contraceptives; Moved to section 005 as modified

008.02A1b Procedures for dispensing approved drugs and devices; Moved to section 005 as modified

008.02A1c Federal and State laws regarding drug dispensing; Moved to section 005 as modified

~~008.02A1d Proper labeling of oral contraceptives and approved drugs and devices;~~ Moved to section 005 as modified

~~008.02A1e Proper record keeping of initial and refilled prescriptions;~~ Moved to section 005 as modified

~~008.02A1f Use of Volumes I and II of the United States Pharmacopeia-Drug Information;~~

~~008.02A1g Proper pharmacist referral;~~ Moved to section 005 as modified

~~008.02A1h Procedures for reaching the consultant or the on-call pharmacist;~~ Moved to section 005 as modified

~~008.02A1i Storage and security of approved formulary drugs and devices; and~~ Moved to section 005 as modified

~~008.02A1j Patient information.~~ Moved to section 005 as modified

~~008.02A2 Persons licensed as a registered nurse or licensed practical nurse who are not certified as a nurse practitioner or nurse midwife shall have eight hours of training in the following:~~ Moved to section 005 as modified

~~008.02A2a Procedures for dispensing initial prescriptions and authorized refills of oral contraceptives;~~

~~008.02A2b Procedures for dispensing approved drugs and devices;~~

~~008.02A2c Federal and State laws regarding drug dispensing;~~

~~008.02A2d Proper labeling of oral contraceptives and approved drugs and devices;~~

~~008.02A2e Proper record keeping of initial and refilled prescriptions;~~

~~008.02A2f The actions, drug interactions, and effects of oral contraceptives and approved drugs and devices;~~

~~008.02A2g Use of Volumes I and II of the United States~~

~~008.02A2h Proper pharmacist referral;~~

~~008.02A2i Procedures for reaching the consultant or the on-call pharmacist.~~

~~008.02A2j Storage and security of approved formulary drugs and devices; and~~

008.02A2k Patient information.

008.02A3 Persons who are public health clinic workers shall have six hours of classroom training in the following: Moved to section 005 as modified

008.02A3a Procedures for dispensing authorized refills of oral contraceptives;

008.02A3b Federal and State laws regarding drug dispensing;

008.02A3c Proper labeling of refills for oral contraceptives;

008.02A3d Proper record keeping of refilled prescriptions for oral contraceptives;

008.02A3e The actions, drug interactions, and effects of oral contraceptives;

008.02A3f Use of Volumes I and II of the United States Pharmacopeia-Drug Information;

008.02A3g Proper pharmacist referral;

008.02A3h Procedures for reaching the consultant or the on-call pharmacist;

008.02A3i Storage and security of approved formulary drugs and devices; and

008.02A3j Patient information.

008.02A4 After the initial training has been completed, persons who are public health clinic workers shall have an annual two hour inservice regarding oral contraceptives. Moved to section 005 as modified

008.02B Documentation of Training. Documentation of attendance of all training shall be maintained in the employee's personnel file and in the public health clinic's policy and procedure manual. It is the responsibility of the public health clinic and the consultant pharmacist to assure that the appropriate training of staff has occurred prior to the dispensing of any drugs and devices and to assure that documentation of training has been completed. Moved to section 005 as modified

008.03 Proficiency demonstration requirements. Following training, public health clinic workers must demonstrate proficiency as follows: Moved to section 005 as modified

008.03A The public health clinic worker shall demonstrate proficiency, to the consultant pharmacist at least annually or as requested by the consultant pharmacist. Moved to section 005 as modified

008.03B The public health clinic worker shall be supervised by one of the licensed or certified health care professionals trained to dispense drugs for the first month that the public health clinic worker dispenses authorized refills of oral contraceptives. Moved to section 005 as modified

008.03C Completed proficiency demonstrations shall be documented in the employee's personnel file and in the public health clinic's policy and procedure manual. Moved to section 005 as modified

009 STANDARDS FOR THE DISPENSING OF LEGEND DRUGS AND DEVICES IN A PUBLIC HEALTH CLINIC WITH A DRUG DISPENSING PERMIT Moved to section 006 as modified

009.01 Consultant Pharmacist Requirement and Duties. All public health clinics which dispense legend drugs and devices pursuant to a drug dispensing permit shall have an actively practicing pharmacist with an unrestricted Nebraska license listed as the consultant pharmacist on the permit. Moved to section 006 as modified

009.01A The consultant pharmacist shall perform and document the following:

009.01A1 That he or she is physically in the public health clinic at least once every thirty (30) days;

009.01A2 That he or she conducts monthly inspections of the environment, inventory, record keeping of all drugs and devices received, stored or dispensed by the public health clinic, storage, security, dispensing and labeling procedures of all drugs and devices;

009.01A3 That he or she approves and maintains a policy and procedure manual governing the storage, control, distribution and dispensing of drugs and devices within the public health clinic as set out in Subpart 004.01A13 of these regulations;

009.01A4 That he or she approves supplemental information and instructions regarding approved formulary drugs and devices dispensed to patients;

009.01A5 That he or she approves the proficiency of public health clinic workers at the public health clinic for the dispensing of authorized refills of oral contraceptives at least annually;

009.01A5a Documentation of proficiency shall be maintained in the employee's personnel file and the policy and procedure manual.

009.01A6 That he or she approves training of public health clinic workers; and

009.01A7 That he or she will report any discrepancies in the inventory of the public health clinic with a drug dispensing permit to the Board of Pharmacy and the administrator of the public health clinic.

009.02 Liability. The public health clinic for which a public health clinic worker is working shall be liable for acts or omissions on the part of the public health clinic worker; except

009.02A The consultant pharmacist shall not be held liable for acts or omissions on the part of a public health clinic worker or of licensed or certified health care staff nor shall the on-call pharmacist be held liable for such acts except as stated in Subsection 010.08 of these regulations.

009.03 Requirements for Dispensing Legend Drugs and Devices. Only approved formulary drugs and devices may be dispensed from a public health clinic holding a drug dispensing permit; and shall be dispensed by a pharmacist, other health care professional or public health clinic worker pursuant to a written prescription generated at a public health clinic where the patient's written records are maintained. Moved to section 006 as modified

009.03A The prescription shall contain the following:

009.03A1 Date of issuance;

009.03A2 Name of patient;

009.03A3 Name of prescriber;

009.03A4 Name, strength, dosage form, and quantity of the drug;

009.03A5 Number of refills authorized for oral contraceptives only;

009.03A5a In no event shall refills be authorized for greater than one (1) year from the date of issuance of the original prescription; and

009.03A6 Directions for use by patient.

009.04 Dispensing when Pharmacist not onsite. If a pharmacist is not onsite but he or she is available as defined in Subsection 002.03 of these regulations, another health care professional or a public health clinic worker may dispense approved formulary drugs and devices under a drug dispensing permit, provided:

009.04A The initial dispensing of all prescriptions for approved formulary drugs and devices are dispensed by a pharmacist or other health care professional pursuant to a prescription written by a medical practitioner; and

009.04B The public health clinic worker only dispenses authorized refills of oral contraceptives. Moved to section 006 as modified

009.05 Dispensing by Pharmacist When dispensing a legend drug or device under a drug dispensing permit:

009.05A A pharmacist shall:

009.05A1 Receive and interpret the written prescription including refill authorization;

009.05A1a Only prescriptions for oral contraceptives may be refilled.

009.05A2 Prepare the prescription by counting or pouring;

009.05A3 Dispense the drug product or device in a suitable container; and

009.05A4 Affix the proper label to the container as prescribed in Subsection 009.06 and 009.07 of these regulations.

009.05B Other health care professionals shall perform the duties set out in Subsections 009.05A1 and 009.05A1a of these regulations.

009.06 Packaging Requirements of Drugs and Devices. All drugs or devices dispensed from a public health clinic with a drug dispensing permit are to be prepackaged by the manufacturer or a pharmacist on-site into the quantity to be prescribed and dispensed at the public health clinic. Moved to section 006 as modified

009.06A All drugs and devices stored, received, or dispensed shall be properly labeled at all times. Properly labeled shall mean that the label is printed and affixed to the container prior to dispensing and contains the following information:

009.06A1 The name, address and phone number of the public health clinic;

009.06A2 The name of the manufacturer;

009.06A3 The lot number and expiration date from the manufacturer or;

009.06A3a If prepackaged by a pharmacist, the lot number and calculated expiration date;

009.06A3a(1) Calculated expiration date shall mean an expiration date on the prepackaged product which is neither greater than twenty-five percent of the time between the date of repackaging and the expiration date of the bulk container nor greater than six months from the date of repackaging.

009.06A4 Directions for patient use;

009.06A5 The quantity of drug inside the prescription container;

009.06A6 The name, strength, and dosage form of the drug; and

009.06A7 Auxiliary labels as needed for proper drug use, storage and compliance.

009.07 Dispensing by other Health Care Professionals. When the drug or device is dispensed by a health care professional other than a pharmacist, or when a refill of an oral contraceptive is refilled by a public health clinic worker, the following additional information printed in typewritten form shall be added to the label of each prescription container:

009.07A The patient's name;

009.07B The name of the prescribing health care professional;

009.07B1 When the prescribing health care professional is a physician assistant, the label shall bear the name of his or her supervising physician,

009.07C The consecutive prescription number; and

009.07D The date dispensed.

009.08 Patient Instructions. Dispensed prescriptions are to be accompanied by patient instructions and written information approved by the Director.

009.09 Availability of Consultant Pharmacists. At any time that dispensing is occurring from the public health clinic with a drug dispensing permit, the consultant pharmacist or any other actively practicing pharmacist licensed to practice pharmacy in Nebraska must be available, either in person or by telephone, to answer questions from clients, staff, public health clinic workers, or volunteers.

009.09A The consultant pharmacist or on-call pharmacist shall inform the public health clinic if he or she will not be available during the time that his or her availability is required and such notification shall be documented by the public health clinic and the pharmacist.

009.10 Nonavailability of Consultant Pharmacists. If a pharmacist is not available, dispensing is prohibited.

009.11 Container Requirements for Prescriptions. All new and refilled prescriptions shall 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 that are specified in Subsections 009.06 and 009.07 of these regulations are met. Moved to section 006 as modified

009.12 Prescription and Prescribed Medical Articles Returns. In order to protect the public health, a public health clinic with a drug dispensing permit is prohibited from accepting for refund or any other purpose the following items: Moved to section 006 as modified

009.12A Unused portions of dispensed prescriptions; Moved to section 006 as modified

009.12B Prescribed devices or products used upon or applied to the human body, except; Moved to section 006 as modified

009.12B1 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; and Moved to section 006 as modified

009.12B2 Those prescribed drugs which are voluntarily recalled by manufacturers or that are recalled by order of the Federal Food and Drug Administration. Moved to section 006 as modified

009.13 Inventory Requirements. A pharmacist shall ensure that the inventory of all drugs and devices in the public health clinic with a drug dispensing permit have affixed to them the original manufacturer's, distributor's or packer's label. Moved to section 006 as modified

009.14 Misbranded Drugs. Information contained on all labels and packages shall be complete, true and accurate. A pharmacist shall ensure that the inventory of all drugs in the drug dispensing area, have affixed to them the original manufacturer's, distributor's, or packer's label which list the drug name, strength, dosage form, expiration date, and lot number. Moved to section 006 as modified

009.14A Drugs stored in the drug dispensing area shall be deemed misbranded if they are not labeled as specified in Subsection 009.06 of these regulations: Moved to section 006 as modified

009.14B Drugs dispensed to patients under a drug dispensing permit shall be deemed misbranded if they are not labeled as specified in Subsections 009.06 and 009.07 of these regulations. Moved to section 006 as modified

009.15 Recordkeeping of Drugs and Devices Dispensed Pursuant to a Prescription

009.15A Recordkeeping for Prescriptions. A public health clinic with a drug dispensing permit shall maintain records of all drugs and devices dispensed by using a recordkeeping system which allows for prescription information to be readily retrievable and in a form which provides a concise, accurate and comprehensive method of monitoring dispensing. Such system shall document the following for each drug or device dispensed: Moved to section 006 as modified

009.15A1 Name of patient;

009.15A2 Consecutive prescription serial number;

009.15A3 Date of filling of the prescription;

009.15A4 Name, strength and dosage form of drug or device:

009.15A5 Directions for use by patient;

009.15A6 Quantity dispensed;

009.15A7 Prescriber's name;

009.15A8 Initials of dispenser; and

009.15A9 Documentation of the number of refills authorized for oral contraceptives and the number of refills dispensed.

009.15B A public health clinic with a drug dispensing permit shall maintain a single file of this prescription information. Moved to section 006 as modified

009.15C The public health clinic with a drug dispensing permit shall maintain records of all drugs and devices dispensed for two (2) years. Moved to section 006 as modified

009.15D If an automated recordkeeping system is utilized there must be a complete backup every seven (7) working days, that is verifiable to prevent loss of dispensing records.

009.15E When an automated 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. Moved to section 006 as modified

009.15F When an automated system is used and requires storage of dispensing records after a certain time period, such system must be capable of producing the stored data within forty-eight (48) hours or two (2) working days upon request of the representatives of the Department.

009.16 Refill Requirements and Limitations. All prescription refills for oral contraceptives must be authorized in writing by the prescriber.

009.16A A prescription for an oral contraceptive shall not be refilled without specific refill limitations as indicated by the medical practitioner.

010 Procedures for Issuing and Renewing Drug Dispensing Permits Moved to section 007 as modified

010.01 Initial Permits. All initial drug dispensing permits issued by the Department shall expire one year from the date of issuance.

010.02 Renewed Permits. All renewed drug dispensing permits shall expire one year from the date of issuance. Any permittee who wishes to continue dispensing drugs shall renew the drug dispensing permit by following the procedures below.

010.02A The Department shall send an annual inspection fee notice to the permittee's address of record at least thirty (30) days prior to the permit's expiration date. The notice shall specify:

010.02A1 The name of the permittee;

010.02A2 The permit number;

010.02A3 The expiration date of the permit; and

010.02A4 The annual inspection fee of $75.00.

010.02B The permittee shall submit to the Department:

010.02B1 The annual inspection fee of $75.00; and

010.02B2 The annual inspection notice.

010.02C The Department shall send to each permittee who fails to renew the drug dispensing permit a second annual inspection notice. Such notice shall specify:

010.02C1 That the permittee failed to pay the annual inspection fees;

010.02C2 That the drug dispensing permit has expired;

010.02C3 That the Department will suspend action for thirty (30) days following the date of expiration;

010.02C4 That upon receipt of the annual inspection fee, the Department shall issue the renewed drug dispensing permit; and

010.02C5 That upon failure to receive the amount then due the drug dispensing permit will be revoked as specified in Subsection 010.03 of these regulations.

010.02D The permittee shall submit to the Department:

010.02D1 The annual inspection notice; and

010.02D2 The annual inspection fee.

010.03 Revocation for Failure to Pay the Annual Inspection Fee. When any permittee fails, within thirty (30) days of expiration of the drug dispensing permit, to pay the annual inspection fee, the Department shall determine to deny, revoke, suspend, or refuse renewal of a drug dispensing permit.

010.03A The Department shall send the permittee, by certified mail, a notice setting forth the particular reasons for the determination.

010.03B The denial, suspension, revocation, or refusal of renewal shall become final thirty (30) days after the mailing of the notice unless the permittee, within such thirty (30) day period, requests a hearing in writing.

010.03C The permittee shall be given a fair hearing before the Department and may present such evidence as may be proper. On the basis of such evidence, the determination involved shall be affirmed or set aside, and a copy of such decision setting forth the findings of facts and the particular reasons upon which it is based shall be sent by certified mail to the permittee.

010.03D The decision shall become final thirty (30) days after a copy of such decision is mailed unless the permittee within such thirty (30) day period appeals the decision pursuant to Neb. Rev. Stat. §71-1, 147.12.

010.03E Hearings before the Department shall be conducted in accordance with Neb. Rev. Stat. Chapter 84, Article 9 and 184 NAC 1, the Rules of Practice and Procedure for the Department.

010.04 The Department may refuse or deny an application for a drug dispensing permit for any one or a combination of the following reasons:

010.04A Conviction of Permittee of any crime involving moral turpitude;

010.04B Obtaining a drug dispensing permit by false representation or fraud;

010.04C Operating a public health clinic with a drug dispensing permit without a consultant pharmacist responsible for the duties specified in Subsection 009.01 of these

regulations;

010.04D Failure to pass an initial or annual inspection;

010.04E Failure to pay inspection costs;

010.04F Failure to pay any fee required by Sections 003 and 010 of these regulations;

010.04G Use of unauthorized persons in the dispensing or administration of drugs or devices;

010.04H The compounding and dispensing of drugs or devices or the filling of a prescription by a person other than a licensed pharmacist or by an intern in pharmacy, without the presence of and the immediate personal supervision of a licensed pharmacist except as provided in Neb. Rev. Stat. §71-1,147.33 or in Sections 008 and 009 of these regulations;

010.04I The dispensing of any drug or device not listed in the approved formulary or failure to provide patient information;

010.04J A conviction of a violation of Neb. Rev. Stat. §§71-1,142 to 71-1,147.61 and these regulations or of a felony or, if a natural person, the revocation or suspension of a drug dispensing permit;

010.04K Unprofessional conduct which shall include, but not be limited to:

010.04K1 Misrepresentation or fraud in the conduct of a public health clinic;

010.04K2 Aiding or abetting an unlicensed person to practice pharmacy;

010.04K3 The 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; or

010.04K4 The dispensing of 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;

010.04L Violation of the rules and regulations governing the practice of pharmacy as adopted and promulgated under authority of Neb. Rev. Stat. §§71-1,147.09 by the Department; and

010.04M Suggesting, soliciting, ordering, assisting, or abetting a pharmacist in the commission of any of the offenses set forth in Neb. Rev. Stat. §71-147 and 71-148.

010.05 A permittee shall not dispense drugs or devices after a permit is revoked or during the time for which the permit is suspended.

010.05A If a permit is suspended, the suspension shall be for a definite period of time to be fixed by the Director.

010.05B The permit shall be automatically reinstated upon the expiration of such period if the current renewal fees have been paid.

010.06 If the permit is revoked, the revocation shall be permanent, except that at any time after the expiration of two years, application may be made for reinstatement by any permittee whose permit has been revoked.

010.06A The application shall be addressed to the Director but may not be received or filed by him or her unless accompanied by a written recommendation of reinstatement by the Board.

010.07 A petition for the revocation or suspension of a drug dispensing permit may be filed by the Attorney General or by the county attorney in the county in which the permittee resides or is operating a public health clinic.

010.07A The petition shall:

010.07A1 Be filed with the Board;

010.07A2 Be entitled "In the Matter of the Revocation (or suspension) of the Permit of (name of permittee) to dispense drugs and devices; and

010.07A3 State the charges against the permittee with reasonable definiteness.

010.07B Upon approval of such petition by the Board, it shall be forwarded to the Department which shall make an order fixing a time and place for hearing thereon, which shall not be less than ten days nor more than thirty days thereafter.

010.07B1 Notice of the filing of such petition and the time and place of hearing shall be served upon the permittee at least ten (10) days before such hearing.

010.08 When appropriate, the Attorney General upon the recommendation of the Board, shall initiate criminal charges against pharmacists, public health clinic administrators, or other persons who knowingly permit public health clinic workers to perform professional duties which require the expertise or professional judgment of a pharmacist.

010.09 Hearing Procedures. If the Department determines to deny an application for a drug dispensing permit or to revoke, suspend, or refuse renewal of a permit, it shall send to the applicant or permittee by certified mail, a notice setting forth the particular reasons for the determination.

010.09A The denial, suspension, revocation or refusal of renewal shall become final thirty (30) days after the mailing of the notice unless the applicant or permittee, within such thirty-day period, requests a hearing in writing.

010.09B The applicant or permittee shall be given a fair hearing before the Department and may present such evidence as may be proper.

010.09C On the basis of such evidence, the determination involved shall be affirmed or set aside, and a copy of such decision setting forth the finding of facts and the particular reasons upon which it is based shall be sent by certified mail to the permittee.

010.09D The decision shall become final thirty (30) days after a copy of such decision is mailed unless the applicant or permittee within such thirty-day period appeals the decision pursuant to Subsection 010.10 of these regulations.

010.09E The procedure governing hearings authorized by this section shall be in accordance with rules and regulations adopted and promulgated by the Department as 184 NAC 1.

010.09F A full and complete record shall be kept of all proceedings. Witnesses may be subpoenaed by either party and shall be allowed a fee at a rate prescribed by the rules and regulations adopted and promulgated by the Department. The proceedings shall be summary in nature and triable as equity actions. Affidavits may be received in evidence in the discretion of the Director of Health.

010.09G The Department shall have the power to administer oaths, to subpoena witnesses and compel their attendance, and to issue subpoenas duces tecum and require the production of books, accounts, and documents in the same manner and to the same extent as the district courts of the state. Depositions may be used by either party.

010.09H Upon the completion of any hearing, the Director shall have the authority through entry of an order to exercise in his or her discretion any or all of the following powers:

010.09H1 Issue a censure or reprimand against the permittee;

010.09H2 Suspend judgment;

010.09H3 Place the permittee on probation;

010.09H4 Place a limitation or limitations on the permit and upon the right of the permittee to dispense drugs or devices to the extent, scope, or type of operation, for such time, and under such conditions as the Director finds necessary and proper. The Director shall consult with the Board in all instances prior to issuing an order of limitation.

010.09H5 Impose a civil penalty not to exceed ten thousand (10,000) dollars. The amount of the civil penalty, if any, shall be based on the severity of the violation. If any violation is a repeated or continuing violation, each violation or each day a violation continues shall constitute a separate violation for the purpose of computing the applicable civil penalty, if any;

010.09H6 Enter an order of suspension of the permit;

010.09H7 Enter an order of revocation of the permit; and

010.09H8 Dismiss the action.

010.10 Appeals. Any applicant or permittee shall have the right of appeal from an order of the Department denying, revoking, suspending, or refusing renewal of a drug dispensing permit. The appeal shall be in accordance with the Administrative Procedure Act.

011 PROCEDURES FOR REINSTATEMENT OF DRUG DISPENSING PERMITS Moved to section 008 as modified

011.01 Reinstatement After Disciplinary Action. A drug dispensing permit which has been suspended or revoked for disciplinary action, may be reinstated by the Department upon the recommendation of the Board.

011.01A A public health clinic whose drug dispensing permit has been suspended for disciplinary action, shall be suspended for a definite period of time to be fixed by the director and shall be automatically reinstated upon the expiration of such period, if the current inspection fees have been paid.

011.01B A public health clinic whose drug dispensing permit has been revoked for disciplinary action shall be revoked permanently, except that at any time after the expiration of two (2) years, petition may be made for reinstatement.

011.01B1 The petitioner must submit:

011.01B1a A verified completed petition for reinstatement on a form provided by the Department, a copy of which is attached as Attachment F and incorporated in these regulations by this reference; and

011.01B1b The required fee.

012 PROCEDURES FOR PROCESSING A COMPLAINT. Any complaint filed against a public health clinic or any staff member, public health clinic worker, volunteer, or consultant in association with work performed under a drug dispensing permit shall be screened by the Department to determine its validity in accordance with procedures as prescribed in Neb. Rev. Stat. 71-168.01.

012.01 If the complaint is valid, the cost of investigating the complaint shall be based upon the actual costs incurred and shall be borne by the public health clinic.

012.02 If the complaint is found not to be valid, the cost of the investigation shall be paid from the Nebraska Pharmaceutical Fund.

013 GROUNDS FOR DENIAL, REVOCATION, SUSPENSION OR REFUSAL TO RENEW.

013.01 The Department shall deny any application for a drug dispensing permit when an applicant fails to meet the requirements in Section 003 and 004 of these regulations or is found to be in violation of any of the provisions of Subsection 013.03 of these regulations.

013.02 The Department shall refuse renewal of a drug dispensing permit if the permittee fails to meet the requirements specified in Section 005 of these regulations or is found to be in violation of any of the provisions in Subsection 013.03 of these regulations.

013.03 The Department may deny, refuse renewal of, suspend, or revoke a drug dispensing permit for any of the following grounds:

013.03A Conviction of permittee of any crime involving moral turpitude;

013.03B Obtaining a drug dispensing permit by false representation or fraud;

013.03C Operating a public health clinic with a drug dispensing permit without a consultant pharmacist responsible for the duties in Subsection 009.01 of these regulations;

013.03D Failure to pass an initial or annual inspection;

013.03E Failure to pay inspection costs;

013.03F Failure to pay any fee required by Sections 003 and 010 of these regulations;

013.03G Use of unauthorized persons in the dispensing or administering of drugs or devices;

013.03H The compounding and dispensing of drugs or devices or the filling of a prescription by a person other than a licensed pharmacist or by an intern in pharmacy, without the presence of and the immediate personal supervision of a licensed pharmacist except as provided in Neb. Rev. Stat. §71-1,147.33 or Sections 008, 009 and 010 of these regulations;

013.03I The dispensing of any drug or device not listed in the approved formulary or failure to provide patient information;

013.03J A conviction of a violation of Neb. Rev. Stat. §§ 71-1,142 to 71-1,147.61 and Section 010 of these regulations or of a felony or, if a natural person, the revocation or suspension of a drug dispensing permit;

013.03K Unprofessional conduct which shall include but not be limited to: Moved to section 010 as modified

013.03K1 Misrepresentation or fraud in the conduct of a public health clinic; Moved to section 010 as modified

013.03K2 Aiding or abetting an unlicensed person to practice pharmacy;

013.03K3 The 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; or Moved to section 010 as modified

013.03K4 The dispensing of 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; Moved to section 010 as modified

013.03L Violation of the rules and regulations governing the practice of pharmacy as adopted and promulgated under authority of Neb. Rev. Stat. §71-1,147.09 by the Department; and

013.03M Suggesting, soliciting, ordering, assisting, or abetting a pharmacist in the violation of any of the offenses set forth in Neb. Rev. Stat. §§71-147 and 71-148.

013.04 If the Department determines to deny, revoke, suspend, or refuse renewal of a drug dispensing permit, it shall send the applicant or permittee, by certified mail, a notice setting forth the particular reasons for the determination.

013.05 The denial, suspension, revocation, or refusal of renewal shall become final thirty (30) day after the mailing of the notice unless the applicant or permittee, within such thirty (30) day period, requests a hearing in writing.

013.06 The applicant or permittee shall be given a fair hearing before the Department and may present such evidence as may be proper. On the basis of such evidence, the determination involved shall be affirmed or set aside, and a copy of such decision setting forth the findings of facts and the particular reasons upon which it is based shall be sent by certified mail to the applicant or permittee.

013.07 The decision shall become final thirty (30) days after a copy of such decision is mailed unless the applicant or permittee within such thirty (30) day period appeals the decision pursuant to Neb. Rev. Stat. §71-1,147.12.

013.08 Hearings before the Department shall be conducted in accordance with Neb. Rev. Stat. Chapter 84, Article 9 and 184 NAC 1, the Rules of Practice and Procedure for the Department.