

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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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.

002 DEFINITIONS.

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.

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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.

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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.

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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.

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.

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.

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;

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;

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;

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;

004.01A13 A current copy of the policy and procedure manual which shall identify and locate at least the following:

004.01A13a Consultant pharmacist monthly inspection reports;

004.01A13b Labeling requirements;

004.01A13c Storage and security of drugs and devices;

004.01A13d Proper patient instruction;

004.01A13e Formulary;

004.01A13f Library resources;

004.01A13g Record keeping, to include the medical chart;

004.01A13h Drug recall procedures;

004.01A13i Policies for licensed or certified health care staff; and

004.01A13j Policies for public health clinic workers.

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.

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.

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%.

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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.

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;

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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.

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:

008.02A1a Procedures for dispensing initial prescriptions and authorized refills of oral contraceptives;

008.02A1b Procedures for dispensing approved drugs and devices;

008.02A1c Federal and State laws regarding drug dispensing;

008.02A1d Proper labeling of oral contraceptives and approved drugs and devices;

008.02A1e Proper record keeping of initial and refilled prescriptions;

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

008.02A1g Proper pharmacist referral;

008.02A1h Procedures for reaching the consultant or the on-call pharmacist;

008.02A1i Storage and security of approved formulary drugs and devices; and

008.02A1j Patient information.

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:

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:

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.

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.

008.03 Proficiency demonstration requirements. Following training, public health clinic workers must demonstrate proficiency as follows:

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

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.

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.

009 STANDARDS FOR THE DISPENSING OF LEGEND DRUGS AND DEVICES IN A PUBLIC HEALTH CLINIC WITH A DRUG DISPENSING PERMIT

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.

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

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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.

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

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009.04B The public health clinic worker only dispenses authorized refills of oral contraceptives.

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.

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.

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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.

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:

009.12A Unused portions of dispensed prescriptions;

009.12B Prescribed devices or products used upon or applied to the human body, except;

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

009.12B2 Those prescribed drugs which are voluntarily recalled by manufacturers or that are recalled by order of the Federal Food and Drug Administration.

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.

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.

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:

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.

009.15 Recordkeeping of Drugs and Devices Dispensed Pursuant to a Prescription

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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:

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.

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

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.

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

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

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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

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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

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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.

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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

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;

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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:

013.03K1 Misrepresentation or fraud in the conduct of a public health clinic;

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

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;

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.

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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.