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PHARMACIES

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CHAPTER 61-02-01
PHARMACY PERMITS

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61-02-01-01. Permit required.

No person, partnership, association, or corporation shall conduct a pharmacy in North Dakota without first obtaining a permit to do so from the board. A fee, set by the board but not to exceed that prescribed by statute, shall be charged for each permit.

1. Each physical location of a pharmacy shall have a separate pharmacy permit. A location is defined as being in the same building at the same physical address. Buildings connected by tunnels, skywalks, or other similar methods must be deemed separate physical locations.

2. Any pharmacy receiving a permit shall advise the board, when applying for the permit and when changes occur, of the name of the employees of the pharmacy who are:

   a. The pharmacist-in-charge of the pharmacy, who shall be a licensed pharmacist in North Dakota in good standing;

   b. All other licensed pharmacists who shall be licensed pharmacists in North Dakota in good standing;

c. All licensed pharmacy interns who shall be licensed pharmacy interns in North Dakota in good standing;

d. All registered pharmacy technicians who shall be registered pharmacy technicians in North Dakota in good standing; and

e. All supportive personnel permitted in the pharmacy area.

3. Nothing in this section prohibits a pharmacy with other than class F permit from delivering drugs or devices through the United States postal service or other parcel delivery service or hand delivery.

4. Classes of pharmacy permits are as follows:

a. Class A - Permit to conduct an outpatient pharmacy. These permits are issued to a pharmacy dispensing drugs or devices to the general public pursuant to a valid prescription.

b. Class B - Permit to conduct a hospital pharmacy. These permits are issued to a pharmacy dispensing drugs or devices to persons who are patients in a hospital, patients who are being discharged, or patients in emergency situations, pursuant to a valid prescription. These permits shall be issued to facilities licensed under North Dakota Century Code chapter 23-16 and shall be issued in the name of the facility.

c. Class C - Permit to conduct a sterile compounding pharmacy. These permits are issued to a pharmacy dispensing sterile injectable drug products and devices to the general public who are not patients within a facility with a class B pharmacy permit pursuant to a valid prescription.

d. Class D - Permit to conduct a long-term care pharmacy. These permits are issued to a pharmacy dispensing drugs and devices to residents of facilities licensed under North Dakota Century Code chapters 23-09.3 and 23-16 pursuant to a valid prescription which are not physically accessed by the general public.

e. Class E - Permit to conduct a nuclear pharmacy. These permits are issued to a pharmacy dispensing or providing diagnostic or therapeutic radioactive drugs or devices for administration to an ultimate user.

f. Class F - Permit to conduct a mail-order pharmacy. These permits are issued to a pharmacy dispensing drugs and devices to the general public exclusively through the United States postal service or other parcel delivery service pursuant to a valid prescription but which are not physically accessed by the general public.

g. Class G - Permit to conduct an out-of-state pharmacy. These permits are issued to any pharmacy operating outside the state of North Dakota which ships, mails, or delivers in any manner a dispensed prescription drug or legend device into North Dakota, which shall obtain and hold a pharmacy permit issued by the North Dakota state board of pharmacy and that part of the pharmacy operation dispensing the prescription for a North Dakota resident shall abide by state laws and rules of the board.

h. Class H - Permit to conduct a governmental agency pharmacy. This permit is issued to a pharmacy operated by the state of North Dakota, dispensing drugs and devices only to patients within correctional facilities or rehabilitation facilities, or for the purpose of teaching at institutions of higher learning, pursuant to a valid prescription.

i. Class I - Permit to conduct a research pharmacy. This permit is issued to a pharmacy in which scientific research is conducted under protocols established by an institutional

review board meeting federal drug administration guidelines. Pharmaceuticals on hand are incident to the research being conducted. Security and storage for pharmaceuticals must meet United States Pharmacopeia and board of pharmacy requirements. A specific application for a pharmacy permit must be made delineating the specific physical facility to be utilized.

j. Class J - Permit to conduct an office practice pharmacy. Any licensed pharmacist may practice in an office pharmacy setting where prescriptions are not routinely dispensed. If legend drugs or devices are maintained, a permit must be obtained by making application to the board of pharmacy delineating specific practice intentions and assuring the board that security and storage requirements are met for any legend drugs or pharmaceuticals on hand.

k. Class K - Permit to conduct telepharmacy. A pharmacy staffed by a registered pharmacy technician with access to its main pharmacy and registered pharmacists by computer link, videolink, and audiolink while open.

l. Class L - Permit for a dispensing device in a long-term care facility, retirement care, mental care, or other facility or institution that provides extended health care to residents. The dispensing device must be located in a facility defined in North Dakota Century Code chapter 50-10.1, as any assisted living facility, any skilled nursing facility, basic care facility, nursing home as defined in subsection 3 of the North Dakota Century Code section 43-34-01, or swing bed hospital approved to furnish long-term care services. The device must be under the control of a licensed pharmacist in the state of North Dakota.

5. Any applicable rule governing the practice of pharmacy shall apply to all permits under this section.

6. Operating in one class does not preclude permitting in another class. Pharmacies wishing to operate in more than one class shall apply on forms prescribed by the board, pay a fee set by the board, and comply with all rules for each class.

History: Effective October 1, 1999; amended effective January 1, 2004; July 1, 2011.
General Authority: NDCC 43-15-34
Law Implemented: NDCC 43-15-34

61-02-01-02. Application for permit.

Applications for permits and renewal of permits to conduct a pharmacy or drugstore shall be made in writing on such form or forms as the board may from time to time prescribe, and shall set forth information required by the board to enable it to determine if the pharmacy or drugstore will be conducted in full compliance with existing laws and with regulations established thereunder by the board of pharmacy. This information shall include:

1. Name and address of proposed pharmacy.

2. Name of current owner.

3. If applicant is a sole proprietor, evidence that owner is a registered pharmacist in good standing.

4. If applicant is a partnership, evidence that each active partner is a registered pharmacist in good standing, names of all partners and ownership interests of each, and copy of partnership agreement.

5. If applicant is a corporation, names of corporate officers, list of shareholders and shares of stock held by each, affidavit of stock ownership showing that a majority of the stock is owned

by registered pharmacists in good standing, actively and regularly employed in and responsible for the management, supervision, and operation of applicant pharmacy, copies where applicable of agreement to form corporation, articles of incorporation, certificate of incorporation, bylaws, employment agreements, financial records as they may pertain to stock ownership requirements, and any other corporate documents relating to ownership or control of applicant pharmacy or corporation, or both.

6. Leases on space to be occupied by applicant or permitholder.

7. Blueprints or drawings of floor plans and physical layout of pharmacy and space to be occupied by applicant.

8. Franchise or license agreements where applicable.

9. Names of registered pharmacists employed.

10. Name of pharmacist in charge.

11. Information showing that adequate technical equipment is maintained.

Documents to be provided herein shall include all changes and amendments. All changes and amendments in documents previously furnished to the board shall be promptly submitted to the board. An application for a renewal of a permit need not include documents previously furnished to the board except where the facts, information, or documents have been changed or amended and not previously furnished to the board. The board shall have the right to require that an applicant or permitholder furnish to the board current documents required hereunder, including all changes or amendments, at any time.

History: Amended effective August 1, 1983.
General Authority: NDCC 28-32-02, 43-15-10(9), 43-15-10(12), 43-15-10(14), 43-15-34, 43-15-35
Law Implemented: NDCC 28-32-03, 43-15-10(9), 43-15-10(12), 43-15-10(14), 43-15-34, 43-15-35

61-02-01-03. Pharmaceutical compounding standards.

The minimum standards and technical equipment to be considered as adequate shall include:

1. Definitions.

   a. "Active chemical or ingredient" refers to chemicals, substances, or other components of articles intended for use in the diagnostics, cure, mitigation, treatment, or prevention of diseases.

   b. "Aseptic processing" is the method of preparing pharmaceutical and medical products that involves the separate sterilization of the product and of the package, the transfer of the product into the container and closure of the container under ISO class 5 or superior conditions, and using procedures designed to preclude contamination of drugs, packaging, equipment, or supplies by micro-organisms during the process.

   c. "Beyond-use date" refers to the date placed on preparation label that is intended to indicate to the patient or caregiver a time beyond which the contents of the preparation are not recommended to be used. The beyond-use date is determined from the date and time compounding of the preparation is completed.

   d. "Component" is any ingredient used in the compounding of a drug product, including any that are used in its preparation, but may not appear on the labeling of such a product.

   e. "Compounded sterile preparation" (CSP) will include all of the following:

(1) Preparations prepared according to the manufacturer's labeled instructions and other manipulations when manufacturing sterile products that expose the original contents to potential contamination.

(2) Preparations containing nonsterile ingredients or employing nonsterile components or devices that must be sterilized before administration.

(3) Biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that possess either of the above two characteristics, and which include baths and soaks for live organs and tissues, implants, inhalations, injections, powders for injection, irrigations, metered sprays, and ophthalmic preparations.

f. "Compounder or compounding personnel" is the pharmacist or other licensed or registered health care professional responsible for preparing the compounded preparations.

g. "Compounding" is the preparation, mixing, assembling, packaging, and labeling of a drug or device in accordance to a licensed practitioner's prescription or medication order. Compounding does not include tablet splitting, reconstitution of oral or topical products as intended by the manufacturer, or repackaging of nonsterile dosage forms for redistribution, dispensing, or administration. Compounding includes:

(1) Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(2) The addition of one or more ingredients to a commercial product as a result of a licensed practitioner's prescription drug order.

(3) Preparation of drugs or devices for the purposes of, or as an incident to, research, teaching, or chemical analysis.

(4) Categories of compounding.

(a) Nonsterile simple. Should be conducted according to USP chapter 795.

(b) Sterile compounds. Risk levels of compounded sterile preparations. Risk levels are assigned according to the corresponding probability of contaminating a preparation with microbial organisms, spores, and endotoxins, or chemical and physical contamination such as foreign chemicals and physical matter. Preparations should be compounded according to USP chapter 797 based on the appropriate risk level.

(c) Radiopharmaceuticals. See article 61-05.

(d) Veterinary pharmaceuticals. Standards for veterinary pharmaceuticals are consistent with all parts of section 61-02-01-03.

h. "Compounding supervisor" is a person who supervises and is responsible for the compounding and dispensing of a nonsterile or sterile preparation. This may be the pharmacist on duty or the pharmacist-in-charge.

i. "Critical site" is a location that includes any component or fluid pathway surfaces (such as injection ports) or openings (such as opened ampules or needle hubs) exposed and at risk of direct contact with air, moisture, or touch contamination.

j. "Direct and contiguous compounding area" refers to the specific area where a compound is prepared.

k. "Disinfection" is the process by which the total number of micro-organisms is reduced to a safe level or eliminated by applying an agent to inanimate objects that destroys disease-causing pathogens or other harmful micro-organisms but may not kill bacterial and fungal spores.

l. "Hazardous drug" is one of those which studies in animals or humans indicate that exposures to them have a potential for causing cancer, development, or reproductive toxicity or harm to organs.

m. "ISO class" is a description of an atmospheric environment characterized by the number of particles of 0.5 microns or larger, within a cubic foot of air. "ISO class 5" atmospheric environment contains less than 100 particles, 0.5 microns or larger in diameter, per cubic foot of air.

n. "Media fill test" refers to tests used to validate aseptic techniques of compounding personnel and of processes that ensure the personnel and processes used are able to produce sterile products without microbial contamination. Testing uses a microbiological growth medium to substitute for actual drug product to simulate admixture compounding in determining the quality of a person's technique.

o. "NDC number" is the national drug code given to each drug separately and specifically approved by the food and drug administration for identification and reporting.

p. "Preparation" is a drug dosage form, dietary supplement, or a finished device. It contains one or more substances formulated for use on or for the patient or consumer.

q. "Primary engineering control (PEC)" refers to a device or room that provides an ISO class 5 or superior environment during the compounding process, including laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACIs).

r. "Product" is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the food and drug administration, accompanied by full prescribing information.

s. "Repackaging" is the transfer of an ingredient from one container to another.

t. "Risk levels" of CSPs determine the level assigned that represent the probability that it will be contaminated with microbial organisms, spores, endotoxins, foreign chemicals, or other physical matter.

u. "Seventy percent sterile isopropyl" or IPA is an antimicrobial used to clean surfaces used in sterile preparations.

v. "Stability" means the extent to which a preparation retains, with specified limits, and throughout its period of storage and use, the same properties and characteristics it possessed at the time of compounding.

w. "US pharmacopeia (USP)" is the book of official compendia of standards for the United States.

2. General compounding.

a. Responsibility of the compounder.

(1) Personnel engaging in compounding must be proficient, capable, and qualified to perform assigned duties in the compounding area while expanding the individual's knowledge of compounding through seminars or appropriate literature.

(2) Compounding personnel must be familiar with USP standards and North Dakota regulations, including:

(a) Certifying all prescriptions orders.

(b) Approving or rejecting all components, drug product containers, closures, in-process materials, and labeling ensuring preparations and ingredients are of acceptable strength, quality, and purity, with appropriate packaging.

(c) Preparing and reviewing all compounding records to assure that errors have not occurred in the compounding process and the finished product has expected qualities as well as implementing procedures to prevent cross-contamination.

(d) Assuring the proper maintenance, cleanliness, sanitization, and use of all equipment used in prescription compounding practice, including the direct and contiguous compounding area allowing for the compounding environment to be suitable for its intended purpose.

(e) Assuring that the drug product and components of drug products are not on the list of federally recognized drug products that have been withdrawn or removed from the market for public health reasons.

(3) Policies and procedures must be established concerning washing and donning the appropriate clothing specific to the type of process performed to protect the personnel from chemical exposures and prevent drug contamination.

b. Training. All compounding supervisors and all personnel involved in compounding must be well trained and must participate in current, relevant training programs. All training activities will be covered by standard operating procedures and must be properly documented. Steps in the training procedure include:

(1) Be familiar with pharmaceutical compounding and nonsterile compounding (USP 795), pharmaceutical compounding and sterile compounding (USP 797), hazardous drug compounding (USP 800), and pharmaceutical calculations in prescription compounding (USP 1160).

(2) Be familiar with all procedures relating to compounding specific to the individual's facility, equipment, personnel, compounding process, evaluation, packaging, storage, and dispensing.

(3) Compounding supervisors must be responsible to follow the instructions below to show that personnel are appropriately trained:

(a) Demonstrate compounding procedures to compounding personnel.

(b) Guide personnel through the compounding process with assistance.

(c) Observe personnel performing a compound without assistance but under supervision.

(d) Review the compound, correct mistakes, and answer questions concerning compounding and associated processes.

(e) Confirm verbal and functional knowledge of the personnel concerning compounding.

(f) Have personnel perform a compounding procedure without supervision, yet checking off the final preparation.

(g) If properly compounded and when satisfied, sign the documentation records confirming appropriate training.

(h) Continually monitor the work of the personnel, including calculations.

(4) The pharmacist on duty and the pharmacist-in-charge are ultimately responsible for the finished product.

c. Procedures and documentation. Procedures must be developed for the facility, equipment, personnel, preparation, packaging, and storage of the compounded preparation to ensure accountability, accuracy, quality, safety, and uniformity in compounding. This allows for a compounder, whenever necessary, to systematically trace, evaluate, and replicate the steps included throughout the preparation process of a compounded preparation.

d. Nonsterile drug compounding must meet the facility, equipment, packaging, storage, and beyond-use date standards set in USP chapter 795. Policies and procedures should be developed to ensure compliance with those standards.

e. Compounding controls for nonsterile preparations.

(1) The compounder must ensure that the written procedures for compounding are available electronically or in hard copy and assure the finished products have the correct identity, strength, quality, and purity.

(2) Procedures must be established that give a description of the following:

(a) Components and their amounts.

(b) Order of component additives.

(c) Compounding process.

(d) Drug product.

(e) Required equipment and utensils, including container and closure systems.

(3) The compounder will accurately weigh, measure, and subdivide all components as appropriate.

(a) The compounder must check and recheck each procedure at each point of the process to ensure that each weight or measure is correct.

(b) If a component is transferred from the original container to another, the new container must be identified with the component, name, weight or measure, the lot or control number, the expiration or beyond-use date, and the transfer date.

(4) The compounder must write procedures that describe the tests or examinations that prove uniformity and integrity of the compounded preparations.

(5) Control procedures must be established to monitor the output and validate the performance of compounding personnel that affect variability of final preparations, such as:

(a) Capsule weight variation.

(b) Adequacy of mixing to assure uniformity and homogeneity.

(c) Clarity, completeness, or pH of solutions.

(6) The compounder must establish an appropriate beyond-use date for each compounded preparation.

(7) Facilities engaging in compounding must have a specifically designated and adequate space for orderly compounding, including the placement and storage of equipment and materials.

f. Labeling of nonsterile preparations.

(1) The compounder's preparation label must contain all information required by North Dakota state law and accepted standards of practice found under chapter 61-04-06, prescription label requirements, plus the beyond-use date and assigned lot number.

(2) The compounder must label any excess compounded products so as to refer to the formula used.

(3) Preparations compounded in anticipation of a prescription prior to receiving a valid prescription should be made in a regularly used amount based on the history of prescriptions filled and they should be labeled with:

(a) Complete list of ingredients or preparation time and reference or established chemical name or generic name.

(b) Dosage form.

(c) Strength.

(d) Preparation date and time.

(e) Inactive ingredients.

(f) Batch or lot number.

(g) Assigned beyond-use date.

(h) Storage conditions.

(4) The compounder must examine the preparation for correct labeling after completion.

g. Records and reports for nonsterile preparations.

(1) Records must be maintained, including a hard copy of the prescription with formulation and compounding records.

(2) Adequate records of controlled substances used in compounds.

(3) All records must be kept for five years according to North Dakota state law and be available for inspection.

(4) Formulation record provides a consistent source document for preparing the preparation to allow another compounder to reproduce the identical prescription at a future date and must list:

(a) Name, strength, and dosage form of the preparation compounded.

(b) All ingredients and their quantities.

(c) Equipment needed to prepare the preparation, when appropriate.

(d) Mixing instructions including order of mixing, mixing temperatures, and other valid instructions, such as duration of mixing.

(e) Assigned beyond-use date.

(f) Container used in dispensing.

(g) Storage requirements.

(h) Any quality control procedures.

(5) Compounding record documents the actual ingredients in the preparation and the person responsible for the compounding activity and includes:

(a) Name and strength of the compounded preparation.

(b) The formulation record reference.

(c) Sources and lot numbers of the ingredients.

(d) Total number of dosage units compounded.

(e) Name of compounding personnel who prepared the preparation.

(f) The date of preparation.

(g) The assigned internal identification number, lot number, and prescription numbers.

(h) Assigned beyond-use date.

(i) Results of all quality control procedures.

(6) Temperature log records the daily monitoring of temperatures in the storage area specifically for the controlled room temperature, refrigerator, freezer, or incubator.

3. Nonsterile compounding. Compounders are to use the following steps to minimize error and maximize the prescriber's intent, specifics can be found in pharmaceutical compounding - nonsterile compounding (USP 795):

a. Judge the suitability of the prescription of the preparation in terms of safety and intended use.

b. Perform necessary calculations to establish the amounts of ingredients needed.

c. Identify equipment and utensils needed.

d. Don the proper attire and properly wash hands and arms.

e. Clean the compounding area and needed equipment.

f. Only one prescription can be compounded at a time in the specified compounding area.

g. Assess weight variation, adequacy of mixing, clarity, odor, color consistency, and pH as appropriate of the completed preparation.

h. Annotate the compounding and formulation records.

i. Label the prescription containers appropriately.

j. Sign and date the prescription or compounding record affirming that all procedures were carried out to ensure uniformity, identity, strength, quantity, and purity.

k. Thoroughly clean all equipment immediately when finished.

4. Compounding process for compounded sterile preparations. Compounders are to follow the USP chapter 797 standards and use the following steps to minimize error and maximize the prescriber's intent:

   a. Judge the suitability of the prescription for the compounded sterile preparation in terms of safety and intended use.

   b. Perform necessary calculations to establish the amounts of ingredients needed.

   c. Identify equipment and utensils needed for the preparation of the compounded sterile preparation.

   d. Sterile compounding areas and critical areas must be structurally isolated from other areas designated to avoid unnecessary traffic and airflow disturbances according to USP chapter 797, separate from nonsterile compounding areas, and restricted to qualified compounding personnel.

   e. Policies and procedures must be established in accordance with USP chapter 797 for personnel cleaning and garbing for protection and avoidance of containment.

   f. Clean and sanitize the compounding area and needed equipment according to USP chapter 797.

5. Facilities for sterile compounding should conform with USP chapter 797.

6. Equipment specific for sterile compounding should conform with USP chapter 797.

7. Poison record book and suitable prescription files.

8. Suitable current reference sources either in book or electronic data form (available in the pharmacy or online) which might include the United States Pharmacopeia and National Formulary, the United States Pharmacopeia Dispensing Information, Facts & Comparisons, Micro Medex, the ASHP Formulary, Clinical Pharmacology, or other suitable references determined by the board which are pertinent to the practice carried on in the licensed pharmacy.

9. Compounding for office use.

   a. It is acceptable to compound human drug products to be used by North Dakota practitioners in their office for administration to patients provided they are prepared by a facility licensed as an outsourcing facility in accordance to North Dakota Century Code section 43-15.3-13 or by a resident North Dakota pharmacy. It is acceptable for a North Dakota licensed pharmacy to obtain a compounded human drug from a licensed outsourcing facility and dispense it to a patient.

b. It is acceptable for any licensed pharmacy to compound veterinary drug products to be used by veterinarians in their office for administration to client's animals. These compounded office use products may be dispensed to clients for use in a single treatment episode, not to exceed a one hundred twenty-hour supply.

c. Sales to other pharmacies, veterinarians, clinics, or hospitals are manufacturing and are not allowed. It is the responsibility of the pharmacy and pharmacist involved in the compounding to ensure compliance with this section for the products they compound.

10. Compounding of hazardous drugs.

a. Hazardous drugs shall be prepared under conditions that protect the health care worker and other personnel in the preparation and storage areas according to USP chapter 800. Appropriate personnel protective equipment shall be worn when compounding hazardous drugs according to USP chapter 800.

b. Hazardous drugs shall be stored and prepared separately from other nonhazardous drugs in a manner to prevent contamination and personnel exposure according to USP chapter 800.

c. Hazardous drugs shall be handled by the pharmacy according to USP chapter 800.

d. All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs according to USP chapter 800.

History: Amended effective August 1, 1983; April 1, 1988; October 1, 1999; December 1, 2003; April 1, 2012; April 1, 2017; December 1, 2019; January 1, 2024.
General Authority: NDCC 43-15-10(9)(12)(14), 43-15-35(2), 43-15-36
Law Implemented: NDCC 43-15-10(9)(12)(14), 43-15-35(2), 43-15-36

61-02-01-04. Permit not transferable.

A permit registers the pharmacy to which it is issued at the location specified in the permit, and is not transferable. It is issued on the application of the owner, or the registered pharmacist in charge, on the sworn statement that the pharmacy will be conducted in accordance with the provisions of law. If it is desired to operate, maintain, open, or establish more than one pharmacy, separate applications shall be made and separate permits issued for each.

General Authority: NDCC 43-15-10(9), 43-15-34, 43-15-39
Law Implemented: NDCC 43-15-10(9), 43-15-34, 43-15-39

61-02-01-05. Change of ownership.

When a pharmacy changes ownership, the original permit becomes void and must be surrendered to the board, and a new permit secured by the new owner or owners. This is required even in case there is no change in the name of the pharmacy or in the registered pharmacist in charge of the pharmacy. The board shall be promptly notified of any change in ownership of a pharmacy. In the case of a corporation holding a pharmacy permit, the board shall be immediately notified at any time when a majority of the stock is not owned by registered pharmacists in good standing, actively and regularly employed in and responsible for the management, supervision, and operation of the pharmacy. In the case of a partnership holding a pharmacy permit, the board shall be notified as to the addition or removal of one or more partners in the partnership.

General Authority: NDCC 43-15-10(9), 43-15-35(5)
Law Implemented: NDCC 43-15-10(9), 43-15-35(5)

61-02-01-06. Affidavit of ownership.

An affidavit shall be filed each year with the application for renewal of a pharmacy permit, indicating in the case of a partnership, that each active member is a registered pharmacist, or in the case of a corporation, that the majority stock is owned by registered pharmacists in good standing, actively and regularly employed in and responsible for the management, supervision, and operation of the pharmacy.

General Authority: NDCC 43-15-10(9), 43-15-35(5)
Law Implemented: NDCC 43-15-10(9), 43-15-35(5)

61-02-01-07. Renewal of permits.

Each pharmacy permit shall expire on June thirtieth of each year, and shall be renewed annually by filing an application therefor, on or before June first of each year, together with a fee set by the board, but not to exceed that prescribed by statute.

General Authority: NDCC 43-15-10(9), 43-15-38
Law Implemented: NDCC 43-15-10(9), 43-15-38

61-02-01-08. Change of location.

Before a pharmacy changes the location of its business, it shall first submit to the board a new application for a permit, setting forth such changes, and shall submit therewith the information and documents required in an initial application for a permit. If the board approves the application, no additional fee shall be made for the new permit.

General Authority: NDCC 43-15-10(9), 43-15-10(11)
Law Implemented: NDCC 43-15-10(9), 43-15-10(11)

61-02-01-09. Permit for heirs at law of pharmacist.

The issuance of a permit to the heirs at law of a pharmacist shall not be refused on the grounds that such heirs at law are not registered pharmacists, provided assurance will be given that when the pharmacy is disposed of by the heirs at law of the registered pharmacist owner, it shall be sold only to a registered pharmacist or a corporation or partnership controlled by a registered pharmacist in North Dakota.

General Authority: NDCC 43-15-10(9)
Law Implemented: NDCC 43-15-10(9)

61-02-01-10. Pharmacist-in-charge - Requirement - Definition - Duties.

No permitholder shall conduct a pharmacy without a pharmacist-in-charge who shall be designated in the application for a pharmacy permit and each renewal of pharmacy permit. The term "pharmacist-in-charge" means a duly licensed pharmacist in North Dakota who has been so designated, and it shall be the pharmacist's duty and responsibility consistent with the accepted standards of professional conduct and practice and in compliance with all applicable laws and regulations to:

1. Establish for the employees of the pharmacy policies and procedures for the procurement, storage, compounding, and dispensing of drugs.

2. Supervise all of the professional employees of the pharmacy.

3. Supervise all of the nonprofessional employees of the pharmacy insofar as their duties relate to the sale or storage, or both, of drugs.

4. Establish and supervise the recordkeeping system for the purchase, sale, possession, storage, safekeeping, and return of drugs.

5. Notify the board immediately upon the pharmacist's knowledge that the pharmacist's services as pharmacist-in-charge have been or will be terminated.

General Authority: NDCC 43-15-10(9), 43-15-35(4)
Law Implemented: NDCC 43-15-10(9), 43-15-35(4)

61-02-01-11. Pharmacist-in-charge - Termination of service.

Each pharmacy shall notify the state board of pharmacy immediately upon knowledge of the termination of the services of the pharmacist-in-charge and further, shall immediately designate a successor pharmacist-in-charge and immediately notify the state board of pharmacy of such designation. The state board of pharmacy upon receiving such notice shall furnish the successor pharmacist-in-charge such form or forms as it may from time to time prescribe which form or forms must be completed by the successor pharmacist-in-charge and filed with the board within ten days after receipt.

General Authority: NDCC 43-15-10(9), 43-15-35(4)
Law Implemented: NDCC 43-15-10(9), 43-15-35(4)

61-02-01-12. Posting of permit.

Each pharmacy permit shall be posted and exposed in a conspicuous place in the pharmacy for which the permit has been issued.

General Authority: NDCC 43-15-10(9), 43-15-39
Law Implemented: NDCC 43-15-10(9), 43-15-39

61-02-01-13. Pharmacist on duty.

Each pharmacy shall have at least one registered pharmacist on duty and physically present in the pharmacy area at all times that the prescription area is open for the transaction of business.

History: Amended effective May 1, 1984.
General Authority: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)
Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-02-01-14. Limitation on rent.

Before a pharmacy permit is issued, in the case of a pharmacy leasing space, a copy of the lease agreement must be furnished to the board which must include rental terms and information. The lease rental amounts, less in-house sales and wholesale sales, may not exceed five percent of the total gross sales of the pharmacy, with the further provision that the landlord shall furnish all utilities including heat, electrical, and janitorial services, but not including telephone service. The board recognizes that the lease terms and rent will depend on the type of pharmaceutical services offered, and therefore, variations for rent may be granted by the state board of pharmacy.

History: Effective April 1, 1988; amended effective July 1, 1996.
General Authority: NDCC 28-32-02, 43-15-10(7)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36
Law Implemented: NDCC 28-32-03

61-02-01-15. Closing a pharmacy.

A permitholder shall follow these procedures to close a North Dakota licensed pharmacy:

1. Notify the state board of pharmacy at least thirty days in advance of the closing date.

2. Notify customers at least fifteen days in advance of the closing date and advise them where their records will be maintained.

3. Notify the drug enforcement administration (DEA) at least fourteen days in advance of the closing date.

4. At the closing date:

   a. Take an inventory of the pharmacy's controlled substances and maintain it for two years.

   b. Return the North Dakota pharmacy permit to the board.

   c. Cover all signage indicating "drugstore" or "pharmacy" until removed in a timely manner.

   d. Send the DEA certificate of registration and any used official order forms (DEA form-222) to the nearest DEA registration field office. The pharmacist should write or stamp the word "VOID" across the face of each official order form before returning them to the DEA.

   e. Notify the state board of pharmacy and the DEA as to where the controlled substances inventory and records will be kept and how the controlled substances were transferred or destroyed. Records involving controlled substances must be kept available for two years for inspection and copying. This requirement applies, even though the business has been discontinued.

History: Effective October 1, 2007.
General Authority: NDCC 43-15-10
Law Implemented: NDCC 43-15-10, 43-15-35

61-02-01-16. Transfer of controlled substances when selling a business.

The permitholder of a pharmacy discontinuing business shall notify the state board of pharmacy and the nearest DEA registration field office at least fourteen days before the date of the proposed transfer of controlled substances in connection with discontinuing the business, and provide the following information:

1. The name, address, and registration number of the pharmacy discontinuing business.

2. The name, address, and registration number of the pharmacy acquiring the business.

3. The date on which the controlled substances will be transferred.

History: Effective October 1, 2007.
General Authority: NDCC 43-15-10
Law Implemented: NDCC 43-15-10, 43-15-35

61-02-01-17. Identification.

All pharmacy employees shall wear a name badge while in the pharmacy, which clearly identifies the person's title.

History: Effective July 1, 2011.
General Authority: NDCC 43-15-10
Law Implemented: NDCC 43-15-10, 43-15-35

61-02-01-18. Policy and procedure manual required.

Each pharmacy must have a written or electronic and easily accessible policy and procedure manual to address all aspects of the pharmacy's operations. The policy and procedure manual must be

available for inspection. The policy and procedure manual must set forth in detail the objectives and operational guidelines of the pharmacy. The policy and procedure manual must be reviewed and revised or reaffirmed on an annual basis.

Inspection procedures, including:

1. Location of controlled substance records, including:

    a. Location of current biennial inventory;

    b. Wholesale records of receipt and sale of controlled substances;

    c. DEA 222 forms, both paper and electronic, executed or not;

    d. Information for running reports from the pharmacy computer system relative to dispensing of specific controlled substances; and

    e. Power of attorney forms if granted and termination forms if executed.

2. Location of most recent inspection forms by the state board of pharmacy, accreditation agencies, or the food and drug administration, if applicable.

History: Effective October 1, 2014.
General Authority: NDCC 28-32-02, 43-15-10(9), 43-15-10(12), 43-15-10(14)
Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)