May 2023

Chapter 61-01-01
Organization of Board

61-01-01-01 Organization of Board of Pharmacy

1. **History and functions.** The 1890 legislative assembly passed pharmacy practice legislation codified as North Dakota Century Code chapter 43-15. This chapter requires the governor to appoint a state board of pharmacy. The board is responsible for examining and licensing applicants for licensure as pharmacists, for issuing permits to operate pharmacies, and for regulating and controlling the dispensing of prescription drugs and the practice of pharmacy for the protection of the health, welfare, and safety of the citizens of the state. The board is to operate and maintain the state's prescription drug monitoring program.
2. **Board membership.** The board consists of seven members appointed by the governor. Five members of the board must be licensed pharmacists, one member must be a registered pharmacy technician, and one member must represent the public and may not be affiliated with any group or profession that provides or regulates any type of health care. Board members serve five-year terms, with one of the pharmacist's terms expiring each year. The term of the public member and registered pharmacy technician member will expire five years from May eighth in the year of their appointment.
3. **Executive director.** The executive director of the board is appointed by the board and is responsible for administration of the activities of the board.
4. **Inquiries.** Inquiries regarding the board may be addressed to the executive director:
   State Board of Pharmacy
   ~~P.O. Box 1354~~ 1838 E Interstate Ave Suite D
   Bismarck, ND ~~58502-1354~~ 58503
   ~~Street address - 1906 East Broadway Avenue~~ Web address - www.nodakpharmacy.com
   Telephone - 701-~~328-9535~~ 877-2404
   Fax - 701-~~328-9536~~877-2405

History: Amended effective August 1, 1983; November 1, 1985; October 1, 1987; February 1, 1993; April 1, 1994; January 1, 2000; January 1, 2004; April 1, 2010; October 1, 2019; January 1, 2024.
General Authority: NDCC 28-32-02.1
Law Implemented: NDCC 28-32-02.1

May 2023

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 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.
   b. 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 28-32-02, 43-15-10(9), 43-15-10(12), 43-15-10(14), 43-15-35(2), 43-15-35(3), 43-15-36

Law Implemented: NDCC 28-32-03, 43-15-10(9), 43-15-10(12), 43-15-10(14), 43-15-35(2),
43-15-35(3), 43-15-36

CHAPTER 61-02-07.1
PHARMACY TECHNICIAN

61-02-07.1-01. Purpose and scope.

1. The board of pharmacy is responsible for maintaining, continuing, and enhancing the development of the educational and professional role of the pharmacists for the protection of the health, welfare, and safety of the citizens of the state.
2. Current practice requires an expanding knowledge base for pharmacists to serve patients with appropriate counseling, advising, evaluating, and cost-effective pharmaceuticals.
3. To assist a pharmacist in technical services related to pharmaceutical product preparation and distribution, the need for a pharmacy technician is appropriate.

History: Effective October 1, 1993.
General Authority: NDCC 28-32-02, 43-15-10(12)(14)
Law Implemented: NDCC 28-32-03, 43-15-10(12)(14)

61-02-07.1-02. Definitions.

1. "Pharmacy Technician" means a person registered by the board of pharmacy who is employed by a pharmacy under the responsibility of the pharmacist-in-charge, or a staff pharmacist so designated by the pharmacist-in-charge, to assist in the technical services of preparing pharmaceuticals for final dispensing by a licensed pharmacist in compliance with subsection 4 of North Dakota Century Code section 43-15-01 and subsection 16 of North Dakota Century Code section 43-15-01.
2. "Pharmacy Technician in Training" is a person who is enrolled in an academic experiential rotation program accredited by the American Society of Health Systems Pharmacists (ASHP)/accreditation council for pharmacy education (ACPE) or in a similarly accredited ~~n~~ on-the-job self-instructional pharmacy technician study program under the supervision of a licensed pharmacist. A Pharmacy Technician in Training, as they progress through their training program, may perform any of the duties of a registered pharmacy technician at the discretion of the pharmacist in charge and the pharmacist supervising their training program unless otherwise specified.
3. "Supportive personnel" means a person other than a licensed pharmacist, pharmacy intern, or pharmacy technician who may be performing duties assigned by the pharmacist under direct supervision.

History: Effective October 1, 1993; amended effective July 1, 1996; January 1, 2024.
General Authority: NDCC 28-32-02, 43-15-10(12)(14)(19)
Law Implemented: NDCC 28-32-03

61-02-07.1-03. Educational preparation.

1. To be eligible to be registered by the board of pharmacy as a pharmacy technician the person must have completed one of the following requirements:
   a. Successful completion of an American society of health systems pharmacists accredited academic program.
   b. An American society of health systems pharmacists accredited on-the-job training program.
2. Technician certification:
   a. An applicant for registration as a pharmacy technician must have obtained certification by a national certification body approved by the board of pharmacy.
   b. A technician registered after August 1, 1995, must obtain certification by a national certification body approved by the board of pharmacy.
   c. The pharmacy technician certification board and national health career association are approved certification bodies.
   d. If a competency examination is developed by the national association of boards of pharmacy to foster transfer of registration between states, this will be accepted in lieu of certification.

History: Effective October 1, 1993; amended effective October 1, 2012; October 1, 2019.
General Authority: NDCC 28-32-02, 43-15-10(12)(14)(19)
Law Implemented: NDCC 43-15-10(12)(14)(19)

61-02-07.1-04. Ratio of pharmacists to pharmacy technicians.

The ratio of pharmacists to pharmacy technicians may not be greater than one to four (one pharmacist to four pharmacy technicians) in a retail and hospital setting. The ratio of pharmacists to pharmacy technicians may not be greater than one to five (one pharmacist to five pharmacy technicians) in a closed-door pharmacy that does not deal directly with patients. This ratio does not include other supportive personnel or interns.

History: Effective October 1, 1993; amended effective January 1, 2005; October 1, 2019.
General Authority: NDCC 28-32-02, 43-15-10(12)(14)
Law Implemented: NDCC 28-32-03, 43-15-10(12)(14)

61-02-07.1-05. Tasks pharmacy technicians may perform.

1. Under the responsibility of the pharmacist-in-charge or designated staff pharmacist the pharmacy technician may perform any service assigned by the pharmacist-in-charge in the preparation of pharmaceuticals to be dispensed by the pharmacist to a patient except as specified in section 61-02-07.1-06.
2. The pharmacist is legally responsible for all the pharmacy technician's activities and services performed.
3. The pharmacy technician may assess a patient receiving a refilled prescription on the need of the patient or their agent to have a consult with the pharmacist or pharmacy intern about the prescription.
   a. Assessment must include a visual display of the medication
   b. Asking appropriate open-ended questions on the medication and their applicable health condition.
   c. Any problematic responses must prompt the pharmacist to intervene with a consultation.

History: Effective October 1, 1993, amended effective July 1, 2017
General Authority: NDCC 28-32-02, 43-15-10(12)(14)
Law Implemented: NDCC 28-32-03, 43-15-10(12)(14)

61-02-07.1-06. Tasks pharmacy technicians may not perform. The pharmacy technician may not:

1. Evaluate the patient's profile relative to the pharmaceuticals that have or will be dispensed.
2. Consult with the patient concerning the utilization of their pharmaceuticals.
3. Make decisions that require a pharmacist's professional education, such as interpreting and applying pharmacokinetic data and other pertinent laboratory data or therapeutic values to design safe and effective drug dosage regimens.
4. Engage in the practice of pharmacy, except as authorized by a licensed pharmacist, as permitted by North Dakota law and rules adopted by the board.

History: Effective October 1, 1993; amended effective July 1, 1996; October 1, 1999.
General Authority: NDCC 28-32-02, 43-15-10(12)(14)(19)
Law Implemented: NDCC 28-32-03

61-02-07.1-07. Pharmacy technician registration requirements.

1. A pharmacy technician must register with the board of pharmacy on an annual basis.
2. The pharmacy technician will be assigned a registration number.
3. The board of pharmacy must provide the pharmacy technician with an annual registration card and pocket identification card.
4. The pharmacy technician certificate and annual registration card, or copy thereof, must be ~~displayed and visible to the public~~ available or on file in the pharmacy where the pharmacy technician is employed.
5. The pharmacy technician must wear a name badge while in the pharmacy which clearly identifies the person as a "pharmacy technician".
6. Pharmacy technicians shall identify themselves as pharmacy technicians on all telephone conversations while on duty in the pharmacy.
7. The northland association of pharmacy technicians shall appoint annually three of their members as an advisory committee to the board of pharmacy.
8. Every registered pharmacy technician, within fifteen days after changing address or place of employment, shall notify the board of the change or make the necessary update on the board's website. The board shall make the necessary changes in the board's records.
9. A pharmacy technician having passed the reciprocity examination of the national association of boards of pharmacy, or any other examination approved by the board, shall be granted reciprocity and shall be entitled to registration as a registered pharmacy technician in North Dakota.
10. A pharmacy technician registered by the board may use the designations "registered pharmacy technician" and "R. Ph. Tech.".
11. A pharmacy technician holding a certificate of registration as a pharmacy technician in North Dakota may go on inactive status and continue to hold a certificate of registration in North Dakota, provided that the technician on inactive status may not practice within North Dakota. A pharmacy technician on inactive status will not be required to meet the continuing education requirements of the board under chapter 61-02-07.1. In order for a pharmacy technician to change an inactive status registration to an active status of registration, the pharmacy technician must complete ten hours of approved pharmacy technician continuing education and thereafter comply with the continuing education requirements of the board.

Evidence of current certification by a national certification body approved by the board of pharmacy meets this requirement.

12. In the case of loss or destruction of a certificate of registration, a duplicate can be obtained by forwarding the board an affidavit setting forth the facts.
13. Provisional registration for a member of the military or military spouse as defined in North Dakota Century Code section 43-51-01.
    a. A provisional registration may be granted upon application for registration if the individual holds a registration or license as a pharmacy technician in another state and has worked under such license or registration for at least two of the last four years.
    b. This provisional registration must be without fee until one year after the first renewal period has passed. This allows a maximum of two years without payment of a registration or renewal fee.
    c. If the applicant does not meet all the criteria for registration under North Dakota laws or rules, the applicant must complete those qualifications before the applicant's provisional registration period expires to continue registration.

History: Effective October 1, 1993; amended effective July 1, 1996; April 1, 2020; January 1, 2022; January 1, 2024
General Authority: NDCC 28-32-02, 43-15-10(12)(14)(19)
Law Implemented: NDCC 28-32-03, 43-51-11, 43-51-11.1

61-02-07.1-08. Supportive personnel. Any duty that is not required to be performed by a registered pharmacist, registered pharmacy intern, or by a pharmacy technician may be performed by other employees of the pharmacy.

History: Effective October 1, 1993.
General Authority: NDCC 28-32-02, 43-15-10(12)(14)
Law Implemented: NDCC 28-32-03, 43-15-10(12)(14)

61-02-07.1-09. Penalties for violation of rule regulating pharmacy technicians. The registration of any pharmacy technician violating drug laws or rules may be revoked by the board of pharmacy. Pharmacists or pharmacies violating drug laws or rules may be subject to the penalties of North Dakota Century Code section 43-15-42.1.

History: Effective October 1, 1993.
General Authority: NDCC 28-32-02, 43-15-10(12)(14)
Law Implemented: NDCC 28-32-03, 43-15-10(12)(14)

61-02-07.1-10. Pharmacy technician continuing education.

1. Each pharmacy technician shall complete at least ten hours of approved pharmacy technician continuing education every year as a condition of renewal of a registration as a pharmacy technician in North Dakota.
2. There may be no carryover or extension of continuing education units with the exception that continuing education units obtained twelve months prior to the beginning of each annual reporting period may be used in the current annual reporting period which begins March first of each year and ends the last day of February, or the previous reporting period. However, they may not be counted as credit in both reporting periods. The failure to obtain the required ten hours of continuing education by the renewal date may result in a suspension for a minimum of thirty days, or a maximum of the period ending the date the continuing education is completed.
3. Pharmacy technicians shall maintain their own records. The records must be maintained for a two-year period.

4. The requirements of this section do not apply to a pharmacy technician applying for a first renewal of a registration.
5. A pharmacy technician registered with the board may make application to the board for a waiver of compliance with the pharmacy technician continuing education requirements and may be granted an exemption by the board.
6. Upon request of the board, proof of compliance must be furnished to the board.

History: Effective July 1, 1996; amended effective January 1, 2005; January 1, 2010; October 1, 2019.
General Authority: NDCC 28-32-02, 43-15-10(12)(14)(19)
Law Implemented: NDCC 28-32-03

61-02-07.1-11. Pharmacy technician in training. A pharmacy technician in training must be designated as a pharmacy technician in training and will be allowed to practice the professional duties of a registered pharmacy technician as determined by the pharmacist-in-charge and the supervising licensed pharmacist. Upon receipt of a request to have a person designated a pharmacy technician in training from a pharmacist-in-charge, the board, if appropriate, shall register the person so enrolled as a pharmacy technician in training. The maximum amount of time to be registered as a technician in training is two years unless an extension is granted.

History: Effective July 1, 1996; amended effective January 1, 2005.
General Authority: NDCC 28-32-02, 43-15-10(12)(14)(19)
Law Implemented: NDCC 28-32-03

61-02-07.1-12. Technicians checking technicians. Activities allowed by law to be performed within a licensed pharmacy by a registered pharmacy technician in the preparation of a prescription or order for dispensing or administration may be performed by one registered pharmacy technician, who may be a technician-in-training and verified by another registered pharmacy technician who may not be a technician in training, working in the same licensed pharmacy, under the following conditions:

1. The licensed pharmacy where the work is being conducted has policies and procedures specifically describing the scope of the activities to be verified through this practice, included in the policy and procedure manual required under section 61-02-01-18.
   a. Training for the specific activity is reflected in a written policy.
   b. A record of the individuals trained is maintained in the pharmacy for two years.
2. The pharmacy has a continuous quality improvement system in place to periodically verify the accuracy of the final product, including:
   a. Recording any quality related events leading up to the final dispensing or administration of the drug prepared.
   b. Recording any errors which actually reach the patient as a result of these activities.
   c. Specific limits of acceptable quality related event levels before reassessment is required.
   d. Consideration must be made for high-risk medications on the institute for safe medication practices (ISMP) list and specific monitoring, review, and quality assurance parameters must be instituted if any of these products are included in the pharmacy's technicians-checking-technicians program.
3. Any error must trigger pharmacist review of the process. This review and subsequent recommendations must be documented.
4. The pharmacy has a system in place to review all quality related events and errors recorded and takes corrective action based on the information to reduce quality related events and eliminate errors reaching the patient.

5. As always, the pharmacist-in-charge and the permitholder are jointly responsible for the final product dispensed or released for administration from the pharmacy.

History: Effective January 1, 2009; amended effective October 1, 2014; January 1, 2024.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 28-32-03

61-02-07.1-13. Pharmacy technician reinstatement. If a registered pharmacy technician fails to pay the fee for a renewal registration within the time required, the executive director of the board shall cancel the registration for nonpayment. Upon application, the delinquent registrant may procure a renewed registration once the payment of, back registration fees, late fees, up to a maximum of 5 years and proof of ten hours of continuing pharmaceutical education obtained within the past year are submitted, evidence of current certification by a national certification body approved by the board of pharmacy meets this requirement, provided there have been no disciplinary actions involved with the registration and the board is satisfied that the applicant is a proper person to receive the same.

History: Effective January 1, 2011; amended effective January 1, 2024.
General Authority: NDCC 28-32-02, 43-15-10(12)(14)(19)
Law Implemented: NDCC 28-32-03, 43-15-10(12)(14)(19)

May 2023

CHAPTER 61-03-01
LICENSURE OF PHARMACISTS

Section
61-03-01-01 Applications
61-03-01-02 Approved Schools
61-03-01-03 Score Required
61-03-01-04 Licensure Without Examination
61-03-01-05 Cancellation of Certificates [Repealed]
61-03-01-06 Duplicate Certificate
61-03-01-07 Posting of Certificate
61-03-01-08 Foreign Graduates
61-03-01-09 Inactive Status
61-03-01-10 Reinstatement Procedures

61-03-01-01. Applications. All applicants for licensure by examination as pharmacists must appear in person before the board of pharmacy at a meeting scheduled for examination of applicants for licensure. ~~Applications must be in the hands of the secretary of the board three days before the examination.~~ All applications must be accompanied by affidavits ~~from former employers~~ of graduation and hours of internship, showing that the applicant has met the requirements ~~had the experience required under a licensed pharmacist~~, as required by North Dakota Century Code section 43-15-15.

History: Amended effective January 1, 2024

General Authority: NDCC 43-15-19
Law Implemented: NDCC 43-15-19

61-03-01-02. Approved schools. ~~The board of pharmacy designates as approved schools~~

1. All colleges of pharmacy which are members of the American association of colleges of pharmacy or maintain standards equivalent to those required for membership in that association, and have been accredited by the accreditation council for pharmacy education.
2. All schools of pharmacy accredited by the Canadian Council for Accreditation of Pharmacy Programs (CCAPP).

History: Amended effective October 1, 2007; January 1, 2024.
General Authority: NDCC 43-15-15
Law Implemented: NDCC 43-15-15

61-03-01-03. Score required. An applicant for licensure as a pharmacist in North Dakota by examination or license transfer ~~reciprocity~~ must obtain a passing score ~~of seventy-five~~ in any written, oral, or practical laboratory examination required by the board.

History: Amended effective August 1, 1983; June 1, 1986; January 1, 2024.
General Authority: NDCC 28-32-02, 43-15-10(3)(12)(14), 43-15-19
Law Implemented: NDCC 28-32-03, 43-15-10(3)(12)(14), 43-15-19

61-03-01-04. Licensure transfer.

1. An applicant seeking licensure by licensure transfer or reciprocity must secure and file an electronic license transfer application ~~blank~~ from the national association of boards of pharmacy. This board will license applicants by reciprocity if they possess the requirements in effect in North Dakota at the time the candidates were licensed by examination in other

states. The applicant must pass the North Dakota law examination and pay the appropriate fees to obtain licensure.

2. Provisional licensure for a member of the military or military spouse as defined in North Dakota Century Code 43-51-01.
   a. A provisional license may be granted upon application for license if the individual holds a license as a pharmacist in another state and has worked under such license or registration for at least two of the last four years.
   b. This provisional license shall be without fee until one year after the first renewal period has passed. This allows a maximum of two years without payment of a registration or renewal fee.
   c. The provisional licensee has three months to successfully pass the multistate pharmacy jurisprudence examination.
3. The provisional licensee must apply and complete all requirements of the electronic license transfer program of the national association of boards of pharmacy
4. An applicant who holds a pharmacy license in Canada that is in good standing and meets all of the following:
   a. The applicant has passed the NAPLEX or both part I and part II of the Pharmacy Examining Board of Canada (PEBC) Pharmacists Qualifying Examination.
   b. The applicant completed educational requirements for a pharmacist license from a school of pharmacy accredited by ACPE or accredited by the Canadian Council for Accreditation of Pharmacy Programs (CCAPP).
   c. If the applicant held a pharmacist license for 1 year in Canada, they have acquired a minimum of 1,500 hours of pharmacy practice either through an approved internship or hours engaged in the practice as a pharmacist.
   d. The applicant must pass the North Dakota law examination and pay the appropriate fees to obtain licensure.

History: Amended effective April 1, 2016, April 1, 2020, January 1, 2022; January 1, 2024
General Authority: NDCC 28-32-02, 43-15-22
Law Implemented: 43-51-11, 43-51-11.1

61-03-01-05. Cancellation of certificates. [Repealed effective January 1, 2006.]

61-03-01-06. Duplicate certificate. In case of a loss or destruction of a certificate, a duplicate can be obtained by forwarding to the secretary an affidavit setting forth the facts in the case. The fee for a duplicate certificate is five dollars.

General Authority: NDCC 43-15-10
Law Implemented: NDCC 43-15-21

61-03-01-07. Posting of certificate. Each ~~pharmacist shall post the~~ pharmacist's certificate or renewal thereof must be available or on file ~~in a conspicuous place~~ in the pharmacy in which the pharmacist is practicing the pharmacist's profession.

History: Amended effective January 1, 2024

General Authority: NDCC 43-15-10(9)
Law Implemented: NDCC 43-15-10(9), 43-15-25

61-03-01-08. Foreign graduates. Any applicant who is a graduate of a school or college of pharmacy located outside the United States, which has not been recognized and approved by the board, but who is otherwise qualified to apply for a license to practice pharmacy in this state, shall be deemed to have satisfied the requirements of subsection 3 of North Dakota Century

Code section 43-15-15 by verification to the board of the applicant's academic record and the applicant's graduation and by meeting such other requirements as this board may establish from time to time. Each such applicant shall have the foreign pharmacy graduate examination committee (FPGEC) certification (which certification is hereby recognized and approved by the board) awarded by the national association of boards of pharmacy. The FPGEC certification includes the test of English as a foreign language and the test of spoken English (which examinations are hereby recognized and approved by the board) given by the educational testing service as a prerequisite to taking the licensure examination provided for in North Dakota Century Code section 43-15-19.

History: Effective August 1, 1983; amended effective January 1, 2006.
General Authority: NDCC 28-32-02, 43-15-10(2)(3)(12)(14), 43-15-15(4)
Law Implemented: NDCC 28-32-03, 43-15-10(2)(3)(12)(14), 43-15-15(4)

61-03-01-09. Inactive status. Any pharmacist holding a certificate of licensure as a pharmacist in North Dakota may go on inactive status and continue to hold a certificate of licensure in North Dakota, provided that the pharmacist on inactive status may not practice pharmacy within North Dakota. A pharmacist on inactive status may not be required to meet the requirements of continuing pharmaceutical education as required by North Dakota Century Code section 43-15-25.1 or rules of the boards under chapter 61-03-04. In order for a pharmacist to change an inactive status certificate of licensure to an active status of licensure, the pharmacist will have to complete ~~internship hours and~~ continuing education hours as determined by the board, based on the length of time of inactive status, and then must comply with continuing pharmaceutical education requirements of the board and state of North Dakota thereafter.

History: Effective April 1, 1988; amended effective January 1, 2005; January 1, 2024.
General Authority: NDCC 28-32-02, 43-15-10(2)(12)(14), 43-15-15, 43-15-25.1
Law Implemented: NDCC 28-32-02, 43-15-10(2)(12)(14), 43-15-15, 43-15-25.1

61-03-01-10. Reinstatement procedures. ~~If a licensed pharmacist in this state fails to pay the fee for a renewal of a license within the time required, the director of the board shall mail the pharmacist a notice, addressed to the pharmacist's last-known place of residence, notifying the pharmacist of failure to obtain a renewal license. The delinquent license holder, within sixty days after the notice is mailed, may procure a renewal license upon the payment of a renewal fee to be set by the board not to exceed two hundred dollars. If the license holder fails to have a license renewed within sixty days after the notice is mailed, the original or renewal license, as the case may be, becomes void and the registry thereof must be canceled. The board, on application of the delinquent license holder and upon the payment of all unpaid fees, may authorize the issuance of a new license without examination, if it is satisfied that the applicant is a proper person to receive the same. The board may require reexamination or completion of internship and continuing education hours as determined by the board.~~ If a licensed pharmacist fails to pay the fee for a renewal of a license within the time required, the executive director of the board shall cancel the license for nonpayment. Upon application, the delinquent licensee may procure a renewed license once the payment of all back licensure fees and proof of fifteen hours of continuing pharmaceutical education obtained within the past year are submitted, provided there have been no disciplinary actions involved with the licensee and the board is satisfied that the applicant is a proper person to receive the same.

History: Effective January 1, 2005. Amended effective January 1, 2024
General Authority: NDCC 28-32-02, 43-15-10(2)(12)(14), 43-15-15, 43-15-25.1
Law Implemented: NDCC 43-15-26

July 2023

CHAPTER 61-04-10
CLIA WAIVED LABORATORY TESTS

Section

61-04-10-01. Definitions. For purposes of this chapter:

1. "CLIA" means the federal Clinical Laboratory Improvement Act of 1988, as amended.
2. "OSHA" means the federal occupational safety and health administration.
3. ~~"Portfolio review" means a review by the board of a pharmacist's records of training logs, control testing logs, and records of patient tests performed to determine that a pharmacist is continuously and consistently providing a service in a quality and competent manner.~~

History: Effective December 1, 1999; amended effective April 1, 2016; January 1, 2024.
General Authority: NDCC 28-32-02, 43-15-10
Law Implemented: NDCC 43-15-25.3

61-04-10-02. Education requirements for pharmacists or pharmacy technicians to perform CLIA waived laboratory tests. A pharmacist and each pharmacy technician delegated must meet the following requirements in order to perform CLIA waived laboratory tests authorized by North Dakota Century Code section 43-15-25.3 or added to the list as allowed by section 61-04-10-06:

1. Successfully complete training and education that incorporates, at a minimum:
   a. Infection control;
   b. OSHA requirements;
   c. Proper technique to collect laboratory specimens;
   d. Recognized screening and monitoring values;
   e. Quality control; and
   f. The manufacturers' instructions for the waived tests being performed.
2. ~~Obtain and recertify the CLIA waived certificate every two years.~~

History: Effective December 1, 1999; amended effective April 1, 2016; January 1, 2024.
General Authority: NDCC 28-32-02, 43-15-10
Law Implemented: NDCC 43-15-25.3

61-04-10-03. Minimum quality standards required. Pharmacists performing CLIA waived laboratory tests must meet the following standards:

1. Develop and maintain a policy and procedure manual that includes the following areas:
   a. Quality control;
   b. Infection control;
   c. Hazardous waste disposal;
   d. Recordkeeping; and
   e. Test result reporting.

History: Effective December 1, 1999; amended effective April 1, 2016.
General Authority: NDCC 28-32-02, 43-15-10
Law Implemented: NDCC 43-15-25.3

61-04-10-04. Proper CLIA registration. The pharmacist-in-charge of a licensed pharmacy performing tests or any pharmacist operating in a facility not licensed by the board is responsible for ensuring that the location ~~pharmacy performing the CLIA waved test~~ has a current ~~proper~~ CLIA waived certificate.

History: Effective December 1, 1999; amended effective April 1, 2016; January 1, 2024.
General Authority: NDCC 28-32-02, 43-15-10
Law Implemented: NDCC 43-15-25.3

61-04-10-05. Notification of the board of pharmacy. The pharmacist-in-charge of a licensed pharmacy that has obtained a CLIA certificate or any pharmacist operating in a facility not licensed by the board of pharmacy must notify the board prior to the initial performance of any CLIA waived tests.
History: Effective December 1, 1999; amended effective April 1, 2016.
General Authority: NDCC 28-32-02, 43-15-10

Law Implemented: NDCC 43-15-25.3

61-04-10-06. Exempt tests and methods. An individual licensed or registered by the board, performing the following food and drug administration-waived tests and using the following methods, is exempt from the provisions of North Dakota Century Code chapter 43-48:

1. Total cholesterol, HDL cholesterol, LDL cholesterol, and triglycerides test by any accepted method.
2. Any of the following tests by nonautomated or automated urinalysis by dipstick:
    a. Bilirubin.
    b. Blood.
    c. Glucose.
    d. Ketone.
    e. Leukocyte.
    f. Nitrate.
    g. Potential of hydrogen (pH).
    h. Protein.
    i. Specific gravity.
    j. Urobilinogen.
3. Fecal occult blood by any accepted method.
4. Ovulation test by visual color comparison.
5. Qualitative urine pregnancy test by visual color comparison.
6. Erythrocyte sedimentation rate by any accepted nonautomated method.
7. Whole blood glucose by any accepted single analyte method.
8. Spun microhematocrit by any accepted method.
9. Hemoglobin by single analyte instrument or manual copper sulfate method.
10. Any of the following tests by immunoassay using a rapid test device that detects antibodies or antigens:
    a. Helicobacter pylori.
    b. Influenza.
    c. Mononucleosis.
    d. Streptococcus group A.

e. Hepatitis C virus.
f. Respiratory syncytial virus.

11. Prothrombin time international normalized ratio by mechanical endpoint.
12. Antibodies to human immunodeficiency virus types 1 and 2.
13. Nicotine or cotinine test by urine.
14. Thyroid stimulating hormone test by blood.
15. Bone mass and bone mineral density test by any accepted method.
16. Drug screening tests by urine.

History: Effective April 1, 2016; amended effective January 1, 2024.
General Authority: NDCC 28-32-02, 43-15-10
Law Implemented: NDCC 43-15-25.3

61-04-10-07. Delegation to Registered Pharmacy Technicians. Under the responsibility of the pharmacist-in-charge or pharmacist, a registered pharmacy technician may assist in performing CLIA waived laboratory tests. The registered pharmacy technician must have met the education requirements in section 61-04-10-02. The responsible pharmacist may not delegate the interpretation of the result of a CLIA waived test or clinical education of the patient to the registered pharmacy technician.

History: Effective January 1, 2024.
General Authority: NDCC 28-32-02, 43-15-10
Law Implemented: NDCC 43-15-25.3

CHAPTER 61-04-12
LIMITED PRESCRIPTIVE AUTHORITY FOR ~~NALOXONE~~ OPIOID ANTAGONISTS

Section
61-04-12-01 Definitions
61-04-12-02 Pharmacists Furnishing Opioid Antagonists

61-04-12-01. Definitions. For purposes of this chapter:

1. "Opioid-related drug overdose" means a condition including extreme physical illness, decreased level of consciousness, respiratory depression, coma, or death resulting from the consumption or use of an opioid or another substance with which an opioid was combined. This would include an overdose that requires medical assistance or a coroner, clinical suspicion for drug overdose (respiratory depression, unconsciousness, altered mental status), and either a urine toxicology screen positive for opiates or negative urine toxicology screen without other conditions to explain the clinical condition.
2. "Patient" means both an individual who is at risk of opioid overdose and a person who is not at risk of opioid overdose but who may be in a position to assist another individual during an overdose who has received patient information.
3. "Patient information" means the information provided to the patient on drug overdose prevention and recognition, opioid antidote dosage and administration, the importance of calling 911, care for the overdose victim after administration of the overdose antidote, and other issues as necessary.

History: Effective April 1, 2016.
General Authority: NDCC 28-32-02, 43-15-10
Law Implemented: NDCC 23-01-42, 43-15-10(23**)**

61-04-12-02. Pharmacists furnishing ~~naloxone~~ opioid antagonists.

1. Protocol.
   a. Pharmacists are authorized to furnish ~~naloxone~~ opioid antagonist drug therapy solely in accordance with the written protocol for ~~naloxone~~ opioid antagonist drug therapy approved by the board.
   b. Any pharmacist exercising prescriptive authority for ~~naloxone~~ opioid antagonist drug therapy shall maintain a current copy of the written protocol for ~~naloxone~~ opioid antagonist drug therapy approved by the board.
2. Procedure. When a patient requests ~~naloxone~~ an opioid antagonist, or when a pharmacist in his or her professional judgment decides to advise of the availability and appropriateness of ~~naloxone~~ an opioid antagonist, the pharmacist shall complete the following steps:
   a. Screen for the following conditions:
      (1) Whether the potential recipient currently uses or has a history of using illicit or prescription opioids (if yes, skip to subdivision b and continue with procedure);
      (2) Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids (if yes, continue with procedure); and
      (3) Whether the person to whom the ~~naloxone~~ opioid antagonist would be administered has a known hypersensitivity to ~~naloxone~~ the opioid antagonist (if yes, do not furnish).
   b. Provide training in opioid overdose prevention, recognition, response, and administration of the antidote ~~naloxone~~ opioid antagonist.
   c. When ~~naloxone~~ an opioid antagonist is furnished:

(1) The pharmacist shall provide the patient with appropriate patient information and counseling on the product furnished, including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. A pharmacist furnishing ~~naloxone~~ an opioid antagonist drug therapy may not permit the patient to whom the drug is furnished to waive the patient information required by the board.
(2) The pharmacist shall provide the patient with any resources and referrals to appropriate resources if the patient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.
(3) The pharmacist shall answer all questions the recipient may have regarding ~~naloxone~~ an opioid antagonist.

3. Authorized drugs.
   a. Prescriptive authority is limited to ~~naloxone~~ all opioid antagonists and includes any device approved for the administration of ~~naloxone~~ an opioid antagonist.
   b. Those administering ~~naloxone~~ an opioid antagonist should choose the route of administration based on the formulation available, how well they can administer it, the setting, and local context.
4. Education and training. Prior to furnishing ~~naloxone~~ an opioid antagonist, pharmacists who participate in this protocol shall successfully complete a minimum of one hour of an approved continuing education program specific to the use of ~~naloxone~~ an opioid antagonist, or an equivalent curriculum-based training program completed in a board-recognized school of pharmacy.
5. Records. The prescribing pharmacist must generate a written or electronic prescription for any ~~naloxone~~ opioid antagonist dispensed and the pharmacist shall record themselves as the prescriber or the protocol practitioner if appropriate. Documentation shall be made in a medication record for the patient. The prescription shall be kept on file and maintained for five years as required in North Dakota Century Code section 43-15-31.
6. Notification. If the patient is the potential individual to whom the ~~naloxone~~ opioid antagonist will be administered, the pharmacist shall notify the patient's primary care provider of any drugs and devices furnished or enter the appropriate information in a record system shared with the primary care provider.
   If the patient does not have a primary care provider, the pharmacist shall provide a written record of the drugs and devices furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

History: Effective April 1, 2016; Amended effective January 1, 2024.
General Authority: NDCC 28-32-02, 43-15-10
Law Implemented: NDCC 23-01-42, 43-15-10(23)