CHAPTER 61-02-07.1
PHARMACY TECHNICIAN

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 must be displayed and visible to the public 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. 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 "RPhTech".
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.
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 current members of the military or their spouses.

    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 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. If the applicant does not meet all the criteria for registration under North Dakota laws or rules, they must complete those qualifications before their provisional registration period expires in order to continue registration.

History: Effective October 1, 1993. Amended effective January 1, 2020
General Authority: NDCC 28-32-02, 43-15-10 (12) (19)
Law implemented: 43-51-11, 43-51-11.1

CHAPTER 61-03-01
LICENSURE OF PHARMACISTS

61-03-01-04 Licensure transfer

1. An applicant seeking licensure by licensure transfer or reciprocity must secure and file an 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 current members of the military or their spouses.

    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 3 months to successfully pass the MPJE examination.

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

CHAPTER 61-04-08
LIMITED PRESCRIPTIVE PRACTICES

Section
61-04-08-01 Purpose
61-04-08-02 Definitions
61-04-08-03 Eligibility and Approval
61-04-08-04 Procedures
61-04-08-05 Initiation of Drug Therapy
61-04-08-06 Modification of Drug Therapy
61-04-08-07 Form

61-04-08-01. Purpose. The purpose of these rules is to implement limited prescriptive practices provisions of the North Dakota Century Code.

History: Effective December 1, 1996.
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4
Law Implemented: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

61-04-08-02. Definitions. For purposes of this chapter:

1. "Collaborative agreement" means the written document signed by a practitioner and a pharmacist which describes the limited prescribing authority granted the pharmacist under North Dakota Century Code section 43-15-31.4.
2. "Immediate notification" means interactive two-way communication between the pharmacist and practitioner within twenty-four hours of the initiation or modification of drug therapy, unless specific reference is made in the collaborative agreement to situations in which a notification time limit of up to seventy-two hours is appropriate.
3. "Initiate drug therapy" means to begin administering for the first time a prescribed drug therapy for treating a patient with an existing diagnosis. A licensed practitioner shall make any diagnosis required.
4. "Medical record" means a written record of clinical care developed and maintained by a patient's practitioner which contains information and data about a patient's condition sufficient to justify the diagnosis and subsequent treatment. The record must contain further appropriate information as described in section 33-07-01.1-20.
5. "Modify drug therapy" means to change, within the same therapeutic class of drugs, a specific drug, the dosage, or route of delivery of a drug currently being administered for an existing diagnosis.
6. "Practitioner" means a licensed physician or advanced practice registered nurse.
7. "Supervision" means the active role taken by the practitioner to oversee the pharmacist throughout the provision of drug therapy to patients under the terms of a collaborative agreement.

History: Effective December 1, 1996; amended effective December 1, 2003; April 1, 2016.
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4
Law Implemented: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

61-04-08-03. Eligibility and approval.

1. A practitioner and a pharmacist who are licensed and practicing their respective professions in this state are eligible, provided the conditions of this section and any applicable statutes are met, to enter into the collaborative agreement allowing the pharmacist to provide prescription drug therapy to patients.
2. The practitioner and the pharmacist must have access to the patient's appropriate medical records. The care provided to the patient by the pharmacist must be recorded in the patient's medical records and communicated to the practitioner.
3. The collaborative agreement may be between a medical director and pharmacist-in-charge. The medical director and pharmacist-in-charge shall report to the respective board of any practitioner and pharmacist covered under the agreement.
4. Each individual collaborative agreement must be reviewed by the board of medicine or the board of nursing and the board of pharmacy, and will not become effective until the respective boards grant approval and notify the parties. Each agreement must be reviewed at least every four years or when modifications to the scope of the pharmacist's prospective practices are proposed by the parties, and must receive continued approval from both boards in order remain in effect. Removal or addition of either practitioners or pharmacists involved in the agreement shall be communicated to all respective boards. Unless deemed necessary, a change in personnel does not necessitate board approval of the collaborative agreement.
5. A collaborative agreement may be terminated by any of the involved boards for good cause, including adverse action taken against either licensee. Noncompliance with the terms of these rules or of a collaborative agreement may be considered evidence of unprofessional conduct by any of the involved boards.
6. Either party of a collaborative agreement may terminate the agreement at will by notifying either board of their desire to do so.
7. Neither party to a collaborative agreement may seek to gain personal financial benefit by participating in any incentive-based program that influences or encourages therapeutic or product changes.

History: Effective December 1, 1996; amended effective April 1, 2016.
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4
Law Implemented: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

61-04-08-04. Procedures. A practitioner who has signed an approved collaborative agreement with a pharmacist shall remain responsible for the care of the patient following initial diagnosis, and for the supervision of the pharmacist as prescriptive authority is exercised. The practitioner shall remain available to receive immediate notification from the pharmacist regarding prescriptive drug therapy being provided. The parties may modify as necessary, within the practice guidelines described in the collaborative agreement, their relationship in the joint provision of care to each patient as the requirements of the patient or drug therapy change.

History: Effective December 1, 1996; amended effective April 1, 2016.
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4
Law Implemented: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

61-04-08-05. Initiation of drug therapy. To initiate drug therapy, a pharmacist must hold a valid North Dakota pharmacist license and have a collaborative agreement with the treating practitioner. The pharmacist must provide immediate notification to the practitioner when the pharmacist initiates drug therapy.

History: Effective December 1, 1996; amended effective April 1, 2016.

General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4
Law Implemented: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

61-04-08-06. Modification of drug therapy.

1. To modify drug therapy, a pharmacist must hold a valid North Dakota pharmacist license and have a collaborative agreement with the treating practitioner. A pharmacist may modify drug therapy as warranted to assure an appropriate course of treatment for the patient. The pharmacist must provide immediate notification to the practitioner when the pharmacist modifies drug therapy.
2. The practitioner and pharmacist entering into a collaborative agreement must have indicated on the form the scope and authority to be exercised by the pharmacist and the type or class of drugs or drug therapy to be utilized or prohibited under the agreement. Authority to prescribe schedule II drugs may not be delegated to a pharmacist. The parties may also indicate the type of medical diagnoses to be included or excluded within the collaborative relationship.
3. The current medical record of each patient receiving drug therapy must be readily accessible to the pharmacist and practitioner. The pharmacist, unless the practitioner directs otherwise, shall provide timely documentation and indications for all drug therapies initiated or modified by the pharmacist as part of the medical record.
4. Contingency treatment should be addressed for treating allergic or acute adverse drug reactions.

History: Effective December 1, 1996; amended effective April 1, 2016.
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4
Law Implemented: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

61-04-08-07. Form.

1. The collaborative agreement form utilized under this section is attached as an appendix to these rules as approved by the board of medicine, board of nursing, and board of pharmacy. Upon request, a board shall supply a copy of the rules and form to any interested party.
2. A copy of each collaborative agreement and subsequent amendments approved by the boards shall remain on file with the boards. Each party shall retain the original or a copy of the agreement and amendments, and either party shall provide a copy to a facility within which an agreement is operative.
3. Either board may disseminate a current listing of the individual parties who are practicing under an approved collaborative agreement.
4. More details may be provided. Further stipulations or details shall be supplied on a separate page.

History: Effective December 1, 1996; amended effective April 1, 2016.
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4
Law Implemented: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

CHAPTER 61-04-11
ADMINISTRATION OF MEDICATIONS AND IMMUNIZATIONS

Section
61-04-11-01 Definitions
61-04-11-02 Qualifications Established to Obtain Certificate of Authority
61-04-11-03 Procedures to Obtain Certificate of Authority
61-04-11-04 Requirements of Physician or Nurse Practitioner Order for a Pharmacist to Administer Injections
61-04-11-05 Requirements of Written Protocol
61-04-11-06 Requirements of Records and Notifications
61-04-11-07 Location of Administration by Injection
61-04-11-08 Policy and Procedural Manual

61-04-11-01. Definitions. For purposes of this chapter:

1. "Authorized pharmacist" means a pharmacist who has successfully completed an appropriate ~~a board-approved course of~~ study or training pertaining to the ~~injectable~~ administration of drugs and maintains continuing competency according to the standard of care ~~rules adopted by the board~~.
2. "~~Certificate of~~ authority" means designation on an active pharmacist license that a pharmacist is providing administrations and has attested they are knowledgeable about and meet the requirements in NDCC 43-15.31.5 and this chapter. ~~documentation provided by the board to an authorized pharmacist, which must be displayed in the pharmacy at which the pharmacist is practicing.~~
3. "Written protocol" means a standing medical order between a duly licensed ~~physician or nurse~~ practitioner and an authorized pharmacist which contains information required by board rules.

History: Effective May 1, 2002; amended effective January 1, 2020.
General Authority: NDCC 43-15-10
Law Implemented: NDCC 43-15-10, 43-15-31.5

61-04-11-02. Qualifications established to obtain ~~certificate of~~ authority. A pharmacist must attest to possessing the following qualifications in order to obtain ~~a certificate of~~ authority from the board:

1. Obtain and maintain a license to practice pharmacy issued by the North Dakota state board of pharmacy;
2. Successfully complete the educational requirements set forward in 43-15.31.5 according to the administrations that a pharmacist intends to perform. The educational requirements may be obtained through their ACPE accredited Doctoral of Pharmacy program in which they are or will complete. Educational requirements may also be obtained through training received after graduation and should be sufficient to ensure any intended administrations can be provided competently to meet the standard of care. ~~a board-approved twenty-hour course of study and examination pertaining to the administration of medications by injection, which includes the current guidelines and recommendations of the centers for disease control and prevention. The course of study must be administered by an approved provider and consist of study material and hands-on training in techniques for administering injections. The course must require testing and completion with a passing score. The provider of the course of study shall provide successful participants with a certificate of completion. A copy of said~~

~~certificate must be mailed to the state board of pharmacy offices and placed in the pharmacist's permanent file. The course of study must include, at a minimum:~~

~~a. Basic immunology, including the human immune response;~~

~~b. The mechanism of immunity, adverse effects, dose, and administration schedule of available vaccines;~~

~~c. Vaccine-preventable diseases;~~

~~d. Current immunization guidelines and recommendations of the centers for disease control and prevention;~~

~~e. Vaccine storage and management;~~

~~f. Management of adverse events due to the administration of medications by injection, including identification, appropriate response, documentation, and reporting;~~

~~g. Patient education on the need for immunizations;~~

~~h. Informed consent;~~

~~i. Physiology and techniques for subcutaneous, intradermal, and intramuscular injection; and~~

~~j. Recordkeeping requirements established by law and rules or established standards of care;~~

3. Obtain and maintain current certification in cardiopulmonary resuscitation or basic cardiac life support;
4. Complete an ~~application~~ attestation process adopted by the board and, upon any request, provide required documentation; and
5. Maintain continuing competency to retain the ~~certificate of~~ authority according to the pharmacist's standard of care. ~~A minimum of six hours of the thirty-hour requirement for continuing education, every two years, must be dedicated to this area of practice.~~

History: Effective May 1, 2002.amended effective January 1, 2020
General Authority: NDCC 43-15-10
Law Implemented: NDCC 43-15-10, 43-15-31.5

61-04-11-03. Procedures to obtain certificate of authority. ~~An authorized pharmacist shall provide the board with a copy of a certificate of completion from a board-approved course, a copy of current certification in cardiopulmonary resuscitation or basic cardiac life support, and other information required on a form supplied by the board. If requirements are met, the board shall issue a certificate of authority that shall be valid for two years. In order to renew the certificate, the pharmacist shall submit evidence of six hours of continuing education dedicated to this area of practice.~~

~~**History:** Effective May 1, 2002.~~
~~**General Authority:** NDCC 43-15-10~~
~~**Law Implemented:** NDCC 43-15-10, 43-15-31.5~~

61-04-11-04. Requirements of ~~physician or nurse~~ practitioner order for a pharmacist to administer injections. The order must be written, received electronically or if received orally be reduced to writing, and must contain at a minimum the:

1. Identity of the ~~physician or nurse~~ practitioner issuing the order;
2. Identity of the patient to receive the injection;
3. Identity of the medication or vaccine, and dose, to be administered; and
4. Date of the original order and the dates or schedule, if any, of each subsequent administration.

History: Effective May 1, 2002; amended effective January 1, 2005. January 1, 2020
General Authority: NDCC 43-15-10

Law Implemented: NDCC 43-15-10, 43-15-31.5

61-04-11-05. Requirements of written protocol. A ~~physician or nurse~~ practitioner may prepare a written protocol governing the administration of medications ~~by injection~~ with an authorized pharmacist for a specific period of time or purpose. The written protocol may be valid for a time period not to exceed two years, subject to earlier withdrawal by the physician or nurse practitioner. The protocol must contain the:

1. Identity of the participating ~~physician or nurse~~ practitioner and the pharmacist;
2. Identity of the ~~immunization or vaccination~~ drug which may be administered;
3. Identity of the patient or groups of patients to receive the authorized drug ~~immunization or vaccination~~;
4. Identity of the authorized routes and sites of administration allowed;
5. Identity of the course of action the pharmacist shall follow in the case of reactions following administration;

~~6. Identity of the location at which the pharmacist may administer the authorized immunization or vaccination~~; and

6.~~7.~~ Recordkeeping requirements and procedures for notification of administration.

History: Effective May 1, 2002; amended effective January 1, 2020.
General Authority: NDCC 43-15-10
Law Implemented: NDCC 43-15-10, 43-15-31.5

61-04-11-06. Requirements of records and notifications. A pharmacist administering ~~by injection~~ shall meet the following recordkeeping and notification requirements:

1. Notification of administration must be made to the ordering physician or nurse practitioner and other authorities as required by law and rule. Notification may be through inclusion of the record in the patient's medical record or by submission to the North Dakota immunization Information System (NDIIS).
   a. When administration has occurred pursuant to an order, the pharmacist shall notify the ordering physician or nurse practitioner within forty-eight hours of the identity of the patient, identity of the medication or vaccine administered, route of administration site of the administration, dose administered, and date of administration and the disposition of any adverse events or reactions experienced by the patient.
   b. When administration has occurred pursuant to a written protocol, the pharmacist shall notify the participating physician or nurse practitioner within fourteen days of the identity of the patient, identity of the medication or vaccine administered, site of the administration, dose administered, and date of administration and the disposition of any adverse events or reactions experienced by the patient.
   c. In the case of immunizations and vaccinations, the pharmacist shall also provide notification to the physician or nurse practitioner of the manufacturer and lot number of the product administered.
2. Every record, including notification, which is required to be made under this section, must be kept by the administering pharmacist and by the pharmacy when in legal possession of the drugs administered for at least two years from the date of administration. Records of administration must contain all information required in subsection 1, plus the name of the ordering physician or nurse practitioner. Records of administration by order must be by patient name and, in the case of administration by written protocol, records may be maintained in roster form.

History: Effective May 1, 2002; amended effective January 1, 2020.
General Authority: NDCC 43-15-10
Law Implemented: NDCC 43-15-10, 43-15-31.5

61-04-11-07. Location of administration by injection. Pharmacists may administer medications ~~by injection within a licensed North Dakota pharmacy or~~ at ~~a~~ any location within North Dakota or may be limited to those specifically identified in a written protocol. The location ~~in the pharmacy~~ must:

1. Ensure privacy;
2. Be maintained to promote an aseptic environment;
3. Have adequate telecommunications devices to summon aid and communicate emergency situations; and
4. Have adequate equipment and supplies to respond to adverse events and emergency situations.

History: Effective May 1, 2002; amended effective January 1, 2020.
General Authority: NDCC 43-15-10
Law Implemented: NDCC 43-15-10, 43-15-31.5

61-04-11-08. Policy and procedural manual. The pharmacy shall maintain a policy and procedural manual, with a section related to the administration of medications ~~by injection~~, in compliance with section 61-02-01-18.

History: Effective May 1, 2002; amended effective October 1, 2014; January 1, 2020.
General Authority: NDCC 43-15-10
Law Implemented: NDCC 43-15-10, 43-15-31.5