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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 "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.
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 <u>member of the military or</u> 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<u>; October 1, 2021</u>

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

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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 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

History: Amended effective April 1, 2016, April 1, 2020, October 1, 2021
General Authority: NDCC 28-32-02, 43-15-22
Law Implemented: 43-51-11, 43-51-11.1

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CHAPTER 61-04-04
UNPROFESSIONAL CONDUCT

Section
61-04-04-01 Definition of Unprofessional Conduct

61-04-04-01. Definition of unprofessional conduct. The definition of "unprofessional conduct" for purposes of subdivision i of subsection 1 of North Dakota Century Code section 43-15-10 for disciplinary purposes includes, but is not limited to, the following:

1. The violating or attempting to violate, directly, indirectly, through actions of another, or assisting in or abetting the violation of, or conspiring to violate, any provision or term of North Dakota Century Code chapter 43-15, the Prescription Drug Marketing Act, the Robinson-Patman Act, or of the applicable federal and state laws and rules governing pharmacies or pharmacists.
2. Failure to establish and maintain effective controls against diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels as provided by state or federal laws or rules.
3. Making or filing a report or record which a pharmacist or pharmacy knows to be false, intentionally or negligently failing to file a report or record required by federal or state law, or rules, willfully impeding or obstructing such filing, or inducing another person to do so. Such reports or records include only those which the pharmacist or pharmacy is required to make or file in the capacity as a licensed pharmacist or pharmacy.
4. Being unable to practice pharmacy with reasonable skill and safety by reason of illness, use of drugs, narcotics, chemicals, or any other type of material, or as a result of any mental or physical condition. A pharmacist affected under this subsection shall at reasonable intervals be afforded an opportunity to demonstrate that the pharmacist can resume the competent practice of pharmacy with reasonable skill and safety to the pharmacist's customers.
5. Knowingly dispensed a prescription drug after the death of a patient.
6. Using a facsimile machine to circumvent documentation, authenticity, verification, or other standards of pharmacy practice.
7. Billing or charging for quantities greater than delivered, or for a brand when a generic is dispensed.
8. Submits fraudulent billing or reports to a third-party payor of prescription charges.
9. Refuses to provide information or answer questions when requested to do so by the patient, which affect the patient's use of medications prescribed and dispensed by the pharmacy.
10. Does not address or attempt to resolve and document a possible prescription error or situation of potential harm to the patient when apparent or should have been apparent to the pharmacist.
11. Does not attempt to affect the possible addiction or dependency of a patient to a drug dispensed by the pharmacist, if there is reason to believe that patient may be so dependent or addicted.
12. The assertion or inference in a public manner of material claims of professional superiority in the practice of pharmacy that cannot be substantiated.
13. The publication or circulation of false, misleading, or otherwise deceptive statements concerning the practice of pharmacy.
14. Refusing to compound and dispense prescriptions that may reasonably be expected to be compounded or dispensed in pharmacies by a pharmacist.

15. Participation in agreements or arrangements with any person, corporation, partnership, association, firm, or others involving rebates, kickbacks, fee-splitting, or special charges in exchange for professional pharmaceutical services, including, but not limited to, the giving, selling, donating, or otherwise furnishing or transferring, or the offer to give, sell, donate, or otherwise furnish or transfer money, goods, or services free or below cost to any licensed health care facility or the owner, operator, or administrator of a licensed health care facility as compensation or inducement for placement of business with that pharmacy or pharmacist. Monetary rebates or discounts which are returned to the actual purchaser of drugs as a cost-justified discount or to meet competition are permitted if the rebates of discounts conform with other existing state and federal rules and regulations.
16. Discriminating in any manner between patients or groups of patients for reasons of religion, race, creed, color, sex, age, or national origin.
17. Disclosing to others the nature of professional pharmaceutical services rendered to a patient without the patient's authorization or by order or direction of a court or as otherwise permitted by law. This does not prevent pharmacies from providing information copies of prescriptions to other pharmacies or to the person to whom the prescription was issued and does not prevent pharmacists from providing drug therapy information to physicians for their patients.
18. Improper advertising. Prescription drug price information may be provided to the public by a pharmacy, if all the following conditions are met: No representation or suggestion concerning the drug's safety, effectiveness, or indications for use, is made. No reference is made to controlled substances listed in schedules II-V of the latest revision of the Federal Controlled Substances Act, North Dakota Uniform Controlled Substances Act, and the rules of the state board of pharmacy.
19. Failure to report to the prescription drug monitoring program as required by North Dakota Century Code chapter 19-03.5.
20. Failure to comply with the reporting requirement of North Dakota Century Code section 43-15-42.3, including:
    a. Actions that affect the licensee's or registrant's practice privileges in a facility.
    b. Actions that result in the loss of the licensee's or registrant's employment or membership in a professional organization due to alleged incompetence, negligence, unethical or unprofessional conduct, or physical, mental, or chemical impairment.
    c. Actions based on a professional liability claim against the licensee or registrant, such as an adverse judgment or settlement, a refusal to issue or renew coverage, or a cancellation of coverage.
    d. Actions resulting in the loss of the licensee's or registrant's authorization to practice by any state or jurisdiction.
    e. Conviction of the licensee or registrant of any misdemeanor or felony in this or any other state, territory, or jurisdiction.
21. Notwithstanding any other provision, a practitioner who diagnoses a sexually transmitted disease, such as chlamydia, gonorrhea, or any other sexually transmitted infection, in an individual patient may prescribe or dispense, and a pharmacist may dispense, prescription antibiotic drugs to that patient's sexual partner or partners, without there having been an examination of that patient's sexual partner or partners.
22. <u>Improper marketing. Utilizing an entity for the purpose of soliciting prescriptions from a consumer, patient or provider without the involvement of a pharmacist at the pharmacy intervening with the patient to determine clinical appropriateness of any additional prescription.</u>

Interpretation of this definition of unprofessional conduct is not intended to hinder or impede the innovative practice of pharmacy, the ability of the pharmacist to compound, alter, or prepare medications, subsequent to a practitioner's order for the appropriate treatment of patients. Further, it is not intended to restrict the exercise of professional judgment of the pharmacist when practicing in the best interest of the pharmacist's patient.

History: Effective November 1, 1991; amended effective December 1, 2003; October 1, 2007; January 1, 2009; October 1, 2021

General Authority: NDCC 28-32-02, 43-15-10(1)(i)(12)(14)

Law Implemented: NDCC 28-32-02

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CHAPTER 61-04-11
ADMINISTRATION OF MEDICATIONS AND IMMUNIZATIONS

61-04-11-01. Definitions.

For purposes of this chapter:

1. "Authorized pharmacist" means a pharmacist who has successfully completed an appropriate study or training pertaining to the administration of drugs and maintains continuing competency according to the standard of care.
2. "Qualified Pharmacy Technician" means a registered pharmacy technician who has successfully completed an appropriate study or training pertaining to the administration of injections and maintains continuing competency.
3. "Authority" means designation on an active pharmacist license that a pharmacist is providing administrations and has attested the pharmacist is knowledgeable about and meet the requirements in North Dakota Century Code section 43-15-31.5 and this chapter.
4. "Written protocol" means a standing medical order between a duly licensed practitioner and an authorized pharmacist which contains information required by board rules.

History: Effective May 1, 2002; amended effective April 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 authority.

A pharmacist must attest to possessing the following qualifications in order to obtain 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 forth in North Dakota Century Code section 43-15-31.5 according to the administrations that a pharmacist intends to perform. The educational requirements may be obtained through the pharmacist's accreditation council for pharmacy education accredited doctor of pharmacy program in which the pharmacist is or will complete. Educational requirements also may 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;
3. Obtain and maintain current certification in cardiopulmonary resuscitation or basic cardiac life support;
4. Complete an attestation process adopted by the board and, upon any request, provide required documentation; and
5. Maintain continuing competency to retain the authority according to the pharmacist's standard of care.

History: Effective May 1, 2002; amended effective April 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.

Repealed effective April 1, 2020.

61-04-11-04. Requirements of 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 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; April 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 practitioner may prepare a written protocol governing the administration of medications 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 practitioner. The protocol must contain the:

1. Identity of the participating practitioner and the pharmacist;
2. Identity of the drug which may be administered;
3. Identity of the patient or groups of patients to receive the authorized drug;
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. Recordkeeping requirements and procedures for notification of administration.

History: Effective May 1, 2002; amended effective April 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 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 immunization information system.
   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 April 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 at any location within North Dakota or may be limited to those specifically identified in a written protocol. The location 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 April 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, in compliance with section 61-02-01-18.
History: Effective May 1, 2002; amended effective October 1, 2014; April 1, 2020.
General Authority: NDCC 43-15-10
Law Implemented: NDCC 43-15-10, 43-15-31.5

61-04-11-09. Qualified pharmacy technician administration of medications

An authorized pharmacist may delegate the administration of a subcutaneous or intramuscular injectable medication to a qualified pharmacy technician given the following:

1. The medication administration has been ordered by the supervising authorized pharmacist and the pharmacist is readily and immediately available to the qualified pharmacy technician.
2. The qualified technician has completed a practical training program that is accredited by an Accreditation Council for Pharmacy Education (ACPE) provider. This training program must include hands on injection technique and the recognition and treatment of emergency reactions to vaccines.
3. The qualified technician maintains a continuing competency on injections of medications which are expected to be performed.

4. The qualified technician has and maintains a current certification in cardiopulmonary resuscitation or basic cardiac life support.
5. The authorized pharmacist maintains the responsibility for all administrations which are delegated to a qualified pharmacy technician. This involves but is not limited to recordkeeping, adverse event reporting, and ensuring the pharmacy technician remains qualified.

History: Effective October 1, 2021
General Authority: NDCC 43-15-10
Law Implemented: NDCC 43-15-10, 43-15-31.5

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CHAPTER 61-04-14
LIMITED PRESCRIPTIVE AUTHORITY FOR IMMUNIZATIONS

Section
61-04-14-01 Definitions
61-04-14-02 Ordering and Administration of immunization

61-04-14-01. Definitions. For purposes of this chapter:

1. "ACIP" means the Center for Disease Control advisory committee on immunization practices.
2. "Authorized Pharmacist" means a pharmacist who has successfully completed an appropriate study or training pertaining to the administration of drugs and maintains continuing competency according to the standard of care.
3. "Immunization" has the same meaning as, and shall be used interchangeable with, the term "vaccine"
4. "Statewide Protocol" refers to protocols developed by Board for the purpose of an authorized pharmacist ordering and administrating immunizations.

History: Effective October 1, 2021.
General Authority: NDCC 28-32-02, 43-15-10
Law Implemented: NDCC 23-01-42, 43-15-10(24)

61-04-14-02. Ordering and Administration of immunization.

1. Authorized Immunizations authorized. The immunizations authorized to be ordered and administered pursuant to a statewide protocol to patients ages 3 or older shall include:
   a. An immunization recommended by ACIP in its approved vaccination schedule for adults
   b. An immunization for influenza
   c. An immunization recommended by CDC for international travel
   d. A Tdap (tetanus, diphtheria, acellular pertussis) vaccination in a booster application
   e. Any other emergency immunization in response to a public health emergency
2. Authorized pharmacist. An authorized pharmacist must be meet the standards in section 61-04-11-02 to obtain and maintain authority to administer immunizations.
3. Assessment. An authorized pharmacist shall assess a patient for appropriateness of receiving a vaccine pursuant to ordering and administering a vaccine pursuant to the statewide protocol.
4. Verification and reporting. Prior to ordering and administration of an immunization pursuant to a statewide protocol, the authorized pharmacist shall consult and review the statewide immunization registry or heath information network. The Authorized Pharmacist or their designee must report any immunization ordered and administered to the patient's primary health care provider and the state immunization registry. If the patient does not have a primary health care provider, the pharmacist may provide the patient with a record of the vaccine administered.
5. Records. The prescribing pharmacist must maintain records of all immunizations ordered and administered through the statewide protocol. Informed consent must be documented in accordance with the statewide protocol. Records shall be maintained at least 5 years from date of administration.

History: Effective October 1, 2021.
General Authority: NDCC 28-32-02, 43-15-10
Law Implemented: NDCC 23-01-42, 43-15-10(24)

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CHAPTER 61-04-15
LIMITED PRESCRIPTIVE AUTHORITY FOR TOBACCO CESSATION THERAPIES

Section
61-04-15-01 Definitions
61-04-15-02 Ordering of Tobacco Cessation Therapies

61-04-15-01. Definitions. For purposes of this chapter:

1. "ACPE" means the Accreditation Council for Pharmacy Education.
2. "Authorized Pharmacist" means a pharmacist who has successfully completed an appropriate study or training to meet the requirements in this rule.
3. "Statewide Protocol" refers to protocols developed by Board for the purpose of an authorized pharmacist ordering tobacco cessation therapies.

History: Effective October 1, 2021.
General Authority: NDCC 28-32-02, 43-15-10
Law Implemented: NDCC 23-01-42, 43-15-10(24)

61-04-15-02. Ordering of Tobacco Cessation Therapies.

1. Statewide Protocol
   a. Prescriptive authority for tobacco cessation therapy shall be exercised solely in accordance with the statewide protocol approved by the Board
   b. An authorized pharmacist exercising prescriptive authority must maintain and have readily available a current copy of the statewide protocol approved by the Board.
2. Education and Training
   a. An authorized pharmacist must successfully complete a course of training accredited by ACPE in the subject area of tobacco cessation drug therapy.
   b. Training must include study and instruction in the following content areas:
      (1) Mechanisms of action for contraindications, drug interactions, and monitoring cessation.
      (2) Current standards for prescribing tobacco cessation therapies.
      (3) Identifying indications for the use of tobacco cessation therapies.
      (4) Interviewing patient to establish need for tobacco cessation therapy.
      (5) Counseling patient regarding the safety, efficacy, and potential adverse effects of drug products for tobacco cessation.
      (6) Evaluating patient's medical profile for drug interactions.
      (7) Referring patient follow-up care with primary healthcare provider.
      (8) Informed consent.
      (9) Record management.
      (10) Management of adverse events, including identification, appropriate response, documentation and reporting.
3. Authorized drugs. Prescriptive authority shall be limited to those drugs delineated in the statewide protocol approved by the Board which include prescription and non-prescription therapies.
4. Labeling. Tobacco cessation therapies ordered and dispensed must be labeled in accordance with section 61-04-06.
5. Reporting. As soon as reasonable possible, the authorized pharmacist shall notify the patient's primary health care provider of the tobacco cessation therapy provided to the

patient. If the patient does not have a primary health care provider, the pharmacist may provide the patient with a record of the tobacco cessation therapy provided and shall advise the patient to consult a practitioner.

6. Records. An authorized pharmacist shall maintain records of the care provided and any tobacco cessation products ordered and dispensed pursuant to the statewide protocol. Informed consent must be documented in accordance with the statewide protocol. All records should be maintained for 5 years.

History: Effective October 1, 2021.
General Authority: NDCC 28-32-02, 43-15-10
Law Implemented: NDCC 23-01-42, 43-15-10(24)