CHAPTER 61-02-01
PHARMACY PERMITS

Section

61-02-01-01. Permit required. No person, partnership, association, or corporation shall conduct a pharmacy in North Dakota without first obtaining a permit to do so from the board. A fee, set by the board but not to exceed that prescribed by statute, shall be charged for each permit.

1) Each physical location of a pharmacy shall have a separate pharmacy permit. A location is defined as being in the same building at the same physical address. Buildings connected by tunnels, skywalks, or other similar methods must be deemed separate physical locations.
2) Any pharmacy receiving a permit shall advise the board, when applying for the permit and when changes occur, of the name of the employees of the pharmacy who are:
   a) The pharmacist-in-charge of the pharmacy, who shall be a licensed pharmacist in North Dakota in good standing;
   b) All other licensed pharmacists who shall be licensed pharmacists in North Dakota in good standing;
   c) All licensed pharmacy interns who shall be licensed pharmacy interns in North Dakota in good standing;
   d) All registered pharmacy technicians who shall be registered pharmacy technicians in North Dakota in good standing; and
   e) All supportive personnel permitted in the pharmacy area.
3) Nothing in this section prohibits a pharmacy with other than class F permit from delivering drugs or devices through the United States postal service or other parcel delivery service or hand delivery.
4) Classes of pharmacy permits are as follows:
   a) Class A - Permit to conduct an outpatient pharmacy. These permits are issued to a pharmacy dispensing drugs or devices to the general public pursuant to a valid prescription.
   b) Class B - Permit to conduct a hospital pharmacy. These permits are issued to a pharmacy dispensing drugs or devices to persons who are patients in a hospital, patients who are being discharged, or patients in emergency situations, pursuant to a valid prescription. These permits shall be issued to facilities licensed under North Dakota Century Code chapter 23-16 and shall be issued in the name of the facility.
   c) Class C - Permit to conduct a home health care pharmacy. These permits are issued to a pharmacy dispensing sterile injectable drug products and devices to the general public who are not patients within a facility with a class B pharmacy permit pursuant to a valid prescription.
   d) Class D - Permit to conduct a long-term care pharmacy. These permits are issued to a pharmacy dispensing drugs and devices to residents of facilities licensed under North Dakota Century Code chapters 23-09.3 and 23-16 pursuant to a valid prescription which are not physically accessed by the general public.
   e) Class E - Permit to conduct a nuclear pharmacy. These permits are issued to a pharmacy dispensing or providing diagnostic or therapeutic radioactive drugs or devices for administration to an ultimate user.

f) Class F - Permit to conduct a mail-order pharmacy. These permits are issued to a pharmacy dispensing drugs and devices to the general public exclusively through the United States postal service or other parcel delivery service pursuant to a valid prescription but which are not physically accessed by the general public.
g) Class G - Permit to conduct an out-of-state pharmacy. These permits are issued to any pharmacy operating outside the state of North Dakota which ships, mails, or delivers in any manner a dispensed prescription drug or legend device into North Dakota, which shall obtain and hold a pharmacy permit issued by the North Dakota state board of pharmacy and that part of the pharmacy operation dispensing the prescription for a North Dakota resident shall abide by state laws and rules of the board.
h) Class H - Permit to conduct a governmental agency pharmacy. This permit is issued to a pharmacy operated by the state of North Dakota, dispensing drugs and devices only to patients within correctional facilities or rehabilitation facilities, or for the purpose of teaching at institutions of higher learning, pursuant to a valid prescription.
i) Class I - Permit to conduct a research pharmacy. This permit is issued to a pharmacy in which scientific research is conducted under protocols established by an institutional review board meeting federal drug administration guidelines. Pharmaceuticals on hand are incident to the research being conducted. Security and storage for pharmaceuticals must meet United States Pharmacopeia and board of pharmacy requirements. A specific application for a pharmacy permit must be made delineating the specific physical facility to be utilized.
j) Class J - Permit to conduct an office practice pharmacy. Any licensed pharmacist may practice in an office pharmacy setting where prescriptions are not routinely dispensed. If legend drugs or devices are maintained, a permit must be obtained by making application to the board of pharmacy delineating specific practice intentions and assuring the board that security and storage requirements are met for any legend drugs or pharmaceuticals on hand.
k) Class K - Permit to conduct telepharmacy. A pharmacy staffed by a registered pharmacy technician with access to its main pharmacy and registered pharmacists by computer link, videolink, and audiolink while open.

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

5) Any applicable rule governing the practice of pharmacy shall apply to all permits under this section.
6) Operating in one class does not preclude permitting in another class. Pharmacies wishing to operate in more than one class shall apply on forms prescribed by the board, pay a fee set by the board, and comply with all rules for each class.

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

CHAPTER 61-02-01
PHARMACY PERMITS

Section

61-02-01-18 Continuous Quality Improvement

Definitions: In this chapter, unless the context or subject matter otherwise requires:

1. "Actively Reports" means reporting all dispensing errors and analysis of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error.

2. "Analysis" means a review of the findings collected and documented on each dispensing error, assessment of the cause and any factors contributing to the dispensing error, and any recommendation for remedial action to improve pharmacy systems and workflow processes to prevent or reduce future errors.

3. "Dispensing error" means one or more of the following discovered after the final verification by the pharmacist:

    a. 1. Variation from the prescriber's prescription drug order, including, but not limited to:

        i. a. Incorrect drug;

        ii. b. Incorrect drug strength;

        iii. c. Incorrect dosage form;

        iv. d. Incorrect patient; or

v. e. Inadequate or incorrect packaging, labeling, or directions.

b. 2. Failure to exercise professional judgment in identifying and managing:

i. a. Therapeutic duplication;

ii. b. Drug-disease contraindications, if known;

iii. c. Drug-drug interactions, if known;

iv. d. Incorrect drug dosage or duration of drug treatment;

v. interactions;

vi. f. A clinically significant, avoidable delay in therapy; or

vii. g. Any other significant, actual or potential problem with a patient's drug therapy.

c. 3. Delivery of a drug to the incorrect patient.

d. 4. Variation in bulk repackaging or filling of automated devices, including, but not limited to:

i. a. Incorrect drug;

ii. b. Incorrect drug strength;

iii. c. Incorrect dosage form; or

iv. d. Inadequate or incorrect packaging or labeling.

4. Incident**:** A patient safety event that reached the patient, whether or not the patient was harmed**.**

5. Near Miss**:** A patient safety event that did not or could not have reached the patient.

6. "Patient safety organization" means an organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41) and is credentialed by the Agency for Healthcare Research and Quality.

7. Unsafe Condition: Any circumstance that increases the probability of a patient safety event.

61-02-01-18 Continuous Quality Improvement Program

(1) Each pharmacy permittee shall establish a Continuous Quality Improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing incidents, near misses, and unsafe conditions.

(2) A pharmacy permittee meets the requirements if they meet the following:

1. Maintains and complies with the policies and procedures as noted in (4);

2. Has a contract with a Patient Safety Organization (PSO)that is-Listed as a Agency for Health Research and Quality (AHRQ) on www.ahrq.gov whose primary mission is pharmacy continuous quality improvement; and

3. The pharmacy reports incidents and near misses and unsafe events.

(3) At a minimum, a CQI Program shall include provisions to:

1. Designate an individual or individuals responsible for implementing, maintaining, and monitoring the CQI Program, which is managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form;

2. Initiate documentation of incidents, near misses, and unsafe conditions as soon as possible, but no more than seven days, after determining their occurrence;

(4) Policies and Procedures in compliance with 61-02-01-19 and must include.

1. Train all pharmacy personnel in relevant phases of the CQI program;

2. Identify and document reportable incidents and near misses and unsafe events;

3. Minimize the impact of incidents and near misses and unsafe events on patients;

4. Analyze data collected to assess the causes and any contributing factors relating to incidents and near misses and unsafe events;

5. Use the findings to formulate an appropriate response and to develop pharmacy systems and workflow processes designed to prevent and reduce incidents and near misses and unsafe events; and

6. Periodically, but at least quarterly, meet with appropriate pharmacy personnel to review findings and inform personnel of changes that have been made to pharmacy policies, procedures, systems, or processes as a result of CQI program findings.

(5) Quality Self-Audit

1. Each Pharmacy shall conduct a Quality Self-Audit at least quarterly to determine whether the occurrence of incidents, near misses, and unsafe conditions has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI Program in the future. Each pharmacy shall conduct a Quality Self-Audit upon change of Pharmacist-in-Charge to familiarize that Person with the Pharmacy's CQI Program.

(6) Protection from Discovery

1. Records that are generated as a component of a pharmacy's ongoing quality assurance program and that are maintained for that program are peer review documents and are not subject to subpoena or discovery in an arbitration or civil proceeding.

2. Records that are generated as a component of a pharmacy's ongoing quality assurance program and that are maintained for that program are confidential and shall not be released, distributed or communicated in any manner, except as provided by these rule or the permitee's policies and procedures. Recognizing the importance of sharing information with staff , experts, consultants, and others is necessary in reducing medication errors, information used as a part of the permitee's quality program in any manner shall not compromise the confidentiality and privilege of such information.

3. This subsection does not prohibit a patient from accessing the patient's prescription records or affect the discoverability of any records that are not generated solely as a component of a pharmacy's ongoing quality assurance program and maintained solely for that program.

(7) The Board's regulatory oversight activities regarding a pharmacy's CQI program are limited to inspection of the pharmacy's CQI policies and procedures and enforcing the pharmacy's compliance with those policies and procedures.

(8) An analysis or summary of findings, produced within six months of submission, shall be evidence of compliance with the records and data collection provisions. A permittee shall not be required to produce data, charts, error reports or findings collected and used in compiling an analysis summary.

(9) Not withstanding paragraphs (6) and (8), If pharmacy is reporting to a Patient Safety Organization whose primary mission is continuous quality improvement all data and records are privileged and confidential as provided in the 2005 Patient Safety and Quality Improvement Act of 2005 and implementing regulations.

61-02-01-19 Policy and Procedure Manual Required

1. Each Pharmacy must have a written or electronic and easily accessible policy and procedure manual to address all aspects of the pharmacies operations. The policy and procedure manual must be available for inspection. The policy and procedure manual must set forth in detail the objectives and operational guidelines of the pharmacy. The policy and procedure manual must be reviewed and revised or reaffirmed on an annual basis
    a. Inspection Procedures including
        i. Location of Controlled substance records including
            1. Location of current biennial inventory
            2. Wholesale records of receipt and sale of controlled substances

3. DEA 222 forms, both paper and electronic, executed or not.
4. Information for running reports from the pharmacy computer system relative to dispensing of specific controlled substances
5. Power of attorney forms if granted and termination forms if executed

ii. Location of most recent inspection forms by the board of pharmacy, accreditation agencies or the FDA, if applicable

History: Effective July 1, 1990. Amended July 1, 2014

2. **General Authority:** NDCC 28-32-02, 43-15-10(9), 43-15-10(12), 43-15-10(14)
3. **Law Implemented:** NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-02-06-04. Written policy and procedures. Written policy and procedures must be available electronically or in hard copy format ~~at each computer location~~, detailing responsibilities of each pharmacist relative to the operation of the computer and its records**.**

History: Effective July 1, 1990.Amended July 1, 2014
General Authority: NDCC 28-32-02, 43-15-10(9), 43-15-10(12), 43-15-10(14)
Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

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 and verified by another registered pharmacy technician 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 61-02-01-19.
    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, and
    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 Technician-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 permit holder are jointly responsible for the final product dispensed or released for administration from the pharmacy.

History: Effective January 1, 2009, Amended July `1,2014

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-03

61-03-02-03. Physical requirements of provider pharmacy licensed on premises or other pharmacy.

1. Area. The pharmacy serving a long-term care facility as an institutional drug outlet shall have floor space allocated to it to ensure that drugs are prepared in sanitary, well-lighted and enclosed places, and meet the other requirements of this section. Floor space shall be allotted to conduct the activities involved with the scope of pharmaceutical services provided.

2. Equipment and materials. The pharmacy serving a long-term care facility as an institutional drug outlet shall have equipment and physical facilities for proper compounding, dispensing, and storage for drugs, including parenteral preparations. As a minimum, the pharmacy shall have the following:

   a. Minimum equipment listed in section 61-02-01-03.

   b. Drugs to meet the needs of the patients of the long-term care facility.

   c. A pharmacy policy and procedures manual in compliance with 61-02-01-19.

   d. Pharmaceutical reference books, which shall include one recent edition (not over five years from publication date) from at least two of the following categories, one of which must include dispensing information:

(1) Drug dispensing information from one of the following:

(a) United States pharmacopoeia dispensing information.

(b) Facts and comparisons.

(c) Hospital formulary.

(2) Categories to choose from:

Drug interactions - poison and antidote information - chemistry toxicology - pharmacology - bacteriology - sterilization and disinfection - patient counseling – rational therapy - parenteral admixtures.

3. Drug room. The drug room of a long-term care facility may utilize the technical equipment and other requirements of a licensed pharmacy for compliance.

4. Storage.

a. All drugs shall be stored in designated areas within the pharmacy to ensure proper sanitation, temperature, light, ventilation, moisture control, and security. Unattended areas: In the absence of a pharmacist, and whenever any area of a pharmacy serving a long-term facility as an institutional drug outlet is not under the personal and direct

supervision of a pharmacist, such areas shall be locked. All areas occupied by a pharmacy serving a long-term care facility as an institutional drug outlet shall be capable of being locked by key or combination, so as to prevent access by unauthorized personnel.

b. When drugs to be dispensed are stored in a long-term facility drug room, the consulting pharmacist shall verify that space will be available at each unit for storage, safeguarding, and preparation of medication doses for administration and shall include provision of at least the following:

(1) A locked drug cabinet or room shall be equipped to ensure physical separation of individual patient prescribed medications. Medications may be stored in these secured individual patient storage areas, or secured portable storage carts providing separate compartments for individual patients may be used.

(2) A container or compartment which is capable of securing controlled substances with a lock or other safeguard system shall be permanently attached to storage carts or medication rooms.

History: Effective August 1, 1983., Amended July 1, 2014

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

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

61-04-11-08. Policy and procedural manual. The pharmacy shall maintain a ~~current~~ policy and procedural manual, with a section related to the administration of medications by injection, in compliance with 61-02-01-19.

History: Effective May 1, 2002., Amended July 1, 2014

General Authority: NDCC 43-15-10

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

61-06-01-05. Drug distribution and control.

1. General. A drug distribution system is the entirety of that mechanism by which a physician's prescription is executed, from the time the drug is ordered and received in the ~~primary~~ pharmacy, to the time the prescribed drug is dispensed to the patient.

2. Purchasing. All drugs and pharmaceutical products purchased and dispensed by a pharmacy providing home health care pharmacy services must meet national standards of quality (USP-NF standards) and must be clearly and accurately labeled by the manufacturer or distributor as to contents.

3. Procedure manual. A policy and procedure manual must be prepared in accordance with 61-02-01-19 ~~and maintained at each pharmacy providing~~, with a section pertaining to home health care pharmacy services ~~and be available for inspection~~. ~~The policy and procedure manual must set forth in detail the objectives and operational guidelines of the pharmacy. The manual must be reviewed and revised on an annual basis. A copy must be provided the board of~~

~~pharmacy when applying for a permit or engaging in this specialized area of practice.~~

4. Prescription. The pharmacist or pharmacy intern acting under the immediate supervision of a pharmacist must receive a written or verbal prescription from a physician before dispensing any compounded, sterile parenteral product. Prescriptions must be filed as required by law or rules of the board.

5. Profile. A pharmacy generated profile must be maintained for each patient as required by North Dakota Century Code section 43-15-31.1, and must also include:

a. Age.

b. Weight.

c. Sex.

d. Patient directions.

e. Other drugs patient is receiving.

f. Drug sensitivities and allergies to drugs and foods.

g. Primary diagnosis.

h. Documentation of patient training and continued competency.

i. Documentation of patient visits.

6. Labeling. Each compounded, sterile parenteral product dispensed to outpatients must be labeled with a permanent label with the following information:

a. Name, address, and telephone number of the pharmacy providing home health care pharmacy services.

b. Date and identifying prescription number.

c. Patient’s full name.

d. Name of each drug, strength, and amount.

e. Directions for use to the patient, including infusion rate.

f. Physician’s full name.

g. Required precautionary information.

h. Date and time of compounding.

i. Expiration date and time.

j. Identity of pharmacist compounding and dispensing.

7. Records and reports. The pharmacist managing the section of the pharmacy providing home health care pharmacy services shall maintain access to and submit, as appropriate, such records and reports as are required to ensure patient's health, safety, and welfare. Such records must be readily available, maintained for five years, and subject to inspections by the board of pharmacy or its agents. These must include, as a minimum, the following:

   a. Policy and procedures manual.

   b. Training manuals.

   c. Policies and procedures for cytotoxic waste, if applicable.

   d. Such other records and reports as may be required by law and rules of the board of pharmacy.

8. Delivery service. The pharmacist managing the section of the pharmacy providing home health care pharmacy services is responsible for the environment control of all products shipped. Therefore, any compounded, sterile parenteral product that is frozen, or requires refrigeration, must be shipped or delivered to a patient in appropriate coolers and stored appropriately in the patient's home.

History: Effective April 1, 1988., Amended July 1, 2014

General Authority: NDCC 28-32-02

Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14), 43-15-31, 43-15-31.1

Article
Title 61-04-02

Chapter 61-04-02
Physician Exemption

Section
61-04-02-01 Physician Exemption

61-04-02-01. Physician exemption. The exemption contained in subsection 1 of North Dakota Century Code section 43-15-02 for a duly licensed practitioner of medicine supplying the practitioner's own patients with such remedies as the practitioner may desire shall exempt such practitioners who dispense remedies as an incident to the practice of their profession for a patient's immediate needs, which would be those drugs required for a seventy-two-hour time period, full course of antibiotic treatment, start pack of pre-packaged medications, or up to a fourteen day supply of initial therapy of a maintenance medication that should be started immediately, but shall not exempt such a practitioner who regularly engages in dispensing such remedies to the practitioner's patients for which such patients are charged either separately or together with charges for other professional services, from recordkeeping, dispensing, labeling, counseling as required by North Dakota Century Code section 43-15-31.2, patient profile system as required by North Dakota Century Code section 43-15-31.1, and all other requirements of the practice of pharmacy as set forth in this chapter or by federal and state laws as they pertain to the regulation of the practice of pharmacy. Documented charts shall meet the requirements of the patient profile system.

History: Effective August 1, 1983, amended
General Authority: NDCC 19-02.1-02(2), 19-02.1-14, 28-32-02, 43-15-10(12), 43-15-10(14)
Law Implemented: NDCC 19-02.1-02(2), 19-02.1-14, 28-32-02, 43-15-10(12), 43-15-10(14)

CHAPTER 61-04-08
LIMITED PRESCRIPTIVE PRACTICES

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 medical examiners and board of pharmacy. Upon request, either 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 the facility within which the 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 October 2013.
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

APPENDIX

COLLABORATIVE AGREEMENT FORM

The pharmacist**s** and physician**s** listed below are parties to this collaborative agreement, through which the pharmacist receives limited prescriptive authority under the supervision of the physician in accordance with North Dakota Century Code section 43.15-31.4 and administrative rules.

Institution **Address** **Phone**

Pharmacist Name	License Number	Physician Name	License Number
Pharmacist Name	**License Number**	**Physician Name**	**License Number**
Pharmacist Name	**License Number**	**Physician Name**	**License Number**
		Physician Name	**License Number**

[Please review the administrative rules governing collaborative agreements which accompany this form before proceeding.]

1. Describe the scope and authority to be exercised by the pharmacist. (If requesting authority to initiate drug therapy, pharmacist must include credential verification.)
2. Indicate any restrictions placed on the use of certain types or classes of drugs or drug therapies under this agreement. (Note: Schedule II drugs are excluded by these rules.)
3. If appropriate, indicate any diagnosis which are specifically included or excluded under this agreement.
4. Attach any protocols or guidelines to be used in decision making or other activities contemplated under this agreement. This must include a protocol for treating acute allergic or other adverse reactions related to drug therapy.
5. Describe approved situations, if any, in which the notification time limit may be extended beyond twenty-four hours (not to exceed seventy-two hours).

Attach additional sheets if necessary.

Pharmacist Signature	Date	Physician Signature	Date
Pharmacist Signature	**Date**	**Physician Signature**	**Date**
Pharmacist Signature	**Date**	**Physician Signature**	**Date**
		Physician Signature	**Date**

Board of Pharmacy	Approval Date	Board of Medical Examiners	Approval Date

ARTICLE 61-08
OUT-OF-STATE PHARMACIES

CHAPTER 61-08-01
REQUIREMENTS FOR OUT-OF-STATE PHARMACIES

61-08-01-08. Administrative inspection. North Dakota pharmacy inspectors may conduct onsite periodic routine inspections during reasonable business hours of out-of-state pharmacies registered to do business in North Dakota. Alternatively, the North Dakota board of pharmacy may contract with the respective out-of-state regulatory authorities to conduct and perfect periodic routine inspections.

(a) To obtain a license as a nonresident pharmacy, an applicant shall:
  (1) Have submitted an application form prescribed by the Board as required under NDAC 61-08-01-02 ;
  (2) Have paid the fees specified by the Board for the issuance of the license as specified in NDAC Article 61-11.

(b) The pharmacy owner, if an individual, and principals and owners who directly or indirectly own greater than ten percent interest in the company, if the company is not publically held, shall have undergone a state and federal fingerprint-based criminal background check as specified by the Board;

(c) The pharmacist in charge or another pharmacist responsible for the North Dakota patients must be licensed in North Dakota.

(d) The facility shall be inspected in a manner and frequency prescribed by the Board:
  (1) For nonresident pharmacies that prepare and ship sterile and/or non-sterile compounded products into this state, the facility must be inspected at least once every 12 months by:
    (i) The Board or its duly authorized agent; or
    (ii) A duly authorized agent of a third party approved by the Board which is the National Association of Boards of Pharmacy Verified Pharmacy Program.
  (2) For nonresident pharmacies that do not ship sterile and non-sterile compounded products into this state, the facility must be inspected at least once every 2 years by:
    (i) The resident state board of pharmacy, if the resident board's inspection is substantially equivalent to the inspection in this state;
    (ii) The Board or its duly authorized agent; or
    (ii) A duly authorized agent of a third party approved by the Board, which if the National Association of Boards of Pharmacy Verified Pharmacy Program.
  (3) Nonresident pharmacies that dispense more than twenty five percent (25%) of the pharmacy's total prescription volume as a result of original prescriptions or refills solicited through the internet, must be accredited by:

(i) The National Association of Boards of Pharmacy Verified Internet Pharmacy Practice Sites Program; or

(ii) The National Association of Boards of Pharmacy Veterinary Verified Internet Pharmacy Practice Sites Program.

(3) Costs for inspections conducted by the Board or an approved third party will be paid by the applicant.

(e) At the time of renewal, the nonresident pharmacy shall:

(1) Submit an application form prescribed by the Board;

(2) Provide proof of a recent inspection as outlined in section (d); and

(3) Submit the National Association of Boards of Pharmacy e-Profile Identification (NABP e-Profile ID) of the Pharmacy and Pharmacist-in-charge.

(f) The Board may waive the requirement for a separate criminal background check in (b). If the nonresident pharmacy is a current participant in a pharmacy verification program that provides complete and accurate owner criminal background screening and licensure, disciplinary, and inspection information to the Board of Pharmacy, this requirement may also be waived.

(g) Any new applicant or renewal application received after July 1, 2015 shall hold the required accreditation from the National Association of Boards of Pharmacy,

History: Effective April 1, 1988; amended effective January 1, 2005. Amended Effective July 1, 2014
General Authority: NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38
Law Implemented: NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

Revised
ARTICLE
TITLE 61

ARTICLE
61-11 FEES

1.	North Dakota Examination	$	100.00
2.	Original or Duplicate Certificate		25.00
3.	Reciprocal Licensure		150.00
4.	a. Internship Licensure – NDSU Professional Student		100.00
	{$90 is paid to the NDSU College of Pharmacy for student programs}		
	b. Internship Licensure – Pre-pharmacy students		10.00
5.	Manufacturer/ Distributor/Warehouse/Reverse Distributor Wholesale Drug License	~~200.00~~	
	Chain Drug Warehouse		200.00
	Chain Pharmacy Warehouse		200.00
	Hospital Offsite Warehouse		200.00
	Jobber or Broker		400.00
	Manufacturer		400.00
	Own Label Distributor		400.00
	Pharmacy Distributor		200.00
	Private Label Distributor		400.00
	Repackager		400.00
	Reverse Distributor		200.00
	Third – Party Logistic Provider		400.00
	Veterinary – Only Distributor		200.00
	Virtual Manufacturer		400.00
	Virtual Wholesaler or Distributor		400.00
	Wholesaler or Distributor		400.00
	Penalty for Late Renewal		50.00
6.	Pharmacy or Drug Store Permit		175.00
	Permitting in additional Classes		- 0 –
	Penalty for Late Renewal		50.00
7.	Annual Renewal for Pharmacist in-state (active)		100.00
	Penalty for Late Renewal		25.00
8.	Annual Renewal for Pharmacist in-state (Inactive Status)		75.00
	Penalty for Late Renewal		25.00
9.	Annual Renewal for Pharmacist out-of-state		35.00
	Penalty for Late Renewal		25.00
10.	Annual Registration for Pharmacy Technician		35.00
	($17.50 is forwarded to the Northland Association of Pharmacy Technicians[NAPT])		
	Penalty for Late Renewal		10.00
11.	Pharmacy Technician-In-Training (2 years allowed) per year		10.00
12.	License Verification (self-addressed return envelope)		25.00

History: Effective January 1, 2006; October 1, 2010 amended effective ~~July 1, 2011~~ _____
General Authority: NDCC 43-15-10
Law implemented: NDCC 43-15-10, 43-15-18, 43-15-20, 43-15-25, 43-15-27, 43-15-35, 43-15-38, 43-15. 1-04, 43-15. 1-05, 43-15. 3-01, 43-15. 3-12

Chapter 61-12-01
PRESCRIPTION DRUG MONITORING PROGRAM

61-12-01-02. Dispenser Reporting.

1. Each dispenser licensed by a regulatory agency in the state of North Dakota who dispenses a controlled substance to a patient shall submit to the central repository by electronic means information regarding each prescription dispensed for a controlled substance. The information submitted for each prescription shall include all data elements in the American Society for Automation in Pharmacy rules-based Standard Implementation Guide for Prescription Monitoring Programs issued ~~August 31, 2005~~ **September 2011**, version ~~003~~ **4**, release ~~000~~ **2.**

2. Each dispenser shall submit the information required by this chapter to the central repository at least once every day unless the board waives this requirement for good cause shown by the dispenser.

3. An extension of the time in which a dispenser must report the information required by this chapter may be granted to a dispenser that is unable to submit prescription information by electronic means if:

   a. The dispenser suffers a mechanical or electronic failure or cannot report within the required time for other reasons beyond the dispenser's control; or

   b. The central repository is unable to receive electronic submissions.

History: Effective December 1, 2006. Amended effective July 1, 2014.
General Authority: NDCC 19-03.5
Law Implemented: NDCC 19-03.5