

**ARTICLE 61-08
OUT-OF-STATE PHARMACIES**

Chapter
61-08-01 Requirements for Out-of-State Pharmacies

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

Section
61-08-01-01 Permit
61-08-01-02 Permit Application - Renewal
61-08-01-03 Fees
61-08-01-04 Pharmacy Permit - Home Jurisdiction
61-08-01-05 Applicable Law and Rules
61-08-01-06 Compliance
61-08-01-07 Reporting
61-08-01-08 Administrative Inspection
61-08-01-09 Records
61-08-01-10 Counseling Services
61-08-01-11 Patient Profile Record System and Prescription Drug Information Required
61-08-01-12 Jurisdiction
61-08-01-13 Agent

61-08-01-01. Permit.

Any pharmacy operating outside the state which ships, mails, or delivers in any manner a dispensed prescription drug or legend drug into North Dakota 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 law and rules of the board.

History: Effective April 1, 1988.

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

61-08-01-02. Permit application - Renewal.

Pharmacy permit application forms must be available from the board and submitted for approval. Pharmacy permits must be renewed annually by July first.

History: Effective April 1, 1988.

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

61-08-01-03. Fees.

The out-of-state pharmacy annual permit fee must be set by the board not to exceed three hundred dollars.

History: Effective April 1, 1988.

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

61-08-01-04. Pharmacy permit - Home jurisdiction.

An out-of-state pharmacy doing business in North Dakota by dispensing and delivering prescription drugs to North Dakota consumers shall maintain a document that it has a pharmacy permit in good standing in its respective home jurisdiction.

History: Effective April 1, 1988; amended effective January 1, 2005.

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

61-08-01-05. Applicable law and rules.

North Dakota pharmacy laws and rules shall be applicable to control interjurisdictional prescription commerce and to govern the practice of pharmacy for that portion of the pharmacy practice or operation.

History: Effective April 1, 1988; amended effective January 1, 2005.

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

61-08-01-06. Compliance.

The pharmacist in charge and pharmacy owner, or partners, or corporate officer and owners where applicable, appearing on the permit or the permittee will be responsible for complete compliance with the North Dakota laws or rules insofar as the standards of practice for the pharmacy operation pertaining to the provisions of receiving, dispensing, and delivering prescription drugs to North Dakota.

History: Effective April 1, 1988.

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

61-08-01-07. Reporting.

The pharmacist in charge appearing on the permit shall submit an affidavit with the initial permit application and renewal applications annually which affirm that the pharmacist understands North Dakota pharmacy laws and rules and that the pharmacy is in complete compliance with applicable standards of care when dispensing prescription orders for delivery to North Dakota consumers. The out-of-state pharmacy shall also disclose the pharmacist in charge and location, names, and titles of all principal corporate officers and all pharmacists who are dispensing prescription drugs to residents of this state. This disclosure must be on an annual basis.

History: Effective April 1, 1988.

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

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.

1. To obtain a license as a nonresident pharmacy, an applicant shall:
 - a. Have submitted an application form prescribed by the board as required under section 61-08-01-02; and
 - b. Have paid the fees specified by the board for the issuance of the license as specified in article 61-11.
2. 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 upon request by the board.
3. The facility shall be inspected in a manner and frequency prescribed by the board:
 - a. For nonresident pharmacies that prepare and ship sterile or nonsterile compounded products, or sterile and nonsterile compounded products into this state, the facility must be inspected at least once every twenty-four months by:
 - (1) The board or its duly authorized agent; or
 - (2) A duly authorized agent of a third party approved by the board which is the national association of boards of pharmacy verified pharmacy program.
 - b. For nonresident pharmacies that do not ship sterile and nonsterile compounded products into this state, the facility must be inspected at least once every two years by:
 - (1) The resident state board of pharmacy, if the resident board's inspection is substantially equivalent to the inspection in this state;
 - (2) The board or its duly authorized agent; or
 - (3) A duly authorized agent of a third party approved by the board, which is the national association of boards of pharmacy verified pharmacy program.
 - c. Nonresident pharmacies that dispense more than twenty-five percent of the pharmacy's total prescription volume as a result of original prescriptions or refills solicited through the internet, must be inspected by the national association of boards of pharmacy verified pharmacy program.
 - d. Costs for inspections conducted by the board or an approved third party will be paid by the applicant.
4. At the time of renewal, the nonresident pharmacy shall:
 - a. Submit an application form prescribed by the board;
 - b. Provide proof of a recent inspection as outlined in subsection 3; and
 - c. Submit the national association of boards of pharmacy e-profile identification (NABP e-Profile ID) of the pharmacy and pharmacist-in-charge.

History: Effective April 1, 1988; amended effective January 1, 2005; October 1, 2014; October 1, 2019.
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

61-08-01-09. Records.

Prescription records documenting prescriptions dispensed and distributed to North Dakota consumers must be readily retrievable and available for board review upon request.

History: Effective April 1, 1988; amended effective October 1, 2019.
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

61-08-01-10. Counseling services.

Out-of-state pharmacies shall provide accessible telephone counseling service for patients' drug inquiries with a licensed pharmacist during regular working hours. Available telephone counseling service must be provided that is consistent with the standard of due care. The pharmacies' telephone number will be prominently identified and affixed on the prescription container label. Guidelines for counseling services shall be consistent with professional practice counseling guidelines set in chapter 61-04-13.

History: Effective April 1, 1988; amended effective July 1, 2017.
General Authority: NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-31.2, 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, 43-15-31.2, 43-15-35, 43-15-36, 43-15-38

61-08-01-11. Patient profile record system and prescription drug information required.

An out-of-state pharmacy shall comply with the patient profile record system requirements of North Dakota Century Code section 43-15-31.1 and the prescription drug information requirements of North Dakota Century Code section 43-15-31.2 for that part of the pharmacy operation dispensing a prescription for a North Dakota resident.

History: Effective April 1, 1988.
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

61-08-01-12. Jurisdiction.

Out-of-state pharmacies soliciting, receiving, and dispensing prescription orders delivered to North Dakota ultimate residents constitutes doing business in the state.

History: Effective April 1, 1988.
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

61-08-01-13. Agent.

The out-of-state pharmacies doing business in North Dakota by dispensing and delivering prescription orders to North Dakota consumers shall designate a resident agent and a registered office in North Dakota for the service of process.

History: Effective April 1, 1988.

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