

### **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 publicly 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