

SECTION .1600 - LICENSES AND PERMITS

21 NCAC 46 .1601 PHARMACY PERMITS

(a) Applications for pharmacy permits, whether original or renewal, shall be made upon forms provided by the Board. The Board shall not issue any original or annual renewal pharmacy permit until the Board is satisfied that:

- (1) The pharmacist-manager is sure that at all times adequate qualified personnel have been secured by the management of the store to properly render pharmaceutical service in the manner prescribed by law.
- (2) The pharmacy posts in a location conspicuous to the public the specific hours that a pharmacist is on duty in the pharmacy. This requirement does not apply to hospitals, nursing homes, and similar institutions subject to the provisions of Section .1400 of this Chapter.
- (3) The pharmacist-manager shall be responsible for obtaining and maintaining equipment in the pharmacy adequate to meet the pharmaceutical care needs of the pharmacy's patients.
- (4) The pharmacist-manager shall be responsible for obtaining and maintaining a reference library in the pharmacy. The library shall include current references, either hard copy or electronically accessible, covering:
 - (A) State and federal statutes and rules relating to the practice of pharmacy and the legal distribution of drugs;
 - (B) Drug interactions, adverse effects, therapeutic use, dosing and toxicology;
 - (C) Patient-oriented reference materials for counseling in proper drug usage as specified in 21 NCAC 46 .2504;
 - (D) Equivalent drug products as defined in G.S. 90-85.27; and
 - (E) Any reference materials otherwise required by state or federal law, including any otherwise required in these Rules.
- (5) The pharmacy is equipped with sanitary appliances including lavatory facilities with hot and cold running water; is well lighted; and is kept in a clean, orderly, and sanitary condition.
- (6) All prescription medications are labeled in accordance with G.S. 106-134 and 106-134.1.

(b) In addition to the requirements for issuance and renewal of a pharmacy permit imposed by statute and rules of the Board, a permit shall not be issued or renewed to any person to operate a pharmacy wherein the prescriptions of medical practitioners are compounded or dispensed and distributed when such distribution is effected by mail and the practitioner-pharmacist-patient relationship does not exist, until the Board is satisfied that:

- (1) The pharmacy maintains records of prescriptions compounded or dispensed and distributed in manner that is readily retrievable;
- (2) During the pharmacy's regular hours of operation but not less than six days per week, for a minimum of forty hours per week, a toll-free telephone service is provided to facilitate communication between patients and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number must be disclosed on the label affixed to each container of dispensed drugs;
- (3) The pharmacy complies with all lawful orders, directions, and requests for information from the Boards of pharmacy of all states in which it is licensed and all states into which it distributes prescription drugs;
- (4) The pharmacy complies with all United States Pharmacopeia and Food and Drug Administration requirements regarding the storage, packaging, and shipping of prescription medications. The pharmacist-manager and all other pharmacists employed in the pharmacies permitted pursuant to this Paragraph shall be subject to all Federal and State statutes and regulations concerning the dispensing of prescription medications including 21 NCAC 46 .1801 and .1805 and 21 CFR 1306.01, 1306.05, and 1306.21.

(c) The Board shall not issue an original or renewal permit to any person to operate a drugstore or pharmacy as a department in or a part of any other business serving the general public (except hospitals, nursing homes, and similar institutions subject to the provisions of Section .1400 of this Chapter) unless such pharmacy facility:

- (1) is physically separated from such other business;
- (2) is separately identified to the public both as to name and any advertising;
- (3) completes all transactions relative to such pharmacy within the registered facility; and
- (4) meets the same requirements for registration as all other pharmacies.

(d) In addition to all of the other requirements for issuance and renewal of a pharmacy permit imposed by statute and rules of the Board, the Board shall not issue any original or annual renewal pharmacy permit to any Internet pharmacy until the Board is satisfied that:

- (1) The Internet pharmacy is certified by the National Association of Boards of Pharmacy under its Digital Pharmacy Accreditation program;
- (2) The Internet pharmacy has certified the percentage of its annual business conducted via the Internet on a form provided by the Board, when it applies for permit or renewal; and
- (3) The Internet pharmacy has provided the Board with the names, addresses, social security numbers, phone numbers, facsimile numbers, email addresses, and titles of all principal corporate officers of the Internet pharmacy; the names, addresses, social security numbers, phone numbers, facsimile numbers, email addresses, and titles of all principal officers of any company, partnership, association, or other business entity holding any ownership interest in the Internet pharmacy; the names, addresses, social security numbers, phone numbers, facsimile numbers, email addresses, and titles of any individual holding any ownership interest in the Internet pharmacy.

This Paragraph does not relieve an out-of-state pharmacy from compliance with all provisions of 21 NCAC 46 .1607 governing out-of-state pharmacies.

(e) Permits to operate pharmacies, whether original or renewal, shall be issued to the pharmacist-manager of such pharmacy pursuant to a joint application of the owner and pharmacist-manager for the conduct and management of said pharmacy. The issuance of said permit shall not be complete and the permit shall not be valid until it has been countersigned by the pharmacist-manager as represented in the application. The permit so issued is valid only so long as the pharmacist-manager to whom it was issued assumes the duties and responsibilities of pharmacist-manager. Permits may be reissued at any time to a successor pharmacist-manager pursuant to the proper amendment of the application for the permit.

(f) Upon application, the Board may issue and renew separate permits for pharmacies operating at one location. Records for each permitted pharmacy must be maintained separately. Prior to issuance of an original permit, each pharmacy shall submit a plan to the Board that shall assure accountability for the actions of each pharmacy at the location.

*History Note: Authority G.S. 90-85.6; 90-85.21; 132-1.10;
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July 1, 1996; September 1, 1995; May 1, 1989; August 1, 1988; March 1, 1984;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,
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