

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. The pharmacy's reference library shall include a medical dictionary and current editions of reference books on drug interactions, clinical pharmacology, USP Dispensing Information or its equivalent, and if IV admixture services are provided, a reference on Parenteral Incompatibilities.
- (4) 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.
- (5) 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 as a Verified Internet Pharmacy Practice Site (VIPPS);
- (2) The Internet pharmacy has certified the percentage of its annual business conducted via the Internet on a form required 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;
Eff. April 1, 1983;
Amended Eff. April 1, 2007; April 1, 2003; April 1, 1999; October 29, 1998; July 1, 1996; September 1, 1995; May 1, 1989; August 1, 1988; March 1, 1984.*

21 NCAC 46 .1602 LICENSE BY RECIPROCITY

(a) An applicant for licensure without examination, must have:

- (1) Originally been licensed as a pharmacist by an examination equivalent to the North Carolina examination specified in Rule .1505(a)(1) of this Chapter;
- (2) Achieved scores on an equivalent examination, such as the NABPLEX examination, which would qualify for licensure in this state at the time of examination; and
- (3) Been licensed by a state which deems licensees from this state to be equivalent to the extent that they are suitable for licensure in that state without further substantial examination.

(b) All applicants shall submit to the Board a signed release form, completed Fingerprint Record Card, and such other form(s) required to perform a criminal history check at the time of application.

(c) The Board shall require an applicant for licensure without examination who has not practiced pharmacy within two years prior to application to obtain additional continuing education, practical pharmacy experience, successfully complete one or more parts of the Board's licensure examination, or a combination of the foregoing, as the Board deems necessary to ensure that the applicant can safely and properly practice pharmacy.

(d) The Board shall also restrict licenses granted pursuant to this Rule for such period of time as the Board deems necessary to ensure that the applicant can safely and properly practice pharmacy.

*History Note: Authority G.S. 90-85.6; 90-85.20;
Eff. April 1, 1983;
Amended Eff. February 1, 2006; July 1, 2005; March 1, 2004; April 1, 2003, July 1, 1996; May 1, 1989.*

21 NCAC 46 .1603 WHEN NEW PERMIT REQUIRED

A new pharmacy, device, or medical equipment permit is required for a new location, a change to a different or successor business entity, or a change resulting in a different person or entity owning more than 50 percent interest in the permit holder or any entity in the chain of ownership above the permit holder, except as provided in 21 NCAC 46 .1604 of this Section. A new permit is required if there is a change in the authority to control or designate a majority of the members or board of directors of a nonprofit corporation holding a pharmacy permit or any nonprofit corporation in the chain of ownership above the permit holder.

History Note: Authority G.S. 90-85.6; 90-85.21; 90-85.22;
Eff. May 1, 1989;
Amended Eff. March 1, 2004; April 1, 2001; August 1, 1998; April 1, 1997; September 1, 1995.

21 NCAC 46 .1604 WHEN NEW PERMIT NOT REQUIRED

- (a) A new pharmacy, device or medical equipment permit is not required in the following situations:
- (1) the permit holder is a publicly-traded corporation and continues to hold the permit; or
 - (2) the permit holder is a corporation which is a wholly-owned subsidiary, and any change in the ownership of any corporation in the chain of ownership above the permit holder is due to the stock of such corporation being publicly-traded.
- (b) A permit which has been served with a notice of hearing for a pending disciplinary proceeding before the Board may not be surrendered.

History Note: Authority G.S. 90-85.6; 90-85.21; 90-85.22;
Eff. May 1, 1989;
Amended Eff. June 1, 2004; April 1, 2001; August 1, 1998; May 1, 1997; September 1, 1995.

21 NCAC 46 .1605 CHARGE FOR VERIFICATION FOR REINSTATEMENT

The Board shall charge persons requesting written verification for reinstatement of a pharmacy license or permit or a device and medical equipment permit a fee of twenty-five dollars (\$25.00) per verification.

History Note: Authority G.S. 90-85.6; 90-85.17; 90-85.21; 90-85.22; 150B-19(5)(e);
Eff. September 1, 1993;
Amended Eff. February 1, 2006; September 1, 1995.

21 NCAC 46 .1606 REQUIREMENT OF PERSONAL APPEARANCE

Prior to issuance of any original permit or device and medical equipment permit, the following persons must appear personally at the Board office on the first Monday of the month, the Monday before the monthly Board meeting, or such other time as scheduled with the Board's staff:

- (1) the pharmacist-manager for the applicant pharmacy; and
- (2) the person in charge of the facility applying for the device and medical equipment permit.

History Note: Authority G.S. 90-18.1; 90-18.2; 90-85.3(a),(r); 90-85.6; 90-85.21; 90-85.22;
Eff. April 1, 1994;
Amended Eff. April 1, 2003; April 1, 1999; September 1, 1995.

21 NCAC 46 .1607 OUT-OF-STATE PHARMACIES

(a) In order to protect the public health and safety and implement G.S. 90-85.21A, the following provisions apply to out-of-state pharmacies that ship, mail, or deliver in any manner a dispensed legend drug into this State.

- (b) Such pharmacies shall:
- (1) Maintain, in readily retrievable form, records of prescription drugs dispensed to North Carolina residents;

- (2) Supply all information requested by the Board in carrying out the Board's responsibilities under the statutes and rules pertaining to out-of-state pharmacies;
- (3) During the pharmacy's regular hours of operation but not less than six days per week, for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients and pharmacists at the pharmacy who have access to the patient's records. This toll-free number must be disclosed on the label affixed to each container of dispensed drugs;
- (4) Comply with all USP and FDA requirements regarding the storage, packaging, and shipping of prescription medications;
- (5) Develop policies governing:
 - (A) normal delivery protocols and times;
 - (B) the procedure to be followed if the patient's medication is not available at the out-of-state pharmacy, or if delivery will be delayed beyond the normal delivery time;
 - (C) the procedure to be followed upon receipt of a prescription for an acute illness, which shall include a procedure for delivery of the medication to the patient from the out-of-state pharmacy at the earliest possible time (such as courier delivery), or an alternative that assures the patient the opportunity to obtain the medication at the earliest possible time; and
 - (D) the procedure to be followed when the out-of-state pharmacy is advised that the patient's medication has not been received within the normal delivery time and that the patient is out of medication and requires interim dosage until mail prescription drugs become available;
- (6) Disclose the location, names, and titles, of all principal corporate officers, if incorporated, and if unincorporated, partners, or owners of the pharmacy. Disclose the names and license numbers of all pharmacists dispensing prescription legend drugs to an ultimate user in this State, the names and, if available, license or registration numbers of all supportive personnel employed by the out-of-state pharmacy who assist such pharmacists in such dispensing. A report containing this information shall be made on an annual basis and within 30 days of each change of any principal office, pharmacist-manager of any location dispensing prescription legend drugs to an ultimate user in this State, principal corporate officer if incorporated, and if unincorporated, partner or owner of the pharmacy. A new registration shall be required for a change of ownership of an established pharmacy to a successor business entity which results in a change in the controlling interest in the pharmacy;
- (7) Submit evidence of possession of a valid license, permit, or registration as a pharmacy in compliance with the laws of the state in which the pharmacy is located. Such evidence shall consist of one of the following:
 - (A) a copy of the current license, permit, or registration certificate issued by the regulatory or licensing agency of the state in which the pharmacy is located; or
 - (B) a letter from the regulatory or licensing agency of the state in which the pharmacy is located certifying the pharmacy's compliance with the pharmacy laws of that state;
- (8) Designate a resident agent in North Carolina for service of process. Any such out-of-state pharmacy that does not so designate a resident agent shall be deemed to have appointed the Secretary of State of the State of North Carolina to be its true and lawful attorney upon whom process may be served. All legal process in any action or proceeding against such pharmacy arising from shipping, mailing or delivering prescription drugs in North Carolina shall be served on the resident agent. In addition, a copy of such service of process shall be mailed to the out-of-state pharmacy by certified mail, return receipt requested, at the address of the out-of-state pharmacy as designated on the registration form filed with the Board. Any out-of-state pharmacy which does not register in this State, shall be deemed to have consented to service of process on the Secretary of State as sufficient service.

(c) The facilities and records of an out-of-state pharmacy shall be subject to inspection by the Board; provided however, the Board may accept in lieu thereof satisfactory inspection reports by the licensing entity of the state in which the pharmacy is located.

(d) An out-of-state pharmacy shall comply with the statutes and regulations of the state in which the pharmacy is located.

(e) Any person who ships, mails, or delivers prescription drugs to North Carolina residents from more than one out-of-state pharmacy shall register each pharmacy separately.

(f) Prior to original registration, a pharmacist who is an authorized representative of the pharmacy's owner must appear personally at the Board office on the first Monday of the month, the Monday before the monthly Board meeting, or such other time as scheduled with the Board's staff. Such authorized pharmacist may represent all pharmacies having the same ownership.

(g) An out-of-state pharmacy shall report to the Board information that reasonably suggests that there is a probability that a prescription drug or device dispensed from such out-of state pharmacy has caused or contributed to the death of any patient. The report shall be filed in writing on a form provided by the Board within 14 days of the pharmacy becoming aware of the death. The Board may not disclose the identity of any person or entity making the report, except when it is necessary to protect life or health of any person. No such report in possession of the Board shall be discoverable or admissible into evidence or otherwise used in any civil action involving private parties, except as otherwise required by law.

(h) The Board may, in accordance with Chapter 150B of the General Statutes, issue a letter of reprimand or suspend, restrict, revoke, or refuse to grant or renew registration to an out-of-state pharmacy if such pharmacy has:

- (1) made false representations or withheld material information in connection with obtaining registration;
- (2) been found guilty of or plead guilty or nolo contendere to any felony in connection with the practice of pharmacy or the distribution of drugs;
- (3) made false representations in connection with the practice of pharmacy that endanger or are likely to endanger the health or safety of the public, or that defraud any person;
- (4) failed to comply with this Rule;
- (5) been the subject of a negligence complaint resulting from the dispensing of prescription drugs to a resident of North Carolina and based on an investigation of such complaint been found to be negligent:
 - (A) by the Board of Pharmacy of the state in which the pharmacy is located;
 - (B) by the North Carolina Board of Pharmacy if the Board of Pharmacy of the state where the pharmacy is located failed to initiate an investigation of such complaint within 45 days after referral of the complaint from the North Carolina Board of Pharmacy; or
 - (C) by the North Carolina Board of Pharmacy if the Board of Pharmacy of the state where the pharmacy is located initiates an investigation of such complaint within 45 days, but later advises the North Carolina Board that it will not make a determination of negligence or that it has made no determination of the issue of negligence within one year after referral of the complaint and has discontinued any active investigation or proceeding for such determination. In any disciplinary proceeding based on negligence, the standard of practice shall be that applicable in the state in which the pharmacy is located. In disciplinary proceedings pursuant to Part (h)(5)(A) of this Rule, the Board shall adopt the findings of negligence by the Board of Pharmacy of the state in which the pharmacy is located as part of the Board's final decision without producing its own evidence of negligence.

(i) An out-of-state pharmacy shall notify the Board within five days of receipt of any order or decision by a Board of Pharmacy imposing disciplinary action on the pharmacy. Notwithstanding the provisions of Paragraph (h) of this Rule, if the permit or registration in the state where the pharmacy is located is suspended or revoked, then the pharmacy's registration in North Carolina will be immediately suspended or revoked for the same period of time.

(j) An out-of-state pharmacy registration shall expire on December 31 of each year.

(k) The fees provided for in G.S. 90-85.21A as maximum fees which the Board is entitled to charge and collect are hereby established as the fees for each original registration and for annual renewal of each registration.

History Note: Authority G.S. 90-85.6; 90-85.21A; 90-85.26; 90-85.28; 90-85.29; 90-85.30; 90-85.32; Eff. July 1, 1994; Amended Eff. March 1, 2006.

21 NCAC 46 .1608 DEVICE AND MEDICAL EQUIPMENT PERMITS

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

- (1) Adequate qualified personnel have been secured by the management of the facility to properly render device and medical equipment services in the manner prescribed by law.
- (2) Such personnel shall be maintained during the period for which the permit is issued.
- (3) If the applicant dispenses medical oxygen to a patient, then the applicant must reasonably ensure that the following medical equipment is maintained:
 - (A) Sufficient backup of oxygen in that patient's home and supplies for equipment serviced to maintain continuation of therapy for 24 hours; and
 - (B) An oxygen analyzer in the permitted facility, if concentrators are dispensed.
- (4) Suitable facilities shall be maintained to house inventory, to allow for fabrication work space, and to record and file prescription orders as required by law.
- (5) A copy of the pharmacy laws of North Carolina, including the North Carolina Pharmacy Practice Act and the rules of the Board shall be present in the facility at all times.
- (6) The facility is equipped with a functioning lavatory where hot and cold running water or hand washing appliances or waterless hand cleaner are available.
- (7) The facility is kept in a clean, orderly, and sanitary condition.
- (8) The applicants' services are accessible to its customer base.
- (9) All prescription medications are labeled in accordance with G.S. 106-134 and 106-134.1.
- (10) The applicant complies with all USP and FDA requirements regarding the storage, packaging, and shipping of prescription medications, including medical oxygen.
- (11) The applicant's services are available 24 hours, seven days per week when essential to the maintenance of life or when the lack of such services might reasonably cause harm.
- (12) The applicant implements and maintains a written procedure at each location for handling complaints and problems, which includes a complaint file documenting complaints and problems and resolution of the complaints or problems.
- (13) The applicant complies with local/state fire and building laws.
- (14) The applicant complies with current Occupational Safety and Health Administration (OSHA) laws and requirements as enforced by the NC Department of Labor/Division of OSHA, including the approach to infection control known as "Universal Precautions."

(b) Device and medical equipment permits, whether original or renewal, shall be issued to the person in charge of the facility pursuant to a joint application of the owner and person in charge. The issuance of said permit shall not be complete and the permit shall not be valid until it has been countersigned by the person in charge as represented in the application. The permit so issued is valid only so long as the person in charge to whom it was issued assumes his duties and responsibilities. Permits may be reissued at any time to a successor person in charge pursuant to the proper amendment of the application for the permit. The hours of operation shall be posted conspicuously at the facility for public viewing. The person in charge or the designee of the person in charge shall be present at the facility during the hours of operation of the facility. The person in charge shall notify the Board in writing of a change in the facility address within 30 days from the date of the change.

(c) When a device and medical equipment dispensing facility is to be closed permanently, the person in charge shall inform the Board of the closing and arrange for the proper disposition of devices and medical equipment and return the permit to the Board's offices within 10 days of the closing date. The person in charge, jointly with the owner (if the owner is someone other than the person in charge), shall provide for the orderly transfer of records to another permit holder for maintenance of patient therapy and inform the public of such transfer by posted notice or otherwise.

(d) Charitable organizations providing devices and medical equipment at no charge must register with the Board. The Board shall waive the fee for a permit upon a showing that the organization meets the Internal Revenue Service charitable purpose requirements for exemption from taxation and that at least 75 percent of the organization's funds are used for a charitable purpose. Loaner closets providing device and medical equipment at no charge, excluding oxygen or other life support devices, must register with the Board but are exempt from the fee for device and medical equipment permits.

History Note: Authority G.S. 90-85.6; 90-85.22;
Eff. September 1, 1995;
Amended eff. April 1, 2007

21 NCAC 46 .1609 PERMIT RENEWAL

Permits issued by the Board expire on December 31 and become invalid 60 days following expiration.

History Note: Authority G.S. 90-85.6; 90-85.21;
Eff. September 1, 1995.

21 NCAC 46 .1610 REINSTATEMENT OF FORFEITED LICENSING PRIVILEGES

An individual whose licensing privileges have been forfeited pursuant to G.S. 15A-1331, shall immediately surrender to the Board office his or her permit or license, current renewal certificate, and wallet card. In order to have the licensing privileges reinstated, the individual must appear before the Board and submit evidence that it would be in the public interest to reinstate the licensing privileges and that he or she can safely and properly practice pharmacy.

History Note: Authority G.S. 15A-1331A; 90-85.19;
Eff. September 1, 1995.

21 NCAC 46 .1611 FEE FOR SUBMITTAL OF DISHONORED AND RETURNED CHECK

(a) Any person, firm or corporation submitting to the Board a check which is subsequently returned to the Board because of insufficient funds or because there is no account open at the bank shall be charged a fee of twenty-five dollars (\$25.00) for processing the check.

(b) Until such time as the payor of the returned check pays the amount of the check and pays the prescribed fee, the payor shall not be eligible to take an examination, review an examination, obtain a license or permit or have his license or permit renewed.

(c) Any license or permit which has been issued based on the payment of a check which is subsequently returned to the Board for reasons stated in Paragraph (a) of this Rule shall be declared invalid until such time as the payor pays the amount of the check and pays the prescribed fee.

(d) Payment to the Board of the amount of the returned check and the prescribed fee shall be made in the form of cash, a cashier's check, or money order.

(e) All examination, license and permit, and license and permit renewal applications provided by the Board shall contain information in a conspicuous place thereon advising the applicant of the applicable fee for returned checks.

History Note: Authority G.S. 25-3-506;
Eff. September 1, 1995;
Amended Eff. February 1, 2006.

21 NCAC 46 .1612 REINSTATEMENT OF LICENSES AND PERMITS

(a) All licenses and registrations issued to individuals that are not renewed by March 1 of the succeeding year, lapse and are subject to the maximum reinstatement and renewal fees set out in G.S. 90-85.24 in order to be reinstated. All permits and registrations issued to locations that are reinstated after March 1 and prior to April 1 of the succeeding year are subject to the maximum reinstatement and renewal fees set out in G.S. 90-85.21A and 90-85.24. After March 31, permits and registrations issued to locations shall submit new applications and are subject to the maximum original registration fees. This Rule also applies to licenses, registrations, and permits reinstated following voluntary surrender or disciplinary action by the Board.

(b) All applicants shall submit to the Board a signed release form, completed Fingerprint Record Card, and such other form(s) required to perform a criminal history check at the time of application.

(c) The Board shall require applicants for reinstatement of a lapsed license who have not practiced pharmacy within two years prior to application for reinstatement to obtain continuing education in addition to that required by Rule .2201 of this Chapter, practical pharmacy experience, successfully complete one or more parts of the Board's licensure examination, or a combination of the foregoing, as the Board deems necessary to ensure that the applicant can safely and properly practice pharmacy.

(d) The Board shall also restrict licenses reinstated pursuant to G.S. 90-85.19 for such period of time as the Board deems necessary to ensure that the applicant can safely and properly practice pharmacy.

History Note: Authority G.S. 90-85.19; 90-85.24;
Eff. April 1, 1999;
Amended Eff. March 1, 2006; July 1, 2005.