

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;

Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.