

21 NCAC 46 .2611 MEDICAL EQUIPMENT

(a) Medical equipment suppliers shall:

- (1) Document information from the physician or other medical personnel as to the patient's specific needs to be met by the equipment delivered as well as the effectiveness of the equipment in meeting those needs;
- (2) In consultation with the referring health professional(s), patient, patient's family and other primary care providers, delineate the appropriate choices of commercially available equipment to meet the specified needs of the patient;
- (3) Participate in the measurement of the patient, utilizing appropriate instruments and techniques to assure the fit and function of the selected equipment;
- (4) Deliver, fit and adjust the prescribed equipment;
- (5) Instruct the patient or family in the safe and proper use and care of the equipment provided in compliance with Rule .2504 of this Chapter;
- (6) Provide service and support for the equipment dispensed or delivered and, within 72 hours, provide a response to patient requests for repair service on equipment supplied; however, such service and support need not be provided unless the patient's account is current;
- (7) Maintain liability insurance of at least one million dollars (\$1,000,000) worth of coverage;
- (8) Demonstrate that each item sold or rented has been checked, is free of defect, and operates within the manufacturers' specifications;
- (9) Refrain from modifying equipment to the extent that the modification might reasonably cause harm;
- (10) Maintain all electrical components so that they do not present a fire or shock hazard;
- (11) Ensure that all appropriate warning labels or labeling, including tags, are present on the equipment provided;
- (12) Maintain documentation demonstrating that a function and safety check of equipment was performed prior to set up;
- (13) Maintain an established protocol for cleaning and disinfecting equipment which addresses both aerobic and anaerobic pathogens including procedures to prevent cross-contamination; and
- (14) Clean and disinfect equipment according to manufacturers' specifications.

(b) Medical equipment suppliers shall implement a preventative maintenance program for rental equipment which includes the following:

- (1) Procedures for problem reporting, tracking, recall, and resolution;
- (2) Performance of service as specified by the manufacturer and the documentation of such performance in the service records; and
- (3) Maintain documentation of repair and maintenance of equipment. The following information shall be documented in the repair log:
 - (A) Type of equipment;
 - (B) Manufacturer;
 - (C) Model;
 - (D) Serial number;
 - (E) Date of repair;
 - (F) Specific repair made; and
 - (G) Name of person or company performing the repair.

(c) In addition to Section .2500 of this Chapter providers of parenteral and enteral nutrition services shall comply with the following counseling requirements:

- (1) Utilize orientation checklists to review:
 - (A) Instructions for use of the equipment;
 - (B) Safety precautions;
 - (C) Cleaning procedures;
 - (D) Maintenance procedures; and
 - (E) Return demonstrations on equipment delivered.
- (2) Instruct the patient about emergency and routine contact procedures;
- (3) Deliver and review with the patient written instruction materials to ensure that the patient receives adequate information to properly operate the equipment; and
- (4) A written plan of service shall be developed, implemented, and documented in the patient record. The plan of service shall include, but is not limited to, the assessment of the safety of the home

environment, the caregiver or patient's ability to comply with the prescription, and the caregiver or patient's ability to operate and clean the equipment as instructed.

History Note: Authority G.S. 90-85.3(e)(11)(r); 90-85.6; 90-85.22;
Eff. May 1, 1997;
Amended Eff. April 1, 1999; August 1, 1998;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.