

SECTION .2600 – DEVICES

21 NCAC 46 .2601 DISPENSING AND DELIVERY

(a) Devices, as defined in G.S. 90-85.3(e), shall be dispensed only in a pharmacy as defined in G.S. 90-85.3(q) or other place registered with the Board pursuant to G.S. 90-85.22. Medical equipment, as defined in G.S. 90-85.3(11) shall be delivered only by a pharmacy as defined in G.S. 90-85.3(q) or other place registered with the Board pursuant to G.S. 90-85.22. Devices dispensed in hospitals and medical equipment delivered by hospitals are presumed to be the responsibility of the hospital pharmacy unless otherwise registered. This Rule shall apply only to entities engaged in the regular activity of delivering medical equipment.

(b) A pharmacy dispensing and delivering devices and medical equipment and not holding a device and medical equipment permit shall operate its device and medical equipment business at the same physical location as the pharmacy and through the same legal entity that holds the pharmacy permit. The pharmacist-manager shall be responsible for the dispensing and delivery of devices and medical equipment.

(c) Device and medical equipment permits shall not be issued to applicants located on residential property.

History Note: Authority G.S. 90-85.3(e), (11), (r); 90-85.6; 90-85.22;
Eff. October 1, 1990;
Amended Eff. March 1, 2006; March 1, 2004; October 1, 1995.

21 NCAC 46 .2602 ORDERS

Devices as defined in G.S. 90-85.3(e), shall be dispensed to outpatients only pursuant to an order from a practitioner. Such orders shall comply in all pertinent respects with G.S. 106-134.1(a) and (b). Use of devices for outpatients shall be in compliance with G.S. 90-85.3(t).

History Note: Authority G.S. 90-85.3(e),(r); 90-85.6; 90-85.22;
Eff. October 1, 1990;
Amended Eff. April 1, 1997.

21 NCAC 46 .2603 EDUCATION AND TRAINING

Persons, other than pharmacists, who are authorized to dispense devices and who dispense devices shall demonstrate to the Board's satisfaction that they have received sufficient education and training in dispensing devices so that they can safely and properly dispense devices. Persons, other than pharmacists, who are authorized to deliver medical equipment and who deliver medical equipment shall demonstrate to the Board's satisfaction that they have received sufficient education and training in the delivery of medical equipment so that they can safely and properly deliver medical equipment.

History Note: Authority G.S. 90-85.3(e), (11), (r); 90-85.6; 90-85.22;
Eff. October 1, 1990;
Amended Eff. September 1, 1995.

21 NCAC 46 .2604 RECORDS

(a) All orders and records for devices and medical equipment shall conform in all pertinent respects with Board Rules .2301 through .2305 of this Chapter and shall be maintained at the dispensing site. In addition to the requirements of those rules, the serial numbers for all devices dispensed and all medical equipment delivered to outpatients shall be preserved as part of the records; provided, that this requirement shall not apply to disposable devices and medical equipment.

(b) All prescriptions and refill orders for devices and medical equipment shall be maintained at the dispensing site for at least three years.

(c) All device and medical equipment permit holders shall maintain a file copy of every item sold or rented with a serial number or tracking number or code in compliance with FDA Medical Device Tracking requirements.

History Note: Authority G.S. 90-85.3(e),(11),(r); 90-85.6; 90-85.22;
Eff. October 1, 1990;
Amended Eff. April 1, 1999; September 1, 1995.

21 NCAC 46 .2605 REGISTRATION OF NON-PHARMACISTS

(a) Registration of persons other than pharmacists dispensing devices or delivering medical equipment, pursuant to G.S. 90-85.22, shall be issued by the Board to the person in charge of the location dispensing the devices or delivering medical equipment. This person shall have responsibilities comparable to those of a pharmacist-manager pursuant to Board Rule .2502 of this Chapter, as applicable. Persons in charge shall keep on file for three years on the premises of each place where devices are dispensed or medical equipment is delivered all information related to warranties provided by manufacturers and the availability of repairs; provided, that this requirement shall not apply to disposable devices and medical equipment. A person shall be in charge of only one location.

(b) A person in charge shall not:

- (1) commit a felony;
- (2) commit any act as a principal in a business entity that causes such entity to be excluded from participation in a federal or state program.

If a person in charge commits the conduct set out in Paragraphs (b)(1) and (b)(2) of this Rule while he or she is a person in charge, he or she shall no longer serve as a person in charge for the existing permit or for any other device and medical equipment permit.

*History Note: Authority G.S. 90-85.3(e); (11), (r); 90-85.6; 90-85.22;
 Eff. October 1, 1990;
 Amended Eff. April 1, 2004; September 1, 1995.*

21 NCAC 46 .2606 CONVEYING WARNINGS

Persons in charge or pharmacists dispensing devices or delivering medical equipment, as defined in G.S. 90-85.22, shall be responsible for promptly conveying to patients all pertinent warnings issued by government agencies or manufacturers.

*History Note: Authority G.S. 90-85.3(e), (11), (r); 90-85.6; 90-85.22;
 Eff. October 1, 1990;
 Amended Eff. September 1, 1995.*

21 NCAC 46 .2607 AVAILABILITY OF RECORDS

All records required to be kept by statute or rule shall be available to Board inspectors or agents as provided in Rule .1803 of this Chapter. All records, including prescription orders, equipment information, and patient counseling documentation, shall be archived in a readily retrievable manner and open for review, copying or seizure by the Board or its designated employees within 48 hours of a request for inspection for a period of three years.

*History Note: Authority G.S. 90-85.3(e),(r); 90-85.6; 90-85.22;
 Eff. October 1, 1990;
 Amended Eff. February 1, 2007.*

21 NCAC 46 .2608 DISPENSING OF MEDICAL OXYGEN

Compressed medical oxygen and liquid oxygen equipment shall be dispensed and controlled according to state and federal laws.

*History Note: Authority G.S. 90-85.3(e),(11),(r); 90-85.6; 90-85.22;
 Eff. September 1, 1995.*

21 NCAC 46 .2609 REHABILITATION EQUIPMENT

(a) Rehabilitation equipment suppliers shall follow the provisions of this Rule rather than the provisions of 21 NCAC 46 .2611.

(b) Rehabilitation equipment suppliers shall:

- (1) Solicit information from the physician, physical therapist, occupational therapist, registered nurse and other medical or educational personnel, as to the results of their

- assessment and evaluation of the patient's physical, functional and associated needs as well as the specific goals to be met by the enabling technology;
- (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 and custom fabricated 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 and family in the safe and proper use and care of the equipment provided;
 - (6) Provide service and support for the equipment delivered through knowledgeable, skilled and trained service personnel 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) Provide a specific, written statement of warranty on the equipment provided, including commercial warranties and those for adapted or custom fabricated items;
 - (8) Maintain liability insurance of at least one million dollars (\$1,000,000) worth of coverage and when involved in the design, fabrication or substantial modification of commercially available equipment, also maintain product liability insurance; and
 - (9) Utilize written, quality assurance procedures including, but not limited to:
 - (A) Reviewing custom designed and fabricated equipment and interfacing techniques with commercial equipment to assure compatibility and safety;
 - (B) Understanding the properties of the materials being used in custom designed and modified equipment to assure long term durability;
 - (C) Documenting goals and objectives of the referring medical or education personnel, as well as short and long term effectiveness of the equipment in meeting those goals and objectives; and
 - (D) Documenting complaints and problems as required in Rule .1608(a)(12) of this Chapter.

History Note: Authority G.S. 90-85.3(e),(11),(r); 90-85.6; 90-85.22;
 Eff. September 1, 1995;
 Amended Eff. April 1, 1999; April 1, 1997.

21 NCAC 46 .2610 MEDICAL GAS, OXYGEN AND RESPIRATORY RELATED EQUIPMENT

- (a) Medical gas, oxygen and respiratory related equipment suppliers shall:
- (1) Comply with all applicable home medical equipment laws of North Carolina;
 - (2) If transporting oxygen and other medical gases in cylinder or liquid form, comply with all current Department of Transportation rules and regulations;
 - (3) If transfilling medical oxygen systems, comply with Food and Drug Administration (FDA) and all state agency requirements regarding transfilling and repackaging;
 - (4) Demonstrate that oxygen provided in cylinder or liquid form meets minimal purity standards for medical grade oxygen;
 - (5) Comply with local/state fire and building laws; and
 - (6) Meet the following safety inspection requirements:
 - (A) Demonstrate that each piece of oxygen/respiratory equipment has been checked, is free of defect, and operates within the manufacturers' specifications;
 - (B) Refrain from modifying equipment to the extent that the modification might reasonably cause harm;
 - (C) Maintain all electrical components so that they do not present a fire or shock hazard; and
 - (D) Ensure that all appropriate warning labels or labeling, including tags, are present on the equipment provided.
- (b) Medical gas, oxygen and respiratory related equipment suppliers shall comply with the following recall procedures:

- (1) Ensure that lot numbers and expiration dates are affixed to each cylinder delivered;
 - (2) Maintain a tracking system for all medical oxygen and gas delivered;
 - (3) Document all equipment serial numbers and model numbers to ensure that equipment can be retrieved if a recall is initiated; and
 - (4) Maintain records for equipment that requires FDA tracking.
- (c) Medical gas, oxygen and respiratory related equipment suppliers shall comply with the following maintenance and cleaning requirements:
- (1) Maintain documentation demonstrating that a function and safety check of equipment was performed prior to set up;
 - (2) Maintain an established protocol for cleaning and disinfecting equipment which addresses both aerobic and anaerobic pathogens;
 - (3) Maintain a Material Safety Data Sheet (MSDS) on file for solutions and products used in cleaning and disinfecting procedures;
 - (4) Maintain segregated areas on the premises and in delivery vehicles for clean, dirty, and contaminated equipment;
 - (5) Clean and disinfect equipment according to manufacturers' specifications; and
 - (6) Instruct the patient on proper cleaning techniques as specified by the manufacturer.
- (d) Medical gas, oxygen and respiratory related equipment suppliers shall implement a comprehensive preventative maintenance program 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) Routine inspection, service, and maintenance of equipment located in the patient's/customer's home according to manufacturers' specifications.
- (e) Medical gas, oxygen and respiratory related equipment suppliers shall maintain repair logs to document repair and maintenance of equipment, including, but not limited to, oxygen concentrators, infant monitors, and mechanical ventilators. The following information shall be documented in the repair log:
- (1) type of equipment;
 - (2) manufacturer;
 - (3) model;
 - (4) serial number;
 - (5) date of repair;
 - (6) specific repair made; and
 - (7) name of person or company performing the repair.
- (f) Medical gas, oxygen and respiratory related equipment suppliers shall maintain testing equipment to ensure accurate calibration. Testing equipment shall be appropriate for the level of service offered. Scales used to weigh liquid oxygen reservoirs shall be properly maintained to ensure accuracy.
- (g) Medical gas, oxygen, and respiratory related equipment suppliers shall implement a written procedure at each location for handling complaints and problems, which includes a complaint file documenting complaints and problems and resolutions of the complaints or problems.
- (h) Medical gas, oxygen, and respiratory related equipment suppliers 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 back up oxygen systems delivered;
 - (2) Instruct the patient about emergency and routine contact procedures; and
 - (3) Deliver and review written instruction materials to ensure that the patient receives adequate information in order to properly operate the equipment.
- (i) 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, an assessment of the safety of the home environment, the caregiver or patient ability to comply with the prescription, and the caregiver or patient 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. September 1, 1995.*

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.

21 NCAC 46 .2612 STORAGE OF DEVICES AND MEDICAL EQUIPMENT

- (a) Devices and medical equipment shall be stored at the location holding the pharmacy or device and medical equipment permit or a location that is within 50 miles of the permitted location. Devices and medical equipment shall not be stored on residential property.
- (b) A device and medical equipment storage site not holding a pharmacy or device and medical equipment permit shall not provide any devices, medical equipment, or services directly to patients.
- (c) Device and medical equipment storage sites shall be subject to inspection by the Board.

History Note: Authority G.S. 90-85.6; 90-85.22; 90-85.32;
Eff. March 1, 2004;
Amended Eff. February 1, 2007.

21 NCAC 46 .2613 DEVICES AND MEDICAL EQUIPMENT IN POSSESSION OF PERMIT HOLDERS

Dispensed devices and medical equipment in the possession of permit holders shall bear a patient-specific prescription label. Permit holders may not collect prescription drugs from a patient or caregiver, nor may a permit holder store prescription drugs on behalf of a patient or caregiver.

History Note: Authority G.S. 90-85.6; 90-85.22; 90-85.32;
Eff. April 1, 2007.