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),(l1),(r); 90-85.6; 90-85.22;*
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