PHARMACY EXAMINING BOARD

Phar 14.02

## Chapter Phar 14 HOME MEDICAL OXYGEN PROVIDERS

Phar 14.01 Application. Phar 14 02 Standards of Professional Conduct.

Phar 14.01 Application. Each applicant for licensure as a home medical oxygen provider shall submit all of the following: (1) An application for licensure on a form provided by the board.

(2) The fee specified in s. 440.05 (1), Stats.

(3) Evidence of accreditation by an organization deemed an accreditation organization for suppliers of durable medical equipment, prosthetics, orthotics, and supplies by the United States department of health and human services, centers for medicare and medicaid services.

History: CR 16-072: cr. Register November 2017 No. 743, eff. 12-1-17; correction in (1), (2) made under s. 35.17, Stats., Register November 2017 No. 743.

Phar 14.02 Standards of Professional Conduct. Licensed home medical oxygen providers and their employees and agents shall do all of the following:

(1) Maintain accreditation status by an organization deemed an accreditation organization for suppliers of durable medical equipment, prosthetics, orthotics, and supplies by the United States department of health and human services, centers for medicare and medicaid services.

(2) Comply with all federal and state laws regarding transporting oxygen in cylinder or liquid form.

(3) Comply with the United States food and drug administration rules and regulations regarding transporting medical oxygen systems.

(4) Demonstrate that oxygen provided to cylinder or liquid form meets purity standards for medical grade oxygen.

(5) Meet safety inspection requirements including all of the following:

(a) Maintain documentation demonstrating each piece of oxygen or respiratory equipment has been checked, is free of defect, and operates within the manufacturer's specifications.

(b) Equipment shall not be modified to the extent that the modification may reasonably cause harm.

(c) Maintain all electrical components so that they do not present a fire or shock hazard.

(d) Ensure that all appropriate warning labels, including tags, are present on the equipment provided.

(6) Maintain recall procedures including all of the following:

(a) Ensure that lot numbers and expiration dates are affixed to each cylinder delivered.

(b) Maintain a tracking system for all medical oxygen and gas delivered.

(c) Document all equipment serial numbers and model numbers to ensure that equipment can be retrieved if a recall is initiated.

(d) Maintain records for equipment that requires food and drug administration tracking.

(7) Comply with the all of the following maintenance and cleaning requirements:

(a) Maintain documentation demonstrating that a function and safety check of equipment was performed prior to set up.

(b) Maintain an established protocol for cleaning and disinfecting equipment which address both aerobic and anaerobic pathogens.

(c) Maintain a material safety data sheet on file for solutions and products used in cleaning and disinfecting procedures.

(d) Maintain segregated areas on the premises and in delivery vehicles for clean, dirty, and contaminated equipment.

(e) Clean and disinfect equipment according to manufacturers' specifications.

(f) Instruct the patient on proper cleaning techniques as specified by the manufacturer.

(8) Implement a comprehensive preventative maintenance program that includes all of the following:

(a) Procedures for problem reporting, tracking, recall, and resolution.

(b) Performance of service as specified by the manufacturer and the documentation of such performance in the service records.

(c) Routine inspection, service, and maintenance of equipment located in the patient's or customer's residence according to manufacturer's specifications.

(9) Maintain repair logs to document repair and maintenance of equipment, including oxygen concentrators, infant monitors, and mechanical ventilators. The repair log shall include all of the following:

- (a) Type of equipment.
- (b) Manufacturer.
- (c) Model.
- (d) Serial number.
- (e) Date of repair.
- (f) Specific repair made.
- (g) Name of person or company performing the repair.

(10) 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.

(11) Provide counseling including all of the following:

(a) Utilize orientation checklists for review of all of the following:

1. Instructions for use of the equipment.

2. Safety precautions.

- 3. Cleaning procedures.
- 4. Maintenance procedures.
- 5. Return demonstrations on back up oxygen systems.

(b) Instruct the patient about emergency and routine contact procedures.

(c) Deliver and review written instruction materials to ensure that the patient receives information regarding the operation of the equipment.

(12) Develop, implement, and document a written plan of services in the patient record, including 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.

(13) Maintain all required home medical oxygen records for a period of 5 years.

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