



## **Ohio Respiratory Care Board Home Medical Equipment Inspection Standards**

### **Standard for Maintaining a Facility**

A licensee is responsible for maintaining a facility that meets the following requirements:

**The facility must have appropriate physical space to safely store, maintain and service on site equipment. (4761:1-9-02 (A) ORC)**

- Facility interior and exterior is clean, safe, organized and free of debris and excess equipment
- “No Smoking” signs are posted in the warehouse and in delivery truck and the no smoking policy is enforced when/if medical gases or combustibles are present
- Fire extinguishers are adequately labeled and are current
- All exits are clearly identified and are not obstructed

**The facility must have departmental separation of business office, patient records, equipment cleaning, maintenance and storage, as applicable (4761:1-9-02 (B) ORC)**

- Business office and equipment are two separate areas
- Equipment cleaning, maintenance and storage areas are well marked and separated within the facility
- Patient records are secured after business hours

**The facility must be able to demonstrate appropriate equipment flows through various departments to ensure that the equipment is properly disinfected, repaired, stored and/or maintained (4761:1-9-02 (C) ORC)**

- Returned equipment is processed in the following categories: clean, dirty, repair/tested, contaminated/quarantined, patient ready
- Employees with patient contact can verbalize the procedure for receiving & processing equipment returned by patients
- Gases are properly transported, secured, quarantined, and safely stored in a well marked area and are in compliance with FDA requirements and state laws

- There is a process for separation of clean and dirty equipment in delivery vehicle

**The facility must maintain inventory on site or by arrangement with a supplier to meet the needs of their current client base (4761:1-9-02 (D) ORC)**

- Back-up equipment is readily available in your facility and/or in subcontractor's facility
- Battery powered equipment is charged and ready for use

**The facility must meet all federal, state and local laws and rules (4761:1-9-02 (E) ORC)**

- HME license is conspicuously posted and current license card is filed in an easily retrievable location. Other licenses available for review, as applicable
- Proof of insurance (Product and Professional Liability coverage, \$1 million per occurrence/\$3 million total aggregate)

**The facility must meet all federal, state and local laws and rules regarding the storage, maintenance and sale of upholstery or bedding, if applicable (4761:1-9-02 (F) ORC)**

- Bedding license is current

**General facility requirements (4761:1-9-02 ORC)**

- Facility has identifying storefront signage that does not include any false, fraudulent, deceptive or misleading information (4761:1-15-02)
- Hours of operation and after hours phone number are posted on front of establishment
- If facility cannot meet patient needs, referral contacts are identified and easily retrieved (4761:1-9-01 E2)
- Facility has a policy on handling patient incidents and patient complaint reporting

### **Standards for Maintaining Equipment**

**Maintain and document equipment in accordance with manufacturers guidelines (4761:1-9-03 (A) ORC)**

- Facility has equipment manufacturer and warranty information filed in an easily retrievable location

- Facility has a tracking mechanism in place for the following:
  - a. Location of equipment, serial numbers, model numbers
  - b. FDA medical device tracking records
  - c. Gases dispensed and lot number tracking by patient/client
  - d. Equipment recall records
- Equipment used to test medical equipment is clean, accurate and is regularly calibrated per manufacturer recommendations
- Preventive maintenance records are in place
- There are policy and procedures for providing emergency supply of gases, supplies and equipment

**Clean, repair, store, segregate and identify all equipment in a manner which makes the equipment safe for use by the public (4761:1-9-03 (B) ORC)**

- Documentation that equipment has been cleaned prior to patient ready storage:
  - a. Proper cleaning agents are used per manufacturer guidelines
  - b. Proper upholstery and mattress agents are used
- Contaminated equipment handling protocols in place
- Proper disposal of single use items
- Delivery vehicle clean and orderly
- Personal protective equipment/universal precautions are being met
- Cleaning area kept orderly
- Repair logs showing the following documentation:
  - a. Type of equipment
  - b. Manufacturer
  - c. Model number or model
  - d. Serial number
  - e. Date of repair
  - f. Specific repair made
  - g. Name of person who performed repair
- Equipment repair tools, including O2 tools, are cleaned and maintained

- Repair area kept orderly
- Equipment is clearly segregated by type

**Insure that all equipment is used within the manufacturers recommended guidelines and expirations dates, if applicable (4761:1-9-03 (C) ORC)**

- Proof that testing of equipment has been performed prior to delivery and as periodically required by manufacturer specifications
- Facility has a policy for handling outdated product – separate from patient ready supplies
- All patient ready equipment and supplies are used within the manufacturer’s specified guidelines and dates for use, if applicable

**Standards for Client Records**

**Records for each client that has been sold or rented equipment, unless the sale is a one time transaction for which no record is required (4761:1-9-04)**

- Client records must be filed and readily available
- The client record must contain the following: (4761:1-9-04 (B) ORC)
  - a. Physician order, if required (original and annual for oxygen)
  - b. Type of equipment
  - c. Date of sale or rental
  - d. Documentation of settings
  - e. Serial #
  - f. Documentation of service checks, follow-up and patient concerns
  - g. Proof of Delivery
- Proof of patient instruction and orientation to include the following:
  - a. Safe and proper use of equipment
  - b. Safe and proper storage of equipment
  - c. Patient maintenance responsibilities
  - d. 24 hour emergency number

Client records must be maintained for seven years from the date of sale or in the case of a minor, the record must be maintained for seven years after the client turns the age of majority (eighteen years of age)

## **Standards for Personnel**

**Facility must employ appropriate staffing to handle the scope of equipment sold, rented and maintained and to appropriately meet the demands of the business (4761:1-9-05 (A) ORC) In addition, the employer must ensure that all staff members are trained and supervised by qualified persons (4761:1-9-05 (B) ORC)**

- The personnel record shall include the following (4761:1-9-05):
  - a. Job description for the position held by the employee
  - b. Application qualifications
  - c. Background check by the Ohio bureau of criminal investigations
  - d. Orientation and training records
  - e. Verification of competence
  - f. Proof of professional license, as applicable
  - g. Performance plan to be completed annually by employer
  
- Employee file must also include a copy of one of the following (4761:1-9-05 C7):
  - a. Birth certificate
  - b. Driver's License
  - c. Social security card
  - d. Passport or permanent resident card
  
- The facility must have on file a copy of the DOT evaluation – if applicable

## **Standards of Practice for License Holders**

**The licensee shall maintain knowledge of the duties, responsibilities, and accountabilities of an HME provider and shall practice in accordance with the following:**

- The laws regulating the provision of HME providers as outlined in Chapter 4752. of the Revised Code (see 4752.07 and 4752.09 ORC)
  
- Any other applicable federal and state laws and rules
  - a. Occupational Safety and Health Administration (OSHA)
  - b. Department of Transportation
  - c. Federal Drug Administration
  - d. Health Insurance Portability and Accountability Act
  - e. American's with Disabilities Act
  - f. State Pharmacy License, if applicable
  - g. Federal and State Labor Laws
  - h. State New Hire Regulations and Forms
  - i. Professional Regulatory Licenses (Resp. Care, Nursing, Orthotic/Pedorthic, etc.

- Position statements, standards of care or guidelines for providing HME services from nationally recognized bodies such as CMS Medicare DMEPOS supplier standards, JCAHO and/or CHAP.

**A licensee and their staff shall demonstrate competence and accountability in all areas as an HME provider in which they are engaged which includes, but is not limited to, the following:**

Appropriate recognition, referral, or consultation and intervention when a complication arises in conjunction with the function of HME or when a change in patient or client complication occurs