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 02 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 care

- 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, Orthodic/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.