

Ohio Respiratory

Care Board

HME Standards for Inspections

Effective 2007



The Ohio Respiratory Care Board
HME Division
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Introduction:

This HME Standards Manual has been developed to assist licensed Home Medical Equipment facilities prepare for inspections performed under the provisions of Chapter 4752. of the Ohio Revised Code. The Board, with the assistance of its field inspection team, created this practical manual to meet the practice standards for a licensed Home Medical Equipment facility.

Under Section 4752.08 of the Ohio Revised Code, the Board is authorized to inspect licensed facilities. The Ohio General Assembly empowered the Board with the ability to inspect the operations and facility, subpoena the records of a licensed facility (if required), and compel the testimony of employees of any home medical equipment facility licensed under Chapter 4752 of the Revised Code. Under this authority, the Board has written specific Ohio Administrative Code rules identifying requirements for regular inspections and the inspection standards required of each licensed facility. Under these rules, each licensed facility is scheduled for a routine inspection once every four years. Additionally, the Board could conduct limited unannounced inspections based upon a filed complaint.

Generally, inspections are intending to be instructional, not punitive or confrontational. The focus of the Board's inspection standards is improved public safety and quality of home medical equipment services rendered to Ohio citizens. At the end of an inspection, the inspector will prepare an inspection report outlining any corrective measures needed to reach full compliance with the Ohio's Home Medical Equipment standards. Facilities are directed to provide a remedial response within 90-days after receiving the official inspection report. A licensed facility may appeal the findings of an inspection, if a facility believes the inspection findings do not accurately portray the operations and facility standards of the business.

General Provisions

§ 4752.02. Home medical equipment services provider to hold license or certificate of registration; exceptions.

- (A) Except as provided in division (B) of this section, no person shall provide home medical equipment services or claim to the public to be a home medical equipment services provider unless either of the following is the case:
- (1) The person holds a valid license issued under this chapter;
 - (2) The person holds a valid certificate of registration issued under this chapter.
- (B) Division (A) of this section does not apply to any of the following:
- (1) A health care practitioner, as defined in section 4769.01 of the Revised Code, who does not sell or rent home medical equipment;
 - (2) A hospital that provides home medical equipment services only as an integral part of patient care and does not provide the services through a separate entity that has its own medicare or medicaid provider number;
 - (3) A manufacturer or wholesale distributor of home medical equipment that does not sell directly to the public;
 - (4) A hospice care program, as defined by section 3712.01 of the Revised Code, that does not sell or rent home medical equipment;
 - (5) A home, as defined by section 3721.01 of the Revised Code;
 - (6) A home health agency that is certified under Title XVIII of the "Social Security Act," 79 Stat. 286 (1965), 42 U.S.C. 1395, as a provider of home health services and does not sell or rent home medical equipment;
 - (7) An individual who holds a current, valid license issued under Chapter 4741. of the Revised Code to practice

but are not limited to:

- (1) The Ohio association of medical equipment services;
 - (2) The American association for home care
 - (3) The American association for respiratory care;
 - (4) The Ohio pharmacists association;
 - (5) The Ohio society for respiratory care; and
 - (6) The Ohio health care association
- (E) An agency that provides continuing education may apply to the board to be recognized as an approved peer review organization. Request for recognition as an approved peer review organization must be made in writing to the board and must provide the board with an overview of their agency and an outline of the continuing education courses provided by that agency.

accredited in-service education;

(b) The remaining hours must come from educational programs specific to the type and level of service provided that are approved and accredited by a professional peer review organization relating to home medical equipment services or specific clinical affiliation; and

(c) Clinical and equipment cleaning/maintenance staff must have one contact hour of continuing education on infection control, equipment cleaning and cleaning agents, rotation of inventory and equipment separation

(C) Continuing education credits shall be documented for employed staff involved in HME service delivery. Records of attendance and completion shall include:

(1) Sign in logs; and

(2) Agendas and training manuals for facility based in-services;

(3) Documentation of completed continuing education courses taken by each staff member must be maintained in that employees personnel file and must be available for review by a board investigator upon demand

(D) Approved professional peer review organizations include,

veterinary medicine;

(8) An individual who holds a current, valid license issued under Chapter 4779. of the Revised Code to practice orthotics, prosthetics, or pedorthics;

(9) A pharmacy licensed under Chapter 4729. of the Revised Code that either does not sell or rent home medical equipment or receives total payments of less than ten thousand dollars per year from selling or renting home medical equipment;

(10) A home dialysis equipment provider regulated by federal law.

Definitions

Chapter 4752. of the Ohio Revised Code and Chapter 4761:1 of the Ohio Administrative Code are the laws and rules, respectively, for the regulation of Home Medical Equipment services in the State of Ohio. Each contains definitions of terms used in the regulations. The Board encourages all providers to obtain a copy of the laws and rules. A copy of both may be obtained on the Ohio Respiratory Care Board's website: www.hme.ohio.gov.

Any person or facility that provides an HME service to Ohio citizens is required to obtain a license or certificate of registration from the Ohio Respiratory Care Board. Facilities that are accredited by a recognized accrediting body or the Joint Commission on Accreditation of Health Organizations (JCAHO) do not have to obtain a license, but must apply for a certificate of registration with the Ohio Respiratory Care Board. The following definitions apply to home medical equipment services:

ORC 4752.01 states:

A. "Home medical equipment" means equipment that can stand repeated use, is primarily and customarily used to serve a medical purpose, is not useful to a person in the absence of illness or injury, is appropriate for use in the home, and is one or more of the following:

(1) Life-sustaining equipment prescribed by an authorized health care professional that mechanically sustains, restores, or supplants a vital bodily function, such as breathing;

- (2) Technologically sophisticated medical equipment prescribed by an authorized health care professional that requires individualized adjustment or regular maintenance by a home medical equipment services provider to maintain a patient's health care condition or the effectiveness of the equipment;
 - (3) An item specified by the Ohio respiratory care board in rules adopted under division (B) of section 4752.17 of the Revised Code.
- B. "Home medical equipment services" means the sale, delivery, installation, maintenance, replacement, or demonstration of home medical equipment.
 - C. "Home medical equipment services provider" means a person engaged in offering home medical equipment services to the public.
 - D. "Sell or rent" means to transfer ownership or the right to use property, whether in person or through an agent, employee, or other person, in return for compensation.

OAC 4761:1-3-01 states:

- A. "24/7 coverage" means that facilities that provide HME services must have a telephone number that is operational twenty four hours a day, seven days a week that clients can call to seek assistance. The telephone line may be an answering service that is monitored on a regular basis by the HME provider and should also alert clients to contact 911 in an emergency.
- B. "Accrediting body" means an organization recognized by the board under rule 4761:1-4-01 of the Administrative Code.
- C. "Approved professional peer review organization" as the term is used in rule 4761:1-13-01 of the Administrative Code means any professional organization that grants continuing education credit based upon objective criteria as a tax exempt professional association.
- D. "The board" is the Ohio respiratory care board.

and findings.

For facilities located outside the State of Ohio, the Board may include expenses for representatives from the Board to travel to the facility and conduct the inspection. The cost of transportation, food, and lodging for a total of two days for each representative may be billed to the facility. The Board must make every reasonable effort to limit the costs associated with the inspection and the cost of transportation, lodging and food.

The current inspection fee is \$350.00 for in state facilities.

Continuing Education Requirements

Pursuant to OAC 4761:1-13-01:

- (A) Each licensed HME facility must demonstrate that a continuing education plan has been developed that provides continuing education for staff that is appropriate to the type and level of HME services rendered by that staff member
- (B) The qualifying continuing education program must meet or exceed the following guidelines:
 - (1) Staff must complete no less than ten contact hours of continuing education per renewal cycle. Of the required hours:
 - (a) No more than five contact hours may be non-

Orthotics/Prosthetics

- Licensed fitters for custom fit items

HR Related

- I9 forms
- Federal & state tax forms

Position statements

CDC

- Hands washed
- TB testing

CMS

- Supplier Standards provided/met
- Quality standards complied with
- Proper patient signatures
- Assignment of benefits obtained
- ABN/hardship & other billing related items

OIG

- Exclusion checks on employees and entities do business with Compliance program

Inspection Fees

Inspection fees are established by Board motion. The Board is authorized under OAC 4761:1-8-03 to bill a facility within thirty days after the inspection is completed. The fee is calculated by the Board giving consideration to the hourly cost of the inspection and the number of hours needed to conduct an inspection, including the time needed to complete the report

- E. "CMS" means the centers for medicare and medicaid services.
- F. "Contact hour" means a period of sixty minutes with a minimum of fifty minutes of instruction. For credit hours earned on an academic quarter system, one credit hour is equivalent to ten contact hours. For credit hours earned on an academic trimester system, one credit hour is equivalent to twelve contact hours. For credit hours earned on an academic semester system, one credit hour is equivalent to fifteen contact hours.
- G. "HME" stands for home medical equipment.
- H. "HME services provider" is the licensed or registered facility that provides home medical equipment services.
- I. "Holder of a certificate of registration" means any person holding or practicing pursuant to a certificate of registration issued by the board under Chapter 4752. of the Revised Code.
- J. "Inactive status" means the status of a license or certificate of registration of a facility that has made a request in writing that the board place the license or registration on inactive status and who has returned their license or certificate of registration to the board. A facility with an inactive license does not hold a current, valid license or certificate of registration.
- K. "Facility based" means that the continuing education program is offered by the HME service provider organization and not an approved peer review organization.
- L. "JCAHO" means the joint commission on accreditation of healthcare organizations.
- M. "Lapsed certificate of registration" mean the status of the certificate of an individual who has failed to fulfill all requirements of certificate renewal, and who has failed to request that the board place the

certificate on inactive status.

- N. "Lapsed license" mean the status of the certificate of an individual who has failed to fulfill all requirements of certificate renewal, and who has failed to request that the board place the certificate on inactive status.
- O. "License" means a license, permit, card or other authority issued or conferred by a licensing agency by the authority of which the licensee has or claims the privilege to engage in the profession, occupation, or occupational activity, or to have control of and operate specific equipment, machinery, or premises, over which the licensing agency has jurisdiction.
- P. "Licensee" means either the person, partnership or corporation to whom the license is issued or renewed by a licensing agency, or the person, partnership, or corporation at whose request the license is issued or renewed.
- Q. "Life-sustaining equipment" means equipment prescribed by an authorized health care professional that mechanically sustains, restores, or supplants a vital bodily function, such as breathing.
- R. "Permanent revoked" means that the license or certificate of registration originally held by a licensee or certificate holder has been permanently declared null and void by disciplinary action taken by the board in accordance with Chapters 4752. and 119. of the Revised Code.
- S. "Provisional license" means a license that is issued to an individual who was engaged for at least twelve months prior to September 16, 2004, in the business of providing home medical equipment services. The provisional license expires one year following the date of issue and may not be renewed.
- T. "Renewal" and "renewed" as used in the chapter includes the continuing licensing procedure. The date of expiration of a license or certificate of registration shall be construed to mean the due date of the annual or other fee for the continuing license.

DOT

- Placards if vehicle weight requires
- Placards if O2 contents require it
- Shipping papers
- Pre/post trip inspections
- Appropriate drivers have - CDL
- Medical evaluation & certificate Q2yrs
- Drug test at hire, post accident and 1/2 of CDL staff annually
- 10 year work history in personnel file

ADA

- Handicap accessible
- Employee medical records in separate/locked location
- Anti-discriminatory practices

Pharmacy

- License for O2
- O2 Rx's renewed at least annually

ORCB

- RCP licenses readily available
- Respiratory therapy practiced by appropriately licensed staff
- Limited permit holders directly supervised by licensed RCP
- Proof of Continuing Education for HME Service providers per OAC 4761:1-13-01

Nursing

- Current license
- LPN's practice under scope of services

- Minimum Wage/FLSA (July 2007)
- OSHA
- EEOC/FMLA (>50 employees (2004)

State

- OH Minimum Wage (May 2007)
- Workers Compensation
- Fair Employment (March 2006)
- No Smoking (Dec 2006)
- Unemployment Insurance (July 1993)
- OSHA (May 2001)

FDA

- Legend items provided by order only
- Medical device tracking for vents & apnea monitors
- Transfilling - cGMP practices followed
- Annual registration
- Required policies
- O2 complaint log/book
- Complete batch production records
- initialed before batch used
- Annual vacuum check to zero
- Lot numbers tracked by patient
- Labels on all tanks/LOX units & legible
- Lot # on all tanks/LOX units
- COA or testing for supply tanks/LOX
- Unused labels under lock & key
- Annual training for fillers
- Analyzer calibration and system/guage certification logs
- Scale certified annually - if applicable
- Proper PPE used during fill

U. "Revoked" means that a license or certificate of registration has been declared null and void by disciplinary action taken by the board in accordance with Chapters 4752. and 119. of the Revised Code. Persons whose license has been revoked may apply for a new license or certificate of registration after more than one year after their initial license or certificate of registration was declared null and void by the board.

V. "Site visit" means an announced or unannounced visit to a HME facility by a board representative to determine whether the program meets or maintains the minimum standards required by the board.

W. "Staff" means employees or their representatives of the licensee or certificate of registration holder.

X. "Suspension" means a loss of a license or certificate of registration for a specific period of time (definite suspension) or until specific conditions are met (indefinite suspension). In the case of an indefinite suspension, the board may specify a minimum period of time during which the licensee may not practice, in addition to other conditions for reinstatement of a license.

Y. "Technologically sophisticated" means medical equipment prescribed by an authorized health care professional that required individualized adjustment or regular maintenance by an HME services provider to maintain a patient's health care condition or the effectiveness of the equipment.

OAC 4761:1-3-02 states:

(A) "Life-sustaining equipment" means equipment prescribed by an authorized health care professional that mechanically sustains, restores, or supplants a vital bodily function, such as breathing, including but not limited to:

- (1) Ventilators;
- (2) Oxygen Concentrators;
- (3) Oxygen Liquid Systems;
- (4) Oxygen Compressed Gas Systems;
- (5) Non Invasive Ventilator System (i.e. Bi-Level, Iron Lungs,

Rocking Beds, Diaphragmatic pacers, etc.);

(B) “Technologically-sophisticated” means medical equipment prescribed by an authorized health care professional that requires individualized adjustment or regular maintenance by an HME service provider to maintain a patient’s health care condition or the effectiveness of the equipment, including but not limited to:

- (1) Oxygen conservation devices;
- (2) CPAP (continuous positive airway pressure) devices;
- (3) Bi-level airway pressure (BiPAP) devices;
- (4) Intrapulmonary percussive ventilation (IPV) devices;
- (5) Intermittent positive pressure breathing (IPPB) devices;
- (6) Cough-assist mechanical in-exsufflator;
- (7) Apnea monitors;
- (8) Percussors for chest physiotherapy;
- (9) Suction machines;
- (10) Feeding pumps;
- (11) Infusion pumps;
- (12) Continuous passive motion (CPM) devices;
- (13) Transcutaneous electric nerve stimulators (TENS);
- (14) Custom seating or positioning systems;
- (15) Custom rehab equipment (i.e. standers & gait trainers);

(C) “Other” equipment is an item specified by the Ohio respiratory care board in rules adopted under division (b) of section 4752.17 of the revised code, including but not limited to:

- (1) Auto-titrating airway devices;
- (2) Pulse oximeters;
- (3) Home photo therapy (Bili lights or blankets);
- (4) Large volume air compressors for tracheostomy;
- (5) Electric wheelchairs and custom scooters;
- (6) In-home patient lifts;
- (7) Individually sized or customized accessories that are an integral part of equipment defined in paragraphs (A), (B), and (C) of this rule.

Additionally, the Board has identified, by resolution, the following additional types of equipment:

1. Bone Growth Stimulators
2. Drop foot Stimulators

annual detailed & specific TB training, surveillance of incidence and prevalence rates & other CDC guidelines

- At hire and annual training
- Annual safety training to include fire extinguisher use
- Protective equipment provided if needed
- Steel toed shoes when required
- Injury reporting and annual summary posting if > 10 employees
- 1st aid kits and eye wash available
- Exit routes free of debris
- Exits have visible exit sign illuminated by outside light or self illuminated
- Exit routes posted if exit not easily seen
- Written emergency action & fire prevention plans if 10 or more employees
- Right to Know program
- MSDS in building and vehicles
- Appropriate training
- Proper labeling of hazardous chemicals

Fire

- Fire Extinguishers current (checked at least annually)
- Extinguishers in areas as required
- O2 areas are free of combustibles & ignition sources
- Self illuminated exit signs tested at least annually

Posters

Federal Latest Revision

- USERRA (Dec 2005)
- Polygraph Protection (June 2003)

Standards of Practice for Licensed Facilities Cont'd

NO.	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:	YES	NO	N/A
F-4	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			

Applicable State and Federal Laws and Rules

HIPAA

- Privacy Notice posted
- Patient receipt of Privacy Notice
- Privacy & security training to staff

OSHA

- Blood borne Pathogens exposure control plan reviewed annually
- Hepatitis Vaccination offer/declination within 10 days of employment
- At hire & annual education for employees with exposure potential
- Proper PPE provided
- Needle stick safety & prevention if applicable
- TB Exposure Control plan
- 1 time N95 mask & fit test for employees with exposure potential
- TB testing for employees with exposure potential
- in lieu of testing (in low/medium risk areas);

Inspection Standards Check Off

Inspection Standards

The following is the actual check off used by the HME inspector. The Statutory Standard is listed in **BOLD** print, followed by the actual cite from the Ohio Administrative Code. Beneath each standard are the specific item (s) the inspector will survey to determine if the standard is met. To prepare for an inspection, review each standard and mark “yes” or “no” to meeting the standard. In rare cases, the standard may not be applicable. These instances are generally related to the type of HME equipment sold. For example, if a standard, such as M-2 below, requires a facility to have a “No Smoking” if medical or combustible gases are present, clearly not all facilities sell or rent medical or combustible gases. **The Ohio Respiratory Care Board recommends telephoning our office to discuss any standards you believe are not applicable.**

Where practical, the Board has inserted examples in *italic*. These examples are added comments and not part of the actual standard. Most of the standards are self-explanatory.

If you mark “no” to a standard, you will need to meet compliance with the standard to pass an inspection. If you have questions concerning the standard, you may telephone the Board’s HME Manager at 614-644-4732.

Standards of Practice for Licensed Holders

NO.	The licensee shall maintain knowledge of the duties, responsibilities, and accountabilities of an HME provider and shall practice in accordance with the following:	YES	NO	N/A
F-1	The laws regulating the provision of HME providers as outlined in Chapter 4752. of the Revised Code (see 4752.07 and 4752.09 ORC)			
F-2	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			
	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.			
F-3	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.			

Personnel Records

NO.	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)	YES	NO	N/A
P-1	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			
P-2	<u>Employee file must also include a copy of one of the following (4761:1-9-05 C7):</u>			
	Birth certificate -			
	Driver's License			
	Social security card			
P-3	Passport or permanent resident care			
	The facility must have on file a copy of the DOT evaluation – if applicable			

Standards for Maintaining a Facility

NO.	The facility must have appropriate physical space to safely store, maintain and service on site equipment (4761:1-9-02 (A) ORC)	YES	NO	N/A
M-1	Facility interior and exterior is clean, safe, organized and free of debris and excess equipment			
M-2	“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 (<i>may not be applicable for all HME facilities depending upon type of services</i>)			
M-3	Fire extinguishers are adequately labeled and are current (<i>inspector will check extinguisher tags for annual check and will verify that pressure manometer is in the “green.”</i>)			
M-4	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)			
M-5	Business office and equipment are two separate areas (<i>Determination up to discretion of inspector. Equipment and business areas may be in same room, but should be separated.</i>)			
M-6	Equipment cleaning, maintenance and storage areas are well marked and separated within the facility (<i>Clean, dirty, maintenance, and storage must be separated and identifiable. Tape on floor is not necessary. Tag system may be acceptable for identification. System must effectively demonstrate a reduced risk of cross-contamination.</i>)			

M-7	Patient records are secured after business hours (Doors should have locks. Inspectors will consider computer security, also.)			
	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)			
M-8	Returned equipment is processed in the following categories: clean, dirty, repair/tested, contaminated/quarantined, patient ready			
M-9	Employees with patient contact can verbalize the procedure for receiving & processing equipment returned by patients			
M-10	Gases are properly transported, secured, quarantined, and safely stored in a well marked area and are in compliance with FDA requirements and state laws			
M-11	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)	YES	NO	N/A
M-12	Back-up equipment is readily available in your facility and/or in subcontractor's facility			
M-13	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)	YES	NO	N/A
M-14	HME license is conspicuously posted and current license card is filed in an easily retrievable location. Other licenses available for review, as applicable (Inspector will ask to see the facility's HME license and all other applicable licenses. Licenses should be conspicuously posted.)			
M-15	Proof of insurance (\$1 million per occurrence/\$3 million total aggregate) (Inspectors will review records. Must include product and professional liability insurance)			

Client Records

NO.	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)	YES	NO	N/A
C-1	Client records must be filed and readily available			
	The client record must contain the following: (4761:1-9-04 (B) ORC) - (Inspector will randomly select a sample of records using size of client base.)			
C-2	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:			
C-3	a. Safe and proper use of equipment			
	b. Safe and proper storage of equipment			
	c. Patient maintenance responsibilities			
	d. 24 hour emergency number			
C-4	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 Maintaining Equipment Cont'd

E-12	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			
E-13	Equipment repair tools, including 02 tools, are cleaned and maintained			
E-14	Repair area kept orderly			
E-15	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)	YES	NO	N/A
E-16	Proof that testing of equipment has been performed prior to delivery and as periodically required by manufacturer specifications			
E-17	Facility has a policy for handling outdated product – separate from patient ready supplies			
E-18	All patient ready equipment and supplies are used within the manufacturer’s specified guidelines and dates for use, if applicable			

NO.	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)	YES	NO	N/A
M-17	Bedding license is current. <i>(may not be applicable for all HME facilities depending upon type of services)</i>			
	General facility requirements (4761:1-9-02 ORC)	YES	NO	N/A
M-18	Facility has identifying storefront signage that does not include any false, fraudulent, deceptive or misleading information (4761:1-15-02)			
M-19	Hours of operation and after hours phone number are posted on front of establishment			
M-20	If facility cannot meet patient needs, referral contacts are identified and easily retrieved (4761:1-9-01 E2) <i>(Inspector will ask to see a list of referral contacts)</i>			
M-20	Facility has a policy on handling patient incidents and patient complaint reporting			

Standards for Maintaining Equipment

NO.	Maintain and document equipment in accordance with manufacturers guidelines - (4761:1-9-03 (A) ORC)	YES	NO	N/A
E-1	Facility has equipment manufacturer and warranty information filed in an easily retrievable location <i>(warranty information should be easily retrievable. Inspector's state equipment manuals are often not available and warranty information cannot</i>			
E-2	Facility has a tracking mechanism in place for the following:			
	a. Location of equipment, serial numbers, model numbers <i>(Inspectors will check for equipment location, serial and model numbers on tracking logs or forms.)</i>			
	b. FDA medical device tracking records			
	c. Gases dispensed and lot number tracking by pa-			
	d. Equipment recall records			
E-3	Equipment used to test medical equipment is clean, accurate and is regularly calibrated per manufacturer recommendations			
E-4	Preventive maintenance records are in place <i>(A process should be in place, regardless of whether any preventative maintenance has been performed. Inspector will check for tools and documentation forms.)</i>			

Standards for Maintaining Equipment Cont'd

E-5	There are policy and procedures for providing emergency supply of gases, supplies and equipment <i>(Inspector will check for procedure on providing back up emergency supplies, gases or equipment. Policy should identify minimum standards for facility.)</i>			
NO.	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)	YES	NO	N/A
E-6	Documentation that equipment has been cleaned prior to patient ready storage:			
	a. Proper cleaning agents are used per manufacturer guidelines <i>(Inspector will check for hospital grade disinfectant. Must be effective for TB and Hepatitis. Policy should explain how agents are to be used.)</i>			
	b. Proper upholstery and mattress agents are used <i>(Inspector will check for proper cleaning agents.)</i>			
E-7	Contaminated equipment handling protocols in place <i>(Inspector will ask provider to verbalize the protocol)</i>			
E-8	Proper disposal of single use items			
E-9	Delivery vehicle clean and orderly			
E-10	Personal protective equipment/universal precautions are being met <i>(Inspector will observe procedures, look for protective kits and masks (N-95 rating or higher, fit tested), universal precautions policy)</i>			
E-11	Cleaning area kept orderly			