

## **ARTICLE XXXVIII MEDICAL EQUIPMENT SUPPLIERS PERMIT**

### **(1) Definitions. For the purposes of this Article:**

- (a) “Home medical equipment” means technologically sophisticated medical equipment and devices usable in a home care setting, including, but not limited to:
  - (i) Oxygen for human consumption, oxygen concentrators and/or oxygen delivery systems and equipment;
  - (ii) Ventilators;
  - (iii) Respiratory disease management devices;
  - (iv) Electronic and computer driven wheelchairs and seating systems;
  - (v) Apnea monitors;
  - (vi) Transcutaneous electrical nerve stimulator (TENS) units;
  - (vii) Low air loss cutaneous pressure management devices;
  - (viii) Sequential compression devices;
  - (ix) Neonatal home phototherapy devices;
  - (x) Feeding pumps; and
  - (xi) Other similar equipment as defined in regulations adopted by the board.

The term “home medical equipment” does not include medical equipment used in the normal course of treating patients by hospitals, hospices, long-term care facilities or home health agencies, or medical equipment used or dispensed by health care professionals licensed by the State of Mississippi if the professional is practicing within the scope of his or her professional practice. In addition, the term does not include items such as upper and lower extremity prosthetics, canes, crutches, walkers, bathtub grab bars, standard wheelchairs, commode chairs and bath benches.

- (b) “Home medical equipment services” means the delivery, installation, maintenance, replacement, and/or instruction in the use of home medical equipment, used by a sick or disabled individual, to allow the individual to be cared for and maintained in a home or noninstitutional environment.
- (c) “Medical gas” means those gases and liquid oxygen intended for human consumption.
- (d) “Order” means an order issued by a licensed practitioner legally authorized to order home medical equipment, legend devices and/or medical gases.

### **(2) Permit required.**

- (a) No person, business or entity located in this state or outside of this state that is subject to this section shall sell, rent or provide or offer to sell, rent or provide directly to patients in this state any home medical equipment, legend devices, and/or medical gas unless such person, business or entity first obtains a Medical Equipment Supplier Permit from the board.
- (b) The permitting requirements of this section apply to all persons, companies, agencies and other business entities that are in the business of supplying home medical equipment to

patients in their places of residence and that bill the patient or the patient's insurance, Medicare, Medicaid or other third-party payor for the rent or sale of that equipment.

- (c) The board shall require a separate permit for each facility location directly or indirectly owned or operated in this state. Permits shall not be issued for facilities located in a residence.
- (d) The application for a permit shall be made to the board on a form supplied by the board and shall be accompanied by a fee of not more than Three Hundred Dollars (\$300.00), as prescribed by the board. Once issued, every permit must be renewed annually, and the renewal fee shall be not more than One Hundred Seventy-five Dollars (\$175.00), as prescribed by the board.
- (e) All permits issued under this section shall expire annually on June 30 of each year. Applications for renewal must be made to the board on or before June 30 and must be accompanied by the fee as prescribed by the board. A late renewal fee of One Hundred Dollars (\$100.00) shall be added to all renewal applications received by the board after June 30 of each renewal period. The permit shall become void if the renewal application, renewal fee and the late renewal fee are not received by the board by September 30 of each year.
- (f) The person who signs the application for a medical equipment suppliers permit or the renewal of a medical equipment suppliers permit shall be the permit holder for that facility and shall be responsible for all activities in the permitted facility which are subject to regulation by the Board. Once issued, a permit cannot be amended, transferred or assigned to another person.
- (g) If the employment of a permit holder is terminated or if for any other reason he/she wishes to be relieved of the responsibilities of the permit holder, he/she must return the medical equipment suppliers permit to the Mississippi Board of Pharmacy with written notice that he/she is no longer the permit holder for that facility. When a permit is thus returned, application for a new permit for that facility must be made to the Mississippi Board of Pharmacy within ten (10) days.
- (h) If a permitted facility is permanently closed or has a change of ownership, the permit holder for that facility shall give notice to the Board of the effective date of closure or change in ownership at least ten (10) days prior to the closure or change of ownership.
- (i) If a permitted facility has a change in name or location, a new permit must be obtained. Application for this new permit must be made to the Board at least ten (10) days prior to the change.

### (3) Exemptions.

- (a) The permitting requirements of this section do not apply to the following entities or practitioners unless they have a separate business entity, company, corporation or division

that is in the business of providing home medical equipment for sale or rent to patients at their places of residence:

- (i) Home health agencies;
- (ii) Hospitals;
- (iii) Wholesalers and/or manufacturers;
- (iv) Medical doctors, physical therapists, respiratory therapists, occupational therapists, speech pathologists, optometrists, chiropractors and podiatrists who use home medical equipment and/or legend devices in their individual practices;
- (v) Pharmacies;
- (vi) Hospice programs;
- (vii) Nursing homes and/or long-term care facilities;
- (viii) Veterinarians; dentists; and emergency medical services.

(b) Although community pharmacies are exempt from the permitting requirements of this section, they shall be subject to the same regulations that are applicable to permitted businesses or entities for the sale or rental of home medical equipment covered by this section.

(c) Nothing in this section shall prohibit trained individuals from using oxygen, liquid oxygen and/or legend devices in emergencies.

(d) Nothing in this section shall prohibit the prehospital emergency administration of oxygen by licensed health care providers, emergency medical technicians, first responders, fire fighters, law enforcement officers and other emergency personnel trained in the proper use of emergency oxygen.

(4) Order required.

Home medical equipment suppliers shall not provide any home medical equipment, legend device or medical gas to a patient without a valid order from an authorized licensed practitioner. All orders must be readily retrievable and must be produced on request by the Board or an agent of the Board. All home medical equipment, legend devices and medical gases require a new prescription order on a yearly basis.

(5) Regulations.

The board shall adopt regulations for the distribution and sale or rental of home medical equipment, legend devices and medical gases that promote the public health and welfare and comply with at least the minimum standards, terms and conditions of federal laws and regulations. The regulations shall include, without limitation:

- (a) Minimum information from each home medical equipment, legend device and medical gas supplier required for permitting and renewal permits;
- (b) Minimum qualifications of persons who engage in the distribution of home medical equipment;

- (c) Appropriate education, training or experience of persons employed by home medical equipment suppliers;
- (d) Minimum standards for storage of home medical equipment;
- (e) Minimum requirements for the establishment and maintenance of all records for the sale, rental and servicing of home medical equipment; and
- (f) Minimum standards of operation and professional conduct to include, but not be limited to:
  - (i) Employment of qualified personnel to properly render medical equipment services in the manner prescribed by law;
  - (ii) Suitable facilities shall be maintained to house inventory, to allow for equipment maintenance work space and the storage and retrieval of all records required to be kept;
  - (iii) A copy of these regulations shall be present in the facility at all times;
  - (iv) The facility is kept in a clean, orderly and sanitary condition at all times;
  - (v) The applicant's services are accessible to its customer base;
  - (vi) The applicant complies with all USP, FDA, DOT and OSHA requirements regarding the storage, packaging, labeling and shipping of medical equipment including medical gases;
  - (vii) The applicant's services are available twenty-four (24) hours, seven (7) days per week when essential to the maintenance of life or when lack of services might reasonably cause harm;
  - (viii) The applicant implements and maintains a written procedure at each location for handling complaints and problems, which includes a complaint file documenting complaints and problems and resolution of the complaints and problems;
  - (ix) The applicant complies with all local/state fire and building laws; and
  - (x) The facility is equipped with a functioning lavatory where hot and cold running water or hand washing appliances or waterless hand cleaner are available.

(6) Additional Regulations for Medical gas, oxygen and respiratory equipment suppliers:

- (a) Comply with all applicable home medical equipment laws and regulations of Mississippi;
- (b) If transporting oxygen and other medical gases in cylinder or liquid form, comply with all current Department of Transportation rules and regulations;
- (c) If transfilling medical oxygen systems, comply with Food and Drug Administration (FDA) and all state agency requirements regarding transfilling and repackaging;
- (d) Demonstrate that oxygen and other medical gases provided in cylinder or liquid form meets minimum purity standards for medical grade oxygen and medical gases;
- (e) Meet the following safety inspection requirements:
  - (i) Demonstrate that each piece of oxygen/respiratory equipment has been checked, is free of defects and operates within the manufacturer's specifications;

- (ii) Refrain from modifying equipment to the extent that the modification might reasonably cause harm;
  - (iii) Maintain all electrical components so that they do not present fire or shock hazard; and
  - (iv) Ensure that all appropriate warning labels or labeling, including tags, are present on the equipment provided.
- (f) Comply with the following recall procedures:
- (i) Ensure that lot numbers and expiration dates are affixed to each cylinder delivered;
  - (ii) Maintain a tracking system for all medical oxygen and gas delivered;
  - (iii) Document all equipment serial numbers and model numbers to ensure that equipment can be retrieved if a recall is initiated; and
  - (iv) Maintain records for equipment that requires FDA tracking.
- (g) Comply with the following maintenance and cleaning requirements:
- (i) Maintain documentation demonstrating that a function and safety check of equipment was performed prior to set up;
  - (ii) Maintain an established protocol for cleaning and disinfecting equipment which addresses both aerobic and anaerobic pathogens;
  - (iii) Maintain a Material Safety Data Sheet (MSDS) on file for solutions and products used in cleaning and disinfecting procedures;
  - (iv) Maintain segregated areas on the premises and in delivery vehicles for clean, dirty, and contaminated equipment;
  - (v) Clean and disinfect equipment according to manufacturers' specifications;
  - (vi) Instruct the patient on proper cleaning techniques as specified by the manufacturer; and
  - (vii) Ensure that all medical gas, oxygen and respiratory related equipment is properly identified by a tag or label as to its current status of use, i.e. out of order or ready for use.
- (h) Implement a comprehensive preventative maintenance program which includes the following:
- (i) Procedures for problem reporting, tracking, recall, and resolution;
  - (ii) Performance of service as specified by the manufacturer and the documentation of such performance in the service records; and
  - (iii) Routine inspection, service, and maintenance of equipment located in the patient's/customer's home according to manufacturers' specifications.
- (i) 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:
- (i) type of equipment;
  - (ii) manufacturer;

- (iii) model;
  - (iv) serial number;
  - (v) date of repair;
  - (vi) specific repair made; and
  - (vii) name of person or company performing the repair.
- (j) 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.
- (k) 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.
- (l) Comply with the following counseling requirements:
- (i) Utilize orientation checklists to review:
    - (1) Instructions for use of the equipment; and
    - (2) Safety precautions; and
    - (3) Cleaning procedures; and
    - (4) Maintenance procedures; and
    - (5) Return demonstrations on back up oxygen systems delivered;
  - (ii) Instruct the patient about emergency and routine contact procedures; and
  - (iii) Deliver and review written instruction materials to ensure that the patient receives adequate information in order to properly operate the equipment.

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 care giver or patient ability to comply with the order, and the care giver or patient ability to operate and clean the equipment as instructed.

#### (7) Additional Regulations for Other Medical Equipment

Persons that shall sell, rent and/or provide other medical equipment or legend devices, as defined in these regulations, shall also comply with the following:

- (a) Provide proper training of personnel for the safe delivery and use of any medical equipment or legend device;
- (b) Ensure that all manufacturer's recommended assembly and maintenance procedures are followed; and
- (c) Meet the following safety inspection requirements:
  - (i) Demonstrate that each piece of medical equipment or legend device has been checked, is free of defect and operates within the manufacturer's specifications;
  - (ii) Refrain from modifying equipment to the extent that the modification might reasonably cause harm;

- (iii) Maintain all electrical components so that they do not present fire or shock hazard; and
- (iv) Ensure that all appropriate warning labels or labeling, including tags, are present on the equipment provided.

(8) Medical Equipment Advisory Committee to the board.

- (a) A Medical Equipment Advisory Committee (MEAC), composed of three (3) members selected by the Mississippi Association of Medical Equipment Suppliers and approved by the board, shall review and make recommendations to the board regarding all regulations dealing with home medical equipment, legend devices and medical gases that are proposed by the board and before they are adopted by the board.
- (b) All MEAC members must have been actively involved in the home medical equipment business for a minimum of five (5) years before the selection to the committee and shall hold and maintain, in good standing, a permit issued by the board under this section.
- (c) The MEAC members shall meet at least quarterly and review all home medical equipment suppliers' inspection reports. All complaints and reports of investigations of violations of law or regulations regarding home medical equipment, legend devices and medical gases shall first be reviewed by the MEAC. After review, the MEAC may make recommendations to the board's Investigations Review Committee regarding further administrative action by the board.
- (d) The MEAC shall keep and maintain minutes of all meetings of the MEAC and shall provide copies of the minutes to the board on a quarterly basis.
- (e) The Mississippi Board of Pharmacy may remove any or all MEAC members on proof of unprofessional conduct, continued absence from the state, being found guilty of any provisions of these regulations or other regulations of the state or federal government or failure to perform the duties of his/her office. Any MEAC member who shall not attend two (2) consecutive regular meetings of the MEAC for any reason other than illness shall be subject to removal by the Mississippi Board of Pharmacy.

(9) Revocation, suspension or restriction of permit and penalties.

- (a) The board may revoke, suspend, restrict or refuse to issue or renew a permit or impose a monetary penalty, in accordance with Section 73-21-103 except that the monetary penalty shall not exceed Ten Thousand Dollars (\$10,000.00) per violation, if the business or holder of a permit or applicant for a permit issued under this section has committed or is found guilty by the board of any of the following:
  - (i) Violation of any federal, state or local law or regulations relating to home medical equipment, legend devices or medical gases.
  - (ii) Violation of any of the provisions of this section or regulations adopted under this section.

- (iii) Commission of an act or engaging in a course of conduct that constitutes a clear and present danger to the public health and safety.
  - (iv) Filing a claim or assisting in the filing of a claim for reimbursement for home medical equipment or home medical equipment services that were not provided or that were not authorized to be provided.
  - (v) Failure to comply with any lawful order of the board.
- (b) Disciplinary action by the board against a business or any person holding a permit under this section shall be in accordance with Section 73-21-9.