TITLE 30: PROFESSIONS AND OCCUPATIO NS

PART 3001: MISSISSIPPI PHARMACY PRACTICE REGUALTIONS

ARTICLE XXXVIII MEDICAL EQUIPMENT SUPPLIERS PERMIT

1. Permit required:

Pursuant to Mississippi Pharmacy Practice Act Section 73-21-108 no person, business or entity subject to this chapter shall sell, rent or provide or offer to sell, rent or provide directly or indirectly to consumers in this state any home medical equipment, legend devices, and/or medical gas unless such person, business or entity first obtains a Medical Equipment Suppliers Permit from the Mississippi Board of Pharmacy. Permitting procedures are as follows:

A. The permitting requirements of this section will apply to all companies, agencies and other business entities that are in the business of supplying home medical equipment to patients in residential settings and which bill the patient or the patient's insurance, Medicare, Medicaid or other third party payor for the rent or sale of that equipment.
B. The application for a permit shall be on a form supplied by the Board and accompanied by a fee of $150.00. Once issued, every permit must be renewed annually. The renewal fee shall not exceed $150.00.
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. All permits issued under this section shall expire annually on June 30, of each year. Application and payment for renewal must be postmarked on or before June 30 and must be accompanied by the fee as prescribed by this section. A penalty of $50.00 shall be added to all late renewals postmarked after June 30, of each renewal period. The Permit shall become null and void if the renewal application, and renewal fee are not received by July 1 of each year.
E. 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.
F. 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.
G. 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.

H. 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.

I. The Board shall not issue any original or annual renewal medical equipment permit until the Board is satisfied that:

(1) Adequate qualified personnel have been secured by management of the facility to properly render medical equipment services in the manner prescribed by law; and
(2) Such personnel shall be maintained during the period for which the permit is issued; and
(3) 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; and
(4) Repealed 2013
(5) A copy of these regulations shall be present in the facility at all times; and
(6) The facility is kept in a clean, orderly and sanitary condition at all times ; and
(7) The applicant's services are accessible to its customer base; and
(8) The applicant complies with all USP, FDA, DOT and OSHA requirements regarding the storage, packaging, labeling and shipping of medical equipment including medical gases; and
(9) 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; and
(10) 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; and
(11) The applicant complies with all local/state fire and building laws; and
(12) The facility is equipped with a functioning lavatory where hot and cold running water or hand washing appliances or waterless hand cleaner are available; and

Exemptions are as follows:

A. The permitting requirements of this section do not apply to the following unless the following have a separate business entity, company, corporation or division that is in the business of providing home medical equipment to patients at their home: home health agencies; hospitals; wholesalers and/or manufacturers; 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; pharmacies; hospice programs; nursing homes and or long term care facilities; veterinarians; dentists; and

emergency medical services.

B. Community pharmacies, long term care facilities and hospitals although excluded from permitting requirements of this section, will be subject to the same regulations for the sale or rental of home medical equipment covered by this section.

C. It is also recognized that oxygen, liquid oxygen and/or legend devices may be used in emergencies by trained individuals.

D. Nothing in this section shall prohibit the pre-hospital 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.

2. Medical Equipment Advisory Committee (MEAC) to the Board:

A. A MEAC committee, 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 on the merit of all regulations dealing with home medical equipment, legend devices and medical gases, which are proposed by the Board and before they are adopted by the Board.
Newly appointed MEAC members shall be assigned to Post 1., Post 2. or Post 3. Subsequent terms of MEAC members shall be for a period of five (5) years and no member shall serve two consecutive terms.

B. All MEAC members shall have been actively involved in the home medical equipment business for a minimum of five (5) years and shall hold and maintain, in good standing, a permit issued by the Board pursuant to 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 violation of law or regulations shall first be reviewed by the MEAC. After review, the MEAC may make recommendations to the Board's Investigations Review Committee as to 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 said 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.

3. Order Required:

Home Medical Equipment Suppliers shall not provide any legend device or medical gas to a patient without a valid order from an authorized practitioner all orders must be readily retrievable and must be produced on request by a compliance agent. All legend items, including oxygen, require a new prescription order on a yearly basis.

4. Medical gas, oxygen and respiratory equipment suppliers shall:

A. Comply with all applicable home medical equipment laws and regulations of Mississippi; and
B. If transporting oxygen and other medical gases in cylinder or liquid form, comply with all current Department of Transportation rules and regulations; and
C. If transfilling medical oxygen systems, comply with Food and Drug Administration (FDA) and all state agency requirements regarding transfilling and repackaging; and
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; and
E. Meet the following safety inspection requirements:
    (1) Demonstrate that each piece of oxygen/respiratory equipment has been checked, is free of defects and operates within the manufacturer's specifications; and
    (2) Refrain from modifying equipment to the extent that the modification might reasonably cause harm; and
    (3) Maintain all electrical components so that they do not present fire or shock hazard; and
    (4) Ensure that all appropriate warning labels or labeling, including tags, are present on the equipment provided.

I. Medical gas, oxygen and respiratory related equipment suppliers shall comply with the following recall procedures:
    A. Ensure that lot numbers and expiration dates are affixed to each cylinder delivered; and
    B. Maintain a tracking system for all medical oxygen and gas delivered; and
    C. Document all equipment serial numbers and model numbers to ensure that equipment can be retrieved if a recall is initiated; and
    D. Maintain records for equipment that requires FDA tracking.

II. Medical gas, oxygen and respiratory related equipment suppliers shall comply with the following maintenance and cleaning requirements:
    A. Maintain documentation demonstrating that a function and safety check of equipment was performed prior to set up; and
    B. Maintain an established protocol for cleaning and disinfecting equipment which addresses both aerobic and anaerobic pathogens; and
    C. Maintain a Material Safety Data Sheet (MSDS) on file for solutions and products used in cleaning and disinfecting procedures; and
    D. Maintain segregated areas on the premises and in delivery vehicles for clean, dirty, and contaminated equipment; and
    E. Clean and disinfect equipment according to manufacturers' specifications; and
    F. Instruct the patient on proper cleaning techniques as specified by the manufacturer; and
    G. Ensure that all medical gas, oxygen and respiratory related equipment is properly identified by a tag or label as to it's current status of use, i.e. out of order or ready for use.

III. Medical gas, oxygen and respiratory related equipment suppliers shall implement a comprehensive preventative maintenance program which includes the following:
   A. Procedures for problem reporting, tracking, recall, and resolution; and
   B. Performance of service as specified by the manufacturer and the documentation of such performance in the service records; and
   C. Routine inspection, service, and maintenance of equipment located in the patient's/customer's home according to manufacturers' specifications.

IV. Medical gas, oxygen and respiratory related equipment suppliers shall 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:
   A. type of equipment; and
   B. manufacturer; and
   C. model; and
   D. serial number; and
   E. date of repair; and
   F. specific repair made; and
   G. name of person or company performing the repair.

V. Medical gas, oxygen and respiratory related equipment suppliers shall 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.

VI. Medical gas, oxygen and respiratory related equipment suppliers shall 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.

VII. Medical gas, oxygen and respiratory related equipment suppliers shall comply with the following counseling requirements:
   A. 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; and
   B. Instruct the patient about emergency and routine contact procedures; and
   C. 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.

5. 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; and

B. Ensure that all manufacturer's recommended assembly and maintenance procedures are followed; and

C. Meet the following safety inspection requirements:

(1) Demonstrate that each piece of medical equipment or legend device has been checked, is free of defect and operates within the manufacturer's specifications; and

(2) Refrain from modifying equipment to the extent that the modification might reasonably cause harm; and

(3) Maintain all electrical components so that they do not present fire or shock hazard; and

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

6. Revocation, Suspension or Restriction, Penalties of Permit shall be as follows:

A. The Board may revoke, suspend, restrict, refuse to issue or renew or impose a monetary penalty, in accordance with Section 73-21-103. Mississippi Code of 1972, Annotated, 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:

(1) Violation of any Federal, State or local law or regulation relating to medical equipment, legend devices or medical gases.

(2) Violation of any of the provisions of these regulations.

(3) Commission of an act or engaging in a course of conduct which constitutes a clear and present danger to the public health and safety.

(4) Filing a claim or assisting in the filing of a claim for reimbursement for medical equipment, medical gases, legend devices or professional services which were not provided or which were not authorized to be provided.

(5) Failure to comply with any lawful order of the Board.

(6) Conviction of a felony.

(7) Entering into any written agreements or other activities which interferes with or otherwise denies a patient the freedom to choose any willing provider of medical equipment or services.

B. Disciplinary action by the Board against a business or any person holding a permit pursuant to this section shall be in accordance with Section 73-21-99 of the Mississippi Code of 1972, Annotated.

Definitions:

For purposes of these regulations:

A. "Home Medical Equipment" means technologically sophisticated medical equipment

and devices usable in a home care setting including, but not limited to:

(1) Oxygen for human consumption, oxygen concentrators, and/or oxygen delivery systems and equipment;
(2) Ventilators;
(3) Respiratory disease management devices;
(4) Electronic and computer driven wheelchairs and seating systems;
(5) Apnea monitors;
(6) Transcutaneous electrical nerve stimulator (TENS) units;
(7) Low air loss cutaneous pressure management devices;
(8) Sequential compression devices;
(9) Neonatal home phototherapy devices;
(10) Feeding pumps;
(11) And other similar equipment as defined in any regulations established by the Board.

B. "Home Medical 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 non-institutional environment.

C. "Medical gas" means those gases and liquid oxygen intended for human consumption.

D. "Order" means an order issued by a licensed medical practitioner legally authorized to order medical gases, legend devices and/or home medical equipment.

E. The term "Home Medical Equipment" does not mean 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---provided that the professional is practicing within the scope of his/her professional practice. Further, that items such as upper and lower extremity prosthetics, canes, crutches, walkers, bathtub grab bars, standard wheelchairs, commode chairs and bath benches are not considered to be home medical equipment.

F. "Pharmacy Board, State Board of Pharmacy or Board" shall mean the Mississippi Board of Pharmacy.

G. The term "Legend Device" shall mean any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory which is required under federal or state law to be prescribed or ordered by a physician and/or practitioner.

Article XXXVIII, Paragraph 1-D REPEAL (Effective 3/6/14) Section was re-numbered after filing final repeal on 2/4/14. MS Administrative Bulletin System Number 20320