ARTICLE XXXVIII MEDICAL EQUIPMENT SUPPLIERS PERMIT

1. 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. MEAC shall follow all statutory requirements of Mississippi Code Annotated Section 73-21-108.
   b. The Board may remove any or all (MEAC) members on proof of unprofessional conduct, 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 Board.

2. 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; and
      x. Feeding pumps.

   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.

3. In addition to the requirements provided in Mississippi Code Annotated, Section 73-21-108(2), Medical Equipment Supplier Permits shall have the following requirements:
   a. Permits shall not be issued for facilities located in a residence.
   b. 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 until a new application is filed and a new updated/amended permit is issued by the Board.
   c. 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 remove his/her name from the medical equipment suppliers permit through the Board Licensing Gateway. When a permit holder is removed from the medical equipment suppliers permit, an application for a new permit for that facility must be made to the Board within fifteen (15) days. If a new updated/amended permit is not obtained within fifteen (15) days, the permit becomes inactive and no business may be conducted until a new permit is issued by the Board.
   d. 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 fifteen (15) days prior to the closure or change of ownership. "Change of ownership", in the case of a partnership, means the removal, addition, or substitution of a partner. In the case of a corporation, the term means the merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation. The transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute a change of ownership.
   e. If a permitted facility will have a change in ownership, name or location, a new updated/amended permit must be issued from the Board in order to doing business under the new name or location.
   f. The Board may declare a pharmaceutical facility/business permit inactive due to the lack of legitimate business activity for sixty (60) consecutive days. The permit holder of any permit declared inactive by the Board must petition the Board to be re-instated.

4. 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.

5. Orders 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.

6. Policies and programs shall be implemented to include:
   a. Policies that specify minimum standards for personnel qualifications, training, experience, and continuing education requirements consistent with the specialized equipment, items, and services it provides to clients;
   b. Policies that describe job descriptions, competencies, disciplinary action measures, rules of employment and employee orientation; and
   c. Polices shall allow unrestricted access to the Mississippi Board of Pharmacy website and regulations.

7. Minimum standards for competency of employees:
   a. All employees shall be competent to perform the services of the position for which they are hired.
   b. Assessment of staff competency shall be reviewed/revised/updated at least every two (2) years.
   c. The competency policy shall outline the competency program including services and tasks performed by each designated staff member based on job function or category. This policy shall be reviewed and signed by each staff member.

8. Minimum standards for education and training of persons employed by home medical equipment suppliers:
   a. Educational topics provided must be relevant to the employee's job function and provided on an annual basis.
   b. Records of staff attendance at all educational programs shall be maintained.
   c. The educational program shall include:
      i. OSHA and safety issues to include fire safety, disaster preparedness, and office security;
      ii. HIPAA, privacy, and security;

d. Orientation and training shall be provided to each employee whose job functions require it within ninety (90) days of employment. Orientation and training of the following areas shall be documented:
    i. Use of the equipment;
    ii. Safety and cleaning precautions and procedures for equipment;
    iii. Preventative maintenance, repair, and testing program for equipment;
    iv. Return demonstrations on back up oxygen systems delivered;
    v. Emergency and routine contact procedures; and
    vi. Delivery and review of written instruction materials to the patient to ensure the patient receives adequate information in order to properly operate the equipment.

9. Minimum standards for physical location and storage of home medical equipment:
    a. Suitable facilities shall be maintained to house inventory, to allow for equipment maintenance workspace and the storage and retrieval of all records required to be kept;
    b. The facility is kept in a clean, orderly, and sanitary condition at all times;
    c. The applicant's services are accessible to its customer base;
    d. The applicant complies with all USP, FDA, DOT and OSHA requirements regarding the storage, packaging, labeling, and shipping of medical equipment including medical gases;
    e. The applicant can be contacted twenty-four (24) hours, seven (7) days per week when services needed are essential to the maintenance of life or when lack of services might reasonably cause harm;
    f. The applicant complies with all local/state fire and building laws;
    g. 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
    h. The facility is temperature controlled and regulated as required by the manufacturer.

10. Minimum standards for selection of equipment, devices, and supplies:
    a. All equipment, devices, and supplies shall be based on patient need;
    b. The permit holder shall obtain copies of features, warranties, and instructions for all items from the manufacturers;
    c. All items shall meet applicable Food and Drug Administration (FDA) regulations.

11. Minimum standards of safety and cleaning requirements for home medical equipment:
    a. Demonstrate and maintain documentation that a function and safety check was performed on each piece of equipment prior to set up~~,~~ and such equipment is free of defects and operates within the manufacturer's specifications;
    b. Document that all appropriate warning labels or labeling, including tags, are present on the equipment provided.
    c. Maintain an established protocol for cleaning and disinfecting equipment which addresses both aerobic and anaerobic pathogens;
    d. Maintain a Safety Data Sheet (SDS) on file for solutions and products used in cleaning and disinfecting procedures;
    e. Maintain segregated areas on the premises and in delivery vehicles for clean, dirty, and contaminated equipment;
    f. Clean and disinfect equipment according to manufacturers' specifications;
    g. Instruct the patient on proper cleaning techniques as specified by the manufacturer; and

h. 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.

12. Minimum standards of comprehensive preventative maintenance, repair, and testing program for home medical equipment:
    a. Provide scheduled preventive maintenance, repairs and testing of all equipment and devices provided to clients as recommended by the equipment or device manufacturer;
    b. Establish a process to identify equipment scheduled for maintenance and provide the needed maintenance or repair of the equipment and devices according to the manufacturer's guidelines or recommendations;
    c. Provide the client with a replacement item when equipment/device in use is scheduled for maintenance or repair;
    d. Establish a process to repair equipment and devices that are reported as damaged or malfunctioning;
    e. Maintain a file of all current manufacturer's maintenance, warranties, repair, and testing instructions and recommendations for all equipment, devices, and supplies the permit provides;
    f. Only qualified staff members perform repairs or maintenance on equipment and devices according to the manufacturer's guidelines;
    g. Report and return to the manufacturer of any defective item and disposition, as appropriate; and
    h. The maintenance and repair data for each piece of equipment or device, as appropriate, includes:
        i. Equipment name, manufacturer, model, and serial number;
        ii. Date equipment went into service;
        iii. Projected dates of manufacturer recommended scheduled maintenance cleaning and calibration;
        iv. Dates maintenance performed include both the dates and reason of performed repairs and the date of disposition after maintenance or repair; and
        v. Name of person or company performing the repair.

13. Implement a written procedure at each location for handling patient complaints and problems, which includes a complaint file documenting complaints and problems and resolutions of the complaints or problems. This procedure shall be in writing, shall be available onsite, either in a hardcopy or immediately accessible electronically, and provided upon the request of an agent of the Board. All patient complaints shall be maintained for at least a three (3) year period.

14. Minimum standards for patient counseling instruction:
    a. Utilize orientation checklists to review:
        i. Instructions for use of the equipment; and
        ii. Safety precautions; and
        iii. Cleaning procedures; and
        iv. Maintenance procedures; and
        v. Return demonstrations on back up oxygen systems delivered;
    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.
d. A written plan of service shall be developed, implemented, and documented in the patient record and shall include 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.

15. Additional Regulations for medical gas, oxygen, and respiratory equipment suppliers:
    a. Oxygen and other medical gases being transported in cylinder or liquid form~~,~~ shall comply with all current State and Federal Department of Transportation rules and regulations;
    b. Transfilling medical oxygen systems~~,~~ shall comply with Food and Drug Administration (FDA) requirements regarding transfilling and repackaging;
    c. Oxygen and other medical gases provided in cylinder or liquid form shall meet minimum purity standards for medical grade oxygen and medical gases; and
    d. 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.
    e. Documentation of all testing of equipment shall be maintained and readily accessible.

16. Medical gas and oxygen suppliers must also meet the following recall procedures:
    a. Ensure that lot numbers and expiration dates are affixed to each cylinder delivered;
    b. Maintain a tracking system for all medical oxygen and gas delivered;
    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.

17. The above required policies, testing and required documentation shall be in writing and shall be available onsite or immediately accessible electronically, and provided upon the request of an agent of the Board.

18. A permit holder shall report to the Board within thirty (30) days any adverse action taken by another licensing jurisdiction, government agency, law enforcement agency, or court.

19. Failure to comply with the required policies and/or standards set forth in this Article shall be deemed a violation of the rules and regulations of the Board and may result in disciplinary action taken by the Board.

ARTICLE XXXVIII MEDICAL EQUIPMENT SUPPLIERS PERMIT

1. ~~(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. MEAC shall follow all statutory requirements of Mississippi Code Annotated, Section 73-21-108.

~~(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 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.~~

   b. ~~(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.~~

2. 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.

3. In addition to the requirements provided in Mississippi Code Annotated, Section 73-21-108(2), Medical Equipment Supplier Permits shall have the following required~~ments~~:
   ~~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.~~ a. 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.~~ b. 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 until a new application is filed and a new updated/amended permit is issued by the Board.

~~g.~~ c. 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~~ remove his/her name from the medical equipment suppliers permit through the Board Licensing Gateway ~~to the Mississippi Board of Pharmacy with written notice that he/she is no longer the permit holder for that facility~~. When a permit holder is removed from the medical equipment suppliers permit, an application for a new permit for that facility must be made to the ~~Mississippi~~ Board ~~of Pharmacy~~ within ~~ten (10)~~ fifteen (15) days. If a new updated/amended permit is not obtained within fifteen (15) days, the permit becomes inactive and no business may be conducted until a new permit is issued by the Board.

~~h.~~ d. 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)~~ fifteen (15) days prior to the closure or change of ownership. "Change of ownership", in the case of a partnership, means the removal, addition, or substitution of a partner. In the case of a corporation, the term means the merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation. The transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute a change of ownership.

~~i.~~ e. If a permitted facility ~~has a~~ will have a change in ownership, name or location, a new updated/amended permit must be ~~obtained~~ issued from the Board~~. Application for this new permit must be made to the Board at least ten (10) days~~ prior ~~to the change~~ to doing business under the new name or location.

f. The Board may declare a pharmaceutical facility/business permit inactive due to the lack of legitimate business activity for sixty (60) consecutive days. The permit holder of any permit declared inactive by the Board must petition the Board to be re-instated.

4. 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.

5. Orders 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. Policies and programs shall be implemented to include:
   a. Policies that specify minimum standards for personnel qualifications, training, experience, and continuing education requirements consistent with the specialized equipment, items, and services it provides to clients;
   b. Policies that describe job descriptions, competencies, disciplinary action measures, rules of employment and employee orientation; and
   c. Polices shall allow unrestricted access to the Mississippi Board of Pharmacy website and regulations.

7. Minimum standards for competency of employees:
   a. All employees shall be competent to perform the services of the position for which they are hired.
   b. Assessment of staff competency shall be reviewed/revised/updated at least every two (2) years.
   c. The competency policy shall outline the competency program including services and tasks performed by each designated staff member based on job function or category. This policy shall be reviewed and signed by each staff member.

8. Minimum standards for education and training of persons employed by home medical equipment suppliers:
   a. Educational topics provided must be relevant to the employee's job function and provided on an annual basis.
   b. Records of staff attendance at all educational programs shall be maintained.
   c. The educational program shall include:

iii. OSHA and safety issues to include fire safety, disaster preparedness, and office security;
iv. HIPAA, privacy, and security;

d. Orientation and training shall be provided to each employee whose job functions require it within ninety (90) days of employment. Orientation and training of the following areas shall be documented:
vii. Use of the equipment;
viii. Safety and cleaning precautions and procedures for equipment;
ix. Preventative maintenance, repair, and testing program for equipment;
x. Return demonstrations on back up oxygen systems delivered;
xi. Emergency and routine contact procedures; and
xii. Delivery and review of written instruction materials to the patient to ensure the patient receives adequate information in order to properly operate the equipment.

9. Minimum standards for physical location and storage of home medical equipment:
a. Suitable facilities shall be maintained to house inventory, to allow for equipment maintenance workspace and the storage and retrieval of all records required to be kept;
b. The facility is kept in a clean, orderly, and sanitary condition at all times;
c. The applicant's services are accessible to its customer base;
d. The applicant complies with all USP, FDA, DOT and OSHA requirements regarding the storage, packaging, labeling, and shipping of medical equipment including medical gases;
e. The ~~applicant's services are available~~ applicant can be contacted twenty-four (24) hours, seven (7) days per week when services needed are essential to the maintenance of life or when lack of services might reasonably cause harm;
f. The applicant complies with all local/state fire and building laws;
g. 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
h. The facility is temperature controlled and regulated as required by the manufacturer.

10. Minimum standards for selection of equipment, devices, and supplies:
a. All equipment, devices, and supplies shall be based on patient need;
b. The permit holder shall obtain copies of features, warranties, and instructions for all items from the manufacturers;
c. All items shall meet applicable Food and Drug Administration (FDA) regulations.

11. Minimum standards of safety and cleaning requirements for home medical equipment:
~~(e) Meet the following safety inspection requirements~~:
a. ~~(i)~~ Demonstrate and maintain documentation that a function and safety check was performed on each piece of ~~oxygen/respiratory~~ equipment ~~has been checked~~ prior to set up~~,~~ and such equipment 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~~
b. ~~(iv)~~ ~~Ensure~~ Document that all appropriate warning labels or labeling, including tags, are present on the equipment provided.

~~(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;~~

c. ~~(ii)~~ Maintain an established protocol for cleaning and disinfecting equipment which addresses both aerobic and anaerobic pathogens;
d. ~~(iii)~~ Maintain a ~~Material~~ Safety Data Sheet (~~M~~SDS) on file for solutions and products used in cleaning and disinfecting procedures;
e. ~~(iv)~~ Maintain segregated areas on the premises and in delivery vehicles for clean, dirty, and contaminated equipment;
f. ~~(v)~~ Clean and disinfect equipment according to manufacturers' specifications;
g. ~~(vi)~~ Instruct the patient on proper cleaning techniques as specified by the manufacturer; and
h. ~~(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.

12. ~~(h) Implement a~~ Minimum standards of comprehensive preventative maintenance, repair, and testing program for home medical equipment: ~~which include 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.~~

a. Provide scheduled preventive maintenance, repairs and testing of all equipment and devices provided to clients as recommended by the equipment or device manufacturer;
b. Establish a process to identify equipment scheduled for maintenance and provide the needed maintenance or repair of the equipment and devices according to the manufacturer's guidelines or recommendations;
c. Provide the client with a replacement item when equipment/device in use is scheduled for maintenance or repair;
d. Establish a process to repair equipment and devices that are reported as damaged or malfunctioning;
e. Maintain a file of all current manufacturer's maintenance, warranties, repair, and testing instructions and recommendations for all equipment, devices, and supplies the permit provides;
f. Only qualified staff members perform repairs or maintenance on equipment and devices according to the manufacturer's guidelines;
g. Report and return to the manufacturer of any defective item and disposition, as appropriate; and
h. The maintenance and repair data for each piece of equipment or device, as appropriate, includes:
    i. Equipment name, manufacturer, model, and serial number;
    ii. Date equipment went into service;
    iii. Projected dates of manufacturer recommended scheduled maintenance cleaning and calibration;
    iv. Dates maintenance performed include both the dates and reason of performed repairs and the date of disposition after maintenance or repair; and

v. Name of person or company performing the repair.

~~(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.~~

13. ~~(k)~~ Implement a written procedure at each location for handling patient complaints and problems, which includes a complaint file documenting complaints and problems and resolutions of the complaints or problems. This procedure shall be in writing shall be available onsite, either in a hardcopy or immediately accessible electronically, and provided upon the request of an agent of the Board. All patient complaints shall be maintained for at least a three (3) year period.

14. ~~(l) Comply with the following~~ Minimum standards for patient counseling instruction ~~requirements~~:
   a. Utilize orientation checklists to review:
      i. Instructions for use of the equipment; and
      ii.~~(2))~~ Safety precautions; and
      iii. ~~(3)~~ Cleaning procedures; and
      iv. ~~(4)~~ Maintenance procedures; and
      v. ~~(5)~~ Return demonstrations on back up oxygen systems delivered;
   b. ~~(ii)~~ Instruct the patient about emergency and routine contact procedures; and
   c. ~~(iii)~~ Deliver and review written instruction materials to ensure that the patient receives adequate information in order to properly operate the equipment.
   d. A written plan of service shall be developed, implemented, and documented in the patient record~~. The plan of service~~ and 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.

15. Additional Regulations for medical gas, oxygen, and respiratory equipment suppliers:
   ~~(a) Comply with all applicable home medical equipment laws and regulations of Mississippi;~~
   a. ~~(b) If transporting~~ ~~o~~Oxygen and other medical gases being transported in cylinder or liquid form~~,~~ shall comply with all current State and Federal Department of Transportation rules and regulations;
   b. ~~If t~~Transfilling medical oxygen systems~~,~~ shall comply with Food and Drug Administration (FDA) ~~and all state agency~~ requirements regarding transfilling and repackaging;
   c. ~~Demonstrate that~~ ~~o~~Oxygen and other medical gases provided in cylinder or liquid form shall meet~~s~~ minimum purity standards for medical grade oxygen and medical gases; and
   ~~(c) 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.~~

d. ~~(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.
e. Documentation of all testing of equipment shall be maintained and readily accessible.

16. ~~(f) Comply with the~~ Medical gas and oxygen suppliers must also meet the following recall procedures:
    a. ~~(i)~~ Ensure that lot numbers and expiration dates are affixed to each cylinder delivered;
    b. ~~(ii)~~ Maintain a tracking system for all medical oxygen and gas delivered;
    c. ~~(iii)~~ Document all equipment serial numbers and model numbers to ensure that equipment can be retrieved if a recall is initiated; and
    d. ~~(iv)~~ Maintain records for equipment that requires FDA tracking.

~~(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.~~

17. The above required policies, testing and required documentation shall be in writing and shall be available onsite or immediately accessible electronically, and provided upon the request of an agent of the Board.

18. A permit holder shall report to the Board within thirty (30) days any adverse action taken by another licensing jurisdiction, government agency, law enforcement agency, or court.

19. Failure to comply with the required policies and/or standards set forth in this Article shall be deemed a violation of the rules and regulations of the Board and may result in disciplinary action taken by the Board.