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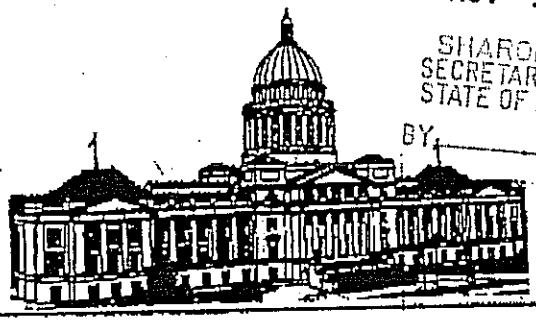

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Name of Agency Arkansas State Board of Pharmacy

Department

Contact Person Sheila Castin, Acting Director

Statutory Authority for Promulgating Rules 17-91-205 (A)

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CERTIFICATION OF AUTHORIZED OFFICER

I Hereby Certify That The Attached Rules Were Adopted In Compliance with Act 434 of 1967 As Amended.

Sheila Castin
Signature

Acting Director
Title

11/8/95
Date

REGULATION 57

57. Medical Equipment, Legend Devices, and/or Medical Gas Regulation

I. Definitions:

(A) "Home Medical Equipment, Legend Device, and Medical Gas Supplier" means a person, business, corporation, agency, company, etc., licensed to supply home medical equipment, medical gases and/or legend devices to patients on an order from medical practitioners licensed to order, use, or administer these products and to other persons, businesses, corporations, agencies, companies, etc., licensed to supply home medical equipment, medical gases, and/or legend devices.

(B) "Home Medical Equipment Services" means the delivery, installation, maintenance, replacement, and/or instruction in the use of medical equipment, used by a sick or disabled individual, to allow the individual to be maintained in a noninstitutional environment.

(C) "Legend Device," means a device which, because of any potential for harmful effect or the method of its use, is not safe -- except under the supervision of a practitioner. These devices, as approved by F.D.A., may be labeled "Caution: Federal (USA) law restricts this device to sale by or on the order of a physician."

(D) (1) "Medical Equipment" means technologically sophisticated medical devices including but not limited to:

- (a) Oxygen and oxygen delivery systems;
- (b) Ventilators;
- (c) Respiratory disease management devices;
- (d) Electronic and computer driven wheelchairs and seating systems;
- (e) Apnea monitors;
- (f) Transcutaneous electrical nerve stimulator (T.E.N.S.) units;
- (g) Low air loss cutaneous pressure management devices;
- (h) Sequential compression devices;
- (i) Neonatal home phototherapy devices;
- (j) Feeding pumps;
- (k) Electrically-powered hospital beds;
- (l) Infusion pumps; and
- (m) Patient Lifts.

(2) The term "medical equipment" does not include:

- (a) medical equipment used or dispensed in the normal course of treating patients by hospitals, hospices, nursing facilities, or home health agencies;
- (b) medical equipment used or dispensed by health care professionals, licensed in Arkansas -- provided the professional is practicing within the scope of that professional's practice act;
- (c) upper and lower extremity prosthetics and related orthotics; or
- (d) canes, crutches, walkers, bathtub grab bars, standard wheelchairs, commode chairs, and bath benches.

(E) "Medical Gas" means those gases and liquid oxygen intended for human consumption.

(F) "Order" means an order issued by a licensed medical practitioner legally authorized to order medical gases and/or legend devices.

II. Licensure Required:

(A) No person or entity, subject to licensure, shall sell or rent or offer to sell or rent directly to patients in this state any home medical equipment, legend devices, and/or medical gases, unless the person or entity is licensed as required by Act 1101

The licensure requirements of this act will apply to all companies, agencies, and other business entities that are in the business of supplying medical equipment to patients in their home 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. The application for a license shall be on a form, furnished by the Board, and shall be accompanied by payment of fee of two hundred dollars ($200). The Board shall require a separate license for each facility directly or indirectly owned or operated, within this state, by the same person or business entity within this state, or for a parent entity with divisions, subdivisions, subsidiaries, and/or affiliate companies when operations are conducted at more than one location and there exists joint ownership and control among all the entities.

(B) (1) The annual license renewal fee is one hundred dollars ($100).

(2) All licenses issued under this act shall expire on December 31, of each calendar year.

(3) Each application for renewal of the license must be made on or before December 31 of each year. Penalties for late payment include: Twenty dollars ($20.00) penalty if not paid by February 1 of each year, forty dollar ($40.00) penalty if not paid by March 1 of each year. The license shall be considered null and void if the fee is not paid by April 1 of each year.

(C) Each license issued hereunder shall be displayed by the holder thereof in a conspicuous place.

III. Standards of Practice:

(A) Written policies and procedures must be available for review and designed to meet all the following standards. Documentation of all staff training must be kept in each employee's personnel file. All local, state, and federal regulatory agency policies concerning HME and oxygen must be followed.

(1) Order Intake: A home medical equipment (HME) provider shall recognize the importance of order intake. The provider is responsible for assuring that order intake personnel are appropriately trained in the following:

(a) Identifying equipment;

(b) Determining patient/caregiver needs;

(c) Determining referral sources needs;

(d) Knowing equipment coverage criteria based on diagnosis;

(e) Responding appropriately during a medical equipment emergency;
(f) Explaining service procedures;
(g) Billing third party; and
(h) Verifying insurance.

The provider must assure that only trained order intake personnel receive referrals.

(2) Selection of Appropriate Equipment:

(a) When providing equipment services for a patient, a provider shall consider: physician orders, equipment needs of the patient, economic situation of the patient and caregiver, and requirement of any third party payor source.

(b) A provider shall recognize those items which require special fitting and evaluation. fitting of custom items shall be performed within a reasonable time frame by specially trained personnel.

(3) Delivery and Set-Up/Patient and Caregiver Education:

(a) A provider shall maintain trained personnel to coordinate order fulfillment and to schedule equipment services with timely delivery. Documentation of training will be maintained.

(b) A provider shall assure delivery personnel are appropriately trained to:

(A) Conduct an environment/equipment compatibility assessment.
(B) Appropriately and safely set up the equipment.
(C) Instruct patient and caregivers in the safe operation and client maintenance of the equipment.
(D) Recognize when additional education and/or follow-up patient compliance monitoring is appropriate.

(c) Written instructions must be provided to the patient/caregiver upon delivery and documentation of receipt of written instruction must be maintained in the patient record.

(4) Services During Use:

(a) A provider shall document that patients are advised of service hours and emergency service procedures. If equipment malfunction may threaten the customer's health, access to 24 hour per day, 365 days per year emergency service must be available for equipment maintenance or replacement.

(b) A provider shall establish a schedule at the time of the initial delivery for any appropriate follow-up HME services such as periodic maintenance, supply delivery and other related activities.

(5) Retrieval/Disinfection/Maintenance:

(a) A provider shall assure that state/federal requirements for equipment disinfection are followed including red-tagging for bio-hazards, maintaining dirty equipment isolation, equipment

cleaning and disinfection areas and procedures, and appropriate staff training on hazard prevention.

(b) Cleaning and disinfection solutions must be bactericidal, tuberculocidal, and viricidal.

(c) CDC Universal precautions and OSHA regulations concerning equipment handling must be followed.

(d) Create and implement a preventative maintenance program based on manufacturers' guidelines which include appropriate record keeping. Trained staff must be utilized.

(6) Patient Record:

(a) A supplier must maintain a record for each customer when required by state or federal law or when a physician's order is required.

(b) The patient record must include an intake form and applicable physician's orders.

(c) Records should be safeguarded from loss and kept confidential.

(d) Documentation of proper patient/caregiver instruction must be maintained in the patient record.

(7) Patient Rights:

(a) The patient has the right to considerate and respectful service.

(b) The patient has the right to obtain service without regard to race, creed, national origin, sex, age, disability, diagnosis or religious affiliation.

(c) Subject to applicable law, the patient has the right to confidentiality of all information pertaining to his/her medical equipment and service. Individuals or organizations not involved in the patient's care may not have access to the information without the patient's written consent.

(d) The patient has the right to a timely response to his/her request for HME services.

(e) The patient has the right to select the HME supplier of his/her choice.

(f) The patient has the right to voice grievances without fear of termination of service or other reprisals.

(g) The patient has the right to expect reasonable continuity of service.

(h) The patient has the right to an explanation of charges for equipment and supplies.

(8) Quality Assurance:

(a) There is an ongoing continuous quality improvement program designed to monitor and evaluate quality of patient care, improvement of patient services, if applicable, and resolution of identified problems.

(b) Continuous quality improvement activities are defined in a written plan.

(c) Issues monitored should be determined by evaluating all complaints or incidents and items that are high volume, high risk or problem prone.

(9) Liability insurance coverage for products provided and operations of each licensed entity is required in the amount of at least $500,000.

(B) Prohibited Practices -- The following practices are prohibited:

(1) Patient Freedom of Choice:

(a) Participation in any plan, agreement, or arrangement which eliminates the patient's right to select a provider, licensed under this act, of their choice shall be considered a violation of this regulation.

(2) Bribes Kickbacks and Rebates:

(a) It shall be considered a violation of this regulation for anyone to knowingly and willfully offer, pay, solicit or receive any payment in return for referring an individual to another person for the furnishing, or arranging for the furnishing, of any item or service covered by this regulation. (10/13/95)